

France Ponders Removing Risky Breast Implants

Angela Charlton, AP

French health authorities are considering whether to suggest that an estimated 30,000 women in France get their breast implants removed, amid warnings by leading doctors about the risks of rupture and possible cancer. The decision also could have repercussions outside France. Tens of thousands of women in Britain and around Europe also have the pre-filled silicone gel implants made by now-defunct French company Poly Implant Prothese, or PIP.

British health authorities say they see no reason so far to get them systematically removed, while Italy's Health Ministry is holding a meeting Thursday to discuss them. The implants were not sold in the United States. Experts from the French Health Ministry will meet Friday to decide what to recommend for women who have the implants, ministry officials said.

More than 1,000 of the implants have ruptured, according to the French health and safety agency AFSSAPS, and eight women with the implants have developed cancer. The implants were taken off the market last year after French authorities discovered the company misreported the type of silicon used. Friday's decision will depend partly on guidance from the French National Cancer Institute, which is studying whether there are links between the implants and the cancer cases.

Doctors studying the implants say the risk of rupture is reason enough for all women to remove them, and want the government to foot the bill. Dr. Maurice Mimoun said the ruptured implants could leak the silicone gel internally, which could require surgery on other parts of the body to remove it. "We have been trying for more than a year to ensure that women with these implants can have them removed without having financial difficulties," said Dominique-Michel Courtois, a doctor for an association of victims of medical accidents. He said he expects French authorities to issue a recommendation that they be removed on a voluntary basis.

Such a recommendation would impose substantial costs to France's state healthcare system and pose logistical challenges in finding enough surgeons to perform the operations. Government spokeswoman Valerie Pecresse said state healthcare would pay for implant removal operations, "if it involves a health and public safety emergency." It is unclear, however, whether the state would pay for replacement implants. Roughly 20 percent of French women with the implants got them for medical reasons, primarily after breast cancer.

Women have filed more than 2,000 legal complaints since the implants were recalled last year, and an investigation into officials at PIP is under way. Investigators suspect the company used cheaper industrial silicone instead of silicone meant for medical use in the implants, cutting costs by up to \$1.3 million a year. The company has suspended its activities and is being liquidated. Its phones are no longer functioning and e-mails sent to its staff were not answered.

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Implant wearer Emmanuelle Maria described burning pain and globules protruding under her arms after both of her implants ruptured last year. Her doctors initially insisted there was nothing to worry about, but eventually she had them both removed and replaced. "The product is dangerous. They told us there was nothing toxic," she told The Associated Press by telephone from her office in La Seyne-sur-Mer in southern France — the same town where PIP was based. She accused the company and surgeons of "playing Russian roulette with the health of others."

A lawyer for women who had ruptured PIP silicone implants says the company exported the implants to countries including Britain, Italy, Spain, Portugal and Ukraine. Some 40,000 women in Britain are believed to have the PIP implants as well. Britain's Medicines and Healthcare Products Regulatory Agency said its own testing had found no evidence of toxicity in the PIP implants and no evidence to suggest that women should have them removed. But the agency said in a statement it would continue to work with French health authorities and "will consider any new evidence which comes to light as a priority."

The British Association for Plastic, Reconstructive and Aesthetic Surgeons said the expected announcement by French medical authorities was "a precautionary measure." "Surgeons will be in contact with any patient who has received this type of implant if any action is required," it said. "If women are worried or believe that their implants may have ruptured, they should contact their implanting surgeon."

The Italian Health Ministry says it is monitoring the "possible health risks linked to the PIP implants signaled by the French authorities" and it has convened a meeting of its top level health experts for Thursday. In Denmark, authorities says less than 100 women had these breast implants and the Danish Medicines Agency is in close contact with French authorities.

In the United States, the Food and Drug Administration banned silicone-gel implants in 1992 amid fears they might cause cancer, lupus and other diseases. However, when research ruled out most of the diseases concerned, regulators returned the implants to the market in 2006, with the requirement that manufacturers continue studying recipients to see how they fare long-term.

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