

French breast implant tycoon hits back as scandal grows

December 28 2011, by Catherine Hours

Holed up at his home in the south of France, the founder of troubled breast implant manufacturer PIP is fighting back against a growing international scandal over his allegedly faulty products.

Between 300,000 and 400,000 women in 65 countries from Europe to Latin America have implants made with sub-standard silicone gel by 72-year-old Jean-Claude Mas's now-bankrupt company Poly Implant Prothese (PIP).

France last week advised 30,000 women to have their PIP implants removed because of an increased risk of rupture and Venezuela's government announced Tuesday that women with the implants could have them removed for free.

Authorities in other countries have advised women to consult their doctors over the implants, while it emerged Monday that US authorities had already raised the alarm over the company in 2000.

Lawsuits filed in the US cite defective merchandise not suited for its intended purpose and violations of consumer legislation by PIP, which was once the world's third-largest producer of silicone implants.

With Mas due in a French court next year, questions are increasingly being asked over why it took until 2010 for French authorities to intervene, while Mas's lawyer has been actively defending his client in the press.

"He's at home... he's not on the run at all. Moreover he can't walk because he's just been operated on," lawyer Yves Haddad told AFP on Tuesday, saying he simply "doesn't want to talk" publicly.

Haddad said that Mas freely admits using unapproved silicon gel, but remains adamant it is safe.

"PIP knew it wasn't in compliance, but it wasn't a toxic product," the lawyer said, adding it "had not been proven" the implants were any more likely to leak.

"The fact that it's an irritant (when ruptured) is the same for all silicone gels," Haddad said, also denying that his client had ever been a sausage butcher or wine merchant, as reported by the French press.

PIP used two types of silicone in its implants, Haddad said. One of them was an approved gel made by American firm Nusal, but it also used an "identical" homemade gel that was five times cheaper.

According to PIP's 2010 bankruptcy filing, it had exported 84 percent of its annual production of 100,000 implants.

Prosecutors in Marseille, near PIP's laboratory at Seyne-sur-Mer on the Mediterranean, have received more than 2,000 complaints from French women who received the implants, and are pursuing a criminal investigation.

A lawyer representing four French women who received the PIP implants, Laurent Gaudon, said Wednesday they would be suing the manufacturer and their surgeons.

Gaudon said he would file the suit next week at a court in the city of Toulon and that the four women would be suing PIP, German company

TUV which provided quality certification for PIP, and their four cosmetic surgeons.

"The doctors must be questioned by experts... They could not have been ignorant of the fact that these implants were fragile," he said, adding that his clients had discovered cracks in their implants but not yet had them removed.

On Tuesday it emerged that the US Food and Drug Administration had already in 2000 sent a letter to PIP warning of "serious" quality control violations involving its saline implants.

Although the complaint targeted saline rather than the silicone implants at the centre of the current scandal, the letter outlined a list of quality assurance problems.

The FDA warned they "may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems."

Mas worked at pharmaceutical giant Bristol-Myers (now Bristol-Myers Squibb) before meeting up with plastic surgeon Henri Arion who introduced breast implants to France in 1965, Haddad said.

Mas's trial for "aggravated fraud" is due to open late 2012, while a manslaughter inquiry has also been opened after at least one suspicious death in France.

French breast implant scare has ripples around the world

Tens of thousands of women in more than 65 countries, mainly in South America and western Europe, have received breast implants produced by

now bankrupt French firm Poly Implant Prothese (PIP).

Here is how the health scare surrounding the implants unfolded:

- March 30, 2010: PIP is shut down and its product banned after it was revealed to have been using non-authorized silicone gel that caused abnormally high rupture rates of its implants.
- December 20, 2011: Media reports emerge that French medical authorities will tell 30,000 women who received defective breast implants to have them removed after eight cases of cancer emerge.
- December 21: A lawyer says more than 250 British women are to take court action after more than half experienced ruptures in breast implants made by PIP.
- December 23: France's health ministry advises women with breast implants made by PIP to have them removed as, while there is no proven cancer risk, they could rupture dangerously.
- In Latin America, Brazil recommends that 25,000 women who received the implants get tested early to make sure the implants are viable.

In Europe, Belgian health authorities encourage women with breast implants made by PIP to have them removed if they suspect any ruptures, while Finland and Italy recommend monitoring.

- December 27: The US Food and Drug Administration says it warned the French firm of "serious" quality control violations involving saline implants in 2000.
- Venezuela's public health service will remove for free the French-made

implants, Health Minister Eugenia Sader says.

- The Dutch health authorities say that the some 1,000 Dutch [women](#) who were given the [implants](#) should see their doctors.

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