Some may regard silicone as old history. Whereas Dr Jack C. Fisher’s book *Silicone on Trial: Breast Implants and the Politics of Risk* does focus on silicone, its greater value may be in addressing the inconsistencies that characterize so many of the practices and policies that are used by the Food and Drug Administration (FDA) in the evaluation of medical devices in general. In this instance, silicone is the vehicle that takes the reader through this odd “neverland” in which it becomes apparent that politics, the courts, the media, and special interests can influence the evaluating and approval process every bit as much as medical facts and scientific truths. Many of the elements that combined to produce and complicate the issues surrounding silicone were not peculiar to silicone: as the reader learns, the nonscientific elements cited above (which are constants in this flawed process) were more instrumental in influencing the unsound rulings that occurred during the silicone hearings than any of the manufacturers’ alleged data deficiencies, oversights, or lack of clinical studies.

As tedious as the beginning chapter, entitled “A Bureau in Search of its Power,” might first seem, after a few pages the narrative becomes absorbing as one begins to appreciate the pattern of dysfunction that has characterized the FDA from its very beginning. This pattern only becomes more obvious and disturbing in the chapter entitled “An FDA Validated and Empowered.” The egos, ambition, politics, and misplaced priorities that have influenced the evolution of this once-small governmental agency into the massive bureaucracy that it is today are described in detail.

Information related to the manufacturer’s strategies when interacting with the FDA is both informative and illuminating. Dr Fisher provides multiple examples of the unsettling corporate decisions that specifically impacted the evaluation of silicone breast implants. The decisions that were made by the manufacturers in regard to the data that might have reasonably been expected to be required for FDA approval may appear baffling to the reader, until it becomes clear that many—if not most—corporate decisions are based on cost/benefit ratios rather than need. A corporate mentality is revealed that appears focused on providing less rather than more. As a matter of policy, many corporate boards dealing with the FDA apparently direct their executives to provide the FDA “only the information that is required.” Clinical studies and additional laboratory information that could have been provided on silicone breast implants were not pursued simply because the manufacturers hoped they would not be required.

Periodically throughout the book, Dr Fisher identifies the various efforts of organized plastic surgeons to influence the breast implant evaluation. Years of open cooperation between plastic surgeons and the manufacturers that related to implant quality and design occurred prior to the implant crisis. Unfortunately, this interaction led to a perception of a too-close relationship between surgeons and manufacturers, a perception that should have been avoided. The reviewer (who was there at the time) believes that Dr Fisher is much too charitable in describing the errors in judgment that caused plastic surgeons to become too

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Dr Cole was a plastic surgeon in private practice (retired) in Louisville, Kentucky. He was President of the American Society of Plastic and Reconstructive Surgeons (now known as the American Society of Plastic Surgeons) in 1992, part of the time period covered in this book.

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closely identified with the manufacturers: this history should provide a lesson as well as a warning for the future.

Dr Fisher’s narrative moves past the introductory segments to emerge at the point in time where the FDA is to formally consider silicone in terms of its safety and efficacy (not silicone per se, but more specifically silicone breast implants). In following the events over the several years that preceded these hearings, the reader will encounter claims and arguments made by various individuals and activist groups that boggle the mind. One example is included in this review: the safety and efficacy of the solid silicone used in medical devices was never questioned, but critics claimed that silicone became an unacceptable risk to humans when it was used as a gel. As illogical and contradictory as it might seem, the critics claimed that the human body’s immune system did not react to the material itself but only to one of its physical configurations. The critics and plaintiff’s attorneys had no proof that such an unlikely causal phenomenon existed, but the medical community and the manufacturers had no proof that it didn’t. Asking for further scientific inquiry followed by further hearings was the initial recommendation of the FDA: entirely reasonable given the successful track record of silicone in all other medical applications. But the non-scientific elements involved in this evaluation process were determined to take scientific inquiry out of the equation, and their ability to do so is now a matter of record.

In one of the references cited by Dr Fisher, public outrage was identified as a powerful influence on those who involve themselves in regulating drugs or medical devices. The goal of activist groups is to be identified as “the public,” and the activities of the individuals and the groups opposed to silicone breast implants are mentioned throughout the book. But opposition was not restricted to only those claiming implants carried a health risk. Some feminine activists who characterized themselves as also representing the public also opposed breast implants in any form. Their concern was not health, but the concept of feminine victimization resulting from society’s artificial standards of beauty. For the first time, social agendas were being promoted as though they were as relevant to the process as the science.

Politicians, self-proclaimed experts, plaintiff attorneys, and others reeled off endless unsubstantiated claims, anecdotal evidence, and rumors to anyone who would listen, most often in venues where they were assured there would be no risk of contradiction. The audiences they wanted were reporters and TV cameras.

Eclipsing all other factors influencing this process was the media. Numerous examples are provided by Dr Fisher in which TV and the print media were used to provide a platform for anyone who alleged that there was a problem: providing proof for their claims was not a requirement. Sadly, credence is often given to outrageous claims simply because the claim appears in print or on TV.

The media were not interested in good news or in science. Editors and producers knew that ratings and readership always increase if issues of alleged corporate irresponsibility, bureaucratic ineptitude, possible innocent victims, and political indifference can be suggested and, in this case, centering it all on women’s breasts was only a bonus.

The limitations of this review do not permit an inventory of all the non-scientific factors and influences that were employed by special interests in their efforts to derail the approval process for silicone breast implants, but to dismiss their impact on the process would be unwise in terms of the future.

The rampant inconsistencies and contradictions that led to the ill-advised moratorium are documented in numbing detail in Chapter 12. The events leading up to the moratorium are beyond the ability of this reviewer to describe; it is a section that has to be read in order to appreciate the absurdity of the decision-making process that resulted in one of the most counterproductive actions ever taken by a governmental agency.

The architect of this disaster was the FDA Commissioner, David Kessler, MD, JD, a recent political appointee who specialized in what it took to achieve maximum personal exposure and recognition regardless of the merit of the issue with which he was involved. In the chapter devoted to Commissioner Kessler, Dr Fisher pillories him justifiably, but to what end? Commissioner Kessler was an aberration. Without question the actions that he unilaterally orchestrated during this entire fiasco were damaging, especially to women who already had implants and who suffered unimaginable fear and anxiety arising from the Commissioner’s mismanagement of this whole affair, especially the moratorium; but he was an anomaly. Those who control such appointments have apparently recognized the negatives that come with such an activist, ambitious, and self-aggrandizing Commissioner. Such an appointment is unlikely to happen again. In the eyes of the politicians now in charge, the most desirable FDA Commissioner for the future is a competent but low-profile bureaucrat who specializes in what the FDA does best: delays.

The various court cases, bankruptcies, the class action suit, the settlement, and other details that appear in the last several chapters are interesting, but other than reinforcing the obvious—ie, plaintiff attorneys are a particularly important special interest group that has a huge monetary interest in regulatory issues, especially those related to product liability—this information is old history and is unlikely to provide contemporary readers with a reaction other than, “How could that have happened?”

CONCLUSION

Silicone on Trial: Breast Implants and the Politics of Risk is a convincing vindication of silicone breast implants, but
Dr Fisher’s revelations regarding the flawed system that produced the silicone controversy in the first place may be of more interest to contemporary surgeons by providing a better understanding of an agency that continues to be influenced by factors that have little to do with medical facts and science. The elements that clearly influenced and compromised the events described in this narrative provide sobering evidence that scientific inquiry can be overwhelmed and marginalized, at least temporarily, by a variety of self-serving special interests to which science is irrelevant.

The very people who choose not to read this book are the very ones who should read it. The future cannot be managed if experiences of the past that continue to remain relevant today are ignored.