The Food and Drug Administration’s (FDA) lifting of the 14-year ban on general access to silicone gel–filled breast implants in November 2006 was welcome news to plastic surgeons and patients seeking additional options for breast enhancement and reconstruction. As physicians who have more than 40 years of clinical experience with these devices, plastic surgeons have long expected the official recognition of implant safety and eventual lifting of most restrictions by the FDA. Nevertheless, the long process that has taken us from the 1992 FDA moratorium to the agency’s current resolution of the controversy exacted a high price, both economically and emotionally.

The breast implant controversy offers an example of how, in the world of modern journalism, emotion can take precedence over reason. Beginning in 1990, following the broadcast of a highly inflammatory segment on “Face to Face with Connie Chung,” patients’ concerns over the safety of breast implants escalated to the level of a pandemic. The plastic surgery organizations, and others in the medical community, attempted to respond to these concerns with both scientific and clinical data. It was extremely difficult, however, to interest journalists in the dry details of scientific investigations or the complicated explanations of doctors when the personal stories of women who believed they had been seriously harmed by their implants were far more compelling to a mass audience.

We soon learned, as well, that a similar mentality often rules the courtroom. The clash between science and the legal process was aptly described in Dr. Marcia Angell’s ground-breaking book, Science on Trial: “In science, the evidence leads to the conclusion; in the courtroom, the expert’s conclusion comes first and becomes the legal evidence. Not surprisingly, the answers yielded by these two approaches may differ greatly.”

There is no doubt that, at the time of the moratorium and despite the availability of a wide range of both scientific and clinical studies, manufacturers lacked the kind of data necessary to answer all the questions posed by the FDA concerning the long-term safety and effectiveness of silicone gel breast implants. There was no way around this fact, nor should there have been. On the opposing team, the trial attorneys certainly lacked evidence to prove implants were associated with the variety of illnesses claimed by their clients. Yet with the help of dramatic “expert testimony,” often based on what we commonly call “junk science,” attorneys were emboldened and juries were swayed.

And so the price was paid. We all know the fate of Dow Corning, once the major manufacturer of breast implants, which emerged from Chapter 11 only as recently as 2004 after having to provide $2.35 billion to settle claims. But what about the many patients who suffered nearly constant anxiety for years while lawyers fueled the fires of debate about implant safety and, it has been reported, even threatened and harassed researchers who sought to develop valid scientific studies that might answer the questions raised about implants and disease? What about the women who, in a panic, needlessly had their intact implants removed—implants that once had provided them with personal fulfillment and enhanced self-esteem? And there is hardly a plastic surgeon of that era who did not have to contend with not only anxious or angry patients but also at least a handful of lawsuits related purely to the implant controversy and not to their surgical skill or the quality of care provided to their patients.

On the other hand, it is clear that the breast implant “crisis” also produced a number of “positives.” Breast implants became among the most studied of all medical devices. New scientific information is now available to help us treat our implant patients more effectively, and the continuation of meaningful research is ensured by FDA mandate. Patient education concerning implant benefits and risks is more complete and sophisticated. Such information, and the one-on-one communication...
necessary to deliver it effectively, can only serve to enhance the doctor-patient relationship, improve the quality of patient care, and increase patient satisfaction. Furthermore, the effort to standardize physician education and qualifications to perform breast implant surgery should help to reduce avoidable complications.

The American public demands the latest and best treatments—in fact, generally believes that such treatments are an inherent right. At the same time, we expect drug and medical device researchers and manufacturers to accept full responsibility for all risks associated with their products—risks that are known, as well as those that may become evident only after many years. While liability concerns will certainly impact the future availability of new and potentially more effective drugs and devices, there remains ample incentive for companies to engage in careful research and responsible product development—provided that science, rather than emotion, rules the courtroom. While some progress has been made with regard to the standards for so-called “expert testimony,” the consistent victory of scientific truth in the medico-legal, not to mention political, arena is likely to require an even higher price than we already have paid.

Reference