

Silicone-Gel Breast Implants: Why Has the Science Been Ignored?

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[1]

EXECUTIVE SUMMARY

In January 1992 the Food and Drug Administration (FDA) implemented a voluntary but strongly-urged moratorium on the sale and use of silicone breast implants pending review of additional information. By April 1992 the FDA had converted this moratorium to what was essentially a ban. The FDA did, however, allow continued use of the implants for women who had undergone mastectomies; it also allowed a small number of women who wanted implants for cosmetic purposes to enroll in long-term studies.

Since 1992 a large number of studies have appeared that exonerate the implants of the charges leveled against them. In 1993 the Council of Scientific Affairs of the American Medical Association (AMA) issued a report urging the AMA to "support the position that women have the right to choose silicone gel-filled or saline-filled breast implants for both augmentation and reconstruction after being fully informed about the risks and benefits." The American College of Rheumatology also issued a statement, that "there is no convincing evidence that these implants cause any generalized disease." Most recently, on June 21, 1999, the Institute of Medicine of the National Academy of Sciences reported the conclusions of a 2-year investigation on the possible role of silicone gel implants in systemic diseases. This investigation discovered no association between silicone gel implants and cancer, immunologic disease, or other systemic diseases; moreover, they reported that implants pose no risk for breast-feeding or to unborn infants. Nevertheless, the FDA's ban remains in effect. **[[UPDATE: The FDA [lifted the ban in 2006](#) [2] with the approval of two silicone implants]].**

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[Silicone-Gel Breast Implants: Why Has the Science Been Ignored?](#) [3]

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[2] <http://www.nytimes.com/2006/11/18/washington/18breast.html?pagewanted=all>

[3] <http://www.scribd.com/doc/111407922/Silicone-Gel-Breast-Implants-Why-Has-the-Science-Been-Ignored>