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Industrial Crime Adversely Affects Global Aesthetic Industry Growth

By Jeffrey Frentzen, Executive Editor

The Poly Implant Prothèse (P.I.P.) breast implant scandal is easily one of the aesthetic industry's worst industrial crimes, rivaling the Dow Corning silicone breast implant debacle of the 1990s. P.I.P. implant shells were known to leak and they contained gel that was allegedly made from industrial grade sources. What's most alarming is that no one really knows how many thousands of people worldwide may have these defective breast implants, manufactured by the now-defunct French firm.

Since 1992, when P.I.P. introduced its implants, the firm took deceptive steps to shave costs and hide the true ingredients of its products. The company's efforts were made easier by a European regulatory regime that had been essentially outsourced to the very companies that it intended to regulate.

In March 2010 the French health authority Agence Francaise de Securite Sanitaire des Produits de Sante (AFSSAPS) accused P.I.P. of using non-medical grade industrial silicone in its products and banned the implants from the market. The company's headquarters was also closed down. In December 2011 the AFSSAPS issued disturbing news, advising around 30,000 women to consider removing their possibly defective P.I.P. implants. Authorities have reported that in 14% of French women whose implants were removed, the product was found to have ruptured or leaked. In January 2012, after weeks of eluding the police, the company's owner, Jean-Claude Mas, was arrested. At present, he is out on bail and awaiting trial.

Initial police and media interviews with Mr. Mas and his former employees painted the P.I.P. scandal in lurid colors, driven by corporate and criminal greed. Not to mention a wanton disregard for patient safety. For example, accounts say that Mr. Mas and his wife would take turns filling implant shells with a homemade brew of gel that reportedly was never tested scientifically.

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To many plastic surgeons and other aesthetic practitioners this scandal came as no surprise. For years, physicians had been noticing that oil from P.I.P. silicone gel implants would leach into women's bodies. Some physicians had been testing the P.I.P. implants for ruptures and defects, and for years they published accounts of inadequate shell design and manufacturing, as well as contaminated gel.

This event has elicited negative feelings in consumers at a time when the world economy is down and aesthetic practitioners need their customers confident and willing to get more procedures – not questioning the competency and safety of the entire industry.

News from France rippled across the Atlantic to many countries that imported the implants. In South America, which had been P.I.P.'s biggest importer for a decade, the implants were installed in untold numbers of women (and men). "We have placed approximately 1,600 pairs of P.I.P. implants from 2005 to 2011," said Guillermo Blugerman, M.D., a specialist in plastic surgery (aesthetic and restorative) in private practice in Buenos Aires, Argentina.

When the P.I.P. fraud was exposed, Dr. Blugerman contacted his patients and recommended ultrasound to determine the implant's integrity. "At that time, we replaced 99 implants. In December 2011, after discovering how the implants were manufactured, we offered free removal for all of our patients and replaced 200 pairs of implants."

Industrial Crime Adversely Affects Global Aesthetic Industry Growth

P.I.P. implants were widely used throughout Europe, notably in France and the U.K., but also in Belgium, Poland, the Czech Republic and Spain. In Spain, it is estimated that 18,500 women have these prostheses and that some 37,000 have been implanted.

"It is unthinkable that in the 21st Century it was possible to commercialize prostheses with the required sanitary authorization for use in people, which do not in fact meet the requisites for such use," said Enrique O. Etxeberria, M.D., Ph.D., an aesthetic and reconstructive surgeon in Bilbao, Spain. "It is not the first time this sort of thing has happened; for example, the soya oil prostheses Trilucent, but this time the end user felt completely deceived because fraud was perpetrated on professionals, surgeons and, of course, the patients."

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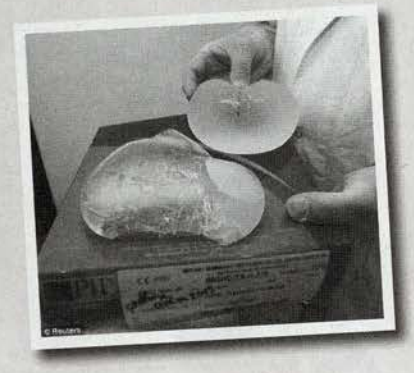
According to Dr. Etxeberria, the latest information available has shown that among other substances the implants contained Baysilone, an additive for fuel that is also used in ship building and electronic components; Silopren and Rhodorsil, which are two substances found in the rubber industry. "The worst of all is that these prostheses had the pertinent authorization from the French health authorities, which meant that no one (neither professionals nor patients) suspected the existence of fraud."

Though many governments have advised people who know they have P.I.P. silicone implants to undergo medical examinations or an MRI, no one has been able to say for certain how many have been affected. Some sources estimate 400,000 worldwide, but no one can account for the thousands more who don't even know if they have P.I.P. implants.

International media has been noticeably and understandably outraged by the P.I.P. revelations, criticizing the government's handling of the scandal. This has led to public calls for a complete overhaul of the regulatory infrastructure in France. Other nations have denounced the entire European medical device approval process as a failure.



News reports have uncovered the reality of what was going on behind the scenes. According to police interrogation transcripts, P.I.P. workers would hide barrels of unauthorized silicone in a separate warehouse when regulators visited for annual audits. Then employees would be asked to erase evidence of the unapproved substances from the computer system before the audits and re-enter the data after.

Grant Stevens, M.D., F.A.C.S.
Plastic Surgeon
Marina Del Rey, CA

"Basically, we had a corrupt company that was going back and forth on their gel," said Grant Stevens, M.D., F.A.C.S., a plastic surgeon based in Marina Del Rey, Calif., who has written extensively about the faults of P.I.P.

implants. "When the government was watching they had the good gel, and when the government wasn't there they used the contaminated gel."

With the P.I.P. implants the shell's silicone elastomer (or Silastic) was heat cured rather than at room temperature or cool cured, which led to early fold failure and shell degradation. This manufacturing process resulted in, "a lesser life of the product," said Dr. Stevens. "The number one cause of fold failure is under-filled implants."

"Not every woman knows what kind of implant she has in her. There are Americans that have had breast implants in other countries and they can't get their records."

Though it's not clear what went into making them, "we are all aware of the fact that there are no long-term studies on P.I.P. implants," said Dr. Etxeberria. "It became quite obvious that the implant shell was less stable due to the amount of low molecular weight species silicone, which migrated into the shell causing swelling and making it unstable. The gel also migrates through the shell into the surrounding tissue and into the lymphatic system, where it causes irritations. This may occur with or without rupture. A controlled prophylactic explantation definitely carries less risk than after rupture, or after the onset of inflammation and / or lymphadenopathy."

In the U.S., P.I.P. implants were banned in 2000. Moreover, the FDA published a strong warning against the use of these products that seemed to fall on deaf ears in France. In Asia, the P.I.P. crisis is inordinately complicated, as these implants were used, but rebranded under multiple product names making identification tough when patient records are either not kept or inconsistent.

Even though the U.S. banned their import, P.I.P. implants have made their way into American women. "Not every woman knows what kind of implant she has in her," said Jane Petro, M.D., a cosmetic surgeon specializing in breast surgery, based in Boston, Mass. "There are Americans that have had breast implants in other countries and they can't get their records. Now they're walking into my office here saying, 'I got my implants in Brazil or Argentina, and I had them from this date to this date, but my doctor won't give me the records, or the doctor is dead.' I have a few patients who know they have P.I.P. implants. Some don't know for sure, but they're afraid they may have them."

Stuart Linder, M.D.
Plastic Surgeon
Beverly Hills, CA

Symptoms of a ruptured implant include lumpiness and swelling of the breast, change in the shape of the breast, loss of upper pole fullness, redness (which may occur on the skin's surface), increased pain and tenderness. "However, in the case of P.I.P. products, the lower grade silicone created a strong inflammatory response, which could cause much more irritation in the tissue than medical grade silicone," advised Stuart Linder, M.D., a plastic surgeon in Beverly Hills, Calif.

Some of the more serious complications include hematoma, infection, recurrence, calcification, recurrent scar tissue contracture, thinning of the tissue,

increased risk of visible ripping, and loss of tissue coverage with the capsulectomy if the encapsulation is severe. "If these implants become extra capsular, meaning they transgressed the capsule and have gone through the lymphatics to the axillary nodes, it can spread to any lymphatic tissue in the body," said Dr. Petro. "I don't know if there's a higher incidence of extra capsular spread of a P.I.P. silicone rupture. They say it's true, but we don't have that data."

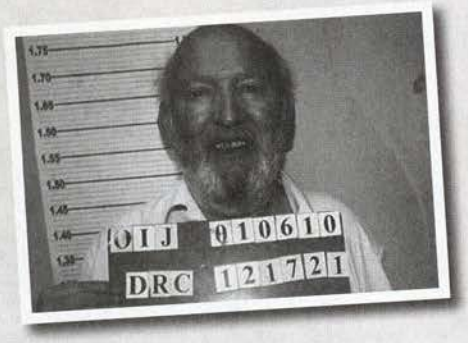
Dr. Stevens, who has removed dozens of bad P.I.P. implants in the U.S., sent some of them to a biochemist for analysis. "One of the implants we thought had ruptured was surrounded by about 30 cc's of a strange, sanguineous material. We cultured it but nothing grew. We were trying to determine what it was that the MRI thought was a rupture, the capsule was very inflamed and contaminated, and had particulate matter floating in it. No one thought it was carcinogenic, but it caused a strong inflammatory reaction."

"European regulators were significantly less stringent than in the U.S., allowing the P.I.P. implants to be put on the market knowing the problems with them."

"European regulators were significantly less stringent than in the U.S., allowing the P.I.P. implants to be put on the market knowing the problems with them," said Dr. Linder. "Now, no organizations in Europe will take responsibility for public safety. With everything out in the open, I believe the regulatory actions in Europe are improving."

In general, many of the affected governments began the crisis by denying responsibility; including in the U.K., which has obfuscated and rejected public paying for replacement implants. "It's an approach that keeps people from coming forward," said Dr. Stevens, who added that nearly 50,000 people in England have P.I.P. implants. So, although public health systems in many countries will finance the removal of the fraudulent prostheses, they will not pay for replacements.

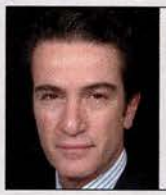
"I personally believe that since the government regulatory controls failed, new implants should be financed 100%, together with all medical check-ups these patients may require in the future," said Dr. Etxeberria.



Ultimately and predictably, the onus will be hoisted on the victim to arrange and pay for replacement implants, said Dr. Petro. "It's a twisted, unfair system that leaves the customer responsible for financing the mistakes of the government that is supposed to protect them, as well as the manufacturer that made a conscious decision to poison the customer. If anything, the P.I.P. scandal will force a rewrite of regulations in the E.U."

An incident of this type should serve to ensure the appropriate measures are taken to prevent this from happening again and the necessary change appears to be in the works. The AFSSAPS, has recommended that clinical trials should be required for products and devices to be approved, and there should be follow-up tests after they're on the market. Also, patients should be given clear and complete information regarding the associated risks, and

regulators should develop reliable feedback systems and improve information sharing and collaboration.



Benjamin Ascher, M.D.
Plastic Surgeon
Senior Course Director
International Master Course on Aging Skin
Paris, France

"We need to ask each manufacturer to publish multicenter research, completely independent and blind studies," said Benjamin Ascher, M.D., a plastic surgeon based in Paris, France and the senior course director of the *International Master Course on Aging Skin* (IMCAS). "It's probably up to the big companies because they have the money to organize these important studies. In addition, all health commissions should be using the same format as the U.S. FDA approval process."

"The authorities who have so clearly failed in this case must listen and be guided by the clear scientific criteria put forward by medical societies, and not reduce the entire crisis to an 'administrative problem.'"

At the E.U. level, health commissioner John Dalli ordered an investigation to reveal how the regulatory system failed to detect P.I.P.'s conspiracies and other illegal practices. The results are expected to be available by May 2012, and will be incorporated into a new regulatory framework that will be created by June 2012.

Dr. Etxeberria stressed, "the authorities who have so clearly failed in this case must listen and be guided by the clear scientific criteria put forward by medical societies, and not reduce the entire crisis to an 'administrative problem.' On the other hand, the commercial companies who develop these types of products must proactively commit to presenting clinical, reliable and epidemiological studies, which scientifically, and with absolute transparency, guarantee the viability of the product – not only with the authorities, but also with physicians. One point that remains clear to me is that the patients affected by the P.I.P. implants are the only ones who are completely blameless."

Dr. Petro aptly quoted Henry Ford: "Don't find fault, find a remedy," she said. "While the consumer is not to blame for the crimes of P.I.P. and the corrupted European approval process, the consumer should take the scandal as a wake-up call to be skeptical, in a healthy way, and do their research," she noted. "They should be proactive and gather all important information prior to surgical procedures that have well-defined dangers and risks."

Dr. Linder feels medical companies must be scrutinized most closely, adding that specific breast implants need to be followed with continued surveillance of the implants rate of rupture and complications. Violations should be enforced as law. "The problem was it was a free for all; there was no regulation. Will a revamped European approval process ever get to U.S. standards? Probably not; especially with the worldwide economy in a recession. When countries like Greece are completely faltering and Italy is going into bankruptcy, it may not be a top concern of these governments to spend billions of dollars on regulation reform. ■