BOOK REVIEWS

Derelictions

Science on Trial. The Clash of Medical Evidence and the Law in the Breast Implant Case. MARCIA ANGELL. Norton, New York, 1996. 256 pp. $27.50 or C$35.

At a time when the medical profession is moving toward more rigorous use of scientific evidence in clinical decision-making several courts in the United States have chosen to take little or no notice of scientific standards in admitting and weighing evidence in cases of medical product liability. One of the most egregious examples concerns silicone-gel–filled breast implants. This is the topic addressed in *Science on Trial*, written by the executive editor of the *New England Journal of Medicine*. This lucidly written and fascinating book both tells the tale of these devices and explores broader issues concerning the nature of scientific knowledge, its interpretation by the legal system, and its often marginal and ambiguous role in society.

The high point of liability litigation for this product occurred one year after David Kessler, Commissioner of the Food and Drug Administration (FDA), virtually banned silicone-gel–filled breast implants in 1991. The implants were introduced in the early 1960s, and an estimated 2 million women had become implant recipients by the time the FDA asserted that manufacturers had not fulfilled their responsibility to demonstrate their safety. This contention came in the absence of epidemiological evidence substantiating purported links between implants and connective tissue diseases. Such evidence, which addresses whether a given factor increases the risk for a particular disease, ought to be essential for evaluating liability claims of this type. At the same time, scientific insight into the mechanisms by which risk factors bring about disease (in contrast to epidemiological evidence, which provides measures of association) ought to be considered. Angell addresses the many failures to adhere to standards in these lines of scientific reasoning in the courtroom, although she does not systematically review the original court transcripts but relies largely on media reports. Early on in the litigation process, no relevant epidemiological evidence was available, but on the basis of uncontrolled clinical experience, experts persuaded the courts that a link existed between implants and disease. When several well-conducted epidemiological studies found no association between implants and connective tissue diseases, courts continued to award damages to plaintiffs. Moreover, some courts allowed the definition of harm to extend to a cadre of ill-defined symptoms that did not constitute any medically recognized disorder, making the connection impossible for the defense to refute and problematic for scientists to substantiate in clinical testing. Finally, several of the most prominent expert witnesses based their testimonies on theories of immunological mechanisms that were either unpublished or had not been subjected to the rigors of scientific review and thus could not be regarded as generally accepted by the scientific community.

Moving beyond the fortunes of science in the courtroom, this book provides a penetrating cultural commentary on the limitations of science in American society. Of particular concern, as Angell sees it, is the emergence of strong anti-science attitudes in some groups, as well as strong social forces (especially economic ones) that moved the breast implant case beyond epidemiological and biological reasoning. Looming large among the institutions and actors Angell discusses is the peculiar legal system in the United States, which is different from those of virtually every other nation in the world in that juries (instead of judges) are frequently used as "finders of fact" in civil cases and plaintiffs' attorneys receive a percentage of damages awarded rather than standard fees. The distorting effects of economic incentives pertain not only to the lawyers but to the expert witness process, as in the case of the "implant disease programs" that worked closely with the plaintiffs' attorneys to make dubious diagnoses, frequently through unnecessary testing, and that administered uncalled-for treatments to concerned and often healthy women with silicone-gel–filled breast implants. The analysis also points to the sensationalism of the media that plays down the uncertainty inherent in scientific findings, as well as to the need for a more socially responsive industry, which might have averted some of the litigation fervor in the breast implant case had it supported epidemiological research at the first hint of a connection between systemic connective tissue diseases and the product.

Such litigation has ripple effects that extend far beyond the immediate manufacturer and device. Product liability claims now often reach back into the deep pockets of the parent companies and biomaterial suppliers, who as a consequence of the financial toll of the product liability process (Dow-Corning's bankruptcy being a case in point) are increasingly choosing to withdraw from the medical arena. As a result medical device innovation is being threatened and current devices, such as surgical grafts and joint implants, could conceivably become unavailable when existing stockpiles of materials are depleted. Because of these broader effects and the aforementioned evidentiary issues that are essential themes in Angell's analysis, this book should be of fundamental interest to the scientific community. Reforms of the sorts called for in the concluding chapter are critical for improving the fairness of the medical product liability process. One obvious question that the book evokes, but does not address, is whether silicone-gel–filled breast implants should be returned to the market, given more current information about the absence of systemic risks and the inadequacy of current alternatives. The timeliness of this question and the need for reforms are underscored by recent reports of a class-action suit in the making against manufacturers of high-tech screws, rods, and other implants used in back surgery. On the *Wall Street Journal's* account of this litigation in the making ("A Screwy Way to Treat Companies," 16 July 1996, by Max Boot), it bears striking parallels to the breast implant debacle and may foretell the downfall of some essential medical devices.

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