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Silicone: Now a solid `maybe'

The breast implants' approval by the FDA was not fine-print free. Women must weigh the impact, and costs, of follow-up care.

November 27, 2006 | Melissa Healy | Times Staff Writer

The days before Thanksgiving are typically quiet in the offices of plastic surgeons. But a long-awaited decision to approve silicone breast implants for women older than 22 prompted a flurry of excited calls and inquiries last week from prospective patients.

The giddy welcome may not last. Even as the two U.S. manufacturers of silicone implants gleefully projected a surge in demand for their products, physicians began poring over the fine print of the Food and Drug Administration's recommendation and finding reasons for caution.

Like a holiday hangover that sets in before the dishes are washed, the sobering details of the government's decision are making some doctors less than exuberant about the newly approved implants. As they begin to share their wariness with patients, some expect many women will stick with saline implants or wait for the FDA to give its blessing to a new generation of silicone implants sometime in the next two years.

The agency's decision "does create a whole host of questions" for women considering silicone breast augmentation and for the doctors who perform those procedures, said Dr. Walter Erhardt, chairman of the American Society of Plastic Surgeons' public education committee.

For The Record
Los Angeles Times Wednesday November 29, 2006 Home Edition Main News Part A Page 2 National Desk 2 inches; 66 words Type of Material: Correction
Breast implants: In Monday's Health section article about breast implants, Diana Zuckerman, the director of the National Research Center for Women & Families, was quoted as saying an MRI to detect the integrity of a breast implant typically costs between $1,500 and $1,800. Additional research, Zuckerman said Monday, showed that the total average cost of such MRIs is just over $2,000, with some costing considerably more.
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Los Angeles Times Monday December 04, 2006 Home Edition Health Part F Page 6 Features Desk 1 inches; 68 words Type of Material: Correction
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"Many women were waiting in the wings to see when [the] FDA would approve silicone," said Brent Moelleken, a plastic surgeon with practices in Beverly Hills and Santa Barbara. Patients intent on getting silicone implants "really look on the bright side of the controversy," he said. Although many prospective patients will inquire, "my recommendation to them may not be to have surgery" at this time, he added.

Key among the questions that doctors are pondering is the cost of using the newly approved gel implants in the manner outlined as safe by the FDA in its Nov. 17 announcement. The agency recommends that

replaced, if needed," the FDA added.

Medical insurance doesn't cover cosmetic breast enhancement. Similarly, the cost of postoperative tracking and repeat surgery, the FDA notes, "may not be covered" by a woman's medical insurance and "may exceed the cost of her initial surgery."

Even if women can afford the original breast implant surgery, a subsequent surgery -- not to mention periodic MRIs -- may be out of their price range.

Cleared but questioned

The FDA's approval -- after 14 years of study -- had been expected to end the controversy around silicone gel implants.

The devices were pulled from the general marketplace in 1992 amid concerns that they could rupture and endanger women, possibly contributing to autoimmune diseases. Although a link to health problems was never proved, long-term safety has remained an issue. In the meantime, the implants have remained available to cancer survivors and a wide range of women who agreed to enroll in studies of the implants' safety.

But the new recommendations present patients and their plastic and aesthetic surgeons with additional uncertainties: Who will pay for the recommended MRI scans? What danger does the FDA foresee if patients, as expected, fail to get them? Does the FDA consider that a ruptured implant device -- even one that presents no discomfort or proven danger to the patient -- must necessarily be surgically removed and replaced? If so, whose financial responsibility would that be?

"Do you think [insurance companies] are going to say, 'No problem, we want what's best for the patient?' " asks plastic surgeon Marcel Daniels of Long Beach. "No. A lot of third-party payers have ruled out payment for any treatment -- including complications -- related to breast implants."

What to do if those MRI scans detect cracks or breaks in an implant "is another conundrum that's created by this [FDA] recommendation," said Erhardt, of Albany, Ga. By calling for costly MRIs to detect silent ruptures and potential replacement surgery in such cases, the FDA is suggesting to patients and physicians that leakage may present safety concerns. "But we still don't have science that [a silent rupture] creates a harmful situation for the patients. And the FDA hasn't addressed that either," Erhardt said.

Plastic and aesthetic surgeons currently are divided on the question of whether "silent ruptures" -- breaks in a silicone implant that are not noticed by the patient -- need to be replaced for safety. Laurie Casas, a Chicago plastic surgeon, says she believes a broken implant could eventually cause inflammation and so "should be replaced, as you would any broken device."

Beverly Hills plastic surgeon Richard Ellenbogen, whose view is widely shared among plastic surgeons, counters, "If it ain't broke, why fix it? Why submit a woman to that trauma?"

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