

France to pay for removal of risky breast implants

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In this photo taken Thursday, Dec. 22, 2011, Chantal Guerin, a 46-year-old accountant and mother of three, displays a breast implant made by Poly Implant Prothese, or PIP, that was removed from her left breast, during an interview with The Associated Press in Paris. Guerin had her left breast removed after cancer and had PIP implants put in both breasts. (AP Photo/Christophe Ena)

France took a costly and unprecedented leap Friday in offering to pay for 30,000 women to have their breast implants removed because of mounting fears the products could rupture and leak cheap, industrialgrade silicone into the body.

Tens of thousands of other women elsewhere in Europe and in South



America have the same French-made <u>implants</u>, but authorities there have so far refused to follow suit. The silicone-gel implants in question are not sold in the U.S.

Over the past week, the safety fears have created a public furor over something usually kept private, even in France. Women, some whose own families didn't know they had their breasts enlarged, marched on Paris to demand more attention to worries about what might be happening inside them. Images of leaky, blubbery implants and women having mammograms have been splashed on French TV.

More than 1,000 ruptures pushed <u>Health Minister</u> Xavier Bertrand to recommend that the estimated 30,000 women in France with the implants get them removed at the state's expense.

Bertrand insisted the removals would be "preventive" and not urgent, and French <u>health authorities</u> said they had found nothing to link the implants to nine cases of cancer in women. The death last month of a woman who had the implants and developed a <u>rare cancer</u> - anaplastic large-cell lymphoma - had catalyzed worries.

The implants, made by the now-defunct French company Poly Implant Prothese, were pulled from the market last year in countries around Europe and South America where they had been sold. The company's website said it exported to more than 60 countries and was one of the world's leading implant makers.

International police agency Interpol put PIP's former director, Jean-Claude Mas, on its most-wanted list, based on a warrant from Costa Rica for crimes involving "life and health." Interpol's website carries a photo of the 72-year-old Mas but no details about his alleged crimes or link to Costa Rica. Mas' lawyer could not be reached for comment Friday.



France's health safety agency says the PIP implants appear to be more rupture-prone than other types. Also, investigators say PIP used industrial silicone instead of the medical variety to save money. However, the medical risks posed by industrial silicone are unclear.

The financial burden of the French government's decision falls on the state health care system, which estimated the removals could cost euro60 million (\$78 million) at a time when the country is teetering on the brink of another recession and struggling with debt.

In recommending removal, the government noted the risks associated with major surgery and general anesthesia.

Because of those risks, many women may decide against removal. The government said those women should be examined every six months.

After the French decision, Britain's Medicines and Healthcare Products Regulatory Agency announced that it doesn't see enough proof of cancer or an excessive risk of rupture to recommend women in Britain have the implants removed. Up to 40,000 women in Britain may have had the implants, even more than in France.

Britain's chief medical officer, Sally Davies, said women "should not be unduly worried."

"While we respect the French government's decision, no other country is taking similar steps because we currently have no evidence to support it," she said.

The president of Brazil's Plastic Surgeons Association, Jose Horacio Aboudib, said it would be premature to have women remove the implants if they are not having any problems. About 25,000 women in Brazil received PIP implants.



"There is always a risk associated with surgery, and there is a cost. In France, the government is paying for it. Here it's not considered a public health risk, so the patient would have to pay for it," he said.

Medical authorities in Argentina and Venezuela recommended closer monitoring of women who have the implants.

In the U.S., concerns about silicone gel implants in general led to a 14-year ban on their use, in favor of saline-filled implants. Silicone implants were brought back to the market in the U.S. in 2006 after research ruled out links to cancer, lupus and some other concerns.

In France, one reason for the alarm was the uncertainty over the ingredients of the silicone used and the risk to internal organs. Also, while all <u>breast implants</u> can burst, especially as they get older, "these implants have a particular fragility" and appear to pose risks of rupture earlier in their life spans than other implants, said Jean-Claude Ghislain of the French health agency AFSSAPS.

France's state health care system normally pays for implants for medical reasons, such as after a mastectomy, but not for cosmetic implants. About 80 percent of those with the PIP implants had them for aesthetic reasons.

Annie Mesnil, who had a PIP implant to replace a breast removed after cancer in 1999, said she was relieved that the Health Ministry "accepts the idea that there is a potential danger." But she added: "It's not enough. They will pay for the removal of the implants, but they will not pay for the replacements."

After the PIP product was recalled last year, a mammogram and ultrasound did not reveal any problems with Mesnil's implant. But Mesnil, 62, had it removed anyway, at her own expense, out of fear.



When her surgeon took it out and studied it, "he discovered it had already burst," she said. "I don't know what's spilled inside my body."

The state health care system only reimburses about 230 euros for implant removal operations, but public hospitals that provide the service for that low fee are rare and overbooked. Most plastic surgeons in France are private practitioners who can charge five to 10 times more than that for a removal. Some plastic surgeons have agreed to lower their fees under government pressure.

Chantal Guerin, a 46-year-old accountant and mother of three, had her left breast removed after cancer and had PIP implants put in both breasts. In 2010, she developed cancer in her right breast.

"One cannot directly incriminate the implant, since there is no scientific proof," she said in an interview. "But we have the right to ask ourselves a lot of questions, because there is a great amount of physical pain involved."

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