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Review Essay

The Breast Implant Fiasco

SCIENCE ON TRIAL: THE CLASH OF MEDICAL EVIDENCE AND THE LAW IN THE BREAST IMPLANT CASE. By Marcia Angell, M.D. New York: W.W. Norton & Co., 1996. Pp. 256. \$27.50 cloth.

Reviewed by David E. Bernstein†

INTRODUCTION

In *Science on Trial*, Dr. Marcia Angell, the executive editor of the *New England Journal of Medicine*, examines how the legal system has dealt with claims that silicone-gel-filled breast implants cause cancer or diseases related to immune system disorders. The subject is certainly worthy of critical attention. Litigation over the alleged health hazards of breast implants has had profound effects on the American economy, particularly the health-care industry.¹ Meanwhile, debate over the meaning of the breast implant litigation reverberates in legal and political circles. To some, breast implants are a powerful symbol of corporate irresponsibility and the need for stricter government regulation of

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1. Billions of dollars have been or will be redistributed from large corporations and insurance companies to women with implants and their attorneys. Leading implant manufacturer Dow Corning, one of the largest corporations in the world, was forced into bankruptcy. *See* Joseph Nocera, *Fatal Litigation*, *FORTUNE*, Oct. 16, 1995, at 60.

Plaintiffs have filed copycat silicone-related lawsuits across the country against products ranging from penile implants to the Norplant contraceptive. *See* Gina Kolata, *Will the Lawyers Kill Off Norplant?*, *N.Y. TIMES*, May 28, 1995, at C1. So many medical devices are vulnerable to spillover effects from the breast implant litigation that for a time the litigation created widespread fears of technological stagnation and even retrenchment in crucial segments of the health-care industry. *See, e.g.*, Katherine Dowling, *A Class Action Nightmare: Wide-Ranging Suits Against Manufacturers May Keep Lifesaving Medical Devices on the Shelf and Out of Reach*, *L.A. TIMES*, Oct. 25, 1995, at B9; Trisha Gura, *Implant Debate to Cripple Innovation?*, *CHI. TRIB.*, Mar. 13, 1995, at C1; Barbara March, *The Products Liability Morass: Complications Set In; Big Suppliers Pulling Out of Medical Market*, *L.A. TIMES*, May 6, 1995, at D1; Elizabeth Neus, *Dow Corning May Quit Medical Sales*, *DET. NEWS*, May 19, 1995, at E3.

industry—including a more punitive tort system. Others see the litigation over implants as a symptom of a tort system run amok, a system divorced from the constraints of scientific knowledge and common sense. Angell is squarely in the second camp.

The greatest strength of *Science on Trial* lies in Angell's familiarity with, and advocacy of, science and the scientific method. She persuasively documents that the risk of contracting systemic disease from silicone breast implants is a phantom risk²—a cause-and-effect relationship whose very existence is unproven, and, as Angell concludes, will likely never be proven.

The bulk of *Science on Trial* is devoted to an insightful history of the breast implant litigation. In the course of recounting this history, Angell demonstrates the weaknesses of the American legal system, particularly the tort system, in dealing with claims based on speculative scientific evidence.

The shortcoming of Angell's approach—at least from a legal scholar's perspective—is that she generally fails to put the breast implant litigation in a broader legal perspective. Despite the legal system's deficiencies, most dubious scientific claims never become the basis of tort litigation, and, of those that do, there is no consistent pattern to the success of the litigation. Yet Angell devotes little attention as to why the claim that breast implants cause disease, unlike many other phantom risk claims, led to spectacularly successful litigation.

Part I of this Review Essay recounts the history of the breast implant litigation. This section elaborates on Angell's analysis, and is based on research undertaken for this Review Essay.³ While Angell emphasizes the non-scientific basis of the legal system's approach to breast implants, this Review Essay focuses on what the breast implant litigation teaches us about how phantom risk litigation arises, and what factors determine the success of such litigation.

The conclusions reached in Part I of this Review Essay about phantom risk litigation provide support for Angell's advocacy of several reforms to aid the tort system in screening out cases based on poor science. She suggests restricting contingency fees, limiting the role of juries in tort cases, and establishing better methods for assuring the quality of scientific evidence admitted into the courtroom. Each of these recommendations is sound, but Angell spends very little time defending her reform proposals, or explaining how they would be implemented.

2. This phrase is not used by Angell, but it fits her views on the risks of implants. For more on phantom risks, see Kenneth R. Foster et al., *A Scientific Perspective*, in *PHANTOM RISK: SCIENTIFIC INFERENCE AND THE LAW* 1 (Kenneth R. Foster et al. eds., 1993).

3. All research in this section is the author's own unless it is cited to the text of *SCIENCE ON TRIAL*.

Her proposals therefore are less persuasive than they might otherwise be. Part II of this Review discusses why and how each of Angell's reform proposals should be carried out.

Throughout *Science on Trial*, Angell implicitly argues that once the underlying scientific issue in the breast implant litigation—whether breast implants cause systemic disease—is resolved, the proper response of the tort system is self-evident. If implants do not cause disease, she contends, women should not be able to recover financially for diseases allegedly caused by implants. Perhaps because scientists are trained to seek truth, Angell does not recognize that many legal scholars and others concerned with civil justice issues do not believe that the tort system should be concerned exclusively with determining the objective validity of plaintiffs' claims, particularly in toxic tort cases. Rather, many commentators see toxic tort cases as opportunities for juries to express their outrage at corporate misbehavior and to deter corporate negligence, with the strength of the scientific evidence supporting causation a secondary concern, at best. Part III of this Review Essay discusses the appropriate balance between the traditional requirement of proof of causation in tort cases and the perceived need in the toxic tort context for the tort system to serve social goals other than compensation for harm caused by a particular defendant to a particular plaintiff or group of plaintiffs. Part III outlines a proposed new federal administrative system to deal with negligent, but not necessarily tortious, corporate behavior.

I

THE HISTORY OF THE BREAST IMPLANT LITIGATION

As Angell explains in *Science on Trial*, and as discussed in detail in this Review Essay, plaintiffs in the breast implant litigation never presented any sound scientific evidence that implants cause systemic diseases such as cancer and connective-tissue diseases caused by immune-system malfunctions. Yet, individual plaintiffs won millions of dollars claiming that implants had caused such diseases. Thousands of other women eventually filed lawsuits against implant manufacturers, leading to a multi-billion dollar settlement, the bankruptcy of one of the largest corporations in the United States, and a nationwide wave of litigation that has yet to subside.

Science on Trial provides a useful summary of the breast implant litigation, but fails to place the breast implant litigation in the broader context of other attempts by plaintiffs and their attorneys to launch tort litigation based on phantom risks, or to explain why the breast implant litigation was peculiarly successful. In an attempt to remedy this omission, this section begins by providing general background on the

origins and nature of phantom risk litigation. After this introduction, this section will recount the history of the breast implant litigation, paying particular attention to the factors that allowed plaintiffs to successfully initiate and foster the litigation.

Based on a review of about a dozen examples of phantom risk litigation, my co-editors and I hypothesized in *Phantom Risk: Scientific Inference and the Law* that the following factors need to be present for a specific phantom risk to become the subject of high-stakes litigation: (1) sensationalistic media coverage; (2) actions by politically motivated individuals and organizations that result in the downplaying of objective scientific inquiry; (3) public outrage at reports of corporate irresponsibility; and (4) financial incentives that encourage attorneys and their clients to pursue claims that have a dubious scientific basis.⁴

The media shapes public reaction to technological risks,⁵ too often by uncritically accepting sensational claims made by parties with a financial interest in the litigation. The notorious Bendectin litigation, for example, took off after the *National Enquirer* published a story in October 1979 linking Bendectin, a popular morning sickness drug, with birth defects.⁶ The *Enquirer* received the story from Melvin Belli, a prominent plaintiffs' attorney who was handling Bendectin cases.⁷ Other media outlets soon joined in,⁸ and suddenly thousands of claims had been filed against Merrell, the company that manufactured Bendectin, despite a lack of sound scientific evidence supporting these claims.⁹

Political actors also help mobilize litigants. Environmentalist and consumer activists with a flair for public relations can help elevate an issue of dubious scientific merit in the public mind.¹⁰ Politicians, who may have their own ideological axes to grind, often see an emerging phantom risk issue as an opportunity to gain a reputation for being concerned with public health, and will therefore adopt and amplify the claims of the activists. Scientists themselves, who could put the risk in perspective, may instead be inclined to overstate a problem as they lobby to elevate their research interests on the public agenda.

4. The discussion that follows is adapted from the discussion in PHANTOM RISK, *supra* note 2, at 32-36.

5. See Paul R. Lees-Haley & Richard S. Brown, *Biases in Perception and Reporting Following a Perceived Toxic Exposure*, 75 PERCEPTUAL & MOTOR SKILLS 531 (1992).

6. See *Experts Reveal . . . Common Drug Causing Deformed Babies*, NAT'L ENQUIRER, Oct. 9, 1979, at 20.

7. See MICHAEL GREEN, BENDECTIN AND BIRTH DEFECTS 134 (1996).

8. See, e.g., Mark Dowie & Carolyn Marshall, *The Bendectin Cover-Up*, MOTHER JONES, Nov. 1980, at 43; John de St. Jorre, *The Morning Sickness Drug Controversy*, N.Y. TIMES, Oct. 12, 1980 (Magazine), at 11.

9. For the full story, see GREEN, *supra* note 7.

10. See, e.g., Louis Lasagna & Sheila R. Shulman, *Bendectin and the Language of Causation*, in PHANTOM RISK, *supra* note 2, at 107-08 (discussing role of an activist organization in promoting the view that Bendectin causes birth defects).

Once the public has become aware of a phantom risk due to media and political attention, the level of public outrage will help determine the scope of the initial wave of litigation. The level of outrage, meanwhile, depends on such variables as whether the risk is voluntary, familiar, detectable, or subject to individual control. The "outrage factor" also helps to determine the outcome of litigation. One jury in a dioxin spill case awarded the plaintiffs only \$1 in actual damages, a reflection of the plaintiffs' inability to prove that the spill had caused their injuries. But the jurors went on to award \$16,250,000 in punitive damages in order to punish the company for exposing the plaintiffs to an involuntary risk. That decision was reversed on appeal,¹¹ but in many other cases, where jury nullification of the causation requirement is not nearly so blatant, the verdict stands and the defendant pays.¹²

Cases based on phantom risks are speculative ventures. To the individual claimant, the results of the litigation process are very uncertain. However, to a tort lawyer who operates on a contingency basis, it can be profitable: a single multi-million dollar verdict that survives all appeals can more than offset a long string of losses. To the company that has to defend itself against many claims, the result is a disaster, even if it "wins" most of the cases.

Moreover, sometimes a lawyer can win just by getting the game in play. Deterred by the possibility of large awards by unpredictable juries, high legal costs, and the notoriety of a trial, many defendants can be induced to offer huge settlements to buy their way out of litigation. For example, Merrell offered \$120 million for a global settlement of the Bendectin litigation. The deal eventually fell through, and although Merrell lost several jury trials, it has yet to pay out a penny in damages.¹³ Merrell, however, would still have been better off settling. According to Merrell's general counsel, the litigation has cost the company more than \$100 million in direct litigation costs, and significantly more in indirect costs, such as deposition time for company employees.¹⁴

Finally, plaintiffs have obvious financial incentives. The plaintiff in most cases has suffered some illness or injury, and often has crushing financial burdens that insurance does not adequately cover. Why suffer

11. *Kemner v. Monsanto*, 576 N.E.2d 1146 (Ill. App. Ct. 1991), *appeal denied*, 584 N.E.2d 1301 (Ill. 1991).

12. *See supra* note 4.

13. *See, e.g.*, *Ealy v. Richardson-Merrell, Inc.*, 897 F.2d 1159 (D.C. Cir. 1990) (finding the link between Bendectin and birth defects not scientifically supported and reversing judgment below for plaintiff); *Brock v. Merrell Dow Pharmaceuticals*, 874 F.2d 307 (5th Cir. 1989) (en banc); *Richardson v. Richardson-Merrell, Inc.*, 857 F.2d 823 (D.C. Cir. 1988) (affirming judgment n.o.v. for defendant based on insufficient evidence of causation).

14. Interview with Glenn Forrester, General Counsel for Marion Merrell Dow (July 10, 1997).

financially from an act of God when a potential defendant with deep pockets can be found?

Thus, four factors—unbalanced media coverage, politics, public outrage, and financial incentives—are generally necessary for litigation over phantom risks to commence. As I discuss below, each of these factors played a significant role in stimulating the breast implant litigation. I conclude the section with a discussion of why breast implant litigation—unlike other examples of phantom risk litigation—spun out of control and led to a multi-billion dollar transfer of assets from the defendants to plaintiffs and their attorneys.

A. *The Early History of Breast Implants*

According to Angell, Dow Corning began marketing silicone breast implants in 1962. She explains that the implants “consisted of a rubbery silicone envelope containing silicone gel” (p. 39). Plastic surgeons soon discovered that a certain (as yet undetermined) percentage of implants rupture on their own, either because of other trauma to the breast or because the implant simply tears. In many cases, the gel stays either in the implants or in the immediate vicinity. In rare cases, the gel may migrate through the body. Moreover, the implants themselves are permeable, and minute amounts of silicone gel that bleed through the implants can also remain in nearby tissue or potentially migrate throughout the body (pp. 39-43).

Dow Corning scientists believed, based on animal and other studies, that the leakage of silicone would not harm women. Angell notes, however, that Dow and later entrants in the implant market never studied women who had received the implants to ensure that the implants were not causing health complications (p. 21). Moreover, breast implant manufacturers failed to ensure that women were adequately informed about the uncertainty over the potential health risks of breast implants.¹⁵ Even when manufacturers attempted to inform women of potential risks through their plastic surgeons, the surgeons often failed to convey the information.¹⁶

15. David A. Kessler et al., *A Call for Higher Standards for Breast Implants*, 270 JAMA 2607, 2608 (1993) (“Many women have told the FDA that they were never informed prior to implantation that the implants might pose health risks or that their safety had not been established.”).

16. See Rebecca S. Dresser et al., *Breast Implants Revisited: Beyond Science on Trial*, 1997 WISC. L. REV. 705, 719 (1997) (noting that many women claimed that their plastic surgeons never conveyed warnings provided by the manufacturers to their patients).

In September 1991, a member of Dow Corning’s outside public relations team wrote:

One of the problems is that the physicians, as is their wont to do, haven’t wanted to bother the pretty little heads of their patients with all this information. The manufacturers, at least [Dow Corning], have provided it to the docs and they haven’t always passed it on. No point in irritating [representatives of the American Society of Plastic and Reconstructive Surgeons] with this. They know some of their own have dropped the ball in this regard.

For many years, breast implants were essentially unregulated by government. The Food and Drug Administration did not have jurisdiction over medical devices, including implants, until the 1976 Medical Devices Amendment to the Food, Drug and Cosmetic Act ("MDA") became law.¹⁷ The MDA "grandfathered" existing devices, such as breast implants, allowing them to remain on the market until the FDA could classify and regulate them.

After much internal wrangling, in 1982 the FDA proposed classifying silicone-gel breast implants as Class III devices, the most stringently regulated category.¹⁸ The FDA expressed concern about the scar tissue that forms around the implant, about potential long-term toxic effects of silicone that might leak from the implants, and about possible health effects from the silicone polymers from which the implant shells were made.¹⁹

Under the relevant regulatory regime, the FDA's recommendation of Class III status was arguably appropriate. The FDA's concerns about toxicity were, however, almost entirely speculative. Beyond a few studies of dubious relevance addressing the effects of directly injecting adulterated silicone into the breast, there was nothing in the published scientific literature to cause alarm about potential serious health risks from breast implants.

B. The Beginning of the Breast Implant Litigation

Despite the lack of scientific evidence linking breast implants to disease, aggrieved implant recipient Maria Stern sued Dow Corning in 1982. Stern's implants had ruptured, and were removed in 1981.²⁰ She suffered from chronic fatigue and joint pains before and after the implants were removed. Her doctors speculated that leakage of silicone gel into her body from the ruptured implants might be the cause of her problems.²¹

Hersh & Hersh, a small plaintiffs' firm in San Francisco that specialized in women's health issues, represented Stern in her suit against

Memorandum from Johnna Hart Matthews, Senior Vice-President, Burson-Marsteller, to Marty Gold & Howard Liebengood 6 (Sept. 9, 1991) (visited Nov. 23, 1998) <http://www.trimaris.com:80/~ussw/media/bm_bull.html>.

Plastic surgeons also too frequently failed to heed the manufacturers' instructions, and mishandled the implants, causing them to rupture (pp. 41-42).

17. Pub. L. No. 94-295, 90 Stat. 539 (1976).

18. See General and Plastic Surgery Devices; General Provisions and Classification of 54 Devices, 47 Fed. Reg. 2810, 2814, 2820-21 (1982) (proposed Jan. 19, 1982) (codified at 21 C.F.R. 878.3540).

19. *Id.* at 2820-21.

20. See *Woman Gets \$1.7 Million in Dow Corning Lawsuit*, WALL ST. J., Nov. 7, 1984, at 3.

21. See Kim S. Hirsch, *Breast-Implant Lawsuits Start to Build Momentum*, PLAIN DEALER (CLEVELAND), Jan. 19, 1993, at 8C; Nocera, *supra* note 1.

Dow Corning. Angell recounts that during discovery proceedings, Dan Bolton, an associate at Hersh & Hersh, found thousands of internal Dow Corning memos relating to breast implants, several of which made the company look extremely irresponsible (p. 52).

Perhaps most significantly, Bolton found several memos showing that Dow Corning officials were aware that silicone gel leaked from their implants, and were also apparently aware that the company did not have adequate data showing that this leakage did not pose a health hazard. One 1983 memo, for example, stated, "I want to emphasize that to my knowledge, we have no valid long-term implant data to substantiate the safety of gels for long-term implant use."²² Bolton used these documents to great effect at the trial in July 1984.²³

As Angell notes, *Stern* set the pattern for later breast implant cases (pp. 111-13). The plaintiff had no valid scientific evidence linking breast implants with her disease, so her attorney emphasized the allegedly irresponsible behavior of the defendant. The jury found that the implants were defectively designed and awarded Stern \$200,000 in damages. The jury also found that Dow Corning had engaged in fraud—apparently it believed that Dow Corning had doctored a dog study²⁴—and awarded \$1.2 million in punitive damages. After the district judge upheld the award, the case was settled before appeal for an undisclosed sum, and the record was sealed (p. 52).

Although Angell argues that after *Stern* it was "inevitable" that many more cases would be brought against implant manufacturers (pp. 111-12), in fact the case received little publicity, and only a few major

22. Memorandum from W. Boley to O. Hatherly, *Biological Safety Testing of Gel for Implants* (Sept. 15, 1983) (on file with author). In addition, Bolton found several memos showing that various Dow Corning employees were concerned that new implants Dow Corning began selling in 1975 bled too much silicone. When the new implants had been shipped out, one marketing official noted that the implants "have a tendency to appear oily." Memorandum from Tom Salisbury to H. Baecker et al., *Oily Phenomenon with New Mammary Protheses* (May 16, 1975) (on file with author). He advised salesmen to make sure samples appear clean by washing them off "with soap & water in the nearest washroom" before making a sales pitch. *Id.* In 1976, a salesman inquired, "[w]hen will we learn at Dow Corning that making a product 'just good enough' almost always leads to products that are 'not quite good enough?'" Memorandum from Tom Talcott to Ron Kelley & Art Rathjen, *Comment on Mammary Prostheses Quality and Request for More Information on the Scottsdale Breast Symposium* (Jan 15, 1976) (on file with author). In 1980, Bob Schnabel, a sales representative, wrote: "[A doctor's] complaint is that . . . he is getting excessive gel bleed on all three pair that were given to him . . . To put a questionable lot of mammarys on the market is inexcusable . . . [I]t has to rank right up there with the Pinto gas tank." Memorandum from Bob Schnabel to Milt Hinsen, *Fred Grazer, M.D.* (Apr. 29, 1980) (on file with author). It is not possible to discern which of these documents Bolton relied on at trial, and to what extent, because the records from the *Stern* case are sealed (p. 52).

23. See Nocera, *supra* note 1.

24. See Thomas D. Talcott, *Wanted: Several Journalists to Function as Investigative Reporters to Study and Publicize the Real Science of Silicones* (visited Nov. 23, 1998) <<http://www.trimaris.com:80/~ussw/media/talcott.html>>.

cases were filed against implant manufacturers over the next several years. In the waning days of the Reagan Administration, however, the FDA's inaction regarding implants became a target of political activists whose vociferous public attacks on implants helped create an atmosphere extremely conducive to future lawsuits.

C. The Politicization of Breast Implants: The Role of Public Citizen Health Research Group

In June 1988, the FDA published its final rule classifying silicone-gel breast implants as Class III medical devices.²⁵ This gave the FDA the authority to demand safety information from the implant manufacturers after thirty months. Meanwhile, absent an FDA order to the contrary, implants could still be marketed.

The FDA's Plastic Surgery Advisory Committee, a seven-member panel of outside experts, was scheduled to review the status of breast implants at a routine meeting on November 22, 1988. Two weeks before the meeting, the attack on implants by Public Citizen Health Research Group ("Public Citizen"), a consumer activist group, began. Public Citizen is mentioned only in passing by Angell (p. 53), but it played a critical role in encouraging the breast implant litigation.

On November 9, Public Citizen publicly called on the FDA to ban implants (p. 53). Public Citizen released internal documents from Dow Corning and the FDA that showed the company's scientists had implanted a blob of the gel under the skin of 200 rats. Between one-fifth and one-quarter of the rats developed fibrosarcoma, a form of cancer.²⁶ Public Citizen's president, Dr. Sidney Wolfe, told the media that implants were dangerous and should be banned.²⁷ Wolfe's comments "sent many women into something of a panic."²⁸ To calm the furor, the FDA agreed to consider the cancer issue at its November 22nd meeting.

Although a few FDA employees expressed concern about the implications of the rat studies,²⁹ Wolfe knew or should have known that

25. See Inflatable Breast Prosthesis Classification, 53 Fed. Reg. 23,856, 23,858 (1988) (final rule) (codified at 21 C.F.R. § 878.3530).

26. See Boyce Rensberger, *Silicone Ban Not Justified at Present, FDA Is Advised: Panel Votes to Collect More Data on Breast Implants*, WASH. POST, Nov. 23, 1988, at A3. The study cited by the group was based on documents leaked from the FDA. See Marilyn Chase, *Consumer Crusader Sidney Wolfe, M.D. Causes Pain to FDA, AMA and the Health Industry*, WALL ST. J., Apr. 7, 1992, at A18.

27. See Boyce Rensberger, *Silicone Gel Found to Cause Cancer in Laboratory Rats*, WASH. POST, Nov. 10, 1988, at A3.

28. Sandy Rovner, *Suspect Silicone: Concerns About Breast Implants*, WASH. POST, Nov. 15, 1988, at Z15.

29. These concerns are recounted in HOUSE HUMAN RESOURCES & INTERGOVERNMENTAL RELATIONS SUBCOMM. OF THE COMM. ON GOV'T OPERATIONS, THE FDA'S REGULATION OF SILICONE BREAST IMPLANTS ¶ 27-29 (Dec. 31, 1992) (visited Nov. 23, 1998) <<http://www.magiclink.com/web/spudnik/fdaregs.html>> (recounting such concerns moving FDA reviewers) [hereinafter FDA'S REGULATION].

fibrosarcoma occurs in rodents in response to the implantation of any large smooth object.³⁰ No one has been able to demonstrate that this phenomenon, known as solid-state carcinogenesis, occurs in humans.³¹ After receiving advice from the National Center for Toxicological Research, the FDA concluded that "the types of tumors seen in the rats would be unlikely to occur in humans, and that, if a human cancer risk does exist, it would be small."³²

The FDA panel unanimously found insufficient evidence of a health risk to warrant banning implants. Instead, the committee called for the establishment of a national registry of women with breast implants so long-term studies could be carried out to determine whether implants create a heightened risk of breast cancer or other health problems. The committee also recommended the drafting of a mandatory, standardized consent form to be signed by breast implant recipients.³³

Linking implants to cancer based on the rat studies was only the first of many unduly alarmist comments made by Wolfe in the course of the breast implant litigation.³⁴ Wolfe was to play a large and persistent role in the breast implant controversy, so it is important to consider his stake in the issue. Wolfe and his organization, Public Citizen, have an agenda that supports massive government regulation of the economy.³⁵ Throughout most of the 1980s, Wolfe was frustrated by the Reagan Administration's general skepticism of regulation.³⁶ Wolfe found the Reagan-appointed head of the FDA, Frank Young, particularly unsympathetic to his views. According to Wolfe, Young believed in deregulating the food, drug, and medical device industries, and Young "continued a significant decrease in overall enforcement activities

30. See Jack W. Snyder, *Silicone Breast Implants: Can Emerging Medical, Legal, and Scientific Concepts Be Reconciled?*, 18 J. LEGAL MED. 133, 140 (1997) (reviewing scientific studies on this issue).

31. See *id.*

32. FDA's REGULATION, *supra* note 29, at ¶ 30-31.

33. See *More Study Urged on Breast Implants*, CHI. TRIB., Nov. 25, 1988, at 34.

34. See, e.g., *Consumer Crusader Sidney Wolfe, M.D., Causes Pain to FDA, AMA, and the Health Industry*, WALL ST. J., Apr. 7, 1992, at A18 (alleging that cancer from implants is "rare" but that risk "is real"); *Further U.S. Ban of Breast Implants Urged*, N.Y. TIMES, Aug. 5, 1994, at A15 (alleging a risk of "chronic illness" from saline implants); Philip J. Hilts, *Implant Restrictions Urged*, HOUS. CHRON., Feb. 21, 1992, at A1 (claiming that breast implants "were shown to be unsafe in both animals and humans").

35. Public Citizen's own explanation of its goals is available on its website (visited Feb. 17, 1998) <http://www.citizen.org/public_citizen/hrg/ABOUTUS.HTM>. This web page lists Public Citizen's successes, all of which involve increased government regulation. Apparently, Public Citizen focuses solely on errors of omission by government agencies, never errors of commission.

36. See, e.g., *Reagan Legacy Hit by Consumer Activists*, CHEM. MARKETING REP., Jan. 23, 1989, at 5 ("According to Dr. Sidney M. Wolfe . . . Reagan Administration efforts to cut back on regulation led to the largely preventable deaths of thousands of adults and children.").

started in 1981.”³⁷ Wolfe was especially troubled that Young sought to cooperate with the industries the FDA regulates, instead of taking an adversarial stance.³⁸

If breast implants could be proven to be unsafe, Public Citizen’s agenda would receive a tremendous boost. Implants had been completely outside of FDA jurisdiction for the first thirteen years of their existence. For the next twelve years, the FDA had the opportunity to regulate implants but did not do so. If Wolfe could persuade the public that the FDA’s inaction had created a significant public health problem, his organization’s pro-regulation outlook would be vindicated.³⁹

Thus, two of the elements that were to create the massive wave of breast implant litigation, potential financial rewards and political interference with scientific inquiry, were already beginning to fall into place. The *Stern* case showed the potential for big money in breast implant litigation, even in the absence of scientific evidence of causation. Public Citizen’s nascent crusade against implants gave anti-implant litigators a respected “neutral” source to help shift public opinion against implants. Public Citizen was aided by Sybil Goldrich, co-founder of an anti-implant organization called the Command Trust Network. Goldrich had become convinced that her implants had ruined her health, and she therefore launched what Angell describes as an “indefatigable” campaign against implants and their manufacturers (p. 53).

D. The Role of the Media: Connie Chung

The media did not immediately pick up on the implant story. After two relatively uneventful years following the FDA hearings, in December 1990 NBC aired an episode of *Face to Face with Connie Chung* which focused on implants. Chung’s show frightened and outraged thousands of implant recipients. Chung referred to silicone gel as “an ooze of slimy gelatin that could be poisoning women.”⁴⁰ She interviewed several women who blamed implants for causing their

37. Michael Unger, ‘Lightning Rod’ Takes on FDA Storm: Commissioner Frank Young Says the Worst Is Over in Generic Drug Scandal, *NEWSDAY*, Sept. 24, 1989, at 62 (quoting Wolfe).

38. See *id.* Wolfe later called Dr. Young “the worst FDA commissioner in the 10 years since Ralph Nader and I started [Public Citizen].” *FDA Resignation Causes a Furor in Washington*. CHEM. MKTG. REP., Nov. 20, 1989, at 3, available in 1989 WL 2544961, at *3.

39. That is not to say that Wolfe did not sincerely believe that implants were dangerous, or at least that their potential risks outweighed their benefits. But it would be difficult to understand Public Citizen’s persistent opposition to the mainstream scientific community’s view on the safety of implants without understanding Public Citizen’s political agenda. Indeed, Public Citizen still publicly argues—against the great weight of scientific evidence—that breast implants may pose a significant risk of cancer and immune-system diseases. See *Statement of Sidney M. Wolfe, M.D., Public Citizen’s Health Research Group, to the Institute of Medicine Committee on the Safety of Silicone Breast Implants* (July 24, 1998) (visited Sept. 24, 1998) <<http://www.citizen.org/HRG/WHAT'SNEW1448.HTM>>.

40. Michael Fumento, *A Confederacy of Boobs*, 27 *REASON*, Oct. 1995, at 37-38 (quoting Chung).

auto-immune diseases, but never questioned the presumed link. Topping off Chung's "sensational treatment of the matter" (p. 53), Sybil Goldrich revealed her chest, disfigured by operations to remove her implants, to Chung's audience.⁴¹

Meanwhile, Chung failed to mention that the two doctors she cited to support a link between implants and immune system disease had never published studies on breast implants in a major medical journal. Nor did she mention that both sources were paid medical experts for plaintiffs' lawyers involved in pending implant litigation, a fact that might have created some skepticism in the audience.⁴² Chung's tendentious coverage favoring the plaintiffs' claims set the tone for media coverage of breast implants for the next five years.

Chung's show aired only a week before Representative Ted Weiss, chair of the House Human Resources and Intergovernmental Relations Subcommittee of the Committee on Government Relations, held hearings on the safety of breast implants (p. 54). Weiss, who died in 1992, was one of the most liberal members of Congress and had strong ties to organizations founded by Ralph Nader, including Wolfe's Public Citizen.⁴³ Like Wolfe, he used the implant example to attack "the anti-regulatory attitude of the Reagan administration."⁴⁴

Not surprisingly, the hearings were heavily skewed against implants. All three of the scientific experts who appeared at Weiss' hearings—Nir Kossovsky, Frank Vasey, and Pierre Blais—were employed as expert witnesses for plaintiffs in breast implant litigation (p. 120).⁴⁵ Among other anti-implant activists, Sybil Goldrich also testified at the hearings. Angell reports that Goldrich stated: "I've gone seven years without a recurrence of cancer but what will happen from the silicone? I shudder when I think about it" (p. 54). Goldrich told the committee she blamed her gynecological problems, which ultimately resulted in a hysterectomy, on silicone that leaked from her implants. She and other witnesses also discussed the possibility that the implants promote cancer

41. See Linda Marsa, *The Breast Implant Backlash*, WORKING WOMAN, Apr. 1998, at 46.

42. See Kathy McNamara-Meis, "It Seemed We Had It All Wrong," FORBES MEDIA CRITIC, Winter 1996, at 40, 43.

43. See, e.g., Linda Himelstein, *Upstaged and Outraged*, LEGAL TIMES, Apr. 2, 1990, at 6 (discussing spat that occurred after Public Citizen funneled documents it gathered to Rep. Weiss); U.P.I., *Weiss Seeks Another Term*, June 22, 1986 (noting Nader's public support for Weiss).

44. Kenneth W. Cowans, *Politics, Not Health, Spur Fight Against Silicone Implants*, L.A. DAILY NEWS, Nov. 24, 1991, at VPT4. The subcommittee published a report of the hearings in December 1992. See FDA's REGULATION, *supra* note 29.

45. Angell notes that Kossovsky and Vasey served as experts in the 1991 *Hopkins* case. See also Joseph Nocera, *Dow Corning Succumbs (Fatal Litigation: Part II)*, FORTUNE, Oct. 30, 1995, at 137 (reporting that Blais was an early and frequent plaintiffs' expert); *Silicone Is Toxic, Expert Testifies at Breast Implant Trial*, HOUS. CHRON., Dec. 12, 1992, at A38 (discussing testimony of Dr. Blais in the *Johnson* trial).

and cause immune reactions leading to serious illnesses, including lupus and rheumatoid arthritis.⁴⁶

As described above, the Chung broadcast and Weiss' hearings promoted the emerging anti-implant coalition's views. Meanwhile, an unanticipated factor further undermined the implant manufacturers' position. On November 8, Dr. David Kessler was sworn in as the new chairman of the FDA.

E. David Kessler and FDA Politics

Leading congressional Democrats were at first uncertain as to what impact the new Republican-appointed head of the FDA would have on the agency's role in regulation. They need not have worried about Kessler's dedication to vigorous FDA action. Kessler unabashedly saw his mission as reinvigorating the FDA after years of what he considered regulatory laxity. He also sought to raise public support for his regulatory agenda. In December 1992, he stated:

I came to a regulatory agency that, in an era of deregulation, had fallen on hard times. End runs around the agency had become a too frequent way of doing business. . . . The people of the agency had heard once too often that government was part of the problem, not part of the solution. It was our job to set a new direction to institute the changes that would win back the trust of the American people. . . . We needed to get things done, we needed to get things done quickly. We needed to send out a message that, ultimately, it was in no one's interest to deregulate a public health regulatory agency.⁴⁷

Soon after Kessler took office, Rep. Weiss made it clear that he expected Kessler to give priority to breast implants. On April 26, 1991, Weiss sent a letter to Kessler criticizing the agency for dragging its feet on the implant issue. "FDA documents indicate that for more than 10 years, FDA scientists expressed concerns about the safety of silicone breast implants that were frequently ignored by FDA officials," Weiss wrote.⁴⁸ He argued that the FDA was understating the potential risk of cancer. Weiss claimed the agency's public reassurances about low cancer risks "do not accurately reflect the conclusions of the FDA's own scientists." "In fact," Weiss wrote, "'the cancer risks . . . may be more than 100 times the level reported by FDA and by Surgitek, the

46. See Kim Painter, *FDA Cracks Down on Breast Implants*, USA TODAY, Dec. 19, 1990, at 1D.

47. David Kessler, Remarks to the Food and Drug Law Institute's 36th Annual Educational Conference (Dec. 8, 1992) (Reuter transcript report, available in LEXIS, Nexis Library, arcnews File).

48. Tim Smart, *Breast Implants, etc.*, Bus. Wk., June 10, 1998, at 94.

manufacturer.”⁴⁹ He said he feared “some at FDA became more concerned with the reputation of the manufacturer than informing the public.”⁵⁰

While Kessler was much more cautious in his scientific assessments than was Weiss, Kessler’s actions ultimately revealed that breast implants presented as tempting a political target for him as they did for the Congressman, or for Sidney Wolfe. What better way to show the folly of lax regulation than to publicize the purported dangers of breast implants, a device that the FDA had failed to regulate for fourteen years, despite its authority to do so? Moreover, as an unusually vigorous advocate of regulation in a Republican administration, Kessler needed the support of liberals like Weiss and Wolfe in order to gain a base of support.⁵¹

A July 9, 1991 deadline for implant manufacturers to prove the safety of their product to the FDA expired. On September 23, 1991, Bristol-Myers Squibb, a major implant manufacturer, announced it would discontinue its implant business because it could not meet the FDA deadline.⁵² Kessler found the other manufacturers’ data inadequate.⁵³ He had the authority to grant them an extension under the law, and he scheduled a meeting of the FDA General & Plastic Surgery Devices Panel for November 1991 to advise him. The panel was composed of a broad range of experts, including representatives from the fields of plastic surgery, oncology, epidemiology, internal medicine, immunology, radiology, pathology, gynecology, toxicology, sociology, biomaterials, and psychology, as well as representatives of industry and consumer groups.⁵⁴

The panel heard testimony from implant opponents and proponents. The witnesses representing medical organizations, including the American Medical Association and the American Cancer Society, urged the panel not to support a ban on implants.⁵⁵ The members of the advisory panel agreed that the manufacturers had not submitted sufficient data to resolve the safety issue. The panel unanimously recommended

49. *Legislator: Breast Implant’s Cancer Risk Understated*, CHI. TRIB., Apr. 28, 1991, at 19.

50. *Id.*

51. See, e.g., Julie Kosterlitz, *High-Wire Act*, NAT’L J., May 30, 1992 (noting that Kessler was cultivating “consumer activists and liberal members of Congress”). Kessler’s political astuteness was proven when he became one of the very few Bush Administration officials to be reappointed by President Clinton.

52. See Alan Friedman, *Bristol-Myers to Sell Business*, FIN. TIMES, Sept. 24, 1991, at I33.

53. See Philip J. Hilts, *Drug Agency Questions Companies’ Safety on Breast Implants*, N.Y. TIMES, Sept. 17, 1991, at B6.

54. *Chronology of Silicone Breast Implants* (visited Feb. 2, 1999) <<http://www2.pbs.org/wgbh/pages/frontline/im-plants/cron.html>>.

55. See *Hearings Before the FDA General and Plastic Surgery Devices Panel* 288-90 (Bethesda, Md. Nov. 12, 1991) (testimony of Mitchell S. Karlan, M.D.); *id.* at 269 (testimony of George Peters, M.D.).

that implants remain available while manufacturers obtained more data on product safety.⁵⁶ Kessler did not immediately announce whether he planned to accept the panel's recommendation.

F. The State of the Litigation

Meanwhile, the legal wheels continued to turn. After the Connie Chung broadcast, the number of lawsuits filed alleging that breast implants cause cancer and/or immune system damage rose substantially. By the Spring of 1991, breast implant plaintiffs' attorneys, Sybil Goldrich and other leaders of anti-implant organizations, and Sidney Wolfe were actively coordinating their attack on implants. In a subsequent interview, Wolfe acknowledged that he intended to help provoke a deluge of lawsuits against implant manufacturers.⁵⁷ By June, the "Silicone Clearinghouse," organized by Public Citizen, had thirty-nine member law firms.⁵⁸

Wolfe was not the only one attempting to stimulate lawsuits. In mid-1991, famed Houston attorney John O'Quinn received fifty breast implant cases by referral from another attorney. O'Quinn then hired Patricia Hill, a former Texas state representative, to work with public relations firms and act as a spokeswoman on implant issues. According to Hill, O'Quinn wished to use her reputation as an advocate for women's health care to attract and publicize implant cases.⁵⁹ Hill says that she traveled through Texas to raise concerns about purported implant dangers, "performing her part in O'Quinn's efforts to drum up national awareness."⁶⁰ In return, she was to get 4% of O'Quinn's earnings from cases she brought in.⁶¹

Meanwhile, cases filed several years earlier began to go to trial. In June 1991, a jury unanimously ruled against a plaintiff who claimed that her breast implants increased her risk of developing cancer and auto-immune disease.⁶² In July, however, a plaintiff won a \$5.35 million verdict based on her claim that her breast implants increased her risk of

56. See Meeting of the General and Plastic Surgery Devices Panel 323 (Nov. 13-15, 1991); Susan Cruzan, *Panel Issues Breast Implant Recommendations*, FDA ANSWERS T91-72 (Nov. 15, 1991) (visited Nov. 23, 1998) <<http://www.fda.gov/bbs/topics/ANSWERS/ANS00362.html>>.

57. See Tim Smart, *Breast Implants: What Did the Industry Know, and When?*, BUS. WK., June 10, 1991, at 94 (discussing a May 1991 meeting of the various anti-implant players).

58. See Document from Public Citizen, *Attorney Members of Silicone Clearinghouse* (June 10, 1991) (on file with author).

59. See George Flynn, *Tobacco-Case Attorney Sued Over '91 Deal*, Hous. CHRON., Jan. 22, 1998, at 25.

60. *Id.*

61. *Id.*

62. See Phillips v. Baxter Healthcare Corp., No. SWC 85999 (Cal. Super. Ct. June 6, 1991), aff'd, No. B061926, 1993 WL 524688 (Cal. Ct. App. Nov. 9, 1993).

contracting cancer, and, secondarily, immune system disease.⁶³ Then, in late November, a New York jury awarded \$4.45 million to a woman who asserted that a 1983 silicone implant with a polyurethane-foam covering caused her breast cancer.⁶⁴

Despite those two new seven-figure verdicts, the implant litigation, while growing, did not yet appear to be a mortal threat to the manufacturers. As of early December 1991, out of the hundreds of thousands of women with Dow Corning implants, 137 had filed lawsuits.⁶⁵ According to media reports, the typical case settled for only a few thousand dollars.⁶⁶ The plaintiffs' major victories in 1991 primarily involved allegations that implants cause breast cancer, and the manufacturers knew from abstracts presented at medical conferences that medical journals would soon publish studies that would debunk this claim.⁶⁷ Moreover, the judges presiding over the successful implant cases expressed their skepticism of plaintiffs' claims. One judge reduced the \$4.45 million award to \$1.25 million.⁶⁸ The other judge cut the \$5.35 million award by more than half,⁶⁹ and wrote that the scientific basis for the plaintiff's expert's testimony was "not generally accepted."⁷⁰

As of late 1991, then, the breast implant litigation still seemed manageable from the defendant's perspective. However, the case of *Hopkins v. Dow Corning*⁷¹ was to lead to a series of events that would burst the litigation floodgates wide open.

63. See *Toole v. McClintonck*, 778 F. Supp. 1543, 1545 (M.D. Ala. 1991) (reducing \$5 million punitive damage award to \$2 million, reducing a \$250,000 damage award to \$150,000, letting stand a \$100,000 award for past damages), *vacated*, 999 F.2d 1430 (11th Cir. 1993) (vacating judgment for plaintiff and remanding for new trial).

64. See *Livshits v. Natural Y Surgical Specialties, Inc.*, 1991 WL 261770 (S.D.N.Y. Nov. 27, 1991) (setting aside a \$2.5 million verdict for past pain and suffering and a \$450,000 verdict for past and future lost wages, but sustaining a \$1.5 million verdict for future damages).

65. See *Frontline: Breast Implants on Trial* (PBS television broadcast, show 1412, Feb. 27, 1996); *Chronology of Silicone Breast Implants* (visited Nov. 23, 1998) <<http://www.pbs.org/wgbh/pages/frontline/implants/cron.html>>.

66. See *Smart*, *supra* note 57.

67. See Hans Berkel et al., *Breast Augmentation: A Risk Factor for Breast Cancer?*, 326 NEW ENG. J. MED. 1649 (1992) (concluding that implants don't increase the likelihood of breast cancer); Dennis M. Deapen & Garry S. Brody, *Augmentation Mammoplasty and Breast Cancer: A 5-Year Update of the Los Angeles Study*, 89 PLASTIC AND RECONSTRUCTIVE SURGERY 660 (1992) (concluding that implants don't increase the likelihood of breast cancer).

68. See *Livshits*, 1991 WL 261770.

69. See *Toole v. McClintonck*, 778 F. Supp. 1543, 1549 (M.D. Ala. 1991), *vacated*, 999 F.2d 1430 (11th Cir. 1993).

70. *Id.*

71. 33 F.3d 1116 (9th Cir. 1994).

G. Hopkins: *The Convergence of Money, Politics, Media, and Public Outrage*

Marianne Hopkins underwent a double mastectomy in 1976, and had her breasts reconstructed with silicone implants (p. 119). Three years later, her doctor diagnosed Hopkins as suffering from a debilitating auto-immune disorder known as mixed connective-tissue disease (p. 119). In November 1988, Hopkins saw Dan Bolton and Sybil Goldrich on the evening news discussing the FDA breast implant advisory panel's ongoing meeting, and elaborating on the health hazard they claimed breast implants presented (p. 119). Hopkins called Bolton's office the next day. A few days later, she sued her implants' manufacturer, Dow Corning, in federal court in San Francisco (pp. 119-20).

The case went to trial in December 1991. Despite the lack of supporting scientific evidence, Bolton found three scientists and doctors willing to testify that in their opinion, breast implants cause immune-system disease. Science was, in any event, a sidelight to Bolton's main story, which focused on the same "bad documents" he had used seven years earlier in the *Stern* case.⁷²

As discussed above, the documents showed that Dow Corning officials, although aware that silicone was leaking out of their implants, had no long-term safety data regarding the implants. Bolton made a strong pitch that Dow Corning had acted improperly, and the jury awarded Hopkins almost \$7.5 million, including \$6.5 million in punitive damages.

The documents Bolton relied upon were under court seal. Nevertheless, the documents were reportedly leaked to Seth Rosenfeld of the *San Francisco Chronicle*.⁷³ Rosenfeld gave the documents to Dr. Norman Anderson of Johns Hopkins Medical Center, who had chaired the FDA panel on implant safety in November. Anderson, in turn, gave the documents to David Kessler.⁷⁴ Anderson sent a cover letter with the documents, offering them as proof of corporate malfeasance.⁷⁵ The letter was then leaked to the media (through Sidney Wolfe) by someone at

72. See Deborah R. Hensler & Mark A. Peterson, *Understanding Mass Personal Injury Litigation: A Socio-Legal Analysis*, 59 BROOK. L. REV. 961, 994 (1993); Richard A. Nagareda, *In the Aftermath of the Mass Tort Class Action*, 85 GEO. L.J. 295, 333 (1996).

73. See Daniel J. Murphy, *Is FDA in Bed with Attorneys?*, INVESTOR'S BUS. DAILY, Dec. 26, 1995, at A1. Around the same time Bolton sent a letter to Dr. David A. Kessler, commissioner of the Food and Drug Administration, describing some company documents revealed during the trial and accusing Dow of "engaging in a consistent pattern of corporate deceit and dishonesty related to the safety of implants." Quoted in Henry Weinstein, *When Law, Tragedy Intersect*, L.A. TIMES, Mar. 26, 1994, at A1; see also Linda Marsa, *The Breast Implant Backlash*, WORKING WOMAN, Apr. 1996, at 46.

74. See Murphy, *supra* note 73, at A1; McNamara-Meis, *supra* note 42, at 46.

75. See McNamara-Meis, *supra* note 42, at 46-47.

the FDA, and was reported in the *New York Times* on Dec. 21, 1991.⁷⁶ Rosenfeld gave the documents to Rep. Weiss as well, and Weiss called for a criminal investigation of Dow Corning.⁷⁷

Never shy about publicity, Dr. Kessler held a press conference on January 6, 1992, the first Monday after the holiday season's media lull. He announced a 45-day "voluntary" moratorium on the sale and use of silicone-gel implants. He justified this moratorium based on his review of the leaked Dow Corning documents.⁷⁸

At the press conference, Kessler did not say the implants were unsafe, but that there was insufficient data on their safety.⁷⁹ In the ensuing media circus, when hyperbolic media stories detailing the alleged dangers of breast implants were omnipresent, this distinction was largely lost on the public. As a result of the moratorium and the attendant publicity, the dozens of lawsuits filed against implant manufacturers turned into hundreds. Reasonable scientific voices that questioned the hysteria over implants, including Angell's,⁸⁰ were drowned out.

Although she disagrees with Kessler's implant ban, Angell asserts that Kessler "almost certainly could not foresee . . . the frenzy of litigation touched off by the ban" (p. 68). Angell is far too generous. In an era where a caller to the Larry King show can set off a panic about brain cancer and cellular phones,⁸¹ leading to several court cases,⁸² Kessler—a savvy and sophisticated individual who has a University of Chicago J.D. to go with his M.D., and who had taught at the Columbia University School of Law—should have been able to foresee the consequences of his actions.

In any event, the breast implant controversy led to exactly the political consequences Kessler, Weiss, and Wolfe wished for—a backlash against Reagan-era deregulation. For example, on the February 13,

76. See *id.*

77. See *id.*

78. The documents contained no new scientific data, so it is unclear why they should have had such a dramatic effect on Kessler. Some media reports have suggested that Kessler had wanted to ban implants even before he saw the leaked documents, but was stymied by his advisory panel's recommendation to keep them on the market. See, e.g., Fumento, *supra* note 40, at 40-41; see also Memorandum from Matthews, *supra* note 16 (reporting the belief that Kessler planned to ban implants). According to this theory, the documents simply gave him the political cover he needed to announce a ban. Based on information provided by Dr. Anderson, however, Angell believes that Kessler was actually planning to leave the implants on the market until he reviewed the leaked Dow Corning documents (p. 56).

79. See David A. Kessler, *Statement on Silicone-Gel Breast Implants* (Jan. 6, 1992) (visited Feb. 1, 1997) <<http://www.fda.gov/bbs/topics/SPEECH/SPE00012>>.

80. See Marcia Angell, *Breast Implants: Protection or Paternalism?*, 326 NEW ENG. J. MED. 1713 (1992).

81. See, e.g., Art Daniels, *Cellular Safety*, NEWARK STAR-LEDGER, July 14, 1996 (discussing the Larry King episode).

82. Shawn Steward, *Wireless Health and Safety Checkup*, CELLULAR BUS., Aug 1, 1995, at 26 (reporting that six lawsuits had been filed alleging cancer caused by cellular phone use).

1992 edition of *PrimeTime Live*, ABC reporter Chris Wallace rebuked the Reagan and Bush Administrations for not regulating breast implants more quickly: "As part of a general push for deregulation, the Reagan and Bush administrations cut back on government enforcement in the health sector. And so after 30 years of selling silicone-gel breast implants, Dow-Corning now faces thousands of women who feel they've been exploited. . . ."⁸³

In February, Dow Corning acquiesced to pressure from the FDA and released its controversial internal memos to the public. Dow Corning's accompanying statement acknowledged that the company had known for twenty years that some silicone gel would seep out of the implants' envelopes, but added that company officials did not believe that the leakage would cause health problems.⁸⁴

In response, Weiss again asked the Justice Department to investigate Dow Corning. Weiss told the media that a review of the recently released Dow Corning documents "presents substantial evidence that the company may have misbranded the device, withheld relevant safety information, failed to report serious risks associated with the device and/or misrepresented their safety data regarding silicone gel breast implants for more than 15 years."⁸⁵

Weiss's remarks were probably intended to influence the FDA General & Plastic Surgery Devices Panel, which was scheduled to meet the next day to decide whether to recommend a permanent ban on breast implants. After three days of hearings, the panel concluded that there was no demonstrated connection between implants and immune system disorders. Nevertheless, the panel voted to recommend limiting access to implants to women requiring reconstruction due to mastectomy, and then only under carefully controlled clinical protocols.⁸⁶ Kessler ultimately implemented this recommendation.⁸⁷

83. *PrimeTime Live* (ABC television broadcast, Feb. 13, 1992) (LEXIS, Nexis library, arcnews File). To take another example, the *St. Petersburg Times* editorialized regarding the FDA: "The agency was virtually defanged during the 1980s deregulation fad under President Reagan, becoming far too chummy with the industries it was supposed to regulate." *Product Safety Costs Money*, ST. PETERSBURG TIMES, Mar. 29, 1992, at 2D.

Wolfe made the point that the implant saga demonstrated the evils of deregulation explicitly in testimony to Congress. See Hearing of the Human Resource & Intergovernmental Relations Subcomm. of the House Gov't. Operations Comm. Subject: Reform of FDA Drug Review Process (Mar. 19, 1992) (testimony of Sidney Wolfe).

84. See Marlene Cimons, *Data Raises New Concerns on Breast Implant Safety*, L.A. TIMES, Feb. 11, 1992, at 1.

85. Weiss Asks Justice to Probe Dow-Corning, L.A. TIMES, Feb. 17, 1992, at D2 (quoting Weiss). A Justice Department probe found no evidence of wrongdoing. *Briefly—Health*, L.A. TIMES, May 18, 1995, at D2.

86. See Council on Scientific Affairs, American Medical Association, *Silicone Gel Breast Implants*, 270 JAMA 2602 (1993); Cruzan, *supra* note 56.

The panel seems to have succumbed to severe political and media pressure, including pressure from Kessler, to "do something" about implants. The scientific evidence had not changed since the panel recommended less than four months earlier that implants remain on the market. In fact, the United Kingdom's Department of Health Special Advisory Group, established to look at evidence of a link between breast implants and immune system disease, found in April 1992 that there was "no scientific case" for restricting the use of implants in the U.K.⁸⁸

Moreover, the FDA panel's new recommendation made no sense: if members of the panel believed that silicone-filled implants were dangerous, recovering cancer patients, who already face health problems, should not have been permitted to have them, particularly when the alternative of saline-filled implants was available. If they were not hazardous, any informed woman should have had access to them. One commentator argues that the decision represented "a grand display of addled logic."⁸⁹ More likely, it represented a display of political logic. Breast cancer survivor groups are well-organized politically, were represented on the FDA panel, and would have bitterly fought a ban on silicone breast implants if the ban had been applied to women who had undergone mastectomies.⁹⁰ Other potential implant recipients were diffuse and unorganized, and had no method of effectively protesting the ban on their use of implants.

Sidney Wolfe expressed disappointment with the panel's failure to recommend a total ban on implants. He told the media: "These devices were shown unsafe in both animals and humans. Now thousands of women will still be guinea pigs."⁹¹ Meanwhile, Wolfe encouraged implant litigation by selling what critics called "how-to-sue" kits to plaintiffs' lawyers for \$750.⁹²

87. See Marian Segal, *Silicone Breast Implants Available Under Tight Controls*, FDA CONSUMER, June 2, 1992 (visited Nov. 23, 1998) <<http://www.fda.gov/bbs/topics/CONSUMER/CON00146.html>>.

88. Letter from Jeremy Tinkler, Toxicologist, United Kingdom Dept. of Health, to Dr. Robert LeVier, Technical Director, Health Care Business, Dow Corning Corp. (May 27, 1992) (on file with author) (summarizing peer-reviewed research reaching this conclusion).

89. Stephen Chapman, *The Breast Implant Panic Lives On*, CHI. TRIB., Mar. 3, 1996, at 19C.

90. This assertion is based on informal conversations the author has had with representatives of breast cancer survivor groups.

91. Philip J. Hilts, *Implant Restrictions Urged*, HOUS. CHRON., Feb. 21, 1992, at A1.

92. *Consumer Crusader Sidney Wolfe, M.D., Causes Pain to FDA, AMA and the Health Industry*, WALL ST. J., Apr. 7, 1992, at A18. According to Wolfe, the kits, which contained reams of medical data culled from journals, FDA papers, and company documents, were sold to aid the plaintiffs' bar's efforts to get compensation for women injured by implants. *Id.*

H. The Litigation Dam Breaks

In April 1992, the *Journal of Plastic and Reconstructive Surgery* published a study that showed no link between breast implants and cancer.⁹³ Two months later, the *New England Journal of Medicine* published another study reaching the same conclusion.⁹⁴

While Wolfe refused to concede that these studies had merit,⁹⁵ plaintiffs' lawyers began to shift their resources from cancer claims to claims that implants cause systemic immune system diseases. There was little evidence to support these claims, but based on what they learned in discovery and from paying attention to what was being presented at scientific meetings in the relevant disciplines, the lawyers knew that it would be several years before contrary epidemiological studies would be published.

In June 1992, the federal Judicial Panel on Multidistrict Litigation certified a multi-district class-action lawsuit against the major implant manufacturers. By December 1992, plaintiffs had filed 3,558 individual lawsuits against Dow Corning.⁹⁶

Angell explains that the litigation dam finally broke for good that month after a jury awarded \$25 million to a breast implant plaintiff, Pamela Johnson (p. 134). Johnson, represented by John O'Quinn, claimed that one of her implants ruptured and that the silicone gel from that implant caused her to get sick (p. 134). Johnson had not been diagnosed with a recognized immune-system disease, but she had a variety of vague, nonspecific complaints (p. 134). Nevertheless, O'Quinn asserted that Johnson suffered from "auto-immune disorder" (p. 134). No one warned her of the potential health risks of implants, O'Quinn said, and the implant manufacturer, Medical Engineering Corp. ("MEC") of Wisconsin, lied to her. Moreover, a second set of implants she received also ruptured, forcing her to have them removed, too, and to get a partial mastectomy. As Angell notes, O'Quinn's presentation of the facts was selective, at best (pp. 134-36).

Johnson's case went to trial in December 1992. Sensing victory, O'Quinn hired a public relations firm that assiduously updated

93. See Dennis M. Deapen & Garry S. Brody, *Augmentation Mammoplasty and Breast Cancer: A 5-Year Update of the Los Angeles Study*, 89 J. PLASTIC & RECONSTRUCTIVE SURGERY 660 (1992).

94. See Hans Berkel et al., *Breast Augmentation: A Risk Factor for Breast Cancer?*, 326 NEW ENG. J. MED. 1649 (1992). A 1993 review of all relevant published data found no evidence that silicone implants cause breast cancer. See Council on Scientific Affairs, American Medical Association, *supra* note 86. A 1995 study confirmed the absence of a linkage between breast implants and cancer. See Heather Bryant & Penny Brasher, *Breast Implants and Breast Cancer—Reanalysis of a Linkage Study*, 332 NEW ENG. J. MED. 1535 (1995).

95. See Jan Gehorsam, *Implants and Cancer: No Link? Research May Aid Efforts to Lift Curbs on Breast Devices*, ATLANTA J. & CONST., June 18, 1992, at A2.

96. See Smart, *supra* note 48.

reporters on the status of the December trial. One public relations agent excitedly talked about possible O'Quinn appearances on *Donahue* and *60 Minutes*.⁹⁷ Court TV broadcast the trial nationwide.

In some ways, O'Quinn had a difficult case. Angell explains that Johnson had received her implants for cosmetic reasons, which could potentially have reduced jury sympathy for her; she did not have a recognized disease; she was a smoker, an alternative possible cause of her problems; and her doctor had mishandled her implants, so he, rather than MEC, may have been at fault for the implant rupture (p. 136).

O'Quinn had several advantages, however. Most important, MEC, like Dow Corning, had created a number of "bad documents" that O'Quinn used to devastating effect at trial. One of these documents was an outline of a 1977 speech MEC's president, Dave Sanders, gave to MEC employees entitled "The Goals of MEC."⁹⁸ The speech opens with the statement "All of us have goals," and soon after that notes that "All of us want the good life." It goes on to argue that the path to the good life is through the use of MEC assets. Nowhere in the speech does Sanders mention service to customers or medical patients as goals of the company. Sanders appeared at trial by videotaped deposition, and did little to dispel the impression that his ultimate concern was profits, not safety.

In addition to making use of the bad documents, O'Quinn artfully cross-examined Neil Rose, a professor at the Johns Hopkins University Medical School and an expert witness for the defendants. O'Quinn asked Rose whether he could understand the fears of women with silicone in their bodies. Rose answered, "I can imagine how they feel. Of course, I'm not in that position myself." O'Quinn retorted "You're lucky." Rose answered, "I am indeed."⁹⁹ Angell notes that it is impossible to tell whether Rose meant he was lucky not to be Johnson, or that he was lucky to be Rose. Rose told Angell that he simply meant to affirm his sympathy for women who had received misinformation about the purported dangers of silicone. A fair reading of the transcript, however, suggests that Rose seemed to be saying that implant recipients' fears were legitimate, and that is almost certainly how the jury understood his testimony.¹⁰⁰ Rose's slip-up undercut his substantive testimony

97. See Richard Connelly, *From Flood to Deluge in Breast-Implant Cases; Houston's Hot in Latest Mass Tort Craze*, TEX. LAW., Jan. 11, 1993, at 1. O'Quinn had hired Churchill Group Inc., Houston's largest public relations firm, to be his breast implant shill as early as 1991. See McNamara-Meis, *supra* note 42, at 43.

98. Handwritten Notes of David Sanders, April 4, 1977 (on file with author).

99. Dr. Neal Rose's Testimony, Trial Transcript at 139, *Johnson v. Bristol-Myers Squibb Co.* (No. 91-021770) (Tex. Harris Cty. Dist. Ct. Dec. 18, 1992).

100. Robert Gordon, a commentator for Court TV, said, "[T]here are moments in trials when one side smiles and the other has a very sinking feeling. This was one of them." Amy Singer, *Look*

that Johnson did not have auto-immune disease and that there is no scientific evidence linking implants with immune system disease (p. 137).

As during the rest of the trial, O'Quinn relied in his closing argument on a combination of jury sympathy for Johnson and a subtle shifting of the burden of proof to the defendants. For example, even though Johnson had no recognized disease, and two studies published earlier in 1992 showed no link between implants and increased risk of cancer, O'Quinn tried to win sympathy for Johnson by stating:

[My client] has seen the women with this disease that has progressed to the point that they can't walk or they can only walk with a cane. Must she not think, Dear God, is this going to happen to me. She's heard of the lymphomas and cancers and all the real serious diseases of that nature that are found among these hundreds of thousands of women with this condition.¹⁰¹

Following the advice of a jury consulting firm,¹⁰² O'Quinn also repeatedly asked the jury to hold the MEC and its parent Bristol-Myers Squibb liable unless they could prove that they knew that breast implants were safe when they marketed them.¹⁰³

O'Quinn's strategy was extremely successful. He persuaded at least one juror that the defendants "really didn't have any regard for humanity."¹⁰⁴ The jury ultimately awarded Johnson \$25 million, including \$20 million in punitive damages. Plaintiffs' attorneys, spotting a lucrative business opportunity, subsequently filed hundreds of new lawsuits during the next several weeks. O'Quinn's firm alone had seven hundred cases pending by the end of 1992 (p. 140). By December 1993, 12,359 individual lawsuits had been filed against Dow Corning.¹⁰⁵ As Richard Laminack, one of O'Quinn's partners, stated, "[T]hat just shows what a \$25 million verdict can do."¹⁰⁶

I. The (Partial) Settlement

In September 1993, breast implant defendants Dow Corning, Bristol-Myers Squibb, Baxter International, and Minnesota Mining & Manufacturing Co. tentatively agreed to a consolidated \$4.75 billion

Over Here: How John O'Quinn Directed a Jury's Attention Toward the Strongest Elements of His Case—and Won the Largest Verdict Ever in a Breast Implant Suit, AM. LAW., Mar. 1993, at 86, 90.

101. Plaintiff's Closing Argument, Trial Transcript at 2503, *Johnson v. Bristol-Myers Squibb Co.* (No. 91-021770).

102. See Singer, *supra* note 100, at 86; see also ANGELL, p. 139.

103. See Plaintiff's Closing Argument, *supra* note 101, at 2477.

104. Singer, *supra* note 100, at 90 (quoting juror Stark).

105. See *Frontline: Breast Implants on Trial*, *supra* note 65.

106. Colleen O'Connor, *Implants in Court*, DALLAS MORNING NEWS, Sept. 7, 1993, at 1C (quoting Jerminack).

settlement of the federal class action.¹⁰⁷ This settlement ultimately collapsed because far more women than had been expected asserted claims against a limited pool of money, and a new agreement proved elusive.

One reason the parties were unable to agree to a new settlement is that thousands of women, often those with the best cases to present to a jury, and including all of O'Quinn's clients, chose to forego settlement and sue individually.¹⁰⁸ Dow Corning declared bankruptcy, throwing the settlement talks into limbo. Eventually, the other implant manufacturers offered a new settlement, which 92% of eligible women accepted.¹⁰⁹

O'Quinn's strategy of refusing to participate in the class settlement seemed particularly prescient in March 1994 when he persuaded a jury to award two breast implant plaintiffs \$19.2 million in actual damages, and another \$10 million in punitives.¹¹⁰ The plaintiffs complained of vague symptoms of fatigue, malaise, and muscle pain after receiving implants. One of the plaintiffs also claimed the implants caused her lupus. Unlike past victorious plaintiffs, the plaintiffs in this case had intact implants. O'Quinn's theory was that even the minute amount of silicone that leak through intact implants causes immune system problems.¹¹¹

O'Quinn had asked the jury for \$150 million in punitive damages. According to the Houston Post, O'Quinn told jurors "it would take at least that much to get the multi-billion-dollar company's attention." In regard to the \$10 million punitive award, he said, "'Frankly, it may not be strong enough.' 'The whole attitude of the corporations has been to write these women off as crazy. That is not so. These women are genuinely sick from this product. They ought to stop it.'"¹¹²

J. And the Results Are In: Scientific Evidence Comes to the Fore

Breast implant manufacturers were not panicking at this point; they knew that several unpublished epidemiological studies showing no relationship between implants and connective tissue disease had already been presented at professional meetings and would be published over the next few years. They hoped that with the help of an aggressive public relations campaign, this new information would turn the litigation, and with it, public opinion, in their favor.

107. Under the settlement agreement, each claimant was to receive payments ranging from \$200,000 to \$2 million. *See Gina Kolata, Fund Proposed for Settling Suits Over Breast Implants*, N.Y. TIMES, Sept. 10, 1993, at A16.

108. *See Robert Elder, Jr., Dow Calls for Texas Implant Summit*, TEX. L.W., Aug. 8, 1994, at 1.

109. *See Thousands Settle Implant Litigation*, ORANGE COUNTY REG., Feb. 12, 1997, at C3.

110. *See Doss v. McGhan Med. Corp.*, No. 92-14155 (Tex. Harris Cty. Dist. Ct. Mar. 4, 1994).

111. *See McGhan, 3M Trial Underway in Houston*, MEALEY'S LITIG. REP.: BREAST IMPLANTS, Feb. 3, 1994.

112. Matt Schwa, *Plaintiffs Happy with \$ 29 Million; Implant Makers Vow to Appeal Jury's Verdict*, Hous. Post, Mar. 4, 1994, at A19 (quoting O'Quinn).

The first of these studies was published in the *New England Journal of Medicine* in June 1994.¹¹³ The study, conducted at the Mayo Clinic, compared 749 women who had breast implant surgery with a similar group of 1,498 women who had not had such surgery. The study found no association between breast implants and a wide variety of connective-tissue diseases.

In an accompanying editorial, Angell noted that the results of the study could not "conclusively rule out some association of breast implants with the disorders studied However, because there was no indication of such an association, any possible risk from breast implants in this population could not be large."¹¹⁴

By this time, the plaintiffs' attorneys also knew that the emerging scientific evidence was against them. They had already shifted their focus to the theory that breast implants may not cause recognized diseases, but do cause clusters of symptoms constituting "atypical connective-tissue disease."¹¹⁵ For example, Frank Vasey, a frequent expert for the plaintiffs, claimed upwards of ninety symptoms associated with "silicone disease."¹¹⁶

The beauty of the atypical disease theory—from the plaintiffs' lawyers' perspective—is that it cannot be disproved. Because no clear definition of an "atypical" disease exists, it is impossible to design an epidemiological study to determine the existence or causes of such a condition (p. 199). Hundreds of thousands of people suffer from a

113. See Sherine E. Gabriel et al., *Risk of Connective-Tissue Diseases and Other Disorders After Breast Implantation*, 330 NEW ENG. J. MED. 1697 (1994). Angell discusses this study in *Science on Trial* (pp. 100-01).

114. Marcia Angell, *Do Breast Implants Cause Systemic Disease? Science in the Courtroom*, 330 NEW ENG. J. MED. 1748, 1748 (1994). For a letter critical of the Gabriel study and the authors' response, see *Correspondence: Breast Implants and Connective-Tissue Diseases*, 331 NEW ENG. J. MED. 1231 (1994).

115. See, e.g., Gary Solomon et al., *Letter to the Editor*, 331 NEW ENG. J. MED. 1231 (1994).

116. See FRANK VASEY & JOSH FELDSTEIN, *THE SILICONE BREAST IMPLANT CONTROVERSY: WHAT WOMEN NEED TO KNOW* (1993) (identifying the following associated symptoms of "silicone disease": suicidal depression, mental lapses, pain in gallbladder, loss of sex drive, chronic exhaustion, night sweats, insomnia, flu-like symptoms, mouth ulcers, poor concentration, memory failure, abdominal pain, pain in groin, fluid retention, asthma-like wheezing, frequent urination, unexplained rashes, arthritis, difficulty swallowing, swollen lymph nodes, dry eyes/mouth, shortness of breath, difficulty breathing, crushing chest pain, muscle weakness, gallbladder pain, gallbladder polyps, Scleroderma, rheumatic disease, human adjuvant disease, auto-immune disease, connective-tissue disease, emotional breakdown, appetite loss, heart attack symptoms, depression, hypertension, tremors, weight loss, weight gain, joint pain, dizzy spell, hair loss, numbness in limbs and head, burning, tingling, hardening of breast, gastrointestinal problems, urinary tract problems, irritable bowel, sleep disturbances, redness of the palms, (palmar erythema), blurred vision, neck pain, fibromyalgia, rheumatoid arthritis, low grade fevers, nausea, tender "points" on body, kidney failure, facial pain, double vision, vertigo, pleurisy, lung pain, migraine headaches, cold sensitivity, multiple sclerosis, small areas of muscle that quiver, twitches, back pain, neck pain, chronic cough, multiple environmental allergies, chronic bronchitis, lupus, Sjogren's disease, heart palpitations, joint inflammation, clumsiness, and morning stiffness).

variety of symptoms—chronic fatigue, insomnia, depression, headaches, muscle and joint pain, and so on—that do not constitute a recognizable immunological disease. Based on chance alone, these symptoms will occur in women with breast implants as well as in women without implants. Yet lured by lucre, an entire industry of what defense attorneys disparagingly call “silicone doctors” developed. These doctors claimed to trace a wide range of symptoms in women referred to them by plaintiffs’ attorneys to silicone poisoning. Using speculative and possibly fraudulent tests never approved by the FDA for diagnosis,¹¹⁷ some of these doctors claimed to be able to detect circulating serum antibodies to silicone, and “autoantibodies” to a number of allegedly “silicone-modified” host proteins.¹¹⁸

The authors of the Mayo Clinic study discussed above did their best to test for an increase in atypical immune system disease among women with implants by checking for symptoms often associated with connective tissue disorders.¹¹⁹ Of the fifteen symptoms studied, only morning stiffness was more prevalent among women who had implants than among those who did not.

A year later, the *New England Journal of Medicine* published a larger, more refined study that also found no association between implants and connective-tissue disorders.¹²⁰ The study was based on data from 87,501 nurses followed for other research purposes from 1976 through 1990. None of the women had connective-tissue disease at the start of the study, but 876 of them had silicone breast implants.

The authors of the study reported that 516 of the nurses had developed definite connective-tissue diseases. Only one of the 516 women had silicone breast implants; two women with other types of implants also contracted connective-tissue disease. The authors concluded they “did not find an association between silicone breast implants and connective-tissue disease, defined according to a variety of standardized criteria, or signs and symptoms of these diseases.”¹²¹

As a result of the two studies, the American College of Rheumatology adopted and released a “Statement on Silicone Breast Implants.” The Statement argued that “these studies provide compelling evidence that silicone implants expose patients to no

117. See *Diagnostic Tests for Silicone Breast Disease*, CDC MORTALITY & MORBIDITY WKLY REP., Feb. 9, 1996, at 111, 111-12 (stating that according to the FDA, “the value and usefulness of these tests remains speculative,” and that they “should not be used for patient diagnosis”).

118. *Id.* at 112.

119. See Gabriel, *supra* note 113.

120. See Jorge Sánchez-Guerrero et al., *Silicone Breast Implants and the Risk of Connective-Tissue Diseases and Symptoms*, 332 NEW ENG. J. MED. 1666 (1995). Angell discusses this study in *Science on Trial* (p. 102).

121. Sánchez-Guerrero, *supra* note 120.

demonstrable additional risk for connective-tissue or rheumatic disease. Anecdotal evidence should no longer be used to support this relationship in the courts or by the FDA.¹²² David Kessler, meanwhile, told Congress that the FDA believed that it could rule out the possibility that implants cause a large increase in the risk of connective tissue disease.¹²³

In early 1996, the *Journal of the American Medical Association* published a study of approximately 400,000 women, about 11,000 of whom had breast implants.¹²⁴ The study found a 24% increase in the incidence of self-reported connective-tissue disease in women with implants. The significance of this increase is unclear, but, as Angell explains, given certain methodological problems with the study,¹²⁵ and the small amount of the increase,¹²⁶ the authors correctly concluded that the study was consistent with other studies that had shown no increase. In any event, the increase, if it really exists, is not nearly sufficient to prove causation for any individual plaintiff by the more probably than not standard, which would require over a 100% increase in risk.¹²⁷

Respectable peer-reviewed medical journals have published over a dozen other studies of varying degrees of persuasiveness showing no link between implants and systemic disease.¹²⁸ Most recently, the *British*

122. American College of Rheumatology, *Statement on Silicone Breast Implants* (Oct. 22, 1995) (on file with author).

123. See Hearing Before the Subcomm. on Human Resources and Intergovernmental Relations of the House Comm. on Gov't. Reform and Oversight 16-17 (Aug. 1, 1995) (statement of David A. Kessler, Commissioner, FDA & D. Bruce Burlington, Director, Center for Devices and Radiological Health, DHHS).

124. See Charles H. Hennekens et al., *Self-Reported Breast Implants and Connective-Tissue Diseases in Female Health Professionals*, 275 JAMA 616 (1996). Angell discusses this study (pp. 101-02).

125. Unlike in the other epidemiological studies, the authors of this study did not review the medical records of the women to ensure that they really had connective-tissue disease. The study was based on self-reported information and conducted after the publicity about breast implants and connective-tissue disease had begun. This publicity may have led women with breast implants to over-report suffering from connective-tissue disease, potentially undermining their reliability (p. 102).

126. Epidemiologists generally agree that very small increases in risk revealed by epidemiological studies cannot be distinguished from statistical noise resulting from the inherent imperfections in such studies. See, e.g., Lynn Rosenberg, *Induced Abortion and Breast Cancer*, 86 J. NAT'L CANCER INST. 569 (1994) (stating that a 50% increase in risk "is small in epidemiologic terms and challenges our ability to distinguish if it reflects cause and effect or if it simply reflects bias").

127. See David E. Bernstein, *The Admissibility of Scientific Evidence After Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 15 CARDOZO L. REV. 2139, 2170-72 (1994).

128. See, e.g., J.V. Lacey Jr. et al., *Epidemiology of Scleroderma Among Women: Assessment of Risk from Exposure to Silicone and Silica*, 24 J. RHEUMATOLOGY 1853 (1997); M.C. Hochberg et al., *Lack of Association Between Augmentation Mammoplasty and Systemic Sclerosis*, 34 ARTHRITIS AND RHEUMATISM 1125 (1996).

Medical Journal published a Swedish study confirming the absence of a link between breast implants and connective tissue disease.¹²⁹

Since the *Nurse* study was published, breast implant defendants have won the vast majority of cases that have gone to trial, though their record is not sufficiently good to halt the litigation.¹³⁰ Meanwhile, thousands of individual breast implant cases continue to be litigated in state and federal courts, the class action settlement is moving toward resolution, and a settlement of the claims against Dow Corning which have been mired in bankruptcy court, is pending.

K. Lessons from the History of the Breast Implant Litigation

The factors that the editors of *Phantom Risk*¹³¹ suggest drive litigation over phantom risks—political posturing, sensationalistic media coverage, public outrage, and financial incentives for plaintiffs’ attorneys—have driven the breast implant litigation. Sidney Wolfe, Ted Weiss, and David Kessler exaggerated the dangers of breast implants, at least in part to gain support for their political agendas. Sensationalistic media coverage by Connie Chung and many others helped fuel public outrage. Public opinion was further inflamed by revelations that implant manufacturers had not followed up on concerns about the potential health effects of silicone. These factors, along with a contingency fee system that encourages speculative litigation, explain why plaintiffs’ attorneys began to launch a courtroom assault on implant manufacturers.

However, this does not explain why particular phantom risks such as breast implants ultimately attract multi-billion dollar litigation, while other phantom risks draw few if any lawsuits. The answer seems to be that plaintiffs’ attorneys must win a few big, early victories to attract the investment by other attorneys that creates an irrepressible flood of litigation. Such early victories, meanwhile, depend on a combination of jury outrage at perceived malfeasance by the defendants, superior lawyering by the plaintiffs’ attorneys relative to the defendants’ attorneys, jury attitudes toward the product at issue, and, most important, the unavailability of scientific evidence favoring the defendant.

The breast implant litigation spun out of control only after plaintiffs won several multi-million dollar verdicts. Poor lawyering by the defendants’ attorneys was a partial cause of these victories. In one early

129. See Olof Nyrén et al., *Risk of Connective-Tissue Disease and Related Disorders Among Women with Breast Implants: A Nation-Wide Retrospective Cohort Study in Sweden*, 316 BRIT. MED. J. 417 (1998).

130. According to information collected on the multi-district litigation website, since January 1996 defendants have emerged victorious in fifteen trials, and plaintiffs have won five. In one of the five plaintiff victories, the jury awarded only \$30,000. See <<http://www.fjc.gov/BREIMLIT/trials.htm>> (visited Oct. 7, 1998).

131. See *supra* note 3 and accompanying text.

case the trial judges granted a remittitur of damages because the plaintiff's scientific evidence was not generally accepted.¹³² At the time, the test for the admissibility of scientific evidence in the relevant federal circuit, the Eleventh Circuit, was unclear.¹³³ However, some courts had begun to apply a relatively strict standard for the admissibility of scientific evidence in the late 1980s. Some courts even applied a test in which "general acceptance" was an important factor.¹³⁴ But as far as can be determined, no motion to exclude a plaintiff's scientific evidence in a breast implant case was made until *Hopkins*. In another example of poor lawyering, recall that Dr. Neil Rose was not adequately prepared for his trial testimony in the extremely important *Johnson* case.¹³⁵

The existence of the "bad documents" also hurt the defendants by inflaming jury sentiment against them and creating a rationale for large punitive damages. Ultimately, however, what probably damaged the defendants most at trial was their lack of investment in scientific studies regarding the safety of breast implants. In this context, it is useful to contrast the breast implant litigation with another example of phantom risk litigation that also potentially encompassed thousands of plaintiffs, yet seems almost certain ultimately to cost defendants far less—litigation alleging that power lines cause leukemia and other cancers.

One can draw explicit parallels between the factors that drove the breast implant litigation and those that have driven the electro-magnetic field litigation.¹³⁶ Unlike the breast implant manufacturers, however, the electric power industry had been voluntarily studying the health effects of its "product," electromagnetic radiation, for years before the personal injury lawsuits began.¹³⁷ Ultimately, this investment in research paid off in the litigation arena. When personal injury suits went to court,

132. See *Toole v. McClintonck*, 778 F. Supp. 1543 (M.D. Ala. 1991), *vacated*, 999 F.2d 1430 (11th Cir. 1993).

133. See *United States v. Piccinonna*, 885 F.2d 1529 (11th Cir. 1989); *United States v. Hope*, 714 F.2d 1084, 1087 & n.3 (11th Cir. 1983).

134. See David E. Bernstein, *Leading Expert Evidence: An American Perspective*, 3 JAMES COOK U. L. REV. 93, 96 (1996); David E. Bernstein, Note, *Out of the Fryeing Pan and into the Fire: The Expert Witness Problem in Toxic Tort Litigation*, 10 REV. LITIG. 117, 130-34 (1990).

135. See *supra* notes 100-01 and accompanying text. Another cause of the plaintiffs' victories may have been jury distaste for the defendants' products. Virginia Postrel suggests that, in their decision to hold breast implant manufacturers liable, jurors may have been influenced by a belief that breast enhancement is a frivolous, unnatural, and unnecessary activity. See Virginia I. Postrel, *Abreast of History*, 27 REASON, Jan. 1996, at 4-5.

136. See San Diego Gas & Electric, *Promoting EMF as the Next 'Mass Tort' (Or, What Really Is Driving the EMF Issue)*, ANDREWS ELECTROMAGNETIC FIELD LITIG. REP., June 1997, at 13 (noting that in both instances, alarmist media coverage, political interference with the regulatory process, and lawyers' financial incentives have driven the litigation, despite the lack of probative scientific evidence supporting the plaintiffs' claims).

137. The Electric Power Research Institute, funded by the utility industry, has been studying the health effects of power lines since its founding in 1973. See Joe Wayne, *Power Struggles*, CAL. LAWYER, June 1993, at 20.

the defendant power companies had scientific data on their side, and plaintiffs' attorneys could not portray the companies as unconcerned with the potential health effects of electromagnetic radiation. Defendants therefore emerged victorious in the first three cases to go to trial,¹³⁸ and personal injury claims against them have come to a virtual halt. The contrast with the history of breast implant litigation is apparent.

Thus, it seems that the breast implant litigation was particularly costly for the defendants primarily because the implant manufacturers had never done the requisite studies to prove that implants were safe. This made it much more difficult to persuade juries to rule in the defendants' favor on causation, and also fed jury outrage, leading to massive punitive damage awards against implant manufacturers in *Hopkins* and *Johnson*. The absence of persuasive studies showing that implants were safe also undoubtedly dissuaded judges from granting summary judgment or directed verdicts to the defendants.

The lesson we can tentatively draw is that when a jury is faced with a plausible claim that a defendant's product injured a plaintiff, and is convinced that the defendant did not adequately research the health effects of that product, it will frequently find for the plaintiff and be upheld on appeal unless the defendant can present solid scientific evidence refuting the plaintiff's claims. If the defendant cannot produce such evidence, jury outrage will manifest itself in punitive damage awards sufficient to create financial incentives to turn small-scale litigation into a mass tort. Once the litigation dam breaks, even favorable scientific evidence will not totally resolve the defendant's problems; although plaintiffs' attorneys have lost the vast majority of breast implant cases that have gone to trial during the last few years,¹³⁹ the average contingency fee from trials and settlements has been sufficient to encourage the attorneys to continue the litigation.

II

REFORMING THE AMERICAN TORT SYSTEM

Angell would like to reduce or eliminate each factor that leads to phantom risk litigation—political interference in the scientific process, sensationalistic media coverage, public outrage that is heedless of science, and financial incentives for plaintiffs and their attorneys that encourage them to bring speculative cases. Of these factors, legislation can only control financial incentives that lead to litigation. Controlling this factor will therefore be the focus of this part of this Review.

138. See Alan K. Stazer & James D. Otto, *Electro-Magnetic Fields: Hazardous Fact or Lucrative Fiction?*, 20 INT'L COMMERCIAL LITIG., June 1997, at 31, 32.

139. See *Breast-implant cases on trial or set for trial* (last modified Jan 24, 1999) <<http://www.fjc.gov/BREIMLIT/trials2.htm>>.

To prevent future litigation fiascoes, Angell suggests radical but sensible reforms of the American tort system that would reduce attorneys' financial incentives to bring scientifically dubious claims. First, Angell strongly recommends that courts establish stricter standards for the admissibility of scientific evidence (pp. 204-05). She also argues that contingency fees should be limited (pp. 203-04). Finally, she suggests that legislators consider eliminating jury trials in tort cases (p. 204). Unfortunately, Angell gives only brief consideration to each of these ideas. This section considers her recommendations in far greater detail than does *Science on Trial*.

A. *Raising the Standards for Scientific Expert Evidence*

Drawing on a pervasive theme in *Science on Trial*, Angell calls for the legal system to raise scientific standards in the courtroom. According to Angell, *Hopkins* illustrates the mischief that can be done when courts allow purported experts to peddle junk science¹⁴⁰ to juries (pp. 120-23, 131-32). Dan Bolton, Marianne Hopkins' attorney, called three expert witnesses to testify at trial. Despite the dubious bases for these experts' testimony, which Angell dissects in detail (pp. 120-25), the district court permitted them to testify over the defendant's objection.

It would be unfair to put too much blame on the district court for this ruling; at the time, the rules for the admissibility of scientific evidence in toxic tort cases were generally liberal. No federal court of appeals clearly adopted a strict test for the admissibility of scientific evidence in toxic tort cases until August 1991.¹⁴¹ Moreover, the most relevant precedents in the Ninth Circuit, where *Hopkins* was decided, seemed to favor the let-it-all-in approach.¹⁴²

The issue of the proper test for the admissibility of scientific evidence under the Federal Rules of Evidence came before the Supreme Court in 1993 in *Daubert v. Merrell Dow Pharmaceuticals*.¹⁴³ The Court established a two-part test for determining the admissibility of scientific evidence under Federal Rule of Evidence 702. First, the Court held that the Rule's requirement of "scientific knowledge" establishes a standard of evidentiary reliability. "Evidentiary reliability," the Court held,

140. This phrase was popularized by Peter Huber. See PETER W. HUBER, GALILEO'S REVENGE: JUNK SCIENCE IN THE COURTROOM (1991).

141. See *Christophersen v. Allied-Signal Corp.*, 939 F.2d 1106 (5th Cir. 1991). The Ninth Circuit adopted a strict test in December in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 951 F.2d 1128 (9th Cir. 1991), *vacated*, 509 U.S. 579 (1993).

142. See *Roy v. Volkswagen of America, Inc.*, 896 F.2d 1174 (9th Cir. 1990) (reinstating a jury verdict in a products liability case vacated by a trial judge who rejected the validity of the plaintiff's expert witness testimony); *Bulthuis v. Rexall Corp.*, 789 F.2d 1315, 1318 (9th Cir. 1985) (holding that a jury verdict may be based on the opinion of a qualified expert, even if the expert fails to explain his reasoning).

143. 509 U.S. 579 (1993).

means “trustworthiness,” and depends on “scientific validity.”¹⁴⁴ Next, the Court held Rule 702 mandates that scientific expert testimony “assist the trier of fact . . . [in making] a valid scientific connection to the pertinent inquiry as a precondition to admissibility.”¹⁴⁵ The Court also enumerated a non-exclusive list of factors that may “bear on the inquiry” as to whether scientific evidence is admissible.¹⁴⁶

Daubert clearly prohibited federal judges from adopting a let-it-all-in approach. Beyond that, the practical implications of the opinion were unclear. Some judges and legal scholars argued that in the toxic tort arena *Daubert* required courts to limit themselves to determining whether a scientific expert witness was relying on studies that used a methodology appropriate for inquiry into the general subject at issue. Others maintained that courts should also review the expert’s reasoning in extrapolating from those studies to causation.¹⁴⁷

This debate was more than simply academic. When the Ninth Circuit ruled on Dow Corning’s appeal of *Hopkins*, it purported to apply *Daubert*.¹⁴⁸ But Judge Proctor Hug adopted the “general methodologies only” approach, and wrote what Angell demonstrates to be a poorly reasoned opinion affirming the district court’s decision to admit the testimony of Bolton’s experts (p. 124). Judge Hug concluded that the plaintiffs’ experts’ evidence was admissible because their opinions were based on the “types of scientific data and utilized the types of scientific techniques relied upon by medical experts in making determinations regarding toxic causation where there is no solid body of epidemiological data to review.”¹⁴⁹ Despite the absence of any published data confirming the experts’ conclusions, Judge Hug found that “the reasoning or methodology underlying” their testimony satisfied *Daubert* and that their “testimony is scientifically valid.”¹⁵⁰

Hopkins was among the first appellate decisions to be issued after *Daubert*. Several other Ninth Circuit opinions, none of which are discussed by Angell, undermined *Hopkins*’ precedential value. First, two

144. *Id.* at 590 n.9.

145. *Id.* at 591-92.

146. The factors include: (1) whether the theory or technique at issue can be, or has been, tested; (2) peer review and publication; (3) the known or potential rate of error of a technique in question, as well as the existence and maintenance of standards controlling the technique’s operation; and (4) the degree of acceptance of the evidence in question in the relevant scientific community. See *id.* at 594.

147. Compare Bernstein, *supra* note 127 (arguing that *Daubert* requires courts to assess reasoning), with Kenneth J. Chesebro, *Taking Daubert’s “Focus” Seriously: The Methodology/Conclusion Distinction*, 15 CARDOZO L. REV. 1745 (1994), and Michael H. Gottesman, *Admissibility of Expert Testimony After Daubert: The “Prestige” Factor*, 43 EMORY L.J. 867, 869-72 (1994) (both arguing that under *Daubert*, courts may only assess experts’ general methodology).

148. See *Hopkins v. Dow Corning Corp.*, 33 F.3d 1116, 1124 (9th Cir. 1994).

149. *Id.* at 1124.

150. *Id.* at 1125.

courts explicitly rejected the methodologies-only approach, and held that courts must examine an expert's underlying reasoning.¹⁵¹ Even more significant, on remand from the Supreme Court the Ninth Circuit issued an extremely influential opinion interpreting *Daubert*.¹⁵² The court held that *Daubert* requires district courts to engage in a searching inquiry that ensures that scientific evidence presented by plaintiffs in toxic tort cases is scientifically valid. According to the *Daubert* remand court, not only must the underlying methodology relied upon by the expert be valid for some purposes, but the expert must be able to extrapolate from that evidence to specific causation in a valid manner.¹⁵³

These stricter Ninth Circuit opinions had a crucial effect on the next breast implant case to arise in the Circuit. In 1996 Federal District Judge Robert E. Jones of Oregon was faced with a motion to exclude all of the plaintiffs' scientific evidence on causation in cases alleging that implants cause silicone-related atypical auto-immune disease.¹⁵⁴ Judge Jones found that the very existence of this disease is "at best an untested hypothesis,"¹⁵⁵ and that the notion that breast implants cause this disease is even more speculative. He therefore ruled that the plaintiffs' evidence was inadmissible. The opinion largely ignored *Hopkins* and adopted the view that expert witnesses must not only use accepted methodologies, they must extrapolate from them in valid ways.¹⁵⁶

151. See *Lust v. Merrell Dow Pharmaceuticals, Inc.*, 89 F.3d 594, 598 (9th Cir. 1996) ("When a scientist claims to rely on a method practiced by most scientists, yet presents conclusions that are shared by no other scientist, the district court should be wary that the method has not been faithfully applied."); *Claar v. Burlington Northern R.R. Co.*, 29 F.3d 499, 500 (9th Cir. 1994) (emphasizing that a district court is "both authorized and obligated to scrutinize carefully the reasoning and methodology" underlying the expert's proffered testimony).

152. See *Daubert v. Merrell Dow Pharmaceuticals*, 43 F.3d 1311 (9th Cir. 1995).

153. See *id.* at 1320 (noting that the expert must explain why it is proper to extrapolate from animal studies to causation in humans); *id.* at 1321 (upholding exclusion of plaintiffs' experts on specific causation issue because they were unwilling to specifically argue that the studies they relied upon show that Bendectin caused the plaintiffs' birth defects).

154. See *Hall v. Baxter Healthcare Corp.*, 947 F. Supp. 1387 (D. Or. 1996).

155. *Id.* at 1402.

156. In fact, two prominent experts on scientific evidence admonished Jones for not heeding the methodology/conclusions distinction. See Joseph Sanders & D.H. Kaye, *Expert Advice on Silicone Implants: Hall v. Baxter Healthcare, Inc.*, 37 JURIMETRICS J. 113 (1997). They suggested that Jones was wrong in excluding Dr. Shanna Swan's testimony after finding that her techniques of re-analyzing epidemiological studies had never been peer reviewed or espoused by anyone else whose work had been subject to the peer-review process. Professors Sanders and Kaye wrote that "even if Dr. Swan's position is aberrational, it easily could be argued that her critique rests on well-known concepts such as statistical power. The problem of distinguishing methodology, which must satisfy *Daubert*, and conclusions, which are outside its scope and need not be generally accepted, looms large here." *Id.* at 122.

At least three other judges have also excluded plaintiffs' expert evidence in breast implant cases. See *Kelley v. Heyer-Shulte Corp.*, 957 F. Supp. 873 (W.D. Tex. 1997); *Johnson v. Baxter*, No. CV-92-07501 (N.M. Cir. Ct. Feb. 23, 1998); *Bailey v. Dow Corning Corp.*, No. 94-1199-A (Tex. Dallas Cty. Dist. Ct. Sept. 16, 1996).

Judge Jones' interpretation of *Daubert* was vindicated, and Judge Hug's put to rest, by the Supreme Court's December 1997 opinion in *General Electric Co. v. Joiner*.¹⁵⁷ The *Joiner* Court acknowledged that under *Daubert* district courts must focus on principles and methodology, and not on the conclusions that they generate. However, the Court added, "conclusions and methodology are not entirely distinct from one another."¹⁵⁸ "Trained experts," it is true, "commonly extrapolate from existing data. *But nothing in either Daubert or the Federal Rules of Evidence requires a district court to admit opinion evidence which is connected to existing data only by the ipse dixit of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.*"¹⁵⁹

Joiner was an extremely important judicial step toward sound science in the courtroom, and a step that would surely please Angell, given her critique of the Ninth Circuit's ruling in *Hopkins*. In fact, since *Joiner*, a Ninth Circuit panel affirmed a district court decision excluding evidence of the alleged toxicity of silicone in a case involving a brain shunt.¹⁶⁰ The opinion failed even to mention *Hopkins*. Also since *Joiner*, a Texas appellate court and a federal district court, both applying *Daubert* and *Joiner*, have excluded plaintiffs' scientific evidence in breast implant cases.¹⁶¹

The development of the law on scientific evidence since *Hopkins* suggests that Angell may be unduly pessimistic when she concludes that *Daubert* did not "herald[] a new, more rational era in the courts" (p. 131). On the other hand, even after *Joiner*, two significant problems with the admissibility of scientific evidence loom.

First, while federal courts are bound by Supreme Court rulings, most state courts have not yet adopted *Daubert*, much less *Joiner*. This leaves plenty of opportunities for "junk science"¹⁶² not meeting the *Daubert/Joiner* standard to filter into the tort system. Just two months after *Joiner* was decided, for example, the Oregon Court of Appeals overturned a trial judge's exclusion of highly dubious evidence in a breast implant case.¹⁶³ The Court of Appeals, interpreting Oregon's evidence code, held that proffered expert testimony merely needs to be

For a short and favorable commentary on *Hall*, see David E. Bernstein, *Breast Implant Science Headed to the Junkyard*, SEATTLE TIMES, Jan. 30, 1997, at B5.

157. 118 S. Ct. 512 (1997).

158. *Id.* at 519.

159. *Id.* (emphasis added).

160. See *Cabrera v. Cordis Corp.*, 134 F.3d 1418 (9th Cir. 1998).

161. See *In re Breast Implant Litigation*, Master File No. 96-S-9620 (D. Colo. June 3, 1998); *Minnesota Mining and Mfg. Co. v. Atturbury*, 978 S.W.2d 183 (Tex. Ct. App. 1998).

162. See David E. Bernstein, *Junk Science in the United States and the Commonwealth*, 21 YALE J. INT'L L. 123 (1996).

163. See *Jennings v. Baxter Healthcare Corp.*, 954 P.2d 829 (Or. Ct. App. 1998).

based on a "hypothesis that depends on relevant, empirical data derived from scientific methodology."¹⁶⁴ In July 1998, meanwhile, the Massachusetts Supreme Court upheld the admission of plaintiffs' expert evidence in a breast implant case.¹⁶⁵ The Court, which purported to apply a test similar to *Daubert* but failed to even mention *Joiner*, emphasized that it agreed with the *Hopkins* court "that the relevant issue was the scientific validity of the methods relied on by the experts to form their conclusions," and that challenges to how these methods were used "go to the weight, not the admissibility, of the evidence."¹⁶⁶

The second post-*Joiner* problem with scientific evidence is that district court judges are not usually well-qualified to engage in the type of scientific inquiry that *Daubert* and *Joiner* require. Angell suggests that "[t]he most important reform we could make to raise scientific standards in the courtroom would be for judges to appoint expert witnesses," rather than relying on adversarial experts (p. 205). This idea has the support of many legal scholars, including Justice Stephen Breyer,¹⁶⁷ and seems sound if procedural obstacles can be overcome. Not only can court-appointed experts provide the court with scientific wisdom, they can also provide judges issuing unpopular and controversial rulings with scientific credibility.¹⁶⁸

Since Angell wrote *Science on Trial*, courts faced with breast implant claims have actively started to use court-appointed experts as advisors. In April 1996, one state and two federal judges in New York City issued a joint opinion appointing a neutral panel, which in turn was to appoint a scientific panel to advise the judges on the state of the scientific evidence regarding breast implants and immune system disease.¹⁶⁹ One of the judges involved was Jack Weinstein, a former evidence professor known for his skepticism of unproven scientific claims. The plaintiffs' steering committee for the federal class action went to Judge Pointer and asked him to appoint his own panel of scientific experts.

164. *Id.* at 834.

165. See *Vassallo v. Baxter Healthcare Corp.*, 696 N.E.2d 909 (Mass. 1998).

166. *Id.* at 918.

167. See, e.g., *General Electric Co. v. Joiner*, 118 S. Ct. 512, 520 (1997) (Breyer, J., concurring) (encouraging appointment of neutral experts); AMERICAN LAW INST., 2 ENTERPRISE RESPONSIBILITY FOR PERSONAL INJURY 339-45 (1991); JOE S. CECIL & THOMAS E. WILLGING, FEDERAL JUDICIAL CENTER, COURT-APPOINTED EXPERTS: DEFINING THE ROLE OF EXPERTS APPOINTED UNDER FEDERAL RULE OF EVIDENCE 706 (1993); PHANTOM RISK, *supra* note 2, at 437; E. Donald Elliott, *Toward Incentive-Based Procedure: Three Approaches for Regulating Scientific Evidence*, 69 B.U. L. REV. 487, 508-09 (1989).

168. Of course, judges who intentionally favor one side or the other despite rules of judicial ethics are unlikely to be stopped by *Daubert* or any other rule. *Daubert* may work better when litigation is limited to a single case than when dozens of cases exist nationwide. The latter situation allows plaintiffs' attorneys to try to consolidate a class action in a friendly jurisdiction or before a friendly judge. The author thanks Ed Richards for raising this point.

169. See Eliot Marshall, *New York Courts Seek "Neutral" Experts*, 272 SCIENCE 189 (1996).

Judge Pointer agreed to do so, and the New York judges suspended their effort.¹⁷⁰

Federal District Judge Robert Jones had appointed his own panel of breast implant experts. In December 1996, he relied on the advice of these experts and delivered an opinion, discussed previously,¹⁷¹ excluding the plaintiffs' evidence in the several dozen breast implant cases pending before him.¹⁷² Meanwhile, Dow Corning filed an unsuccessful motion asking the bankruptcy court to appoint a scientific advisory panel to help it estimate the extent of the company's liability.¹⁷³ Neutral scientific panels may very well be the wave of the future in toxic tort litigation.

Despite Angell's justified attack on the role of junk science in creating and sustaining litigation over breast implants, it is not clear whether loose or ambiguous standards for the admissibility of scientific evidence are primarily to blame for encouraging litigation involving phantom risks. Other common-law countries have not faced a deluge of such litigation, even though they have much more liberal rules for the admissibility of scientific evidence in civil cases than does the United States.¹⁷⁴ These other countries, however, have largely abolished civil juries, banned contingency fees, enforced the loser-pays fee-shifting rule, and limited punitive damages.¹⁷⁵ The rules for the admissibility of scientific evidence have been subjected to intense scrutiny in the United States. Perhaps it is time to start paying a bit more attention to our legal system's anomalous procedural rules. Two of these anomalies—the prevalence of virtually unregulated contingency fees and the use of civil juries—are criticized by Angell and are discussed below.

B. Limiting Contingency Fees

Angell argues that “[t]he practice of paying lawyers contingency fees in tort cases . . . means that plaintiffs' attorneys can mass-produce lawsuits of very little merit with almost no risk to themselves” (p. 203). Plaintiffs' attorneys in the United States therefore find that playing the litigation lottery is profitable: they bring the same dubious multi-million dollar claim before many juries in the expectation that a few random victories will more than compensate for a larger number of losses. One attorney who only handles breast implant cases boasts that he “tell[s] everyone I've got a license to gamble.”¹⁷⁶

170. See *In re Breast Implant Cases*, 942 F. Supp. 958, 960 (E. & S.D.N.Y. 1996).

171. See *supra* text accompanying notes 154-156.

172. See *Hall v. Baxter Healthcare*, 947 F. Supp. 1387 (D. Or. 1996).

173. See *In re Dow Corning Corp.*, 211 B.R. 545 (E.D. Mich. 1997).

174. See *Bernstein*, *supra* note 162.

175. See *id.*

176. Mike Tolson, *A Matter of Proof*, HOUSTON CHRON., Oct. 26, 1997, at A1.

Also, Angell notes that if a defendant loses just one major lawsuit, as in the *Hopkins* breast implant case, that loss can stimulate an avalanche of copycat lawsuits, with the stakes potentially growing higher each time (p. 158).¹⁷⁷ Defendants understand this dynamic and will settle even dubious tort claims for large sums of money, especially if they can thereby avoid a courtroom battle with formidable opponents such as John O'Quinn.

Moreover, while the recent string of manufacturer victories has reduced settlement values,¹⁷⁸ it has not done much to stem the litigation. The cases still have substantial settlement value, given the occasional large awards to plaintiffs.¹⁷⁹

In order to reduce the incentive for plaintiffs' attorneys to file dubious but potentially lucrative claims, Angell proposes that contingency fees be banned in the United States, as they are in most other common-law jurisdictions. At the very least, she argues, contingency fees should be limited, and perhaps should only be available to clients who cannot afford a fixed fee (p. 203). With some justification, legal scholars have attacked Angell for advocating such far-reaching proposals without a much more thorough discussion of both the underlying rationale for contingency fees, which is to promote access to the court system, and of possible ways in which this access could be preserved while still reforming or eliminating contingency fees.¹⁸⁰

One attractive option that Angell does not explore is the United Kingdom's "conditional fee" system, which seems to split the difference between that nation's historic policy of banning contingency fees entirely and the current American practice of leaving them unlimited. Attorneys may now enter agreements with British plaintiffs that provide for fees to be waived if a claim is unsuccessful¹⁸¹—one of the most familiar features of the American way of litigation. If a plaintiff does recover damages, however, the successful British attorney may not cash in

177. Cf. William B. Griffin, *Breast-Implant Stampede: How Mass Tort Plaintiffs Wield Undue Leverage Over Manufacturers* (visited Nov. 23, 1998) <<http://www.brobeck.com/sslitplg/73.htm>> ("Defendants can win 80 percent to 90 percent of the cases. But the risk of a single \$25 million verdict, like the 1992 Pamela Johnson breast-implant case in Texas, creates an unacceptable risk of financial disaster for corporations big and small.").

178. See Matthew C. Guilfoyle & Jill Panagos, *Implant Lawyers Now Target of Unhappy Plaintiffs' Wrath*, MED. LEG. ASPECTS BREAST IMPLANTS, Nov. 1997, at 1; personal communication with Joe Redden, defense attorney, Aug. 4, 1996.

179. See Bill Miller, *\$10 Million Awarded in Breast Implant Suit*, WASH. POST, Jan. 5, 1999, at B1.

180. See Dresser et al., *supra* note 16, at 771-72; cf. Rochelle Cooper Dreyfuss, *Galileo's Tribute: Using Medical Evidence in Court*, 95 MICH. L. REV. 2055, 2056 (1997) (reviewing MARCIA ANGELL, SCIENCE ON TRIAL (1996) and SHEILA JASANOFF, SCIENCE AT THE BAR (1995) (contending that Angell's recommendations are "made without considering what due process requires by way of giving parties the opportunity to present their cases").

181. See Conditional Fee Agreements Regulations, S.I. 1995, No. 1675.

a piece of the action by taking thirty-three or forty percent of the award. Instead, she collects up to twice her reasonable and ordinary fee as a deduction from the award. United Kingdom lawyers have taken to calling these conditional fees to distinguish them from American-style contingency fees, which remain banned as unethical.

By allowing “double or nothing” fee agreements, the British system permits poor and middle-class plaintiffs access to the court system, as does the American system. From an American perspective, then, the most notable features of the conditional fee are the things it does not do. Since the marginal dollar belongs to the client, not the attorney, the lawyer has no personal stake in exaggerating a solid medium-sized claim into a lottery-sized one, as in the United States. The incentive to take speculative cases differs as well. Given the allowable fee uplift of 100 percent, the British attorney might have an incentive to take a case with at least a 50 percent chance of leading to an adequate settlement. It would be a losing game, though, to press to trial five cases, each of which has a twenty percent chance of victory. Thus the U.K. conditional-fee scheme discourages speculative litigation while providing access to the courts for claims with a solid basis but some degree of unavoidable uncertainty.

Adopting the conditional fee in this country would require a considerable change in the way our legal profession does business. Most American plaintiffs’ lawyers neither maintain hourly work records nor charge a standard hourly fee for tort cases because they accept such cases only on a contingent basis. There are a number of ways of dealing with this problem so as to obtain some or all the benefits of the British rule. All would require plaintiffs’ lawyers to keep hourly records of time spent, as most other lawyers already do, with greater or less provision for judicial review after the fact if clients challenge the claimed number of hours. As for hourly fee rates, lawyers would presumably have to begin setting them and disclosing their amount at the time of retainer. Such a system would offer the substantial additional advantage of encouraging more “comparison shopping” and control of lawyers by plaintiffs.

C. Limiting the Role of Juries in Tort Cases

Perhaps even more radical than Angell’s views on the contingency fee system are her views on civil juries. She argues that the “use of juries for tort cases is [] problematic,” as is the “growing size of jury awards, especially punitive damages” (p. 204). Angell thus joins a growing list of commentators who question the utility of civil juries.¹⁸²

182. See, e.g., FRANKLIN STRIER, RECONSTRUCTING JUSTICE: AN AGENDA FOR TRIAL REFORM 111-17 (1996); David E. Bernstein, *Procedural Tort Reform: Lessons from Other Nations*,

As Angell points out, in complex cases, jurors sometimes fail to comprehend the significance of the evidence before them (p. 204).¹⁸³ Partly for this reason, civil juries have been largely abolished in almost every common-law jurisdiction other than the United States.¹⁸⁴ In the few common-law jurisdictions where civil juries still sit with some frequency, such as Northern Ireland, judges do not hesitate to use their statutory discretion to take matters involving scientific evidence away from the jury. Even routine medical malpractice issues are considered beyond the comprehension of jurors.¹⁸⁵

Another (and related) problem with juries, Angell notes, is that emotion too often sways them (p. 204). Lacking scientific evidence supporting their clients' claims, plaintiffs' attorneys in breast implant cases have consistently relied on emotional appeals to juries. Two of John O'Quinn's partners put the matter bluntly. To win a breast implant case, they argue, "you must prove that the manufacturers are evil. They are not good people who make bad decisions, not good people who just did not know, but just plain evil." Once "you have proven that these manufacturers are evil," you then explain your causation theory to the jury.¹⁸⁶

In keeping with this theory, in his opening statement in *Laas v. Dow Corning*, O'Quinn analogized the defendants, Dow Corning and its parent, Dow Chemical, to murderers and cigarette companies.¹⁸⁷ In his closing argument, O'Quinn asked the jury to ignore the scientific evidence presented by the defendants because it is just "Dow investigating Dow." He suggested to the jury that instead of relying on research

19 REGULATION 71, 73-76 (1996); Bill Matchner, *The Unfinished Business of Civil Justice Reform, COMMON SENSE*, Winter 1995, at 102; George L. Priest, *Justifying the Civil Jury*, in *VERDICT: ASSESSING THE CIVIL JURY SYSTEM* 103 (Robert E. Litan ed. 1993).

183. See generally Bernstein, *supra* note 162 (noting that jury incompetence with regard to scientific issues is a recognized problem in other common-law countries); Steven I. Friedland, *The Competency and Responsibility of Jurors in Deciding Cases*, 85 Nw. U. L. REV. 190, 190-91 (1990) (discussing cases in which juries had comprehension problems).

184. See Bernstein, *supra* note 182.

185. See, e.g., *Monteith v. Western Health & Soc. Servs. Bd.*, 1984 N. Ir. 257 (1984) (finding what would be a routine medical malpractice case in the United States to be too complex for the jury).

186. Thomas W. Pirtle & Richard N. Laminack, *Winning a Breast Implant Case: The Plaintiff's Point of View*, MED. LEG. ASPECTS BREAST IMPLANTS, Oct. 1997, at 4; see generally E. Donald Elliott, *Why Courts? Comment on Robinson*, 14 J. LEGAL STUD. 799, 801-02 (1985) (noting that juries often make rulings based on the perceived blameworthiness of a defendant, rather than based on the scientific evidence).

187. See Plaintiff's Opening Statement, Trial Transcript at 25, *Laas v. Dow Corning Corp.* (No. 93-04266) (Tex. Harris Cty. Dist. Ct. Nov. 21, 1994) (analogizing defendants' attorneys to a criminal defense attorney who will "[t]alk about anything except the fact that [his client] coldbloodedly murdered someone else"); *id.* at 33 (stating that just as the defendants' attorneys will argue that there is no proof that implants harmed the plaintiffs, cigarette companies argue that their product does not cause lung cancer).

funded by malevolent companies, it rely on “common sense,” “circumstantial evidence,” and *post hoc ergo propter hoc* reasoning.¹⁸⁸

Another plaintiffs’ attorney in *Laas*, Richard Mithoff, appealed to the jury’s emotions even more directly. He begged the jury to “come to a true and just verdict and say by your verdict, ‘We believe you, Jenny Ladner, we believe you, Gladys Laas, when you tell us what has happened to you. We believe in ethics, we believe in integrity and we believe in justice being done.’”¹⁸⁹ Of course, the relevant legal issue in the case was not whether the jury believed that the plaintiffs were sincere, but whether breast implants caused their immune system disease.

Angell suggests that the problems of juror incompetence and emotional decision-making go hand in hand. “To evaluate whether a product has caused a disease,” notes Angell, “is difficult for nearly anyone. For a jury it is especially difficult, because its members usually have no competence in the area. They are often left to make judgments largely on the basis of the emotional appeals of the lawyers and their expert witnesses” (p. 204). While skilled defense attorneys are experts at neutralizing the effects of such appeals, emotional appeals still succeed all too frequently.

Both of the problems with jury decision-making identified by Angell arose in *Laas*. The *Laas* jury awarded \$5.2 million dollars to one of the plaintiffs, Gladys Laas, for injuries allegedly caused by her breast implants. The PBS television program *Frontline* asked two of the jurors in *Laas* how the jury reached its verdict. As the excerpt in the footnote below shows, the jury ignored the most significant piece of scientific evidence that existed at the time of the trial, and based its decision largely on sympathy for Ms. Laas, shifting the burden of proof to the defendants to disprove causation.¹⁹⁰

188. Plaintiff’s Closing Argument, *Laas* (No. 93-04266). Another plaintiffs’ attorney, Richard Mithoff, made a similar argument during his opening statement (visited Nov. 23, 1998) <<http://www2.pbs.org/wgbh/pages/frontline/implants/legal/plaintiffargue.html>>.

189. *Id.*

190.

Narrator: How did the jury reach its verdict? Two jurors agreed to talk to us. We asked if they were satisfied that silicone caused Gladys’s disease?

José Ramírez: No, I don’t think so.

Judy Sorensen Nauman: Uh-uh. Couldn’t.

José Ramírez: No.

Judy Sorensen Nauman: No.

Narrator: Why not?

Judy Sorensen Nauman: Evidence.

José Ramírez: I don’t think there is in those studies—I think they’re probably still studying them right now to figure out if they really do cause disease.

Narrator: *Was there any evidence that the implants hurt Gladys? Did the evidence prove that the implants were actually harmful?*

Judy Sorensen Nauman: *No, there isn’t enough evidence—*

José Ramírez: *No, there isn’t.*

Judy Sorensen Nauman: *—for that*

Similarly, reporter Mike Tolson interviewed several jurors in a 1997 breast implant case in which the jury awarded over \$1.5 million to the plaintiffs. He asked one juror whether he believed that implants had made the women sick. The juror responded, “I don’t know. I’m not an expert on that.” Another juror acknowledged that the panel had no idea whether implants actually cause disease. “But [the defendant] w[as] selling a product and w[as] responsible for it. Our decision comes down on responsibility. That outweighed the sickness, to be honest with you.” The juror who most vigorously favored the plaintiffs could not recall any study that particularly influenced her view on causation.¹⁹¹

One obvious though radical solution to the problems with civil juries, endorsed by Angell, is to abolish them, particularly in cases involving complex scientific issues. While this position is defensible as a policy matter, the Seventh Amendment of the United States Constitution and its state equivalents are barriers to its implementation, though not necessarily insurmountable ones.¹⁹² An even greater problem is that the political will necessary for such a reform seems lacking.

Several commentators have suggested that judges presiding over complex civil cases should appoint “blue ribbon” juries composed of

Narrator: Was there enough evidence to prove the implants were safe?

Judy Sorensen Nauman: No.

José Ramírez: No. They didn’t—

Judy Sorensen Nauman: Nope.

Narrator: But what about the prestigious Mayo Clinic study that Dow Corning had pinned their hopes on? Did that figure much in the deliberations?

Judy Sorensen Nauman: Uh-uh.

José Ramírez: No.

Judy Sorensen Nauman: That didn’t really impress me that much. Uh-uh.

José Ramírez: I don’t think we went over that during the deliberations, either.

Narrator: *So why, then, did they award Gladys such a large sum of money?*

José Ramírez: *She had a couple of years to retire. We added that up. That went into the—the \$5 million.*

Judy Sorensen Nauman: She’s having to have help—

José Ramírez: Yeah.

Judy Sorensen Nauman: —with her housework. *She can no longer cook. Her husband’s having to do a lot of the cooking. They used to travel a lot and go on vacations—*

José Ramírez: Yeah.

Judy Sorensen Nauman: —and they can’t do that anymore.

José Ramírez: The future medical bills.

Judy Sorensen Nauman: I mean, it’s just—you know.

José Ramírez: All those added up together.

Judy Sorensen Nauman: Her life has been changed, both of them.

Frontline: Breast Implants on Trial (PBS television broadcast, show 1412, Feb. 27, 1996) (transcript at 9-10) (emphasis added).

191. Tolson, *supra* note 176, at A1.

192. See *In re Japanese Electronic Prods. Antitrust Litig.*, 631 F.2d 1069 (3d Cir. 1980) (finding a complexity exception to the Seventh Amendment); Douglas King, Comment, *Complex Civil Litigation and the Seventh Amendment Right to a Jury Trial*, 51 U. CHI. L. REV. 581, 584 (1984) (suggesting that very complex cases may be outside the scope of the Seventh Amendment). Worker’s compensation cases are typically heard without a jury. See Arthur Larson, *WORKERS’ COMPENSATION FOR OCCUPATIONAL INJURIES AND DEATH* (1991).

well-educated jurors, or of jurors with appropriate technical backgrounds.¹⁹³ These suggestions have gone nowhere, and are likely to continue to founder because of their perceived elitism.

One viable ambitious and far-reaching measure legislatures could take to limit the role of juries would be to reserve the issue of damages calculation, as distinct from liability, to judges. Damages calculations show the civil jury at its worst. Juries are given almost no guidance about how to make damage awards, aside from what the attorneys on both sides tell them. Sympathy and anger factors are at a height. As a result, jury awards are both far more inconsistent¹⁹⁴ and, according to some studies, for much higher amounts than awards by judges.¹⁹⁵

Two distinct types of damages reform should be implemented in the U.S. One is to constrain damage calculations by distinct formulas and rules, so that they are not done arbitrarily. Already, some states have placed explicit limits on the amounts that may be awarded for some of the most notoriously subjective categories of damages, such as pain and suffering and punitive damages.¹⁹⁶ Even greater legislative oversight of damages awards to ensure predictability and consistency would be welcome.

The other reform that should be implemented is to remove damages calculations from the hands of the jury to those of the judge to secure the advantages of written explanation, precedent, visibility, experience, and greater ease of appeal. State legislatures have taken some initial steps toward assigning responsibility to judges. Three states have passed legislation that continues to allow juries to decide if punitive damages are appropriate, but leaves the amount of damages in the hands of presiding judges.¹⁹⁷

193. See, e.g., Dan Drazan, *The Case for Special Juries in Toxic Tort Litigation*, 72 JUDICATURE 292 (1989); Franklin Strier, *The Educated Jury: A Proposal for Complex Litigation*, 47 DEPAUL L. REV. 49 (1997).

194. See Peter H. Schuck, *Mapping the Debate on Jury Reform*, in *VERDICT*, *supra* note 182, at 311-12.

195. One study showed that jury awards in Ireland in personal injury cases were six times higher than awards by judges in England. Largely for this reason, Ireland abolished most civil jury trials in 1988. *See Ireland Courts Act No. 14* (1988); *see also* Jim Hutton, *Laws of Commerce on the Judge's Bench*, SUNDAY PRESS, July 31, 1988 (stating that the main reason for the abolition was complaints by insurance companies that juries awarded inflated damages to victorious plaintiffs).

196. As of 1996, twenty-seven states had enacted constraints on punitive damages awards. *See* Troy L. Cady, Note, *Disadvantaging the Disadvantaged: The Discriminatory Effects of Punitive Damage Caps*, 25 HOFSTRA L. REV. 1005, 1026 (1997). Twenty-three states have enacted statutory limitations on pain and suffering awards. *See* Heidi Li Feldman, *Harm and Money: Against the Insurance Theory of Tort Compensation*, 75 TEX. L. REV. 1567, 1567 (1997).

197. *See* CONN. GEN. STAT. ANN. § 52-240b (West Supp. 1998) (regarding product liability actions); KAN. STAT. ANN. § 60-3702 (Supp. 1997) (regarding any civil action); OHIO REV. CODE ANN. § 2307.80(B) (Anderson Supp. 1997) (regarding product liability actions), *declared unconstitutional*, Zoppo v. Homestead Ins. Co., 644 N.E.2d 397, 401 (Ohio 1994), *cert. denied*, 516 U.S. 809 (1995). For detailed arguments that judges, not juries, should decide the amount of punitive

Legislatures should now place the issue of damages solely in judicial hands, with statutory guidelines as to the appropriate amounts to award. While some may raise Seventh Amendment objections to such a regime, almost no one thinks it remarkable, let alone unconstitutional, that in criminal cases juries decide guilt or innocence and judges then take sole charge of sentencing, with direction from the legislature. Analogously, judges should determine the amount of damages civil defendants owe if they are found liable.¹⁹⁸

Even under these proposals, juries would still determine liability. Given that civil juries seem to be here to stay, it is worth discussing what can be done to improve their performance.

First, courts should give jurors the tools they need to bridge at least part of the competence gap between jurors and judges. Beyond educational and cognitive limitations, and the fact that they are not repeat players in the system, the biggest problem jurors face is that in most jurisdictions, they must listen to days of oral testimony without being allowed to take notes or ask questions. Meanwhile, they only receive instructions at the end of the trial, after they have heard all the testimony, and these instructions are also oral and often incomprehensible. Various jurisdictions have experimented with ways of mitigating these problems through pre-instructions, written instructions, more comprehensible instructions, the right to take notes, and the right to question witnesses. These reforms are taking root slowly, and, as courts determine which ones seem to work, should improve jury decision making.¹⁹⁹

Decreasing jury reliance on emotion is a more difficult problem. To some degree, such reliance is inevitable, particularly when the issues of causation, negligence, and reckless behavior (for punitive damages) are conflated into one trial.

One model, then, is for courts to segregate these issues through bifurcation or similar procedural techniques. For example, in a Bendectin class action case involving over 1,000 plaintiffs, U.S. District Judge Carl Rubin trifurcated the trial process. The first part of the trial was a common-issue trial focusing solely on causation. To avoid unfair prejudice to the defendant, Judge Rubin barred live plaintiff testimony,

damages, see David G. Owen, *Punitive Damages in Products Liability Litigation*, 74 MICH. L. REV. 1258, 1320-22 (1976), and Lisa M. Sharkey, Comment, *Judge or Jury: Who Should Assess Punitive Damages*, 64 U. CIN. L. REV. 1089 (1996).

198. *But cf.* *Kennon v. Gilmer*, 131 U.S. 22, 28-30 (1889) (holding that a jury's assessment of damages may be waived only if unsupported by the evidence or "given under the influence of passion or prejudice"). It is unclear whether this is a constitutional requirement. Some would argue that the Seventh Amendment's guarantee of a civil jury trial should be read to require that the jury perform exactly the same functions as it did when the Seventh Amendment went into effect. This argument, while certainly not frivolous, is not persuasive. If it was correct, why should any of the rules of civil procedure be permitted to change?

199. See Schuck, *supra* note 194.

forbade children with visible birth defects from the courtroom, and prohibited mention of the defendant's questionable history of marketing unsafe products, including Thalidomide.²⁰⁰

Similarly, in the now-famous Woburn trial, the subject of the best-seller *A Civil Action*,²⁰¹ the trial judge trifurcated the case. This forced the plaintiffs to prove that the defendants contaminated the local groundwater before they could ask for damages from injuries resulting from this contamination. Professor Charles Nesson of Harvard Law School, one of the plaintiffs' attorneys, objected to the trifurcation precisely because it forced jurors to act as dispassionate fact finders. According to the author of *A Civil Action*, Nesson worried that "the jurors would come into the courtroom expecting to hear a human drama about the poisoning of the Woburn families. Instead, they'd first have to sit through a case about geology and groundwater movement."²⁰² Nesson complained to the judge that the proceedings shouldn't start with a "bloodless issue."²⁰³

Whether or not a judge is inclined to segregate issues, she can create a fairer trial atmosphere by policing attorneys' opening and closing statements.²⁰⁴ Attorneys are theoretically barred from introducing inadmissible materials during opening statements and closing arguments, engaging in inflammatory rhetoric, misstating the law, and otherwise abusing their prerogatives.²⁰⁵ In practice, however, until recently, courts were quite deferential to attorneys, and generally allowed them to go beyond appropriate argument to the jury.²⁰⁶

200. See GREEN, *supra* note 7, at 227.

201. JONATHAN HARR, *A CIVIL ACTION* 285-88 (1995).

202. *Id.* at 287.

203. *Id.*

204. A lengthier version of the material presented here on opening statements and closing arguments was published in the Journal of the American Judges Association. See David E. Bernstein, *The Abuse of Opening Statements and Closing Arguments in Civil Litigation*, 34 COURT REVIEW 16 (1997).

205. Various courts have held that improper remarks during opening statements and closing arguments include:

- 1) Addressing a juror by name;
- 2) Stressing irrelevant facts or issues;
- 3) Attacking a party, counsel, or a witness;
- 4) Making disparaging comments;
- 5) Stating a fact in opening statement that will not be proven;
- 7) Instructing jurors on the law;
- 8) Misstating the law;
- 9) Expressing a personal belief in the merits of the client's case;
- 10) Making prejudicial or inflammatory remarks;
- 11) Mentioning settlement discussions;
- 12) Discussing subsequent repairs; and
- 13) Mentioning the wealth or poverty of a party.

See KENT SINCLAIR, *TRIAL HANDBOOK* §§ 3.08, 5.05 (2d ed. 1990).

206. See Bernstein, *supra* note 204, at 16.

To the extent judges policed jury argument in the past, they relied mainly on “invited response” and limiting instructions.²⁰⁷ Invited response gives a party disadvantaged by abusive jury argument leeway to respond in kind. However, the parties may not be equally capable of taking advantage of leeway given to them by the trial judge. When a case involves an individual plaintiff suing a large corporation, as in the breast implant litigation, it is unlikely that the defendant’s attorney will be able to counter unfairly prejudicial remarks made by the plaintiff’s attorney effectively. Limiting instructions, meanwhile, are of dubious value in this as in other contexts.

More recently, judges seem inclined to crack down on the abuse of jury argument.²⁰⁸ For several years, plaintiffs’ attorneys made illicit remarks in breast implant cases without attracting judicial reprimand.²⁰⁹ In April 1996, however, in *Shaw v. Bristol-Myers Squibb*,²¹⁰ Judge Frank Bearden concluded that attorneys from prominent breast implant plaintiffs’ firm Williams & Troutwine had made several improper statements in opening and closing arguments. Judge Bearden concluded that the attorneys had made allegations in opening statements that they never supported during trial, used inappropriate rhetoric, attempted to prejudice the jury against the defendant for being a large and wealthy corporation, and, during jury argument over punitive damages, tried to take unfair advantage of an opposing counsel’s absence due to the death of his father.²¹¹ As a result of Bearden’s findings, he vacated the \$1.5 million plaintiff’s verdict and ordered a new trial.

Other judges are finding creative ways to control the content of jury argument without having to resort to mistrials. Judges are, for example, increasingly granting motions *in limine* barring parties from misuse of jury argument. Violations of such orders may result in a finding of contempt of court or a referral of the offending attorney to the state bar for disciplinary action.²¹² Moreover, illicit jury argument that violates an order *in limine* is far more likely to result in a mistrial, or a reversal on appeal, than if no such order was issued.

207. *Id.* at 18.

208. See Bradly R. Johnson, *Closing Argument: Boom to the Skilled, Bust to the Overzealous*, 69 FLA. BAR J., May 1995, at 12, 13; John W. Reis, *Improper Jury Argument: Gilding the Lustre of the Golden Rule*, 69 FLA. BAR J., Jan. 1995, at 60 (discussing improper jury argument in various litigation contexts).

209. See Bernstein, *supra* note 204, at 16-18.

210. No. 9312-08347 (Or. Cir. Ct. Apr. 22, 1996), *appeal pending*, No. A92973 (Or. Ct. App.).

211. See *id.* slip op. at 6-8, 13-17.

212. See Michael S. Quinn, *Closing Arguments in Insurance Fraud Cases*, 23 TORT & INS. L.J. 744, 768 (1988); see also Borden v. Young, 479 So.2d 850, 851 (Fla. Dist. Ct. App. 1984) (noting that court made referral to the Florida ban because attorney conduct in closing arguments was likely unethical).

Some courts have decided to control directly the content of jury argument. The federal district court for the District of Connecticut, for example, has adopted the following rule: "Opening Statements. Opening statements by counsel in jury trials are not allowed, except on application made to the presiding Judge out of the hearing of the jury."²¹³

Most Connecticut federal judges allow opening statements on application from a party if opposing counsel does not object. However, the judges typically limit the time and content of the opening statements, interrupting counsel if necessary. Some judges require that written opening remarks be submitted to the judge before trial for approval of content. After reviewing the opening statement, the judge may allow counsel to read the opening statement as submitted. The judge may also restrict counsel to reading appropriate sections of the opening statements.²¹⁴ It is not clear whether the Constitution would permit similar policies to be applied to closing arguments.²¹⁵

It is unclear whether declaring mistrials, issuing orders *in limine*, or directly controlling jury argument is the best way to prevent attorney misconduct in jury argument. What is clear is that judges must experiment with these and other methods of enforcing the rules governing jury argument if jury decision making is to be dispassionate and fact based, rather than based on emotion and prejudice.

III DETERRING CORPORATE MISBEHAVIOR

If the recommendations advocated in Part II of this Review—stricter standards for the admissibility of scientific evidence, adoption of the conditional fee system, and limitations on jury discretion—had been implemented years ago, the breast implant litigation would almost certainly never have gotten off the ground. Both Angell and I believe that this would have been a salutary outcome. Nevertheless, it leaves some troubling questions. Angell concludes in *Science on Trial* that breast implant manufacturers negligently failed to undertake systematic studies of the health effects of breast implants (p. 21). If Angell is correct, can

213. D. CONN. R. CIV. P. 12 (d).

214. See Interview with Robin Tabora, Deputy Clerk, Federal District Court for the District of Connecticut (July 19, 1996).

215. Several courts have held that civil litigants have a federal or state constitutional right to final arguments in civil cases. See, e.g., Lewis v. Federal Servs. Discount Corp., 170 A.2d 235 (D.C. Muni. Ct. App. 1961); Fuhrman v. Fuhrman, 254 N.W.2d 97 (N.D. 1977); Nestor v. George, 46 A.2d 469 (Pa. 1946); Speer v. Barry, 503 A.2d 409 (Pa. Super. Ct. 1985). It is not clear whether direct judicial control of closing arguments would be permissible.

The Second Circuit has twice held that there is no federal constitutional right to an opening statement in a civil case; so clearly, Connecticut federal judges can place some reasonable restrictions on opening statements. See United States v. Salovitz, 701 F. 2d 17, 21 (2d Cir. 1983); United States v. 5 Cases, 179 F.2d 519, 522 (2d Cir. 1950).

it really be the case that the tort system offers no way of punishing companies for negligently risking the health of hundreds of thousands of women?

In response to breast implant manufacturers' perceived negligence and other troubling examples of perceived corporate misbehavior, Professor Margaret Berger argues that the causation requirement should be dropped entirely from toxic tort litigation.²¹⁶ Rather, defendants should be held liable if juries find that the defendant was negligent in failing to develop and disclose information necessary to assess serious latent risks. Defendants would only escape liability if they could prove either that the plaintiffs' alleged adverse health reactions "could not plausibly arise from exposure to defendant's product," or was attributable to another cause.²¹⁷ Defendant would bear the burden of persuasion on all of these issues.

Professor Wendy Wagner and co-authors similarly argue that, in the mass tort context, the burden of proof should be reversed if the defendant was negligent in failing to test properly a potentially dangerous substance before exposing thousands of people to that substance.²¹⁸ More tentatively, Professor Heidi Li Feldman suggests that courts might shift the burden of proof on causation in the toxic tort context "whenever the plaintiff could establish strong uncertainty about general causation."²¹⁹

Science can never prove the absence of hazard, but only place an upper limit on risk. Moreover, the true causes of many illnesses are not known. Because of these uncertainties, an "expert" could almost always be found who would link the substance at issue to the plaintiffs' injury, and the other side would have an extremely difficult time disproving the expert's theory. Each of the schemes discussed above would therefore have the same ultimate results if implemented—once a company was found to have violated appropriate testing standards, it would face near-absolute liability for any injury suffered by any plaintiff exposed to its product.²²⁰

216. See Margaret A. Berger, *Eliminating General Causation: Notes Towards a New Theory of Justice and Toxic Torts*, 97 COLUM. L. REV. 2117 (1997).

217. *Id.* at 2144-45.

218. See Wendy E. Wagner, *Choosing Ignorance in the Manufacture of Toxic Products*, 82 CORNELL L. REV. 773 (1997); Dresser et al., *supra* note 16, at 775.

219. Heidi Li Feldman, *Science and Uncertainty in Mass Exposure Litigation*, 74 TEX. L. REV. 1, 45 (1995); see also *Allen v. U.S.*, 588 F. Supp. 247, 415 (D. Utah 1984) (holding in a toxic tort case that the jury may find for the plaintiff "absent persuasive proof to the contrary offered by the defendant"); Thomas W. Henderson, *Toxic Tort Litigation: Medical and Scientific Principles in Causation*, 132 AM. J. EPIDEMIOLOGY S69 (1990) (arguing that in toxic torts cases courts should shift the burden of proof to the defendants to prove that they did not cause the plaintiff's injury).

220. Recall the highly implausible list of injuries and symptoms Dr. Vasey attributes to breast implants. See *VASEY & FELDSTEIN*, *supra* note 116. Wagner argues that manufacturers should "fully assess the health hazards a chemical poses" or face liability. Wagner, *supra* note 218, at 838. Would

Berger, Feldman, and Wagner argue that it is proper to use the tort system to punish under-investment in safety research, even in the absence of evidence of an injury, because the tort system is not simply about compensation for injury, but also about deterring actions that may harm society. Moreover, Berger argues, “eliminating causation furthers tort law’s corrective justice rationale that liability is linked to moral responsibility.”²²¹

All of these authors advocate a radical change in the way our tort system operates. Negligence alone has never been an appropriate basis for finding a defendant liable in the absence of proof of causation. Even extremely reckless behavior, manifesting a gross indifference to human life, does not by itself create tort liability. For example, let us posit the case of a truck driver who is driving through a school zone at 2:35 p.m., just after school lets out. This driver is driving 90 miles per hour, is very drunk, is on tranquilizers and anti-depressants, is legally blind, and is driving a truck that he knows has shoddy brakes. Miraculously, he doesn’t hit any children, and makes it safely to his next stop. What can the current tort system do to punish our driver, and prevent him from engaging in similar behavior in the future? Nothing. As this example shows, despite the general expansion of the American tort system over the past few decades, liability is still based on causation of injury, not just misbehavior.

On the other hand, Berger and Wagner have a point when they argue that traditional tort doctrine seems inadequate in the context of products or substances that are not tested properly before thousands of people are exposed to them. It is one thing to allow individual misbehavior that puts a few lives at risk to go unpunished and thus undeterred by the tort system, particularly when criminal sanctions are available as a deterrent, as in the reckless driver example. It is quite another thing to allow a company to put thousands of lives at risk negligently with no common law or criminal remedy, as occurs in the toxic tort context when exposed plaintiffs are unable to prove causation.

The absence of a remedy for behavior that put thousands of people at risk but fortunately did not injure anyone is particularly troubling, as Berger, Feldman, and Wagner note, because the current tort regime fails to provide sufficient incentives for manufacturers to test the safety of their products, and may even discourage them from doing so.²²² After

breast implant manufacturers have had to check silicone against all of the symptoms identified by Dr. Vasey?

221. Berger, *supra* note 216, at 2119.

222. *See id.* at 2137 (explaining how current rules may discourage safety research); Dresser et al., *supra* note 16, at 732-34 (arguing that current system provides inadequate incentives for early safety research); Feldman, *supra* note 219, at 41 (noting that companies may make a conscious

all, they argue, if corporations fail to produce research on their products, plaintiffs will be less likely to be able to prove causation.²²³

As the three authors point out, juries frequently rule against manufacturers in the absence of sufficient evidence of causation to punish them for misbehavior, particularly when there is scientific uncertainty on the underlying causation issue. Berger, Feldman, and Wagner would encourage and even formalize this process.

This is not an appropriate response to the problem of corporate misbehavior. The United States has thirteen federal circuits and fifty state court systems. If Berger, Feldman, and Wagner's ideas were enacted, a single state class action verdict in favor of a plaintiff could easily bankrupt virtually any defendant in a mass torts case. Such bankrupting litigation could occur even if each court in every other jurisdiction ruled that the defendant had met the appropriate standard of care.

Given the inconsistencies of jury verdicts, there would be no way for manufacturers to be sure that dealing with toxic products would not bankrupt them unless the federal government created a clear checklist or safe harbor, compliance with which would absolutely shield the manufacturer from liability. Otherwise, in order to avoid potentially ruinous litigation, manufacturers would be deterred not so much from misbehavior, as from producing anything that could potentially have any toxic effects, bringing the United States's economy to a virtual halt.²²⁴ Indeed, Wagner concedes that "specific congressional action" may be needed to provide a "definitive statement of what constitutes adequate testing."²²⁵ But once such Congressional action is contemplated, Berger and Wagner's schemes cease to be proposals for radical reform of the tort system, and instead become calls for more stringent federal regulation of industry enforced by a private cause of action that imitates, but does not truly emulate, tort actions.

Perhaps a preemptive federal tort, which could only be brought in one circuit, could alleviate the inconsistent verdict problem. Even then, it is not at all clear that the tort system is even a remotely efficient venue through which to try to deter corporate misbehavior. First, one would not want a lay jury to be deciding such complex and financially

choice not to undertake safety research); Wagner, *supra* note 218, at 774 ("rather than promoting safety testing for latent harms, the current common law liability rules act to penalize it").

223. See Berger, *supra* note 216, at 2149-50; Dresser et al., *supra* note 16, at 740; Feldman, *supra* note 219, at 40-41; Wagner, *supra* note 218, at 794-96.

224. This assertion, while seemingly fantastic, is likely not an exaggeration, for there are enough manufacturers of potentially toxic products—the chemical industry, the oil refining industry, the semiconductor industry, the electrical industry, and the nuclear industry, just to name a few—for this to happen.

225. Wagner, *supra* note 218, at 843.

significant cases, particularly given the obvious hindsight bias juries will face in determining what constitutes adequate testing.²²⁶ Second, the deterrence effect of even a perfectly functioning system, which accurately discerned and punished truly dangerous examples of misbehavior through non-causation-based toxic tort suits, would probably be negligible. The world of toxic torts is one in which most defendants are well-covered by liability insurance, where there are severe principal-agent problems, and where any litigation over corporations' negligence will often occur many years after the relevant acts, when the individuals who engaged in negligence may no longer be subject to sanctions for their behavior. Third, it is not at all clear why members of the plaintiff class who were not in fact injured by the defendant's product should get a windfall along the lines of the multi-million dollar breast implant verdicts, or why the value of the plaintiffs' injuries, not proven to be caused by the defendant, would be the appropriate measure of deterrence.²²⁷ Berger and Wagner's proposals simply would not create discernible benefits to public health, but would create enormous damage to the economy.

What, then, should be done about the threat to public health and safety posed by irresponsible corporations? Peter Huber has persuasively argued that the primary responsibility for protecting public health should rest with administrative agencies vested with that responsibility because courts are institutionally incapable of balancing public risks against public benefits in a rational manner.²²⁸ There are nevertheless reasons why the responsibility for risk regulation should not *solely* rest with agencies.

First, it may take legislative bodies time to respond to new public health threats. In the meantime, the public remains unprotected by regulation. Second, agencies can over-regulate as well as under-regulate. For example, while some have attacked the FDA for failing to regulate aggressively breast implants and other products under its jurisdiction,

226. See generally Jeffrey J. Rachlinski, *A Positive Psychological Theory of Judging in Hindsight*, 65 U. CHI. L. REV. 571 (1998) (discussing hindsight bias).

227. To avoid this problem, Berger suggests that judges could award the plaintiffs far less than the actual value of their injury. Given that the verdict would not be based on causation, and damages not based on the value of injury, it is unclear what relationship Berger's scheme has to the tort system as it has operated for centuries.

228. See Peter Huber, *Safety and the Second Best: The Hazards of Public Risk Management in the Courts*, 85 COLUM. L. REV. 277 (1985) (arguing that a "judicial role" in the calculus of risk is imprudently biased against many progressive, risk-reducing technologies); see also PETER H. SCHUCK, *AGENT ORANGE ON TRIAL: MASS TOXIC DISPUTES IN THE COURTS* (1986) (offering alternatives to court adjudication of toxic tort litigation); W. KIP VISCUSI, *REFORMING PRODUCTS LIABILITY* 171-72 (1991) (arguing that administrative agencies, *inter alia*, are better able to efficiently regulate risks than courts). But see Clayton P. Gillette & James E. Krier, *Risks, Courts, and Agencies*, 138 U. PA. L. REV. 1027 (1990) (detailing purported advantages of courts over agencies in dealing with risk regulation).

the FDA has also come under fire for unnecessarily delaying the approval of important new drugs at the expense of many lives.²²⁹

The problems of both over- and under-deterrence are exacerbated by the fact that, as Justice Breyer has noted, agencies "are politically responsive institutions, with boards, commissioners, or administrators appointed by the President, confirmed by the Senate, written about by the press, and, from time to time, summoned by Congressional committees to give public testimony."²³⁰ Moreover, agency personnel may themselves have strong political agendas, as David Kessler did. To expect agencies to be purely objective scientific decision makers is to expect too much.

Moreover, most regulatory agencies have small staffs and are ultimately dependent on the companies they regulate for data demonstrating that the companies are complying with the regulations. There is little that agencies can do *ex ante* to prevent companies from defrauding them.

If agencies are highly imperfect mechanisms for controlling corporate misbehavior, and the tort system is even worse, what else can be done? Perhaps the solution is to establish federal legislation, akin to whistle-blower statutes and *qui tam* provisions, that would permit individuals to bring an action in a federal tribunal against a company that is negligently putting the health of the public at risk. The point would not so much be to deter corporate behavior through the threat of an *ex post* damages award, as in a tort system, but to supplement the regulatory system. For example, if Dow Corning was indeed putting breast implants that it knew might be dangerous on the market without properly testing them, a knowledgeable employee could have brought an action against the company over twenty years ago, stopping the public health risk then and there.

Describing exactly how such a system would work would require at least a full article, but a basic outline would look something like this:

- The tribunal would be composed at least in part of experts on what constitutes safe, responsible corporate practices. They would be appointed for long terms, perhaps for life, to reduce political interference. Lay jurors would have no role on the tribunal.
- Corporate practices would be considered not only for the risks they create, but for the risks they reduce. It was certainly not negligent of Dow Corning to put implants on the market in 1962, when the most common alternative for breast augmentation was silicone injections, which are far more dangerous than implants. Dow Corning's testing and

229. See Sam Kazman, *Deadly Overcaution: FDA's Drug Approval Process*, I. J. REG. & SOC. COSTS 35 (1990).

230. STEPHEN BREYER, *BREAKING THE VICIOUS CIRCLE* 49 (1993).

marketing practices once implants were on the market are more open to question.

- Defendants would be exempt from liability if they follow the safety practices of government agencies. For example, automobile manufacturers would not be liable for assuming when they do cost-benefit analyses of safety equipment that a human life is worth x million dollars if the National Highway Traffic Safety Administration makes the same assumption when considering safety regulations.
- To avoid a moral hazard problem, someone who made a substantial contribution to the corporation's alleged negligence could not be the plaintiff in a relevant action.
- There would be strict statutory guidance on fines, with reasonable caps. Such factors as the severity of the misconduct, its potential health consequences, and other factors should be taken into account. The amount of damages that would accrue to the plaintiff should be set high enough to encourage whistle-blowing; additional fines would go to the Treasury.
- To avoid nuisance suits and speculative litigation, a loser-pays system would be established.
- Arguably, gross negligence, not simple negligence, should be the operative standard to avoid overly deterring corporations from working with potentially hazardous substances.
- To prevent fishing expeditions, contingency fee agreements between the plaintiff and her lawyer would not be permitted. Conditional fee agreements would be permitted.

This proposed administrative system could resolve several problems with the current regulatory apparatus. First, it should be possible to set up a system in which politics plays a minimal role.

Second, the proposed system would provide a method of regulating industries that are not yet subject to direct regulation.

Third, centralized agencies currently face severe information problems in knowing exactly what and how to regulate.²³¹ The system proposed here would give thousands of individuals with dispersed knowledge a financial incentive to monitor and challenge corporate misbehavior as it is occurring. Employees within the company, for example, would have an incentive to acquire information about unsafe or fraudulent practices unknown to the relevant agency.

Fourth, companies could be held responsible for their misdeeds close to the time they occur, since the whistle-blower could report misbehavior during or soon after its occurrence. By contrast, under the

231. This is a manifestation of the general problem of the use of knowledge in society, identified by F. A. Hayek, Nobel prize-winning economist. See F.A. Hayek, *The Use of Knowledge in Society*, 35 AM. ECON. REV. 519 (1945).

current system, agencies and tort victims frequently find out about misconduct only years or even decades after it occurs. By that time, the principal players may have moved to another company or be retired and are therefore no longer subject to any meaningful punishment for their misconduct. Shareholders in the company at the time the misconduct is discovered, meanwhile, unfairly pay for conduct that occurred when other people owned the company.

Finally, corporations themselves might ultimately benefit from an administrative venue for negligence complaints, because the existence of such a venue could reduce pressure on agencies to over-regulate, and reduce political obstacles to civil justice reform. As the only administrative bodies with direct responsibility for protecting the public health, regulatory agencies inevitably face public pressure to regulate more strictly than is wise.²³² The alternative system suggested here, if implemented, would relieve some of that pressure. Moreover, because the tort system is currently the main alternative regulatory body to agencies, tort reform advocates face uncomfortable questions about how the public's health would be protected from toxic threats if lawsuits became more difficult to bring and win. The system under consideration here would reduce this barrier to tort reform. The proposed system may even make jurors in toxic tort cases more likely to concentrate on whether the plaintiffs have actually proven causation, as they will know that a separate venue exists to address claims of corporate misbehavior as such.

CONCLUSION

As the title *Science on Trial* suggests, Angell believes that science has been on trial throughout the breast implant controversy, and has lost. Science lost out to the agendas of Sidney Wolfe and David Kessler. Science lost out in the tort process, where juries awarded millions of dollars to breast implant recipients based on sympathy for the plaintiffs, dislike/distrust of the defendants, and the patina of science provided by the "educated guesses" of a few expert witnesses who believed that implants cause disease. Science lost out to the profit motive, first when manufacturers negligently failed to invest resources in adequate studies, and then when contingency fee attorneys exploited the resulting uncertainty. And science especially lost out in the media, where reporters preferred sensational tales alleging implant dangers to a dispassionate accounting of the relevant scientific evidence.

Angell makes a lengthy plea in favor of science and the scientific process. She is troubled by the anti-science bias she perceives among many humanists, multi-culturalists, environmentalists, ecologists, and

232. See Kazman, *supra* note 229 (explaining why agencies typically face pressure to over-regulate).

proponents of alternative medicine. More generally, most Americans are appallingly ignorant of basic scientific concepts.²³³ As Angell points out, if the public were more knowledgeable about and favorably inclined toward science and the scientific process, the breast implant controversy would likely have unfolded in a far more sensible way (pp. 190-91).

Science on Trial should serve as a call to members of the mainstream scientific community to join the battle against scientific dissembling in the media and in the legal and political arenas. Many scientists privately bemoan the misuse of science in the tort system, but fail to speak up in public for fear that it will distract them from their work. For the greater good of science and technological progress, however, these individuals would do a great service if they followed Marcia Angell's example, and turned their disgust into constructive criticism of how our legal system deals with scientific issues.

Equally important, influential members of the bench and bar should heed this criticism to avoid disasters like the breast implant litigation. As we have seen, phantom risk litigation feeds on political manipulation, baseless media scare stories, unthinking public outrage, and plaintiffs' attorneys' financial incentives to bring speculative but potentially highly remunerative cases. Beyond maintaining a detached, skeptical outlook on the "scare of the month," the legal establishment can do little about the indifference and hostility shown to science by politicians and political activists, reporters, and the public at large.

That does not mean, however, that the legal community should not get its own house in order by reducing the incentives to initiate litigation over phantom risks. A short-term start would be for judges to require plaintiffs to present sound scientific evidence before they can maintain a claim. Science panels, such as those appointed by Judges Jones and Pointer, can help judges with this task. Ultimately, the current contingency fee and civil jury systems also need to be reformed if we are to prevent future mass tort debacles.

Finally, lawmakers should consider adopting an administrative system along the lines proposed here to deter corporate misbehavior that creates public health risks. This system would be both far more effective and far less disruptive of the economy than alternatives that would shift the burden to defendants in toxic tort cases to disprove causation. At the same time, this system would maintain the integrity of the tort system by not burdening it with responsibilities that are logically outside its purview.

233. See Dan Vergano, *Not that Kind of Poker*, NEW SCIENTIST, Sept. 26, 1998 (discussing recent studies showing lack of scientific knowledge among Americans).