

## Hundreds expected for French breast implants mega-trial

April 15 2013, by Catherine Hours

France will launch one its biggest-ever trials on Wednesday as five managers from company PIP face charges of selling faulty breast implants that sparked a global health scare.

More than 5,000 women have registered as plaintiffs in the case, which sees the defendants including 73-year-old PIP founder Jean-Claude Mas charged with aggravated fraud for using industrial-grade silicone in implants.

An estimated 300,000 women in 65 countries are believed to have received the implants, which are twice as likely to rupture as other brands.

News of the faulty implants in 2011 sparked fears worldwide, but <u>health</u> <u>officials</u> in various countries have said they were not toxic and did not increase the risk of <u>breast cancer</u>. A 10-year case study has been launched in France to determine the long-term effects.

More than 4,000 women have reported ruptures in the implants and in France alone 15,000 have had the PIP implants replaced.

Hundreds of the victims, as well as some 300 lawyers, are expected to attend the trial in the southern port city of Marseille, near PIP's former headquarters.

Authorities have moved the proceedings to a hall of the city's congress



centre that seats 700 people and provided three other rooms where more than 800 others will be able to watch video transmissions.

The logistical costs of the trial have been estimated at 800,000 euros (\$1 million).

The defendants face up to five years in prison and the trial is set to last until May 17.

Victims say they are anxious to see PIP representatives held to account for the trauma suffered by women with the implants.

"Even if not all the women have significant physical or psychological after-effects, they have all been marked for life," said Joelle Manighetti, a 56-year-old breast cancer survivor who received a PIP implant after a mastectomy.

Mas, a former travelling salesman who got his start in the medical business by selling pharmaceuticals, founded PIP in 1991 to take advantage of the booming market for cosmetic implants.

He built the company into the third-largest global supplier of implants, but came under the spotlight when plastic surgeons began reporting an unusual number of ruptures in his products.

Health authorities later discovered he was saving millions of euros by allegedly using industrial-grade gel in 75 percent of the implants. PIP's implants were banned and the company eventually liquidated.

PIP had exported more than 80 percent of its implants, with about half going to Latin America, about a third to other countries in western Europe, about 10 percent to eastern Europe and the rest to the Middle East and Asia.



France is the only major country that has compensated women for having the implants replaced, but at ceiling of 4,200 euros (\$5,500).

Many of the plaintiffs are hoping the trial will open the door to more widespread compensation, including for women outside France.

Lawyers for some plaintiffs have called for plastic surgeons and the German safety standards firm that gave the implants the all-clear to also face criminal charges.

The German firm, TUV Rheinland, is facing a separate civil trial in France where it is being sued by PIP distributors from Bulgaria, Brazil, Italy, Syria, Mexico and Romania, as well as thousands of victims, for more than 50 million euros (\$66 million).

Arie Alimi, a lawyer representing Venezuelan plaintiffs in the Marseille criminal case, said the European Union should also be forced to create a compensation fund for victims, arguing that its "lax" controls "are the cause of this disaster".

## How PIP breast implant health scare, legal case unfolded

France will launch one of its biggest-ever trials on Wednesday as five managers from company PIP face fraud charges for allegedly selling faulty breast implants that sparked global health fears.

Here is how the health scare and criminal investigation unfolded:

**—** 2010 **—** 

- March 30: PIP is shut down and its product banned after it was



revealed to have been using non-authorised silicone gel that caused abnormally high rupture rates of its implants.

- June 10: 500 women who received the implants file a legal complaint against PIP in the southern city of Marseille, near its corporate headquarters.
- September 28-29: French health authorities call for increased monitoring of PIP implants.

— 2011 —

- December 8: Prosecutors in Marseille open a preliminary investigation into the implants following the death of a woman from breast cancer.
- December 20: Media reports emerge that French medical authorities will tell 30,000 women who received defective implants to have them removed after eight cases of cancer emerge.
- 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 the following days, authorities in Latin America and Europe also urge women to have the implants checked.

- December 27: The US Food and Drug Administration says it warned the French firm of "serious" quality control violations involving saline implants in 2000.

**—** 2012 **—** 

- January 5: PIP founder Jean-Claude Mas admits to using cheaper,



industrial-grade gel in the implants but says they pose "no health risk whatsoever".

- January 17: The World Health Organisation recommends women have the implants checked for possible ruptures.
- January 27: Mas and Claude Couty, PIP's former general manager, are charged. Three other former employees are charged in late February.
- March 6: Mas is jailed for failing to pay his 100,000 euros bail.
- October 29: Mas is released pending trial.
- 2013 —
- January 30: German safety standards firm TUV Rheinland, which gave the <u>implants</u> the all-clear, is sued by PIP distributors from Bulgaria, Brazil, Italy, Syria, Mexico and Romania, as well as thousands of victims, for more than 50 million euros (\$66 million).
- April 12: Health safety authorities report that nearly 15,000 French women have had the <u>PIP implants</u> removed.

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