

**SCIENCE ON TRIAL: THE CLASH OF MEDICAL EVIDENCE  
AND THE LAW IN THE BREAST IMPLANT CASE**

By Marcia Angell, M.D.<sup>1</sup>

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Mass tort litigation is a relatively new and controversial development in American law. Causation issues, which are often problematic in these cases, were particularly troublesome in the recent breast implant litigation. In *Science on Trial*, Marcia Angell provides an engaging introduction to the regulation of and litigation over silicone breast implants in the United States. She addresses three broad areas: the factual history of the controversy, including the relevant epidemiology; tort law and its failings, especially with regard to causation determination; and the relationship between scientists and the public. The book provides an interesting overview of the topic, although it is probably too basic to be of practical use to those already well versed in it. Thumbnail descriptions of the relevant people, cases, and more dubious scientific studies enliven Angell's account of the controversy. Her descriptions of epidemiology and medical research are particularly clear and well-written.

In the early chapters of the book, Angell describes breast implants and their use. The first known attempt to enlarge a woman's breasts (using fat from a benign tumor on the woman's back) occurred in 1895 (p. 35). Subsequent techniques made use of petroleum jelly, beeswax, vegetable oils, and most commonly, paraffin or silicone injected directly into the breast (pp. 35-36). The use of breast implants did not become common in the United States until the 1970s (p. 33-34), however, after the introduction of silicone breast implants. These implants, consisting generally of a "rubbery silicone envelope containing silicone gel" (p. 39), were first introduced in 1962 (p. 39). Silicone, which is widely used for medical devices (e.g., artificial joints and needle lubrications), was a logical choice for implant manufacture since it is stable, resists bacterial contamination, and is well tolerated by the body (p. 36).

Between 1979 and 1992 (when silicone breast implants were banned<sup>2</sup> by the Food and Drug Administration ("FDA")), 100,000 to

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1. Marcia Angell, M.D., is executive editor of the *New England Journal of Medicine*.

2. See Partial Denial of Approval of McGhan Intrashiel, UHP, and Biocell Fixed Volume Prostheses and Variable Volume Prostheses Premarket Approval Application, 57 Fed. Reg. 45,811 (1992); Partial Denial of Approval of the Premarket Approval Application for Mentor Low Bleed Gel-Filled Mammary Prosthesis Smooth or Siltex Textured, 57 Fed.

150,000 American women had their breasts enlarged each year (p. 34). Angell estimates that doctors earned between \$300 million and \$450 million per year for these operations, and that implant manufacturers made between \$50 million and \$75 million in annual sales (p. 34).

When the FDA mandate was extended to cover medical devices in 1976,<sup>3</sup> breast implants were grandfathered, remaining unregulated because they had been on the market for thirty years (p. 51), even though the implants' effects had never been systematically studied (p. 21). In 1982, however, an Australian physician published a report on three women with breast implants who had connective tissue disease. In 1988, amid growing concerns that silicone breast implants might cause connective tissue diseases, such as scleroderma, lupus, and rheumatoid arthritis (p. 21), the FDA asked that the manufacturers demonstrate the safety and effectiveness of the devices (p. 52). Four years later, when the manufacturers still had not provided the required information, the FDA banned silicone breast implants (pp. 54, 56-57). Although the price of breast implants did increase after the ban, breast augmentation (now using saline implants) has remained popular. Indeed, in 1994, it was the third most common cosmetic operation in the United States (p. 34). Discordantly, also in 1994, a class action in Alabama on behalf of women with breast implants resulted in the largest class action settlement<sup>4</sup> to that date: \$4.25 billion (p. 22).

Unsurprisingly, given Angell's background, she is at her best when discussing science. Her description of observational epidemiology in Chapter 5 is particularly clear and interesting, and her explanation of the health risks associated with breast implants (divided between Chapters 2 and 5) justifies reading the book. Many of the side effects associated with breast implants are part of the body's inflammatory response and are analogous to the effects of failing to remove a splinter (pp. 37, 40). These side effects include scarring of the breast around the implant followed by hardening and contracture of the scar tissue, which can be painful (p. 40). Doctors would often try to relieve excessive contracture by squeezing the breast so as to rupture the scar; this would frequently rupture the implants themselves, and Dow Corning, the leading breast implant manufacturer, began to warn doctors against the procedure in 1980 (pp. 41-42). Other local side effects include difficulty in perform-

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Reg. 45,812 (1992); Partial Denial of Approval of Mentor Becker Expander/Mammary Prosthesis Smooth or Siltex Textured Surface Premarket Approval Application, 57 Fed. Reg. 45,813 (1992).

3. See Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (codified as amended in scattered sections of 21 U.S.C. and in 15 U.S.C. § 55).

4. See *Lindsey v. Dow Corning Corp.*, No. CV 92-P-10000-S, 1994 WL 578353 (N.D. Ala. Sept. 1, 1994).

ing mammography on women with implants (pp. 42-43) and leakage of silicone from the implants (p. 41). In a 1975 memo, a member of Dow Corning's Mammary Task Force had instructed company salespeople to wipe leaked silicone off sample implants to hide this problem (pp. 58-59).

The second major theme of the book bases a critique of the tort system on the breast implant litigation. The major breast implant lawsuits<sup>5</sup> were premised on the idea that breast implants increase the recipient's risk of developing connective tissue disease (p. 21). One medical rationale for this theory is that implants may provoke an immune reaction that might spread to tissues in other, silicone-free parts of the body (p. 107). Alternatively, silicone might trigger "an intense overstimulation of the immune system," resulting in connective tissue disease (p. 108). These theories remain unproven; furthermore, no epidemiological evidence has shown that breast implants cause connective tissue disease. Indeed, the major studies in the area show that there is probably no link between breast implants and connective tissue disease (p. 197). Unfortunately for the breast implant manufacturers, the first such study was not published until 1994 (on the day before the plaintiffs' opt-out deadline for the Alabama settlement) (p. 142). In the meantime, plaintiffs successfully drew on anecdotes, some dating back to the days of direct silicone injections, to support their theory in court (pp. 103-05). Angell believes that this anecdotal evidence assumed unwarranted significance in litigation as women with connective tissue disease-like symptoms consulted doctors (and lawyers) known for their pro-plaintiff work in the field (pp. 103-06).

Angell's discussion of law is less authoritative than other parts of the book and is even confused at times. For example, when discussing trends in litigation in Chapter 4, she appears to equate tort law with personal injury law (pp. 70-71). She criticizes tort law generally as an unreliable compensatory scheme and an inappropriate regulatory mechanism (pp. 69-89). In her opinion, the tort system overdeters medical manufacturers and threatens to drive valuable products off the market through inappropriately large awards. She is particularly concerned that the threat of liability may lead bio-material manufacturers to withdraw their products from medical use (p. 84). Angell also criticizes others who benefited financially from the breast implant controversy, including lawyers, expert witnesses, and some doctors (pp. 133-53).

Although her discussion of tort law is mostly unremarkable, she makes the interesting point that the current system may inhibit biomed-

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5. See, e.g., *Hopkins v. Dow Corning Corp.*, 33 F.3d 1116, 1122 (9th Cir. 1994).

cal research. She notes that lawyers use the popular press to discredit studies unfavorable to their positions. In addition, the discovery process can make inordinate demands on the time of all participants, even that of disinterested scientists (pp. 144-46).

Angell also describes legal evidence and how it differs from scientific evidence (pp. 90-132). She portrays the testimony of expert witnesses as an ineffective (if not counterproductive) means of communicating accurate scientific information (pp. 117-18). However, she is hopeful that the Supreme Court's decision in *Daubert v. Merrell Dow Pharmaceuticals*<sup>6</sup> will improve this situation, even though the "decision doesn't seem to have helped much, at least not yet" (p. 132).

The book's final topic, and second major policy theme, is the importance of rational evaluation of scientific issues by the public. Chapters 8 and 9 provide an inspiring defense of rational thought and the scientific method, and criticize the American public for neglecting them. Angell observes the conflict between the news media's bias toward quick, simple stories and the complexity and tentativeness of most scientific findings (p. 171). This conflict tends to result in sensationalist news that oversimplifies the science in question and overstates the dangers or benefits of the product or process (pp. 154, 169-73). The coverage of the breast implant "scare" exemplified these difficulties (p. 31), although reports on the recent epidemiologic work have been less problematic (p. 174-75).

The public responds to sensational stories with a combination of cynicism and gullibility that displaces critical analysis (pp. 157-59). Angell describes the process of critically reading science news:

If, for example, there is a report that some food or habit or device is dangerous, people should ask themselves whether the news comes from a usually reliable source, whether it comes from one source or many, whether the alleged danger is large or small, and whether it is consistent with everything else we know about the subject. Then, unless the evidence is overwhelming or the problem urgent, we should defer a final judgment. The information can be stored away on a mental shelf until further information is forthcoming. Not all Americans are knowledgeable enough to perform such a preliminary analysis, at least not in all cases, but in my view most could do much better than they do (p. 157).

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6. 509 U.S. 579 (1993), *on remand*, 43 F.3d 1311 (9th Cir. 1995).

More broadly, in terms of the public's perception of science more broadly, Angell sees an anti-science and anti-medicine backlash as a fairly recent intellectual trend (pp. 177-79). The backlash includes some "humanists, multiculturalists, environmentalists, ecologists, feminists, and proponents of alternative medicine" (p. 178). The rejection of rational (scientific) thought creates a vacuum which is being filled by "speculation and mysticism" (p. 183), exemplified by increasing belief in alien abduction, the occult, and the efficacy of alternative medicine (pp. 183-87). Angell persuasively defends the scientific method as the only effective way to learn about the natural world (pp. 188, 189-90), and she reserves special criticism for anti-science feminists who not only misrepresent science but also discourage women from entering science just when it is becoming widely possible for them to do so (pp. 188-91).

The problem as Angell describes it is one of societal attitude, not one of education. She describes the public's tendency not to critically analyze the news as if it only applied to news about science and medicine and as if it were a development of the last two or three decades. While the factors she identifies may well play a special role in the case of science news, they seem too limited to provide a complete explanation of the public's attitude. Similarly, it is unlikely that an anti-science backlash is the sole cause of the increasing acceptance of occult and "new age" phenomena. Poor education, the decline of traditional religions in the United States, and the quest for ever-more-lurid entertainment all may play a role.

Although Angell's analysis of the social and legal issues surrounding the breast implant controversy is neither deep nor comprehensive, she raises some interesting ideas about the courts' and the public's failure to responsibly and thoroughly analyze scientific information. The real strength of the book, however, is its discussion of the science of breast implants itself. As an introduction to epidemiology and the role it should play in litigation and public discourse, *Science on Trial* is an enjoyable and very accessible book.

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