



THE CLASH OF MEDICAL EVIDENCE AND THE
LAW IN THE BREAST IMPLANT CASE

SCIENCE ON TRIAL

MARCIA ANGELL, M.D.

EXECUTIVE EDITOR OF THE NEW ENGLAND JOURNAL OF MEDICINE

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*To Lara and Elizabeth,
once again with love*

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PREFACE

A few years ago I would have been surprised to be told I would one day write a book about breast implants. I had no particular interest in the subject, and it would have seemed unlikely that I would develop one. To be sure, as a physician I was aware that cosmetic surgery was a part of health care. But I considered it a relatively minor part, dwarfed by the many more crucial matters facing doctors and patients—life-threatening disease, unremitting pain, profound disability. Nor would my responsibilities as executive editor of the *New England Journal of Medicine* have been likely to involve me in the study of breast implants. My job is to help evaluate the many reports of medical research submitted to the *Journal*, of which only about 10 percent are selected for publication. Reports of breast implant research were rarely among the submissions and, until recently, never among the papers selected for publication. Not very much research was being done on the subject, and what there was wasn't very good. So how did the idea for this book come to be?

The short answer is that I was drawn to the issue by two manuscripts submitted to the *Journal*, one in 1992 and the second in 1994. In 1992 David Kessler, the commissioner of the FDA, banned silicone-gel-filled breast implants from the market because they had not been proven safe. The ban caused widespread alarm among the 1 million to 2 million women

who already had implants. It also led to a torrent of lawsuits against the manufacturers of breast implants. Shortly after Kessler announced the ban, he submitted a manuscript to the *New England Journal of Medicine* explaining his reasons. In reviewing the manuscript I began to realize that the matter was more complicated than I had suspected. Kessler's decision involved not just science, but public opinion, politics, and the law. I thought the consequences of the FDA's decision would be far more wide-ranging than Kessler seemed to believe, and I wrote an editorial to that effect to accompany his article. That was my first exposure to the subject.

Two years later, in 1994, Dr. Sherine Gabriel of the Mayo Clinic submitted to the *New England Journal of Medicine* her report of the first epidemiologic study of whether breast implants increase the risk of certain diseases and symptoms. By this time, thousands of lawsuits had been filed alleging that they did. Some women received huge damages from sympathetic juries (the record was \$25 million). For every jury verdict, many more cases were settled for the plaintiff out of court. The situation became unsustainable for the breast implant manufacturers, and so they agreed to set aside \$4.25 billion to meet the claims of all women with breast implants once and for all—the biggest class-action settlement in history. Yet the Mayo Clinic study, published shortly after the class-action settlement was announced, did not show a link between breast implants and disease. I was struck by the discrepancy between the legal findings and the scientific evidence. Why were the courts so sure, when the scientists were not at all certain? I suggested some possible answers to this question in another editorial, which accompanied the Mayo Clinic study. That was my second foray into the subject, and by this time I was hooked.

But the most important reason I decided to write about

the breast implant controversy is because it illuminates important themes in American life. It richly illustrates the interplay of regulation, litigation, commercial interests, media coverage, and consumer pressure in the public confrontation of a major health issue. In the decade leading up to the FDA ban, the safety of implants was debated in the courts, in medical journals, and in the popular media. The debate occurred against a political backdrop of controversy about the relative excesses of big business and government regulation. Were large corporations like Dow Corning, the leading manufacturer of breast implants, knowingly foisting off dangerous products on the public or were they responsibly meeting consumer demands? Should the FDA have moved more promptly to pull implants off the market or should women have been allowed to make their own choices? After the ban, the focus shifted to the courts, where matters of scientific fact were decided not by scientists, but by lawyers, juries, and judges. On what basis did they reach their conclusions? And what effect did public opinion have on the outcome? The media covered the controversy fully, if not always accurately, and the public took a lively interest in the matter. Did public opinion drive the FDA's actions and the courts' conclusions? And how was the unfolding of the breast implant story affected by greed and the expectation of personal profit? Vast amounts of money, not just the \$4.25 billion in the original class-action settlement, are still at stake in the thousands of individual lawsuits that have been filed and will be filed.

What fascinated me most about the contradictory opinions and accusations, the frenetic legal activity, and the huge sums of money at stake was the question of evidence. As I investigated the subject, I realized that the breast implant controversy is simply one example of the difficulty we Americans

have in dealing with scientific evidence, particularly on matters of health. We depend greatly on science and its technological fruits, we like to talk about what research shows and what it doesn't, we think we understand risks, but when it comes to the recurrent medical scares that sweep across the land like locusts, all our sophistication goes out the window. Just give us the conclusion, tell us whom to blame, and don't bother with the evidence.

In this book, I will use the breast implant story to illustrate the broader themes that concern me. How do scientists reach conclusions about questions of health risks, such as whether breast implants increase the chance of developing a disease? How does the legal system reach its conclusions about the same question? Do the differences in methods account for the vast differences in outcome? What are the essential distinctions in the way science, the law, and the public regard evidence, and what are the consequences for our society?

I will begin with a brief review of the breast implant controversy to provide the narrative. To set the context further, I will describe in some detail the implants themselves, as well as the history of breast augmentation and the more recent use of implants for reconstruction after cancer surgery. In the remaining chapters, I will widen the focus to the themes illustrated by the breast implant story: the role of regulation and litigation in American life, the nature of scientific evidence, the way in which legal evidence is different, the distorting effect of greed and corruption on the usual process for deciding medical matters, the public's all-or-nothing response to health news, and the ripple effects of a paroxysm like the breast implant controversy.

Finally, a brief personal note to give the reader some idea of the point of view I bring to this subject. I consider myself a

feminist, by which I mean that I believe that women should have political, economic, and social rights equal to those of men. As such, I am alert to discriminatory practices against women, which some feminists believe lie at the heart of the breast implant controversy. I am also a liberal Democrat. I believe that an unbridled free market leads to abuses and injustices and that government and the law need to play an active role in preventing them. Because of this view, I am quick to see the iniquities of large corporations. I disclose my political philosophy here, because it did not serve me well in examining the breast implant controversy. The facts were simply not as I expected they would be. But my most fundamental belief is that one should follow the evidence wherever it leads. From time to time, it is important to look up and see where you have been led and who is there with you, but you should not turn back. That is what this book is all about.

MARCIA ANGELL