PIP HEALTH FRAUD

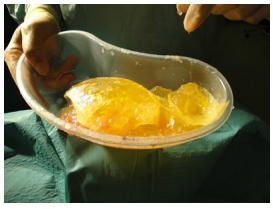
3 January 2014

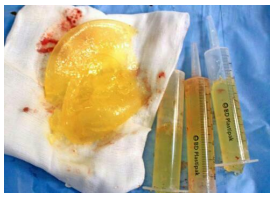
"There is currently no convincing medical, toxicological or other data to justify removal of intact PIP implants as a precautionary approach."

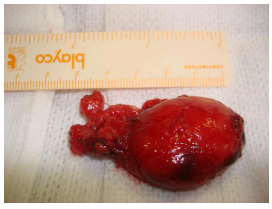
SCENIHR

PIP PUBLIC CONSULTATION
scenihr

By PIP Action Campaign International Victims Association







Fraudulent PIP Breast Implants: affecting 100,000 women in the EU, the majority of reproductive age, involving **CRIMINAL NON COMPLIANT** implantable, high risk **Category III** medical devices of **unknown materials**, **unknown manufacturing processes**, **unknown risks** and documented **harm**.

Task One
Obtain Reliable Data

Task 1: Obtain reliable data on the incidence of implant failure of PIP devices in different countries

SCENIHR concluded that ***three main factors contribute to implant failure***: the physicochemical properties of the implant, the quality of the surgical implantation and the time since implantation. Silicone breast implants may fail, regardless of manufacturer, and the probability of failure increases with time since implantation. Based on clinical studies of PIP implants, the probability of rupture can be estimated to be around 25-30% for PIP implants at 10 years after implantation and with many ruptures occurring or being diagnosed after about 5 years of implantation. ***Other breast implants from the same calendar time have been found to have an estimated probability of rupture of 2% - 15% after approximately 10 years.*** Therefore these findings indicate that the manufacturing process of the PIP implants was of inferior quality.

"If you want to encourage surgeons to report adverse incidents with medical devices how does it help if their surgical skills & technique are questioned?"

- Any Fool

VICTIMS & PATIENTS conclude the three main factors contributing to PIP global health scandal:

1. Complex Criminal Fraud
2. Full scale failure of Regulatory Authorities
3. Lack of Reliable Data

SCENIHR is relying on EQUIVALENCE to reach invalid conclusions about **non-compliant**, High Risk Category III Implantable medical devices.

EVIDENCE:

1. French Police reports show there were no technically qualified staff at the PIP factory.
2. Unknown raw materials
3. Unknown manufacturing processes

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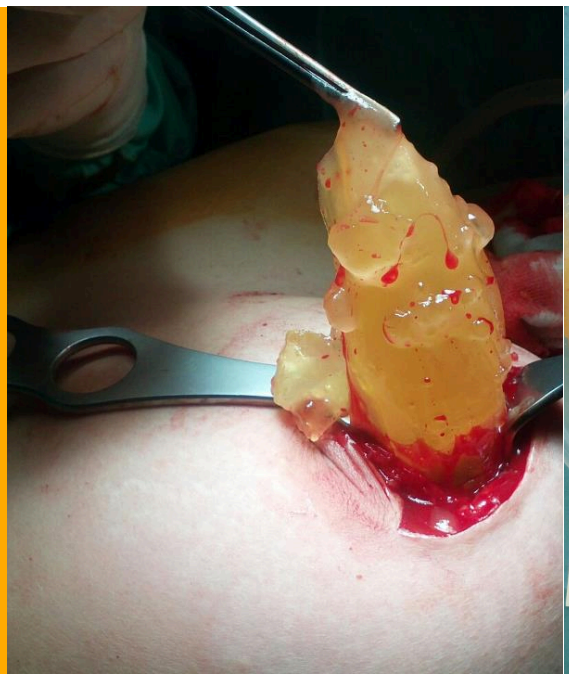
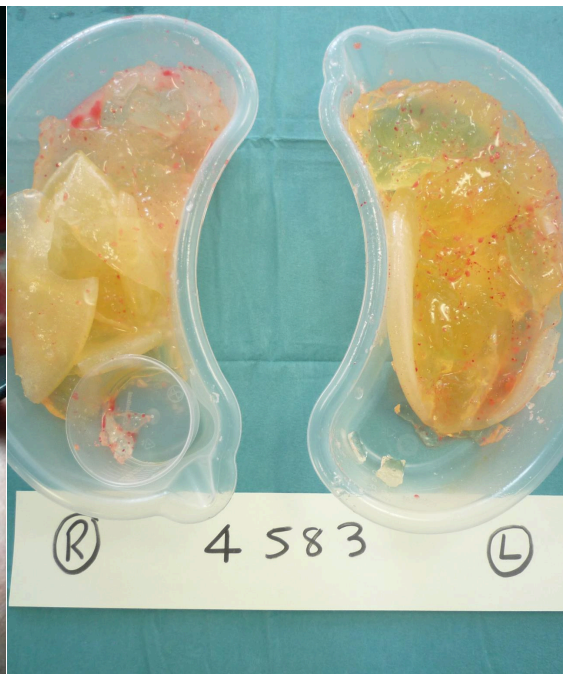
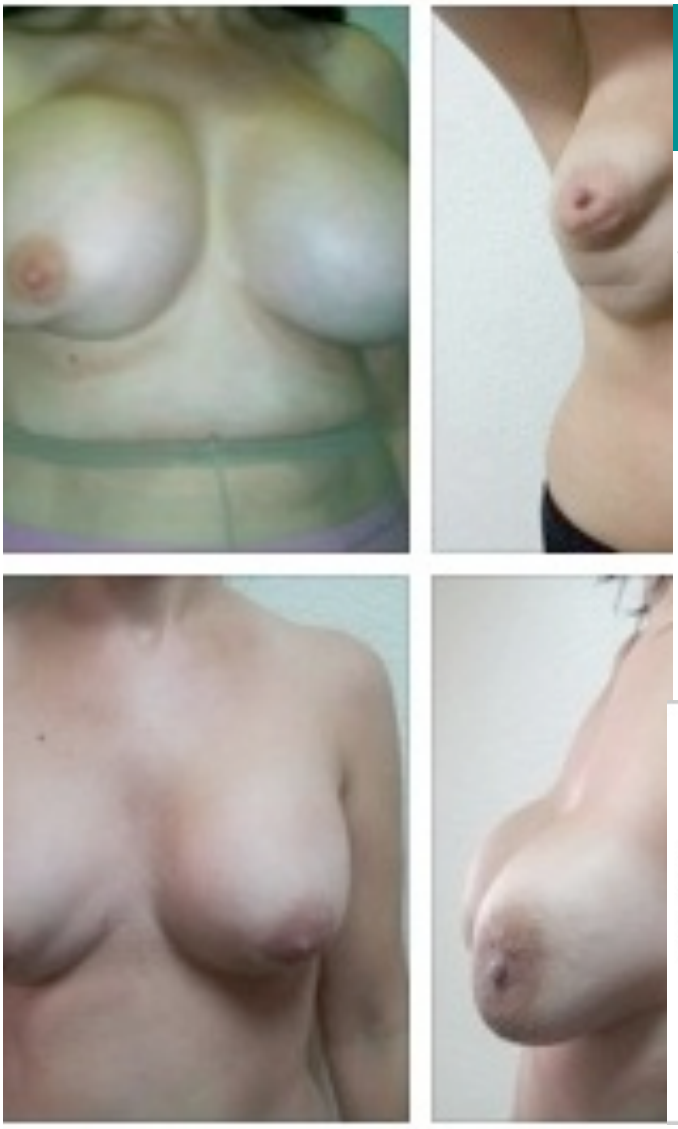
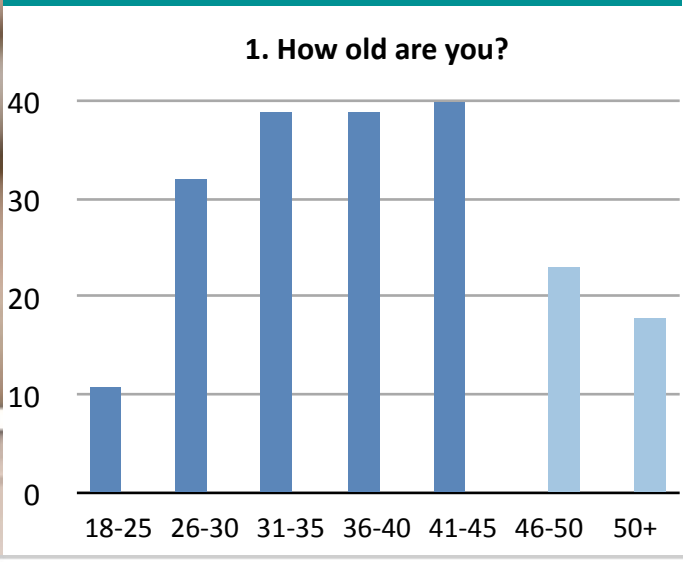
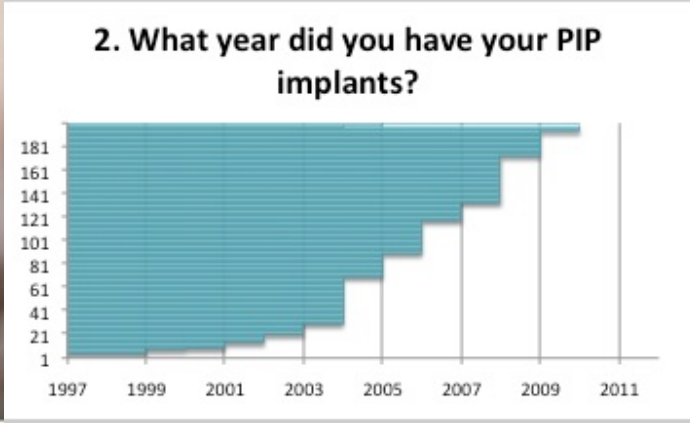






The Majority of women affected are of reproductive age. (source PIP Action Health Survey)





Task Two
Toxicity of PIP Implants

Task 2: Identify the physicochemical factors that might influence PIP implant failure in particular the influence of the implant contents

All silicone based implants contain low molecular weight siloxanes. Batches of PIP devices have been found to contain higher amounts of these siloxanes than those of other manufacturers in particular the cyclic siloxanes D4, D5 andD6. It is however noted that all individuals, regardless of whether or not they have a breast implant, are likely to have significant levels of D4, and D5 in their blood and tissues as these chemicals are widely used in consumer products. Thorough analysis of breast implants has failed to detect any other components of significance. Thus, the questions arise as to whether the higher levels of D4 (octamethylcyclotetrasiloxane), D5 (decamethylpentasiloxane) and D6 in the PIP devices could be the cause of the higher failure rate or could have adverse health consequences for patients when released due to leakage or rupture. Following a thorough toxicological review on the properties of the two most studied siloxanes, D4 and D5, **the conclusion of the SCENIHR is that these compounds are of low acute and chronic toxicity.**

VICTIMS & PATIENTS challenge SCENIHR to produce evidence for their highlighted assertions.

EVIDENCE: **Repro-Toxic D4, CAS 556-67-2 Octamethylcyclotetrasiloxane** is currently classified as follows:

1. Human health Repro. Cat 3 R62:
   Possible risk of impaired fertility.
2. Human health Hazard class and category: Repr. 2.
   Hazard statement: H361f:
   Suspected of damaging fertility.
3. D4 is categorized as an endocrine disruptor (cat 1)

Task Three
Adverse Effects on patients

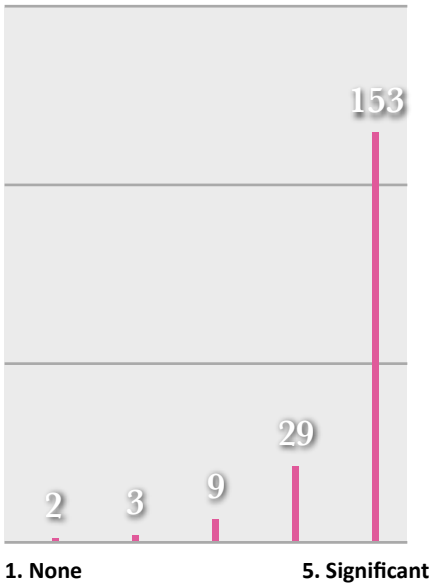
Task 3: Examine whether the adverse effects of a PIP implant failure differ qualitatively and/or qualitatively from the impacts of the failure of breast implants from other manufacturers

The SCENIHR concluded that there is no good evidence that the adverse consequences of a PIP silicone breast implant failure are greater than those resulting from the failure of an implant from another manufacturer. Adverse effects due to free silicone and/or gel-bleed (in the form of siliconomas, lymphadenopathy, lumps etc.) have been reported less uniformly than implant ruptures. The SCENIHR also agreed that there is no indication of a specific association between other effects such as capsular contraction, marked psychological impact on patients and cancer with PIP silicone breast implants. In view of the high rupture rates, many women can expect to experience a ruptured breast implant within their life span, regardless of manufacturer. There is inevitably a higher intra- and postoperative risk associated with the removal of ruptured implants than with intact implants.

VICTIMS & PATIENTS challenges SCENIHR to produce evidence for their highlighted assertions.

EVIDENCE: MHRA (UK) PIP Implant adverse reporting, ANSM (France) published reports, peer-reviewed clinical studies, victims testimonies, PIP Action Health Survey *202.

14. How anxious are you about PIP implants?



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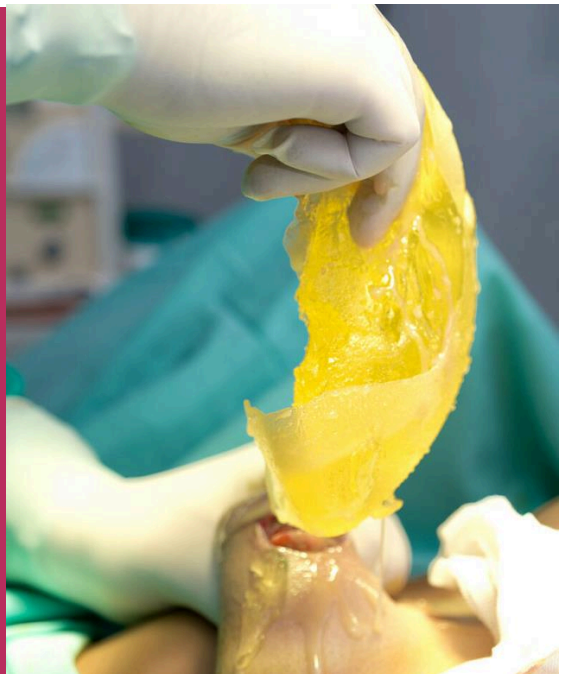

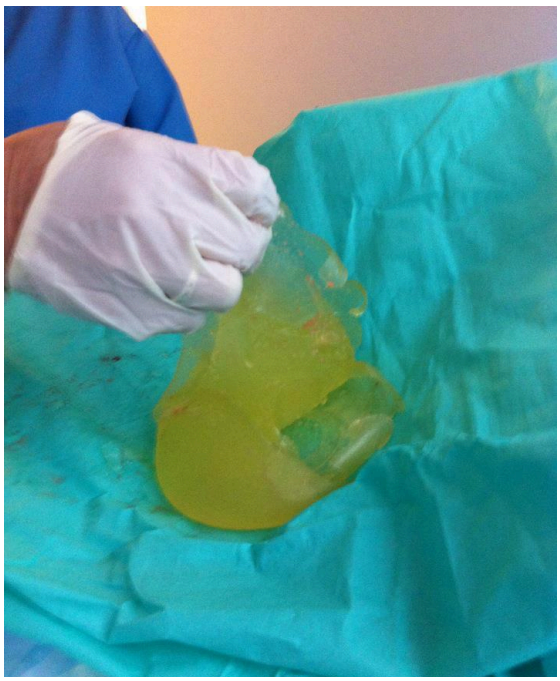

Health Survey *202
Symptoms

Blurred vision	**68**	36%
Difficulties tolerating bright or fluorescent lights	**43**	23%
Dry and/or itchy eyes	**72**	38%
Headaches/ Migraines	**108**	57%
Poor concentration	**119**	63%
Memory loss	**96**	51%
Cognitive loss (difficulty finding the right words)	**82**	43%
Depression	**106**	56%
Suicidal thoughts	**35**	18%
Anxiety	**131**	69%
Mood swings	**114**	60%
Anaemia	**31**	16%
Bleeding gums	**54**	28%
Tinnitus (ringing in your ears)	**46**	24%
Pulsatile Tinnitus (hearing your own pulse)	**32**	17%
Shortness of breath	**73**	38%
Stiffness or pain in joints	**115**	61%
Muscle seizures, cramps or spasms	**75**	39%
Muscle weakness	**64**	34%
Previously undiagnosed asthma	**13**	7%

Dry mouth	**65**	34%
Dry skin	**67**	35%
Skin rashes	**67**	35%
Hypersensitivity of skin (can feel like sunburn)	**36**	19%
Tingling or numbness in hands	**96**	51%
Swollen joints	**36**	19%
Excessive sweating	**73**	38%
Night sweats	**98**	52%
Extreme tiredness or fatigue	**141**	74%
Increased bleeding and painful menstrual periods	**40**	21%
Unexplained absence of menstrual periods	**15**	8%
Bladder problems	**46**	24%
Pain in kidneys	**32**	17%
Bowel Problems	**62**	33%
Pain in your breasts	**128**	67%
Itching, tingling or loss of sensation in your breasts	**99**	52%
Swelling or lumps in your breasts	**59**	31%
Swelling or lumps in your armpits	**60**	32%
Hair thinning or hair loss	**73**	38%
Loss or reduction in sex drive	**94**	49%
Unexplained lumps and bumps	**30**	16%
Other	**33**	17%

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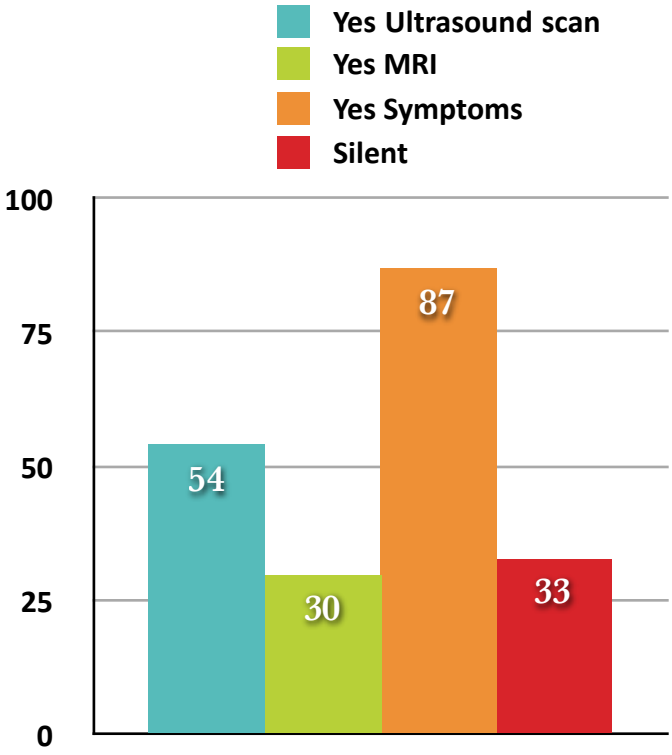
7. Any indication of gel bleed or rupture before surgery?



Task Four
Knowledge Gaps

Task 4: Knowledge gaps

Registration of all breast implantations on a national or international level could help to collect more evidence for future studies. Continuous surveillance of the different products on the market would enable development and improvements of safe and compliant products as well as be a significant tool in the future scientific research and product monitoring. In order to identify why an implant has caused a significant adverse reaction, it is necessary to analyse the explant involved through a careful selection of explanted devices. The registration of all explantations could be of enormous relevance both from scientific and public health perspective. There is still a need for low cost reliable tests suitable for routine use to identify implant status (leakage, rupture) in patients.

VICTIMS & PATIENTS challenges SCENIHR to produce evidence for their highlighted assertions.

EVIDENCE:

Criminally NON COMPLIANT PIP Implants have failed to meet the essential requirements referred to in **Article** 3; **Article** 8; **Article** 10; **Article** 14b, **Article** 15 (6) and **ANNEX I ESSENTIAL REQUIREMENTS I. GENERAL REQUIREMENTS** of the COUNCIL DIRECTIVE **93/42/EEC**