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F.D.A. Will Allow Breast Implants Made of Silicone

By STEPHANIE SAUL

The Food and Drug Administration yesterday lifted a 14-year ban on the use of silicone gel breast implants in the United States after decades of contentious debate and litigation over their safety.

The federal agency approved implants manufactured by two California companies, Mentor and Allergan, for breast reconstruction and cosmetic breast augmentation, but limited cosmetic use of the implants to women ages 22 and older.

The decision appeared to end a controversy over the safety of silicone implants that lasted more than two decades and resulted in thousands of lawsuits by women who claimed the implants leaked and caused a number of diseases, including cancer and rheumatoid arthritis. The dispute led to the bankruptcy of the manufacturer Dow Corning, a federal moratorium on the use of the implants, and, finally, findings by both the Institute of Medicine and the Food and Drug Administration that the devices do not cause major illnesses.

Because the implants made of silicone gel are softer than the saline implants currently available, plastic surgeons said they would quickly become preferred among the more than 300,000 women in this country who have breast implants each year.

Critics of the decision lambasted it and said that longstanding safety concerns had not been resolved. But supporters of the implants, including leading surgeons, applauded it.

“For us, it’s a triumph of science,” said Dr. Richard A. D’Amico of Engelwood, N.J., president-elect of the American Society of Plastic Surgeons. “We’ve always felt that the science would bear out the use of the implants.”

Dr. Daniel G. Schultz, director of the F.D.A.’s Center for Devices and Radiological Health, said that the agency’s review, based on company-sponsored studies as well as long-term use of the implants abroad, had determined that their sale is in the best interest of women.

But Dr. Schultz warned that no device is foolproof and that there was a possibility that women would have to have the implants replaced at some point, sometimes because they rupture. Studies have found that the majority of women with silicone implants would have a rupture at some point. According to the federal agency, one study found that 69 percent of women had a rupture.

“Women should know that breast implants are not lifetime devices,” he said in a telephone briefing for

reporters last night.

“Women having these procedures done need to be prepared for the fact that there is a likelihood they will require additional surgery,” he said.

He also recommended regular M.R.I.’s to monitor the devices for “silent rupture,” which can occur without a woman’s knowledge. He said the first M.R.I. should be performed when the implants are 3 years old. Because many of the procedures are cosmetic, it was not clear whether those M.R.I.’s would be covered by insurance.

Critics of the agency said yesterday that the devices should not have been approved, and cited the same safety concerns that have dogged the devices for years.

Dr. Sidney Wolfe, chief of Public Citizen’s Health Research Group, which claimed in the 1980s that breast implants cause cancer, called the implants “the most defective medical device ever approved by the F.D.A. The approval makes a mockery of the legal standard that requires ‘reasonable assurance of safety.’ ”

Amy Allina, program director at the National Women’s Health Network, also sharply criticized the decision, saying that the federal agency had approved the implants even though the manufacturers had failed to answer basic safety questions, such as exactly how long implants would last without rupturing, and whether there would be health effects if the silicone leaked out and traveled to other parts of the body.

She predicted that the companies would begin a “massive, massive marketing campaign,” and that women might be taken in by it and assume that the F.D.A.’s stamp of approval means implants are safe.

Mentor Corporation of Santa Barbara, Calif., which calls its product Memory Gel, had already initiated one Web site last night to advertise the product: Mentor4Me.com. The site has a function allowing patients to find a plastic surgeon.

Defending the decision to lift the ban, Dr. Schultz said, “We have been looking at this data continuously for the last 10 years. We have been watching as data had been collected, we have been watching as data has accumulated. We believe that from a scientific standpoint, the decision that we’re making tonight is, in fact, in the best interest of American women.”

But he said the agency would require the companies to conduct post-approval studies involving a total of 80,000 women to continue monitoring the safety of the implants. He said that information would be collected about rates of rupture, cancer and autoimmune diseases and effects of the implants on reproduction. That would enable the agency to evaluate concerns about the implants in a large number of women.

But Ms. Allina questioned the validity of such studies. “The F.D.A. has no credibility to assert post-approval studies will be any better,” Ms. Allina said. “Once again, the F.D.A. is putting the interests of this administration’s allies, the economic interests of the industry, over public health.”

The agency approved the devices for all women for reconstruction following breast cancer, trauma, or for developmental disorders affecting the chest. But the agency said that they would not be available to women under 22 for cosmetic use.

“We wanted to make sure that breast development had been completed before these devices had been implanted,” Dr. Schultz said, adding that the agency also did not have clinical data on younger women. “We concluded that age 22 was the appropriate age for the lower limit for augmentation.”

Some surgeons, who have participated in studies, will be able to implant the devices as early as Monday. For others, there will be a wait of up to several weeks because the F.D.A. is requiring them to participate in a training program before receiving shipments.

Silicone breast implants were available in the United States as early as the 1960s. Following complaints and lawsuits in the 1970s and 1980s that the devices ruptured and became hard and painful and that some women developed cancer and autoimmune diseases, implant makers agreed to take their products off the market in the United States in 1992, except for treating mastectomy patients and in some other special cases and only when the patients were enrolled in clinical studies.

Eventually, thousands of women in this country and elsewhere sued the manufacturers of breast implants, resulting in class-action settlements by several companies, including 3M, Baxter, Bristol-Myers and Dow Corning. All got out of the silicone breast implant business.

In 1999, the Institute of Medicine, an arm of the National Academy of Sciences, said that while the implants could rupture and become hard and painful, there was no definitive evidence that they were associated with serious diseases, including autoimmune disease or cancer.

Dr. Scott L. Spear, the chief of plastic surgery at Georgetown University who has conducted clinical research for Allergan of Irvine, Calif., said the devices had been improved.

“The shells themselves are made of different materials, a barrier shell, that is relatively much more impermeable,” Dr. Spear said. “The shells are thicker than in ‘91, much thicker than they were in earlier generations. The material inside is more cohesive, the stuff tends to stick together.”

In Canada, which also withdrew the devices, the implants were cleared for sale and implantation in October.

Denise Grady contributed reporting.