



## AACS ADVOCATES PATIENT SAFETY IN BREAST IMPLANTS

The U.S. Food and Drug Administration (FDA) recently approved (Nov. 17, 2006) the reintroduction of silicone gel-filled breast implants. The American Academy of Cosmetic Surgery (AACS) urges the FDA to continue to make patient safety the primary factor in approving and monitoring the reintroduction of silicone implants. The Academy is committed to patient safety and believes that patient safety and well being should always come first.

AACS also understands the benefits of allowing doctors to offer their patients more options and a choice of appropriate and safe products. In doing so, AACS supports the FDA's decision to monitor the use of silicone implants through post market studies. Current plans call for following 40,000 women for 10 years after receiving breast implants.

### **Breast Implant Safety Studies**

One of the longest and largest studies to date on the health effects of implants was conducted by the **National Cancer Institute (NCI)** in 1992 involving 13,500 women with an average follow-up time of 13 years. The study included women with silicone and saline breast implants. One of the key study findings was that **NCI researchers found no association between breast implants and the subsequent risk of breast cancer.**

**The National Academy Institute of Medicine** issued a 1999 report concluding that "In an overall consideration of the epidemiological evidence, the committee noted that because there are more than 1.5 million adult women of all ages in the United States with silicone breast implants, some of these women would be expected to develop connective tissue diseases, cancer, neurological diseases or other systematic complaints or conditions. **Evidence suggests that such diseases or conditions are no more common in women with breast implants than in women without implants.**"

### **AACS Policy Recommendation:**

While the FDA currently has a "MedWatch" system in place that allows consumers to report serious reactions, product quality problems and product use errors with human medical products such as drugs and medical devices, **AACS also strongly recommends that federal policy makers create and implement a national voluntary registry for breast implants.**

The purpose of a voluntary national registry with strong confidentiality protections would be to allow all breast implant patients to share positive and negative effects of these devices. This would create a significant database of information for consumers and their doctors.

AACS is an active member of the American Medical Association (AMA). We and our physician colleagues view improving patient safety and quality care as a top priority. We welcome the opportunity to work with the FDA and Congress on efforts to develop evidence-based performance measures to improve the quality of care.

December 2006

### **For More Information about the American Academy of Cosmetic Surgery**

please contact Charlie Baase, AACS Marketing and Communications Manger at (312) 981-6769 [cbaase@cosmeticsurgery.com](mailto:cbaase@cosmeticsurgery.com) or our Washington Representative Julie Shroyer, Senior Vice President, Wheat Government Relations at (703) 271-8760 [jshroyer@wheatgr.com](mailto:jshroyer@wheatgr.com).