PIP **Action** Campaign

Responding to European Commission's SCHEER Committee Call for Information on PIP BREAST IMPLANTS with

REAL WORLD EVIDENCE

October 26, 2016

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Scheer Committee

“There are no acceptable circumstances in which women should be living with banned PIP implants in their bodies in 2016.”

PIPActionCampaign.org

Background

- Breast implants are Class III, high risk, surgically implantable medical devices
- PIP implants fail to fulfill relevant essential requirements of medical devices regulations
- PIP used experimental, untested materials & unsafe production methods
- PIP employed unqualified staff
- PIP used unknown raw materials
- PIP used unknown manufacturing techniques

Medical Devices Directive 93/42/EEC

Material Equivalence : doesn't apply

PIP implants do not fulfil the relevant ***essential requirements*** of the medical devices directive 93/42/EEC.

There is no demonstrated ***material equivalence*** between non compliant PIP implants and other brands according to the requirements for clinical evaluations Annex IX, 93/42/EEC.

For a device to be substantially equivalent, it must share the same intended use and have the same technical characteristics to another legally marketed device; or

- **if they have different characteristics, there shall be no new questions of safety or effectiveness; and**
- **demonstration that the device is at least as safe and effective as the legally marketed device.**
- Data shall adequately demonstrate compliance with relevant essential requirements

PIP implants do not comply with legal requirements of the Medical Devices Regulations.

New and long delayed Medical Devices regulation has yet to be implemented.

Evidence: 93/42/EEC Material or substantial equivalence cannot apply where non-conformity has been established. PIP are not substantially equivalent to other implants.

European Parliament Resolution 2003

Attention is drawn to Texts adopted Thursday, 13 February 2003 - Strasbourg on Breast implants. The European Parliament recognises "thousands of women have petitioned the European Parliament to take a stand on the dangers inherent in the use of silicone breast implants" resulting in the European Parliament resolution on the communication from the Commission on community and national measures in relation to breast implants (COM(2001) 666 – C5-0327/2002 – 2002/2171(COS))[1]

The European Parliament:

1. Calls for the adoption and implementation of essential specific measures designed to improve information provided to patients, tracking and surveillance, quality controls and quality guarantees, key research on silicone breast implants and their components, and on their clinical evaluation after they are placed on the market, in particular in relation to:
   - the lifespan of implants;
   - methods of improving the protection of the recipient's health;
   - a full assessment of the health implications and risks;

2. Recommends that implants in women under 18 years of age should be authorised only on medical grounds;

3. Seeks a guaranteed control over the marketing of breast implants, so as to avoid incorrect and misleading information;

4. Underlines the need to facilitate consensus on, and to promote and support, effective surveillance systems to report adverse and long-term effects;

5. Welcomes the fact that the Commission, with a view to addressing the many problems posed, has declared itself in favour of a Community-wide policy, and has set out in its communication to Parliament, the Community and national provisions already applicable in this area;

6. Welcomes the fact that the Commission has adopted virtually all of Parliament's suggestions, particularly with regard to advertising, the information required to be given to patients, the greatest possible guarantees of the quality of implants and the keeping of national registers;

7. Supports the proposed reclassification of implants as a Class III product under Directive 93/42/EEC, as this will have the welcome effect of reinforcing assessment procedures;

[1] http://www.europarl.europa.eu/sides/getDoc.do?type=TA&reference=P5-TA-2003-0063&language=LT

8. **Considers silicone breast implants a health priority** and requests that funds be made available in the EU research programmes, focusing specifically on the shortcomings of some of the research to date;

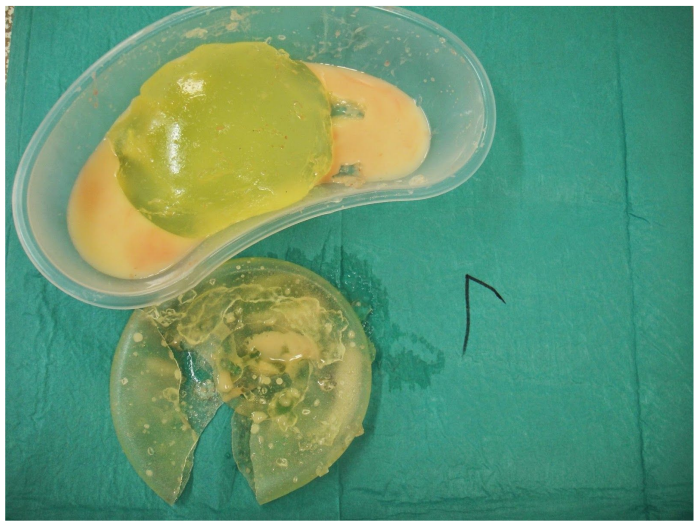
9. Considers that the labelling of silicone-gel implants should include a warning of the potential health risks;

Evidence: The 2003 Adopted Texts (8) states the European Parliament Considers silicone breast implants a health priority. The intention of the European Parliament's adopted texts are clear, yet **not a single recommendation in the Adopted Texts has been enacted by the European Commission**, putting the health and well-being of all women with breast implants at unnecessary risk.

European Parliament Resolution 2012

The European Parliament adopted texts in Strasbourg on the 14th June 2012 on "defective" silicone gel breast implants made by French company PIP (2012/2621(RSP))

The June 2012 resolution[2] identifies several critical points regarding "dangerous Class III medical devices" by repeating elements of the 2003 Resolution and adding the clear recognisable need for collective redress for victims of health fraud.



The European Commission has not acted on or implemented any of the recommendations in the 2003 Resolution, nor many of the same resolutions of the European Parliament in 2012.

Women exposed to PIP implants have been failed spectacularly by the European Commission's refusal to act on the Resolutions of the European Parliament despite calls from tens of thousands of women in 2002.

The European Commission has failed to respect the consumer, patient and victims rights of the 100,000 EU women, believed to have been exposed to banned PIP implants. By producing a pseudo-scientific risk report, which not only denies women their rights, the report also helps agencies with clear duties and obligations to women with Class III medical devices to avoid responsibility and accountability.

[2] http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P7-TA-2012-0262+0+DOC+XML+V0//EN#def_1_9

hashtag #PIPCrimes

In March 2010, following repeated concerns raised by senior medical professionals in France, Spain and UK, the French regulator, Afssaps, conducted an unannounced inspection of the PIP facility just as the FDA had done in 2000. (The FDA had refused to licence PIP implants in the USA, after having found an unacceptable number of major non-compliance issues). Immediately following Afssaps inspection, the police made arrests and closed the factory. Eleven tons of unauthorised silicone were discovered at the PIP manufacturing site.

Scenihr Opinion

In February 2012, the Scenihr published a preliminary opinion on PIP in response to the European Parliament request for an **urgent opinion**, which was prompted by the death of 53yr-old Frenchwoman Edwige Ligoneche. **Edwige died with ruptured PIP implants** in November 2011.

This news was made public in international news headlines 22 months after the closure of the PIP Factory and just days before the Christmas holidays in 2011. Hundreds of thousands of women, were left in the dark by the health regulators and authorities over the christmas holidays and were then made to wait over 2 years for the Scenihr final opinion to be published in May 2014.

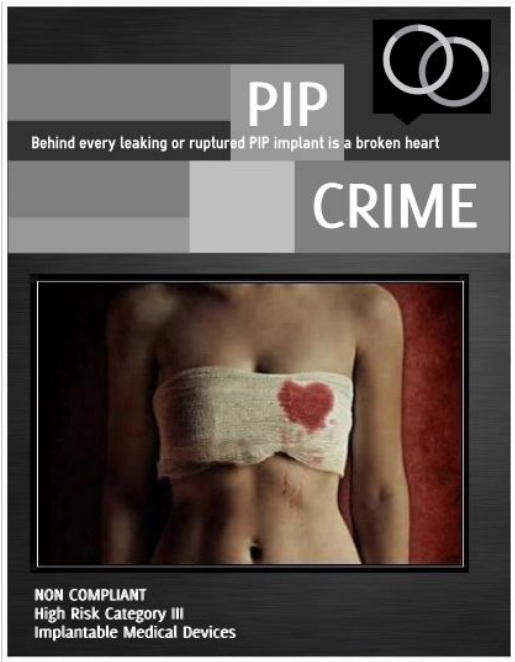
Edwige Ligoneche had ruptured PIP implants and died from BIA-ALCL

The 2014 Scenihr opinion concluded ***"There is currently no convincing medical, toxicological or other data to justify routine removal of intact PIP implants".***

More than 500,000 women globally are thought to have been exposed to CE marked PIP implants. **The number of women who have died with PIP implants is unknown.**

PIP Action Campaign

PIP Action Campaign is a small, international social-networking group of women directly affected by PIP breast implants based in the UK, but widely connected with international groups of women in France, Spain, Italy, Ireland, the Netherlands, Sweden, Venezuela, Colombia, Australia, Canada and the USA.

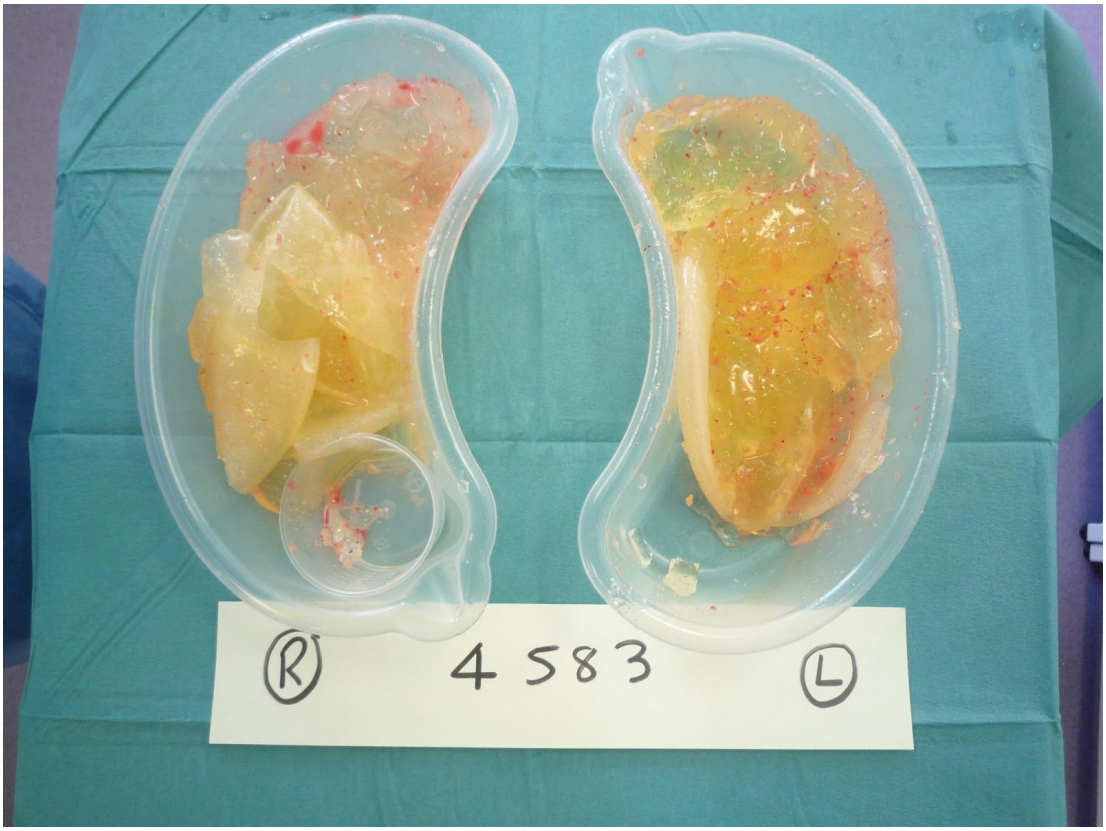


PIP Action Campaign has already submitted evidence in the form of peer-reviewed studies, national research findings and data from health and regulatory authorities to the European Commission's SCHEER committee's Call for Information.

However, the real world evidence[3], from our own experiences and support for victims of the PIP health fraud is included here.

In this submission, PIP Action Campaign not only references the work or words of independent experts, scientists, surgeons, surgeons associations, pathologists, ER doctors, researchers, General Practitioners, Regulatory specialists, Regulatory and Health Authorities and National Competent Authorities. As part of a **real world evidence submission** to the European Commission, we also include the voices of women who have been exposed to PIP breast implants and have completed our online **health and information surveys.**

[3] Action plan to strengthen the use of evidence, information and research for policy-making in the WHO European Region



‘Women are entitled to expect a high level of inquiry into their concerns, as well as: information, support, advice, future health monitoring for themselves and any PIP exposed children. Women should be reimbursed for the costs they have incurred as a consequence of non-compliant PIP and compensated for the pain and injuries they have suffered, and in some cases continue to suffer.’

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Real World Evidence

Demonstrates

1. Failure of banned Class III PIP implants
2. Failure to conduct adequate toxicological testing
3. Failure to protect women from known repro-toxicity of PIP implants
4. Evidence of symptoms of PIP leaks and ruptures
5. Evidence of health concerns, including deaths, reported in women with PIP
6. Failure to monitor women with PIP implants or recommend and fund on-going research, bio-monitoring or teratogenic testing of women/children exposed to PIP
7. Failure to implement operational registries, conduct on-going surveillance/vigilance by regulatory authorities
8. Lack of accountability
9. Evidence of Regulatory Negligence
10. Failure of the European Commission to recognise the rights of women exposed to PIP implants
11. Failure to act urgently and with caution to protect women from dangerous, toxic PIP implants
12. Failure to offer all those exposed to PIP urgent care, redress and compensation.

Concerns for women with PIP Implants

include:

1. Biofilm, texturised shell & capsular contracture
2. BIA-ALCL, breast, lung and brain cancer in women exposed to PIP implants
3. Breast Feeding with leaking and/or ruptured PIP implants
4. Symptoms & consequences of inflammation linked to PIP implants
5. Toxicity: Repro-toxicity, Immunogenicity, Carcinogenicity, Teratogenicity
6. Pregnancy, miscarriage & still birth
7. Breast Implants and health consequences for children
8. Endocrine Disruptor Chemicals/ Xenoestrogens/ Persistent Organic Pollutants/ substances with pbt characteristics
9. Concerns raised by peer reviewed PIP Breast Implant Studies
10. Anxiety , Depression and Suicide in women with PIP implants
11. PIP Yellow - decomposition dangers and half-lives of toxins in PIP implants
12. Harmful chemicals in the blood of women & children exposed to PIP implants
13. Dangers of Nanoparticles in leaking and ruptured PIP implants
14. Urgent Action Required to protect the health & safety of women & children exposed to PIP implants
15. Future Research, Care & Monitoring Required
16. Accountability & Justice for the women & children exposed to PIP implants

Types of Evidence

Meta-Analysis

A type of research that looks at the published papers on a subject i.e. After reading papers authors arrive at conclusions. (This type of evidence is easily manipulated, it is possible to prove virtually anything with meta-analysis). Meta-Analysis can and, sometimes, is used to undermine genuine evidence.

Research

Some research is based on actual studies which is then published with peer reviewed results .i.e. dr conducts a study which looks at death records for women with implants and publishes the findings.

In our SCHEER submission we focused on the papers where actual studies have been conducted - this is amongst the most valuable and convincing evidence.

Quality of Research

A recently published peer reviewed study[4] concluded "Investigators with a financial conflict of interest are significantly more likely to publish plastic surgery studies with a positive conclusion compared with investigators with no conflicts of interest." A more recent study by the same author has been published[5] August 2016 concludes "Self-reported Conflicts Of Interest are uncommon in plastic surgery research" and goes on "***our results provide evidence that certain types of financial Conflicts of Interest are more likely than others to be associated with the presentation of positive findings***."

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[4] Financial Conflicts of Interest: An Association between Funding and Findings in Plastic Surgery.

[5] The Impact of Financial Conflicts of Interest in Plastic Surgery: Are They All Created Equal?

These studies linking positive outcomes with conflicts of interests[6] [7]demonstrate how the positive presentation of findings can often undermine genuine safety concerns.[8]

Ann Plast Surg. 2007 Nov;59(5):569-80. PMID: 17992155

The safety of silicone gel-filled breast implants: a review of the epidemiologic evidence.

McLaughlin JK, Lipworth L, Murphy DK, Walker PS.

Abstract

Few implantable medical devices have been studied for their safety more extensively than silicone gel-filled breast implants. We summarize the epidemiologic evidence on the safety of breast implants, most of which is drawn from large cohort studies with long-term follow-up. The topics addressed in this report include cancer, breast cancer detection, connective tissue disease, suicide, offspring effects, neurologic disease, implant rupture, and local perioperative complications and additional surgery. **We conclude that the weight of the epidemiologic evidence does not support a causal association between breast implants and breast or any other type of cancer, definite or atypical connective tissue disease, adverse offspring effects, or neurologic disease.** Women with breast implants do not present with more advanced stages of breast cancer or suffer impaired survival after breast cancer diagnosis. The only study to examine an actual incidence rate of breast implant rupture reported rupture-free survival of 98% at 5 years and 83%-85% at 10 years for newer "third-generation" implants. Future studies are needed to determine whether the consistently observed excess of suicide among women with implants reflects underlying psychiatric illness prior to breast augmentation surgery or other factors.

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[6] Evidence for association between silicone gel breast implants, long-term health outcomes inconclusive

[7] Long-Term Health Outcomes in Women With Silicone Gel Breast Implants: A Systematic Review

[8] Silicone Gel Breast Implants: What We Know About Safety After All These Years

JK McLaughlin, one of the authors of the epidemiological review was on the original Scenihr committee, he also played a pivotal role in the reintroduction of silicone implants to the USA. In a detailed review of the evidence titled ***Breast implants: a research and regulatory summary*** *By Diana Zuckerman, PhD, Elizabeth Santoro, RN, MPH, Emily Moore, BA and Judith Faucette, JD Updated 2012*[9], McLaughlin (referred to as a 'co-author') is mentioned in conclusions:

Conclusions

In 1990, breast implants had been sold for more than 25 years **but there were no published epidemiological studies or clinical trials.** There are now more than 100 studies of women with implants, most of them funded by Dow Corning, implant companies, or medical associations with a financial interest in the outcome. These studies are persuasive in showing that breast augmentation does not dramatically increase the risk of diseases in the short-term. A co-author of most of those studies, who served as a consultant to Inamed, argues that studies "with a mean follow-up of a decade and almost three decades of follow-up for the longest-term implant recipients" is "long enough."[62], [63] However, there are numerous shortcomings in the studies he cites and co-authored, such as including many women whose implants were only a few months or a few years old at the time of the study, and therefore did not have the statistical power to draw meaningful conclusions about long-term safety. The small number of women providing relevant long-term data is especially a problem when studying diseases such as cancer, scleroderma, and lupus which take years to develop and diagnose. Careful scrutiny of the research indicates an increase in symptoms in many studies, but it is primarily in the studies where all the augmentation patients had implants for at least six years that increases in disease risks are statistically significant.

[9] http://center4research.org/medical-care-for-adults/breast-implants-and-other-cosmetic-procedures/breast-implants-a-research-and-regulatory-summary/#_edn63

It is also notable that the independently funded studies tend to focus on women with implants for longer periods of time, and often show increased risks that are not apparent in the industry-funded studies."

Citations: 62 and 63 read: [62] **McLaughlin JK**. Long-term follow-up of women with cosmetic breast implants: How long is long enough? *Plastic and Reconstructive Surgery*. 2004; 114: 801-03.
[63] **McLaughlin JK**, Lipworth L, Murphy DK, Walker PS. The safety of silicone gel-filled breast implants: a review of the epidemiologic evidence. *Annals of Plastic Surgery.* 2007 Nov; 59(5): 569-80.

Conflicts of Interests in the Cosmetic Surgery industry

In 2011 Public Citizen[10] wrote to the FDA:

> "A concerned plastic surgeon has just sent us portions of a transcript from a members-only webinar held on February 3, in which the presidents of the two leading plastic surgery organizations, **the American Society of Plastic Surgeons (ASPS) and the American Society for Aesthetic Plastic Surgery (ASAPS), essentially urged members to inaccurately downplay the significance of recent evidence about the risks of breast implant-related cancer when speaking to female patients.**"
>
> Dr. Phil Haeck, president of ASPS, said, in referring to ALCL in association with breast implants:
>
> "[Y]es it's classically a malignant tumor, but it has such a benign course that when we were discussing ways to talk to the media we decided that **we would call this a condition when we talked to the media, not a tumor, not a disease and certainly not a malignancy. Um, because, and I would recommend that you use the same**

[10] Letter on Inaccurate Communications Regarding Risks of Breast Implant-Related Cancer

> **terms with your patients rather than disturb them by saying this is a cancer, this is a malignancy. The best word is this is a condition**.
>
> "If you develop this condition here's how we are going to treat it, the way we are going to diagnose this condition is this, and that's very reassuring when you are using that word and not using the word cancer or malignancy. And **I think you are certainly justified**, with what we know now, **in downplaying the malignant potential of these.**""

Here is another example from Public Citizen illustrating manufacturers selective use of evidence in a "*Letter to the FDA from a Mentor Employee June 22, 2006* [11]"

> The ..."June 22, 2006 letter sent to the FDA by a former senior scientist from Mentor—one of the two companies seeking FDA approval of silicone gel breast implants—accusing the company of withholding from the FDA important new safety information concerning dangerous physical and chemical properties of their implants."[12]

The former Mentor scientist identified 5 key concerns for breast implants in 2006:

1) Diffusion Testing Validation

The gel bleed or diffusion testing for low molecular weight siloxanes representing Round Gel Mammary Implants is invalid. ...The two major issues with the test method were the signal-to-background ratios (~0.1) and recovery for the duration of the study.

2) Explant Semivolatile Extractable Testing

...Results showed that explanted device gel exhibited exceedingly large quantities of low molecular weight siloxanes compared to devices that had not been implanted.

3) Explant Mechanical Testing

...Results indicated that a significant reduction of some mechanical properties had occurred compared to devices that had not been implanted. These results were misinterpreted in a manner to conceal the relative change compared to control devices such that only absolute changes were reported during implantation.

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[11] Letter to the FDA from a Mentor Employee June 22, 2006
[12] Letter Calling for Criminal Investigation of Breast Implant Manufacturer October 12, 2006

This presentation of the data yielded the apparent result of minimal degradation. No further testing was conducted to determine the origin of the discrepancies between control and explant test results.

4) Device Projection Fatigue Testing

...Results showed that the device projection and lifetime were inversely proportional. In other words, as the device projection increased the estimated lifetime decreased. Both smooth and textured high profile devices yielded fatigue data statistically unique from moderate profile devices with a corresponding shorter lifetime. This has not been communicated with the FDA.

5) Platinum Valence

Chemical test data exists that indicates platinum is present in the shell with valence Pt (II). This is far more toxic than platinum valence Pt (0) which is the chemical species currently used for potential toxicological exposure.

Concerns about the safety of breast implants are not new, neither are the concerns for the commitment to patient safety by the industry. **Safety concerns prompted a 14 year ban on silicone breast implants in the USA and a 6 year ban in France**.

For women, the excessive and inevitable leaking and ruptures of PIP implants, the silicone saturated, swollen and painful neck and axilla lymph nodes, the wide range of common symptoms like breast pain and unusual presentations like granulomas in the lungs and BIA-ALCL are all associated with PIP implants and reported in medical journals. The evidence shows that PIP's (a) manufacturing experiments using (b) untested raw materials for the shells and the gels, with (c) unknown decomposition dangers have *inevitably* contributed to PIP implant failures.

The scenihr was unable to identify any convincing evidence of toxicity or links to cancer and did not associate any dangers with intact PIP implants.

Evidence: Health concerns expressed by women are often undermined by surgeons and surgeons associations:

Above: Tweet **29 July 2016**

Even in relatively large scale study from 1996: ***Risk of Connective Tissue Disorders among Breast Implant Patients***[13] making any concrete association between 'any type of autoimmune disease' and breast implants is extremely difficult.

Trained abstractors reviewed medical charts and entered data directly into laptop computers using standardized software. Information on vital status and location was sought through various tracing sources. In total, 10,778 (79.9 percent) of the implant patients and 3,214 (81.7 percent) of the comparison patients were traced, with 364 being identified as deceased (245 implant patients and 119 comparison subjects).

Death certificates were obtained for 91.4 percent and 95.8 percent of the deceased implant and comparison patients, respectively.

[13] Risk of Connective Tissue Disorders among Breast Implant Patients

Beginning in June 1995, subjects were sent mailed questionnaires requesting information on demographic factors, subsequent plastic surgeries, current health status, and lifestyle factors that could affect health. **Respondents were asked whether they had ever received a physician's diagnosis of rheumatoid arthritis, arthritis of another type, scleroderma, systemic lupus erythematosus, Sjögren's syndrome, Raynaud's phenomenon, fibrositis/fibromyalgia, vasculitis, chronic fatigue syndrome, or multiple sclerosis. They were also asked whether they had received any other CTD diagnosis and, if so, which one. For each condition, patients were asked to provide their age at first diagnosis and the physician's name and address. Nonrespondents were given the opportunity to complete questionnaires by telephone. Questionnaires were obtained from 7,447 (70.7 percent) of the living implant patients and 2,203 (71.2 percent) of the comparison patients.**

Risk of Connective Tissue Disorders among Breast Implant Patients

TABLE 1.
Relative risk of self-reported connective tissue disorders and other conditions among patients with breast implants in comparison with other plastic surgery patients, southeastern United States, 1960–1996

Condition*	No. of implant patients (n = 7,234) (87,199 person-years)	No. of comparison patients (n = 2,138) (23,724 person-years)	Relative risk†	95% confidence interval
Connective tissue disorders	351	62	2.0	1.5, 2.8
Rheumatoid arthritis	258	49	1.9	1.4, 2.7
Scleroderma	23	3	3.0	0.8, 10.9
Systemic lupus erythematosus	72	10	2.1	1.1, 4.2
Sjögren's syndrome	43	2	11.7	2.5, 54.9
Other conditions				
Other arthritis	724	201	1.3	1.1, 1.6
Raynaud's phenomenon	97	10	2.6	1.3, 5.1
Fibromyalgia	311	57	1.3	0.9, 1.7
Vasculitis	21	4	1.4	0.5, 4.6
Chronic fatigue syndrome	246	27	2.4	1.6, 3.6
Multiple sclerosis	26	5	0.7	0.2, 1.9
Other disorders	202	24	2.5	1.6, 3.9

* Conditions are not mutually exclusive.

† Adjusted for age at follow-up (5-year intervals through age 85 years), calendar period of follow-up (1960–1964, ..., 1990–1994, 1995–1996), and race (White or Black).

Patient reported diagnoses are predictably undermined:

"These results indicate that self-reports of connective tissue disorders are influenced by reporting and surveillance biases. **Given the diagnostic complexities of these diseases, excess risks, if they exist, may be beyond detection even in a study of this size.**"

The "Memory Hole" of Science & Evidence

How much data is now available on PIP?

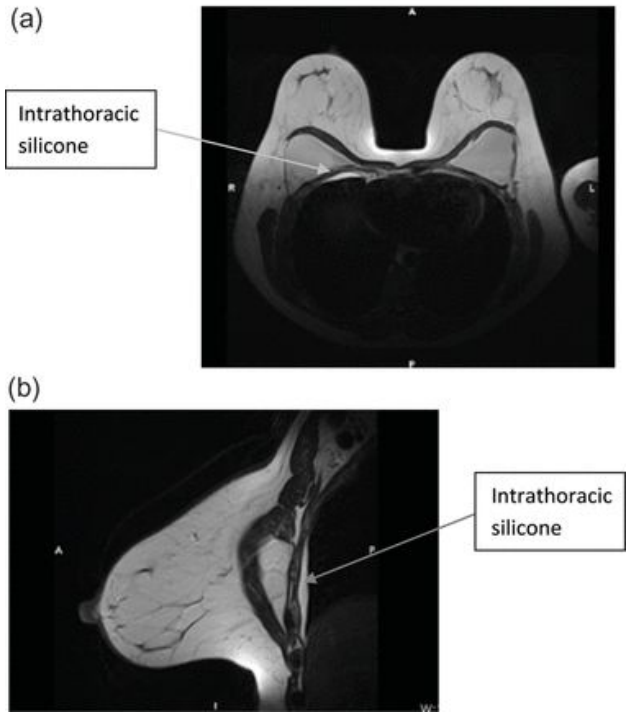
Which competent authorities are continuing to monitor adverse events in PIP?

How many regulatory authorities have discharged their duties?

How many member states have functioning breast implant registries?

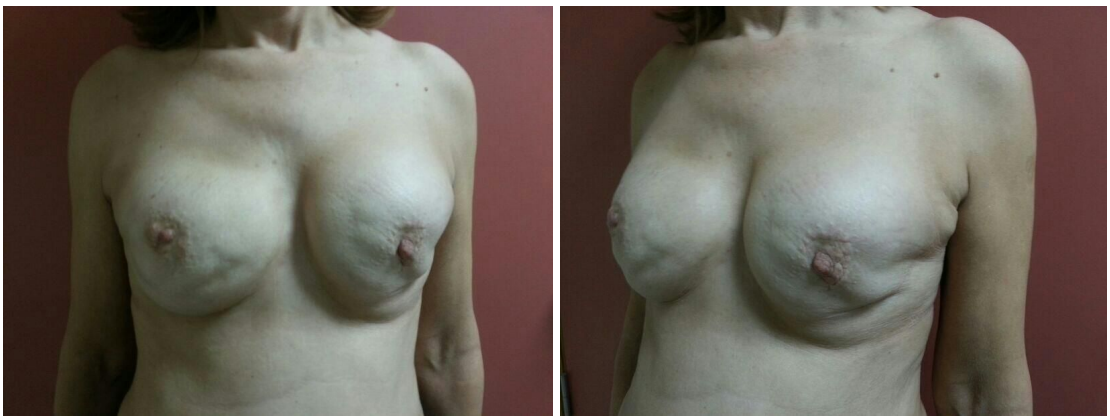
How is adverse event reporting being collated and shared among member states?

Notwithstanding the lack of available data at the time of the Scenihr preliminary and final opinions, the pronouncement of PIP as a "fraud" obscured some very important facts and details known to national competent authorities and regulatory authorities, such as, knowledge of previous problems at PIP with carcinogenic hydrogel implants.



Real World Evidence

PIP Action Campaign compiled a Health Survey and asked women to report their personal experiences of symptoms and observations.



In the beginning we were not sure which questions to ask, women affected by PIP implants told us or showed us. in the case of symptoms, we refined a detailed list, when >50% of women had responded positively to any of the symptoms listed we added the symptom to the “commonly associated symptoms” in the Health Survey. The Health Survey can be found on the PIP Action Campaign website.

We quickly realised many women with PIP were living with very worrying symptoms. It was clear that most women had not been receiving appropriate information on their implants, surgery or follow-up. Some had already realised their symptoms were linked to their PIP breast implants, such as breast pain and swelling.

Women with PIP were showing other alarming symptoms such as painful engorged lymph nodes under the arms, in the chest, neck and groin. Women were also reporting extreme fatigue.

Our results looked quite different from those published by the UK national competent authority (MHRA).

MHRA Adverse Events (April 2014-June 2015)

0 reports of breast pain with PIP implants?

4. Please provide a full update on (i) the number of Adverse Event reports received for PIP and (ii) the type of adverse events reported

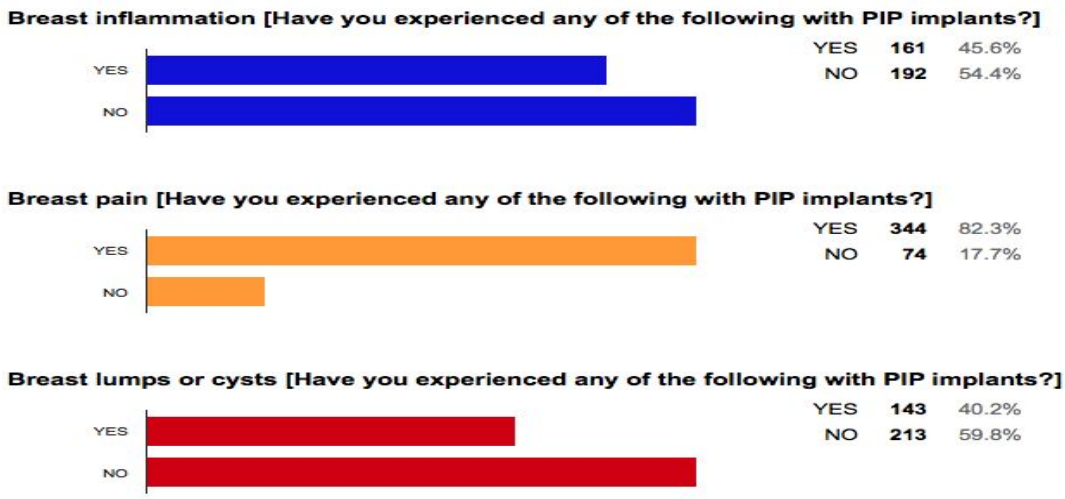
Since the last update provided to you in March 2014 the MHRA has received 181 reports associated with PIP breast implants. The table below provides details of the reports received between April 2014 and June 2015.

Type of Failures	Rupture	Leak. Gel bleed, Gel migration	Swelling, Allergic reaction, Seroma, Lymphoedema	Capsular Contracture	Anaplastc Large Cell Lymphoma	Wrinkling, Rippling, Shape change	Breast Pain	Other e.g. Anxiety, Infection	Unknown
PIP April 2014 - June 2015	128	120	4	29	0	3	0	5	28

Please note that this table details the number of occasions that each term has been listed, and may not represent the total number of reports. In one report more than one term may have been listed.

It is important to note that inclusion of a report on the MHRA adverse incident database does not necessarily mean that the events described were caused by the implant. Therefore, reports submitted to MHRA may be adverse reactions to the implant or they may be purely coincidental events that would have occurred anyway in the absence of the device (e.g. events due to underlying medical conditions). These events are therefore not a summary of known or proven adverse reactions to the implant, and must not be interpreted and used as such.

Women with PIP implants told us

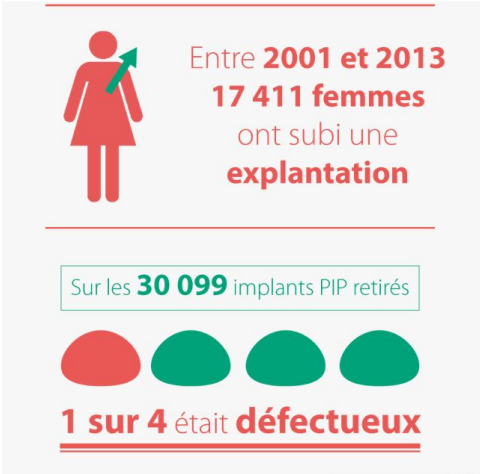


The SCENIHR Search for Evidence

"This Committee deals with questions related to emerging or newly identified health and environmental risks and on broad, complex or multidisciplinary issues requiring a comprehensive assessment of risks to consumer safety or public health and related issues not covered by other Community risk assessment bodies. Examples of potential **areas of activity include potential risks associated with interaction of risk factors, synergic effects, cumulative effects, antimicrobial resistance, new technologies such as nanotechnologies, medical devices including those incorporating substances of animal and/or human origin, tissue engineering, blood products, fertility reduction, cancer of endocrine organs, physical hazards** such as noise and electromagnetic fields (from mobile phones, transmitters and electronically controlled home environments), and methodologies for assessing new risks." It may also be invited to address risks related to public health determinants and non-transmissible diseases.

1.1 (Scenihr) Evidence of actual PIP rupture rate

There has been considerable difficulty in establishing an accurate rupture rate of PIP. The most reliable data to date comes from ANSM in France where the largest numbers of women exposed to PIP have had their PIP preventatively removed. Following a decision by the French Health Authorities in 2011, French women were helped into treatment to remove or to remove and replace their PIP implants if they chose to do so.



The majority of women have two implants, therefore the published findings of the ANSM reveal shocking **evidence**: that **one in every two women has at least one 'defective' PIP implant**

PIP Failure Rate

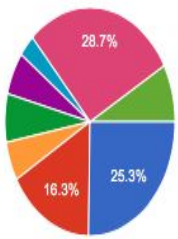
The SCENIHR acknowledges the “higher failure rate of PIP implants” and goes some way to acknowledge the considerable variability in the manufacturing process at PIP. But shies away from what it calls a “*precise estimate*” of the excessive failure rate of PIP implants as a result of lack of evidence.

Failure Rate 10 years after implantation (Scenihr)	
2-15%	Silicone Breast Implants
25-30%	PIP Breast Implants

This is what women with PIP told us when we asked about ruptured or leaking implants:

PIP Action Campaign’s Health Survey Rupture and Leak Rate

About your PIP implants



One Rupture	**96**	25.3%
Both Ruptured	**62**	16.3%
One Gel Bleed	**21**	5.5%
Both Gel Bleed	**26**	6.8%
Removed intact, unsure about gel bleed	**23**	6.1%
Removed intact, no gel bleed	**12**	3.2%
Waiting for removal	**109**	28.7%
Waiting for removal, confirmed rupture	**31**	8.2%

Health Survey **Rupture Rate** (Completed by Women with PIP implants)	
25.3%	One PIP Breast Implant Rupture
16.3%	Both PIP Breast Implants Ruptured
41.6%	**Rupture Rate**
12.3%	One or both leaking PIP implants
53.9%	**Women with ruptured or leaking PIP implants**

We are especially concerned for the health and wellbeing of the 36.9% of women waiting for PIP removal surgery and for the 8.2% of women living with ruptured PIP implants.

1.2 Chemical composition of PIP implants

Published by the TGA : Australia

PIP breast implants

AFSSAPS has reported that there are at least three different formulations of filler gel used in PIP breast implants. The different formulas are detailed in the table below. According to AFSSAPS, the authorised gel was manufactured with NUSIL 3MED6300 gel, while the unauthorised gels were manufactured using a combination of other brands of silicone raw materials, with two different formulations identified as PIP1 and PIP2. Apparently, PIP1 was manufactured prior to 2008 and PIP2 from the beginning of 2008.

It is not clear when NUSIL was used to manufacture the gel used in PIP breast implants, but it appears that this gel was used in micro-textured PIP breast implants after the middle of 2006, although this type of implant does not appear to have been supplied in Australia.

This table provides details on the different formulations of filler gel

	NUSIL		PIP 1		PIP 2	
Manufacturer of raw materials	Nusil		Bluestar - Rhodorsil product Momentive - Silopi product		Bluestar - Rhodorsil product Momentive - Silopi product	
Formula	NUSIL 3 MED 6300	100%	Silicone oil trimethylated Silopi (W1000) **or** Rhodorsil (H47V1000)	94.3%	Silicone oil trimethylated Silopi (W1000) **or** Rhodorsil (H47V1000)	90.2%
			Vinyl terminated silicone oil Silopi (U165)	4.4%	Vinyl terminated silicone oil Silopi U165	8.3%
			Rhodorsil RTV 141 Part A	1.1%	Rhodorsil RTV 141 Part A	1.1%
			Rhodorsil RTV 141 Part B	0.2%	Rhodorsil RTV 141 Part B	0.4%
			Ratio of Rhodorsil RTV A:B = 5.5 compared to manufacturer's recommendation of 10		Ratio of Rhodorsil RTV A:B = 2.75 compared to manufacturer's recommendation of 10	

Cyclic Volatile Methyl Siloxanes in PIP implants : The 'D' Series

The SCENIHR opinion addresses the issue of Cyclic siloxane toxicity in the ABSTRACT:

"Cyclic siloxanes D4, D5 and D6 are non-toxic and not irritant in standard tests."

Concentrations of cyclic siloxanes / Cyclic volatile methyl siloxanes have been found in PIP implants, including : octamethylcyclotetrasiloxane (D4), decamethylcyclopentasiloxane (D5), and dodecamethylcyclohexasiloxane (D6) amongst others in the D series.

Cyclic volatile methyl siloxanes D4, D5 and D6 found in PIP implants (SCENIHR)

Table 4:Levels of D4, D5 and D6 in devises from various manufacturers

	D4 (ppm)	D5 (ppm)	D6 (ppm)
TGA – PIP*	136	434	474
TGA – Nusil	ND**	ND	ND
MPA – PIP2*	134	457	604
MPA – PIP Nusil*	ND	18	30
MPA – Brands A and B	ND	20	22
MPA – Brand C	30	72	132

** TGA tested several samples – the median result is quoted here. MPA tested one new implant and one explant of each PIP2 and PIP-Nusil; the highest result is quoted here.*
*** ND = not detected*

Even though the rules of procedure provide access to toxicological expertise from ECHA (European Chemical Agency) and experts in EU chemical regulation REACH (EU Chemical Regulator), the SCENIHR committee failed to refer to either. Instead choosing to rely on the (inappropriate and already superseded) SCCS Opinion published in 2010. The SCCS is another European Commission committee, it was providing an opinion on the use of D4 and D5 in certain consumer products, its findings **do not** apply to surgically implanted class III medical devices.

Evidence: D4 and D5 are both REACH Substances of Very High Concern (**SVHC**) D4 is a Xenoestrogen, which have known **endocrine disrupting properties (EDCs) while evidence points to D5 carcinogenicity.**

TGA Australia

The Australian health Regulator TGA, was the first to approve French manufactured PIP breast implants for use. The Australian regulatory authorities had a representative on the SCENIHR committee. The TGA conducted tests on a small number of new, unused PIP implants and compared them with the product made with approved gel fillings and shell.

Evidence (TGA) Freedom of Information Requests to the TGA show PIP deviated from manufacturing processes outlined in the Technical Dossier & required by the Medical Devices Directive. TGA noted several major and minor non-conformities following regulatory audits, in particular TGA noted **PIP's custom curing times** - at odds with suppliers recommendations.

Evidence: Published evidence from TGA shows PIP failure to respect multi-part, silicone cross-linking.

Afssaps / ANSM France

The French Health Regulator, then Afssaps, identified D4 in PIP implants in 2010 and knew of EU chemical regulations surrounding its use. Concerns over D4 repro-toxicity was communicated by French authorities to other international regulators including the TGA. Late in 2011 following the death of Edwidge Ligoneche, who had ruptured PIP implants and fatal BIA-ALCL, **the then French health minister announced the preventative removal of all PIP implants in France.**

MDA Sweden

The Swedish health Regulator MDA, undertook studies on PIP implants that had been removed after having been in the body for a long period, maintained at body temperature, in some cases over many years. Following the publication of the studies the **Swedish authorities also recommended the preventative removal of all non-conforming PIP breast implants in Swedish women**.

Evidence: national authorities including Afssaps/ANSM, MDA and TGA were aware of potential for PIP implant toxicity from D4. The majority of national authorities chose to

disregard the Opinion of the Scenihr Committee and recommended the precautionary removal of all PIP implants.

REACH Regulation and implantable medical devices

Materials used in the manufacture of Class III implantable medical devices are assessed for **biocompatibility**, while Adverse Event Reporting and manufacturers studies are assessed under the Clinical Evidence requirements of the MDD 93/42/EEC.

TUV Rheinland, the Notified Body that certified PIP, has not released the Clinical Evidence, nor biocompatibility evidence it relied on to certify PIP.

The TGA had already identified concerns over sterilisation and deviations in silicone curing undertaken at PIP in addition to other major and minor non-conformities.

ECHA, the European Chemicals Agency

ECHA conducted a consultation into the potential dangers of D4 and D5. Following a lengthy assessment, a 'restriction' or ban of D4 and D5 in the environment and in shampoo was proposed.

German researchers have shown D4, D5 and D6 are found in the blood of women with ruptured and leaking implants. Indeed, they have proposed a 'less expensive' and 'more effective' test method for identifying PIP/Rofil implant ruptures than MRI.[14]

Evidence: Low weight molecular siloxanes D4, D5 and D6 have blood transport to every organ in the body.

[14] Cyclic volatile methylsiloxanes in human blood as markers for ruptured silicone gel-filled breast implants

Toxicity: Repro-toxicity, Immunotoxicity, Teratogenicity Carcinogenicity, Geno-toxicity

Reprotoxicity

The UK Competent Authority (CA) for REACH, submitted proposals to Restrict (ban) D4 and D5, the Substances of Very High Concern (SVHC) which are found in PIP Implants. Stakeholders were invited to take part in a Public Consultation by the European Chemicals Agency (ECHA) in 2013.

Evidence: DG Grow and Reach Director confirmed D4 repro-toxicity in correspondence addressed to PIP Action Campaign in 2012.

PIP Action Campaign raised concerns about repro-toxic D4 and known reprotoxic dangers of decomposing PIP implants with the MHRA (UK), the SCENIHR committee, DG Grow, REACH UK & EU, ECHA director Nina Cromnier, Paola Testori DG Sanco, Commissioner Mimica and the President of the European Commission.

The international pictogram for chemicals that are sensitising, mutagenic, carcinogenic or toxic to reproduction.

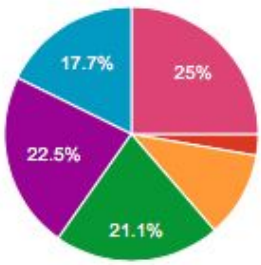
Reprotoxicity is a particular concern for women with PIP implants because:

> "Reproductive toxicity is a hazard associated with some chemical substances, that they will interfere in some way with normal reproduction; such substances are called reprotoxic. It includes adverse effects on sexual function and fertility in adult males and females, as well as developmental toxicity in the offspring.[15]"

[15] https://en.wikipedia.org/wiki/Reproductive_toxicity

PIP Action Campaign's Health Survey shows the majority of women exposed to PIP are of reproductive age.

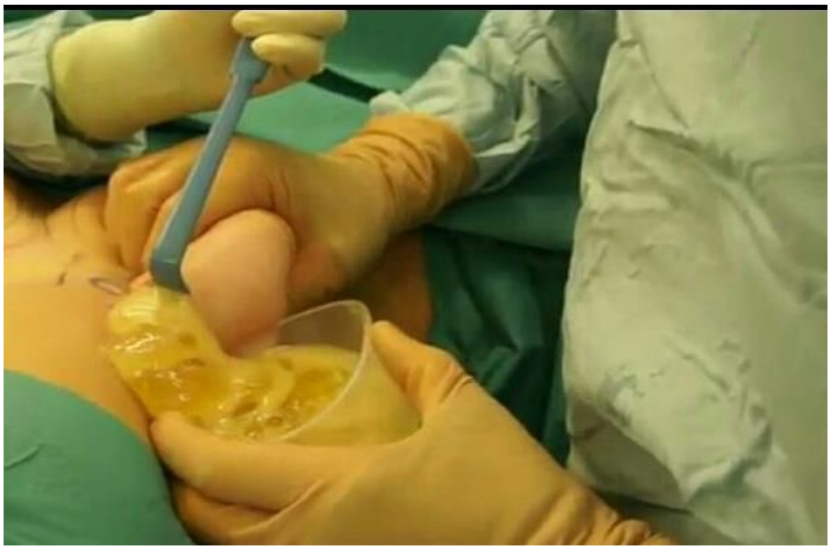
How old are you?



under 21	**0**	0%
21-25 years	**12**	2.7%
26-30 years	**48**	10.9%
31-35 years	**93**	21.1%
36-40 years	**99**	22.5%
41-45 years	**78**	17.7%
46+ years	**110**	25%

Degradation and Decomposition of PIP Implants

Decomposing PIP implants contain high concentrations of PBT (Persistent, bioaccumulative and toxic) chemicals which are regulated under REACH but diligently overlooked by the Scenihr committee.



Evidence: of failure to protect women from the risks posed by decomposing, leaking and ruptured PIP implants and long half-lives of the chemical toxins in them.

THE Sun
Sunday, November 25, 2012

Burst PIP implant 'gave my breast-fed girl cancer'

Horrified mum's claim

Tragic ... Lucy Petagine with five-year-old Luna
DAVID NEW

EXCLUSIVE By CHRIS POLLARD and RHODRI PHILLIPS *Published: 03rd February 2012*

A DISTRAUGHT mother whose PIP implant exploded while she was breast-feeding fears it could have caused her daughter's cancer.

Lucy Petagine's five-year-old daughter Luna was diagnosed with an incurable brain tumour at just 18 months.

Medics say they can't rule out a link between her breast implants — made with industrial-grade silicone designed to be used as mattress filler — and Luna's illness.

Luna, Lucy Petagine's daughter, shown here at age 5 years has sadly died since this article appeared in the press in 2012.

Immune Disorders **Immunogenicity**

A study dating back to 1993 demonstrates links to silicone breast implants to collagen antibodies:

"Using ... stringent criteria, there was a statistically significant incidence of antibodies to collagen in women with silicone breast implants. In fact, 35% of women with silicone breast implants had such antibodies; **this is higher than we have observed in any other autoimmune disease and is similar to that of chronic erosive rheumatoid arthritis**.

We believe that silicone breast implants, in genetically susceptible hosts, may pose a significant risk for immunopathology.[16]

"The patterns of reactivity against collagens by sera from women with silicone implants suggest that silicone can act as an adjuvant to enhance the immunogenicity of type I collagen."

"...excessive deposition of collagen occurs in scleroderma." [17]

In a case study Scleroderma and breast implants, published in 2014

Learning Point for Clinicians

A number of studies have associated silicone breast implants with the development of connective tissue diseases. However, the role of free silicone gel in relation to idiopathic or typical connective tissue disease is not clear. This is the first case report of scleroderma-induced pulmonary hypertension following ruptured silicone implants.

In another 2014 case report: Scleroderma renal crisis following silicone breast implant rupture: a case report and review of the literature Authors "**report** the case of a 52-year-old woman who presented with rapid development of skin thickening followed by scleroderma renal crisis (SRC) following rupture of silicone breast implants. This is the first published case of SRC in this setting.

[16] Anti-collagen autoantibodies are found in women with silicone breast implants.

[17] http://www.bu.edu/aldolase/biochemistry/html_docs/CollagenTypes&Disorders.pdf

Silicone implant incompatibility syndrome (SIIS): a frequent cause of ASIA (Shoenfeld's syndrome). **A report from Maastricht University published in 2013**

"Remarkably, silicon in silicone-filled breast implants is considered to be safe, not increasing the risk of developing autoimmune diseases. We analyzed the impact of silicone-filled breast implants on the immune system in 32 consecutive patients attending a specialized autoimmunity clinic. All 32 patients had silicone implant incompatibility syndrome and complaints fulfilling the diagnostic criteria of ASIA (autoimmune/inflammatory syndrome induced by adjuvants). Furthermore, in 17 of the 32 patients, a systemic autoimmune disease was diagnosed, and 15 of the 32 patients had an impaired humoral immune system. **Patients developed symptoms and signs after long-term follow-up, suggesting that these symptoms and signs started after implant aging and/or rupture. We postulate that silicon in silicone-filled breast implants may increase the risk of developing (autoimmune diseases and immune deficiencies."**

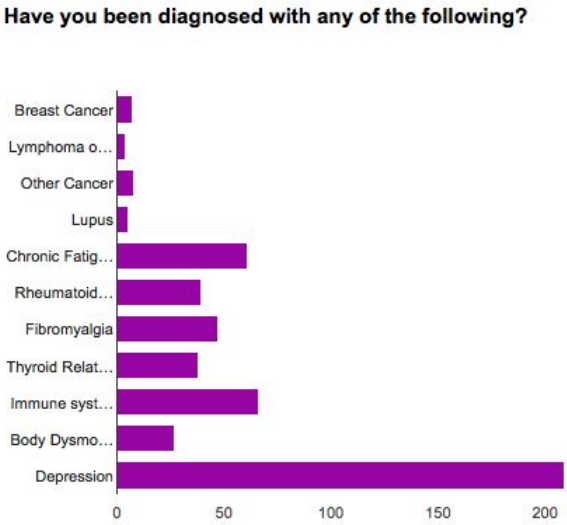
In a report co-authored by Schoenfeld, Autoimmune/inflammatory syndrome induced by adjuvant (ASIA) evolution after silicone implants. Who is at risk?[18] published in Clinical Rheumatology in 2015, the following observations are noted.

"Silicone implants have been in use since the mid-twentieth century, especially in the field of reconstructive breast surgery, and have long been considered as biologically inert and harmless. **However, growing body of evidence from the past two decades links silicone with subsequent autoimmunity-related complications, collectively known as autoimmune/inflammatory syndrome induced by adjuvant--ASIA."**

[18] Autoimmune/inflammatory syndrome induced by adjuvant (ASIA) evolution after silicone implants. Who is at risk?

We asked women if they had received any diagnoses while they had PIP implants.

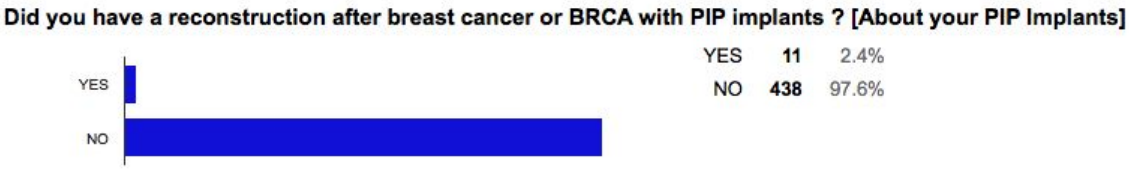
Over 50% percent of the women with PIP implants reported diagnosed immune illness.



Breast Cancer	7	2.7%
Lymphoma or ALCL	4	1.6%
Other Cancer	8	3.1%
Lupus	5	1.9%
Chronic Fatigue Syndrome	61	23.6%
Rheumatoid or Inflammatory Arthritis	39	15.1%
Fibromyalgia	47	18.2%
Thyroid Related illness	38	14.7%
Immune system illness	66	25.6%
Body Dysmorphia	27	10.5%
Depression	209	81%

Some women received PIP implants following breast cancer

A very small number, official estimates of 5%, but showing 2.4% in our health survey, of women already diagnosed with breast cancer or with BRCA, received PIP breast implants following body-modifying, life saving surgery.



YES	11	2.4%
NO	438	97.6%

In the UK, only 10 out of >350 NHS Trusts used PIP implants, including St George's Hospital in Tooting, a university hospital, providing breast cancer treatment for patients from all of South London.

The Scenihr Opinion recognised a higher risk from PIP implants to these patients

Scenihr 4.1.4. Possible adverse health consequences

Capsular contracture has been reported the most frequent reason for additional surgery in women with breast implants with fractions ranging from 2% to 23%. Clinically, capsular contracture is classified according to the Baker classification scheme with no or slight contracture as I and II, more substantial and serious contracture, respectively, as III and IV, with additional dislocation in IV. **Apart from aesthetic consequences, Baker III and IV contracture may cause persisting pain**.

Possible health effects of silicone breast implants that have been investigated in epidemiological studies include:

a) **Lymphoma: A causal link between breast implants and lymphoma has not been established.**

ALCL: A very rare type of lymphoma, the Anaplastic Large Cell Lymphoma (ALCL) has been found in the scar capsular tissue around breast implants, globally, 130 cases have been reported so far.

b) **Breast cancer and other cancers: Several high-quality studies have been conducted and they have provided clear evidence against an increased risk of breast cancer or any other type of cancer. An increased risk of lung cancer found in some studies appears to reflect a higher frequency of smoking among women with implants.**

c) Connective Tissue Diseases (CTDs): Although there were initial reports of associations with various forms of connective tissue disease, subsequent, **large- scale epidemiologic investigations provided no evidence for these claims.**

d) Effects on offspring: There were a few early case reports of children born or breastfed by women with silicone breast implants who developed swallowing difficulties, irritability, non-specific skin rashes, fatigue, and other symptoms. However, subsequent **epidemiologic studies of these issues found no evidence of an association.**

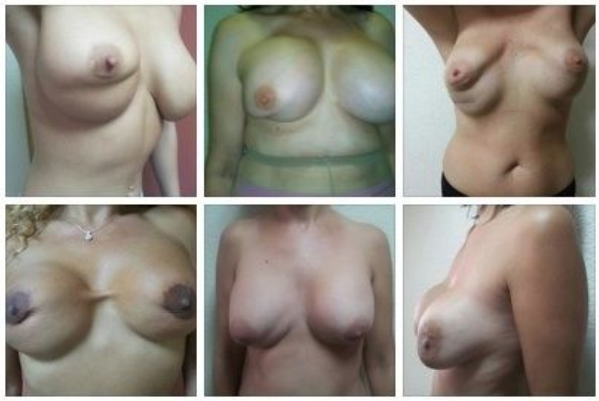
e) **Immunological effects: adverse reactions have been reported in a small number of women with breast implants.**

f) Suicide and psychological issues: It is a consistent observation that the population of **women with breast implants for cosmetic reasons exhibits a two- to three-fold higher rate of suicide than similar-aged women in the general.**

g) Infection rates rank low among the potential complications of breast reconstruction or breast augmentation. They could appear early or be detected as subclinical in the pathogenesis of fibrous contracture.

The causes of adverse effects were also addressed. Consideration was given both to the released polymeric material and to the release of siloxanes. Data on the identification and the consequently the relevant toxicology of the siloxanes was both limited and preliminary. The distribution of polymeric material and its effects were discussed.

REAL WORLD **Evidence** demonstrates Bio-film infection, caused by bacterial contamination of textured breast implants causes capsular contracture. What the industry refers to as "unhappy results" is amongst the most common reason given for re-operation in women with breast implants. photo: capsular contracture in women with PIP implants



Evidence: **The causal link between breast implants and anaplastic large cell lymphoma is established.**

In the Database of Abstracts of Reviews of Effects (DARE): Quality-assessed Reviews 2013 "**published research suggested that cosmetic breast augmentation has a negative impact on the survival of women if they were subsequently diagnosed with breast cancer**" as a result authors conclude: "further investigations are warranted regarding diagnosis and prognosis of breast cancer among women with breast implants.[19] In another review authors observed: "**at diagnosis, breast cancers tended to be at more advanced stages among women with cosmetic breast implants**" and once again recommended "further investigations of the effect of breast implants on breast cancer prognosis are warranted"[20]

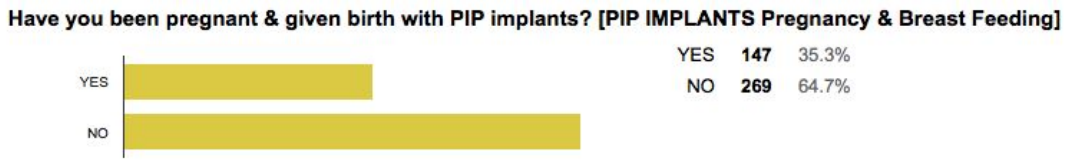
[19] Breast cancer detection and survival among women with cosmetic breast implants: systematic review and meta-analysis of observational studies.

[20] Do breast implants adversely affect prognosis among those subsequently diagnosed with breast cancer? Findings from an extended follow-up of a Canadian cohort.

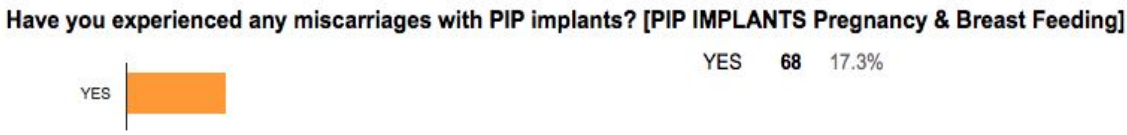
While Real World and other research studies demonstrate clear links between CTDs and Breast implants and to health concerns in children. In both instances meta-analysis has been used to dismiss these concerns.

Pregnancy, miscarriage & still birth : Implants and Children

Pregnant women, developing foetuses and breastfeeding infants are amongst the most vulnerable groups exposed to toxic PIP implants. We asked women with PIP implants about their pregnancies and their children.



Some of the questions asked were very painful for some women:



We later asked women who have been pregnant with PIP implants to respond to 20 questions about their pregnancy and their babies. The Original 20 Questions Survey is available here: [PIP Action Mums 20 Questions about PIP]

We recently published a summary of the responses we received to the PIP Mums 20 Questions Survey. http://pipactioncampaign.org/pip-action-mums-survey-2016/

In the Scenihr Final Opinion, published in 2014, two paragraphs are devoted to the issue of pregnant and breastfeeding mothers.

> 9.2. Risk to the children of women with PIP implants
>
> 9.2.1. Impacts on the foetus
>
> Based on both one and two generation studies there is no evidence that the cyclic siloxanes cause developmental toxicity, or have an adverse effect on rat fertility. Taken in conjunction with the bioavailability and other considerations discussed above it can be concluded that no risk, due to the release of D4 and D5, is anticipated.
>
> 9.2.2. Nursing infants
>
> Low levels of siloxanes in breast milk have been found in a single subject with a ruptured PIP implant. However, siloxanes have been found at **detectable levels in over 20% of breast milk samples taken from women without breast implants**. Moreover, commercially available semi-skimmed cow's milk was found to contain considerably higher levels of total silicone than the sample of breast milk taken from women with a ruptured PIP implant. Thus, no identifiable increased risk for the nursing infant is anticipated from breast milk from a mother with ruptured breast implants.

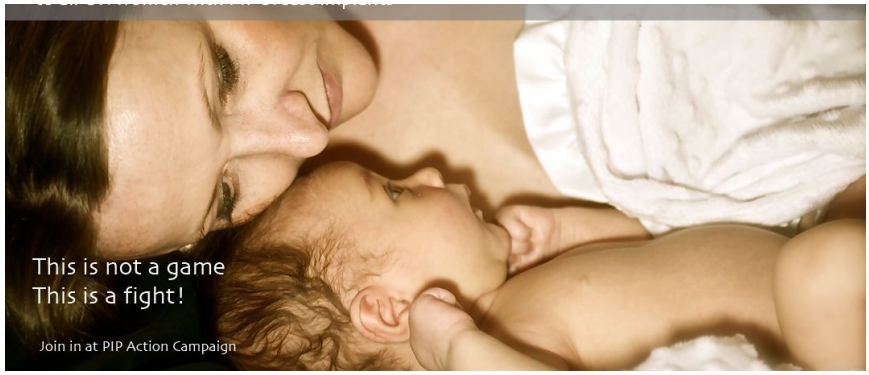
Evidence: None of the evidential references relied upon are cited.

The specific reference to *"detectable levels in over 20% of breast milk samples taken from women without breast implants"* is a **deliberate fabrication**. We specifically requested details of this study from the MHRA, where this claim first appeared. **The study in question does not include any specific data for breast implants. There is no way of knowing from the findings if the women had breast implants or not.**

Furthermore: the MHRA experiment involving one sample of breast milk from one pregnant mum with PIP compared to semi-skimmed supermarket milk is among the clearest and most shocking examples of the unacceptable standards overseen by the Commission in its 'scientific' opinion on PIP.

Pregnant with PIP Implants

The majority of women affected are of reproductive age, some have been pregnant with PIP. The *Journal of Long-Term Effects of Medical Implants Breast Implant Surveillance Reports to the U.S. Food and Drug Administration: Maternal-Child Health Problems (2006)*[21] More than 300 adverse events associated with breast implants are recorded and analysed.



Evidence: No reporting on Maternal-child health problems in women with PIP implants has taken place by national authorities.

We asked mothers with PIP about breastfeeding and noted a significant number of mums experiencing difficulties:

Have you breast-fed with PIP implants? [PIP IMPLANTS Pregnancy & Breast Feeding]

Have you experienced breast feeding difficulties with PIP implants? [PIP IMPLANTS Pregnancy & Breast Feeding]

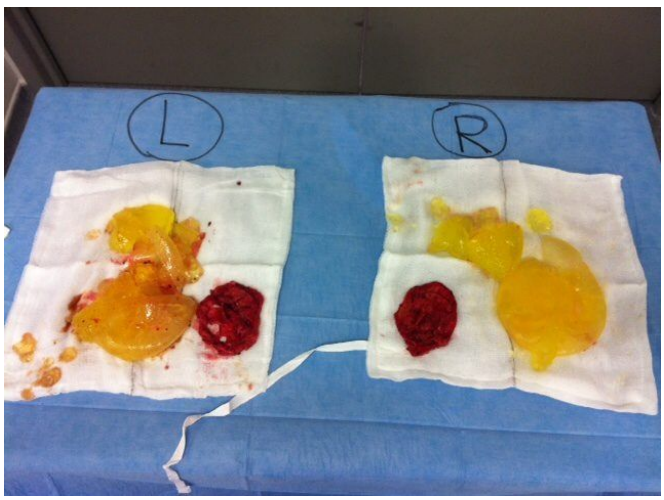
[21] Breast implant surveillance reports to the U.S. Food and Drug Administration: maternal-child health problems.

We went on to develop another survey, this time we compiled 20 questions specifically relating to women's experience of pregnancy with PIP implants. By the 2nd October 2016 we had received 60 replies from **58 pregnant PIP mums**.

Some of the responses are of a personal nature or they need to be read in association with the respondent: for example, "How many years have you had PIP?" all other responses are recorded in The PIP Mums' Survey Response Summary[22] which makes **very concerning** reading. PIP Mums are providing enormously valuable information.

Real World Evidence in our PIP Mums Survey demonstrates, not only, the fears, pressures, pain and anxiety women with PIP implants are facing, but the real health concerns they have for themselves and for their PIP exposed children.

Unusual reporting in children and neonates exposed to silicone have been recorded as early as 1994. In Autoantibodies and clinical rheumatic complaints in two children of women with silicone gel breast implants, authors, Teuber and Gershwin also report that in Europe at the time "women with silicone breast implants are advised not to breastfeed."



In-utero exposures of neonates and breastfed infants are of major concern for women with PIP implants not only because women are unable to undergo implant removal surgery while pregnant.

Breast Cancer UK In-utero exposures
http://www.breastcanceruk.org.uk/science-and-research/in-utero-exposures/?platform=hootsuite

[22] http://pipactioncampaign.org/PIPMumsResults.pdf

Endocrine Disruptor Chemicals

Endocrine Disruptor Chemicals (EDCs) are of concern to women, particularly women with PIP implants.

TWO members of the SCENIHR committee, Prof Dr Konrad Rydzynski & Dr Emanuela Testai were both signatories to a highly controversial Open Letter to Anne Glover, (Chief Scientific Advisor to former EC President Barroso) urging her to rethink plans to regulate endocrine disrupting chemicals (EDCs) and dismiss the 'precautionary principle'.[23]

The letter was supported by the The British Toxicology Society. Professor Kimber was on the board of Directors of the BTS at the time. Professor Kimber is the MHRA toxicologist and member of the Scenihr working party.

The EDC issue sparked unprecedented controversy in the EU not only amongst toxicologists[24]. **Sweden threatened the European Commission with legal action for its failure to act to regulate EDCs and won in a landmark case in December 2015**.[25]

In September 2012 Jim Bridges chairman of the PIP SCENIHR committee gave a talk "Challenges in assessing the risks from potential endocrine disruptors"[4] at a workshop organised by the European Parliament.

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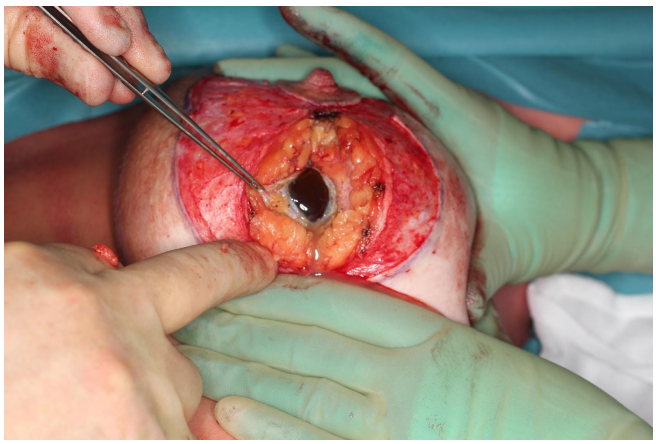
[23] Toxicologists enter the fray on endocrine disruptors

[24] 89 scientists join call for EU action on hormone-disrupting chemicals

[25] Sweden wins case over EDC criteria delay General Court rules Commission 'failed to fulfil its obligations' 16 December 2015 / Biocides, Europe

EDCs in PIP Implants



Endocrine Disruption is of particular concern to women with PIP as even the tiniest level of exposure to EDCs at critical points during pregnancy can have a devastating impact on child development. Women, developing embryos and breast feeding infants are being exposed to cyclic siloxanes in PIP. According to many scientists, there is no 'safe level' of exposure for embryos and infants.[26]

Indeed, in a meeting with Anne Glover, representatives from all sides of the EDC debate agreed:

"The impact of EDCs on the early development stage of organisms where disruption might cause irreversible damage ("window of vulnerability") is a key concern" "There was agreement that the impact on reproductive development is indeed an important issue."

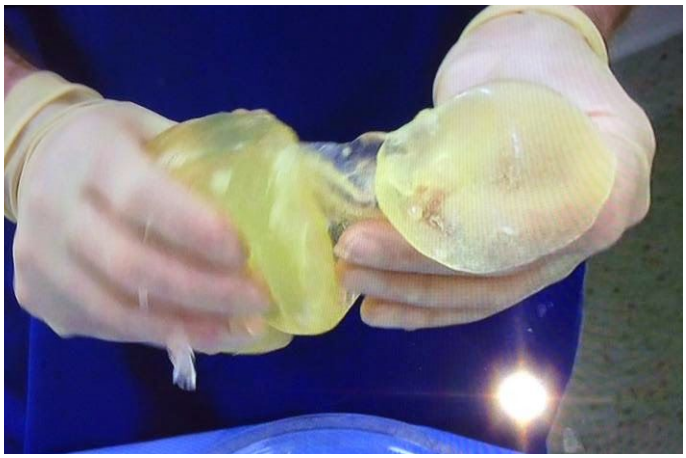
Evidence: "While most regulatory levels of impurities in breast implants are considered acceptable in the range of a few parts per million, Le et al.[27] showed that EDCs are capable of affecting developing neurons in vitro at concentrations of less than one part per trillion"[28].

[26] Experts Dispute Conclusion of PIP Breast Implant Scandal Investigation

[27] Bisphenol A is released from polycarbonate drinking bottles and mimics the neurotoxic actions of estrogen in developing cerebellar neurons

[28] The PIP scandal: an analysis of the process of quality control that failed to safeguard women from the health risks

PIP Action Campaign has raised the issue of EDCs in PIP with the European Commission and ECHA; at least 5 members of SCENIHR Committee are actively involved in the debate surrounding EDCs and even though EDCs are at the root of legal action taken and won by Sweden against the European Commission, EDCs are not mentioned in either the preliminary or final SCENIHR Reports into PIP implants.



"The WHO-UNEP 2012 report "State of the science of Endocrine Disrupting Chemicals"[29] mentioned the following **diseases in connection with ED exposure: prostate cancer and breast cancer, female and male reproductive health disorders, thyroid and metabolic disorders, neurodevelopment and immune disorders."**

EVIDENCE: Endocrine Disruption provides an explanation for the wide range of painful, debilitating physical symptoms seen by physicians and GPs in large numbers of women affected by PIP Implants.

[29] World Health Organization (WHO) 2012. State of the science of Endocrine Disrupting Chemicals 2012. Summary for Decision-Makers. Ed. Bergman Å., Heindel, J.J., Jobling S., Kidd, K.A., and Zoeller R.T. Retrieved from: http://www.unep.org/pdf/WHO_HSE_PHE_IHE_2013.1_eng.pdf

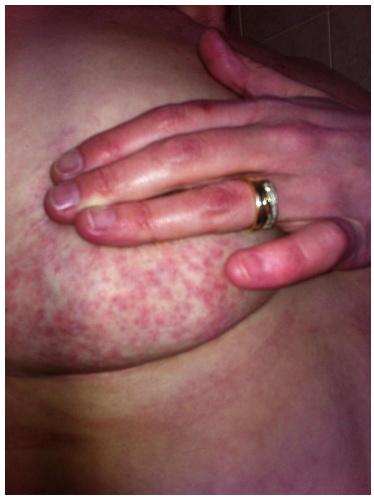
1.3 Exposure considerations

Risk = hazard x exposure

PIP: Repeat-dose toxicity. **Target organs** of D4 and D5 are liver, lungs and brain.

The Scenihr committee failed to consider the: (i) decomposition (ii) bioaccumulation (iii) persistence of cyclic siloxanes, (iv) the Xenoestrogenic effect and (v) long half-lives of cyclic siloxanes and other chemicals in PIP.

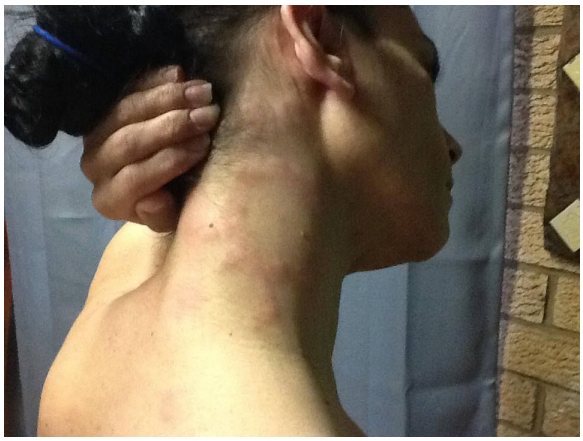
Women with PIP implants, like large number of doctors, surgeons and healthcare professionals treating them, find it hard to trust the scientific committee's findings which don't correlate with actual experiences of PIP.

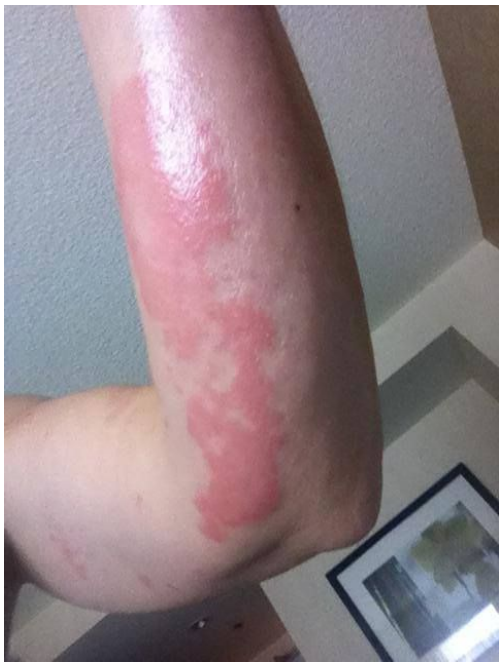


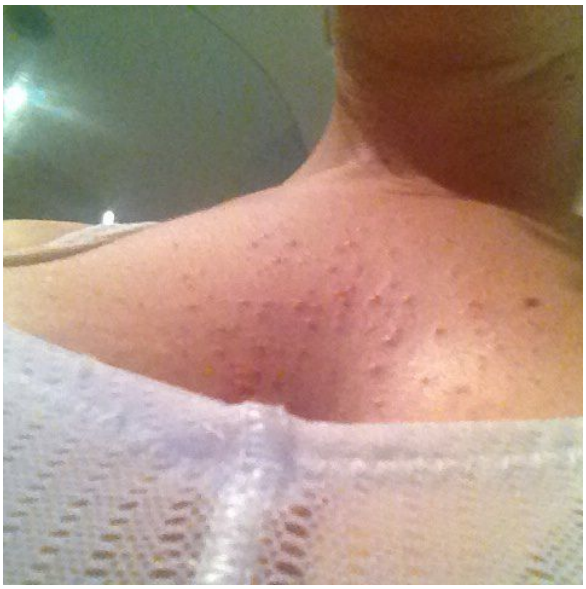
Allergic Reactions in women with PIP implants

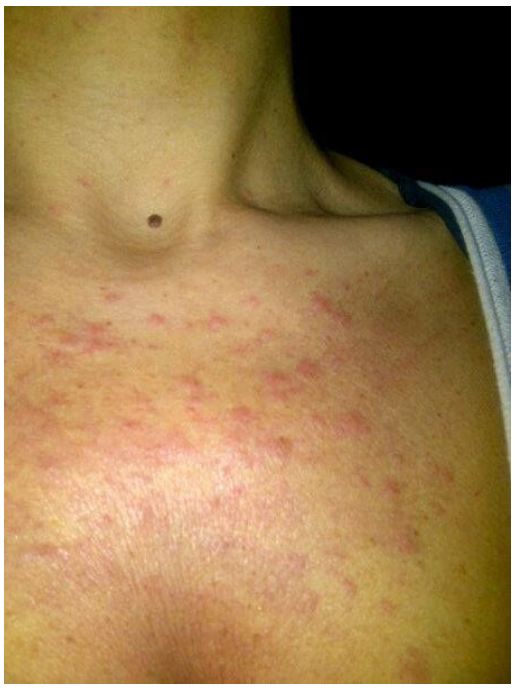
Allergic reactions are common in women with leaking or ruptured PIP implants and in PIP exposed children.

Evidence: Allergic reactions are indications for sensitization. Sensitization plays a key role in the development of cancer.









Evidence : Rashes are common in women with PIP implants.

Oestrogen Sensitive Breast Cancer : **ER Positive Breast Cancer**

Official figures suggest five percent (5%) of all women with PIP implants received them as part of their reconstructive/ cosmetic treatment following breast cancer surgery.

Cancer surgeons & consultants treating breast cancer patients should be aware that D4 has, what Kent Woods, former head of the MHRA, called **'a weak oestrogenic effect'** and inform patients of this risk.

'Breast cancer cells often have receptors (proteins) that hormones or other proteins can attach to and stimulate the cancer to grow. A pathologist does tests on the cancer to find out if receptors are present and what type they are.

Breast cancers with receptors for the hormone oestrogen are called oestrogen-receptor positive or ER positive breast cancer. ***About 70% of breast cancers are ER positive.'*** (Macmillan Cancer Support UK[30])

Chemicals found in PIP have a 'weak oestrogenic effect', in other words, xenoestrogenic.

Evidence: D4 which is found in PIP breast implants is xenoestrogenic. And very probably others in the D series are xenoestrogenic too.

The potential ecological and human health impact of xenoestrogens is of growing concern. Xenoestrogens are also called "environmental hormones" or "EDC" (Endocrine Disrupting Compounds). Most scientists that study xenoestrogens, including The Endocrine Society, *regard them as serious environmental hazards that have* hormone disruptive effects *on both wildlife and* ***humans****. (Wikipedia on xenoestrogens[31])*

D4 is xenoestrogenic and repro-toxic.

30 http://www.macmillan.org.uk/information-and-support/breast-cancer/treating/treatment-decisions/understanding-your-diagnosis/receptors-for-breast-cancer.html

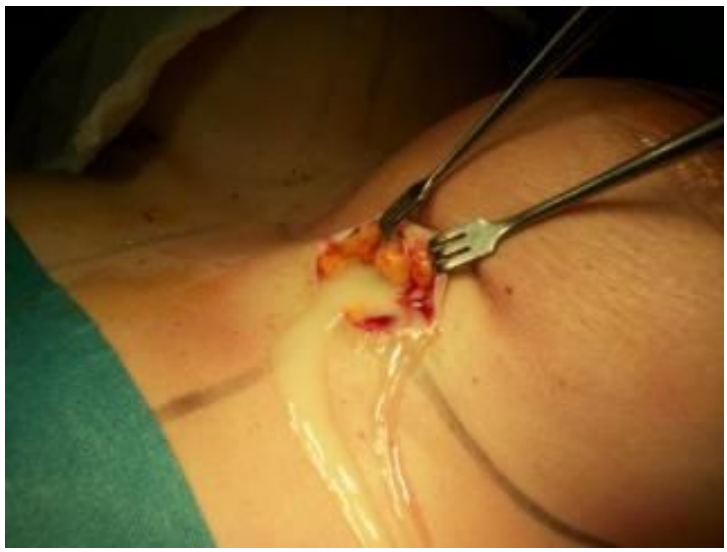
31 https://en.wikipedia.org/wiki/Xenoestrogen

1.4 Toxicological Properties

Women rightly expect an extremely high level of inquiry into the repro-toxicity, genotoxicity, teratological and carcinogenicity of PIP implants, using appropriate bio-monitoring, cytology, biopsy and real world evidence.

Poorly arranged experiments conducted outside normal protocols are unacceptable.

Evidence of sub-standard experimental testing (such as breast milk experiment and those commented on by the laboratory as outside acceptable protocols) is demonstrated by MHRA UK Health Regulator.



1.5 Consequences of leaking & ruptured PIP Implants for women

Have you visited your GP more than once with health concerns related to PIP implants? [PIP IMPLANTS : the impact on your life]

YES	**344**	77%
NO	**103**	23%

In addition to:

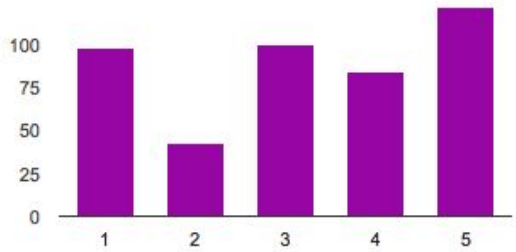
- Financial costs
- Re-operation downtime
- Risks from Surgery (hematoma, pulmonary embolism)
- Anxiety associated with PIP ruptures and leaks

Have you taken any time off work due to PIP implants? [PIP IMPLANTS : the impact on your life]

YES	**261**	58.4%
NO	**186**	41.6%

Women's relationships are under added pressure:

Have you experienced relationship problems due to PIP implants or your symptoms?



None: 1	**98**	21.9%
2	**43**	9.6%
3	**100**	22.4%
4	**84**	18.8%
Significant: 5	**122**	27.3%

Women with PIP implants report a wide range of distressing and debilitating symptoms, some are commonly associated with trauma.

Reported General Symptoms

Depression [Have you experienced any of the commonly reported general symptoms linked to PIP implants?]

YES	**283**	75.9%
NO	**90**	24.1%

Anxiety [Have you experienced any of the commonly reported general symptoms linked to PIP implants?]

YES	**317**	81.9%
NO	**70**	18.1%

Mood swings [Have you experienced any of the commonly reported general symptoms linked to PIP implants?]

YES	**305**	82%
NO	**67**	18%

Shortness of breath [Have you experienced any of the commonly reported general symptoms linked to PIP implants?]

YES	**215**	61.8%
NO	**133**	38.2%

Women with PIP implants Reported General Symptoms (2)

Stiffness or pain in joints [Have you experienced any of the commonly reported general symptoms linked to PIP implants?]

YES	**294**	78%
NO	**83**	22%

Muscle seizures, cramps or spasms [Have you experienced any of the commonly reported general symptoms linked to PIP implants?]

YES	**202**	60.5%
NO	**132**	39.5%

Muscle weakness [Have you experienced any of the commonly reported general symptoms linked to PIP implants?]

YES	**190**	56.9%
NO	**144**	43.1%

Dry mouth [Have you experienced any of the commonly reported general symptoms linked to PIP implants?]

YES	**170**	53%
NO	**151**	47%

Women with PIP implants Reported General Symptoms (page 3)

Dry skin [Have you experienced any of the commonly reported general symptoms linked to PIP implants?]

YES	**200**	58.8%
NO	**140**	41.2%

Skin rashes [Have you experienced any of the commonly reported general symptoms linked to PIP implants?]

YES	**171**	52.1%
NO	**157**	47.9%

Tingling or numbness in hands [Have you experienced any of the commonly reported general symptoms linked to PIP implants?]

YES	**239**	66.4%
NO	**121**	33.6%

Excessive sweating [Have you experienced any of the commonly reported general symptoms linked to PIP implants?]

YES	**187**	56.8%
NO	**142**	43.2%

Women with PIP implants Reported General Symptoms (page 4)

Night sweats [Have you experienced any of the commonly reported general symptoms linked to PIP implants?]

YES	219	65.6%
NO	115	34.4%

Extreme tiredness or fatigue [Have you experienced any of the commonly reported general symptoms linked to PIP implants?]

YES	327	84.3%
NO	61	15.7%

Bowel Problems [Have you experienced any of the commonly reported general symptoms linked to PIP implants?]

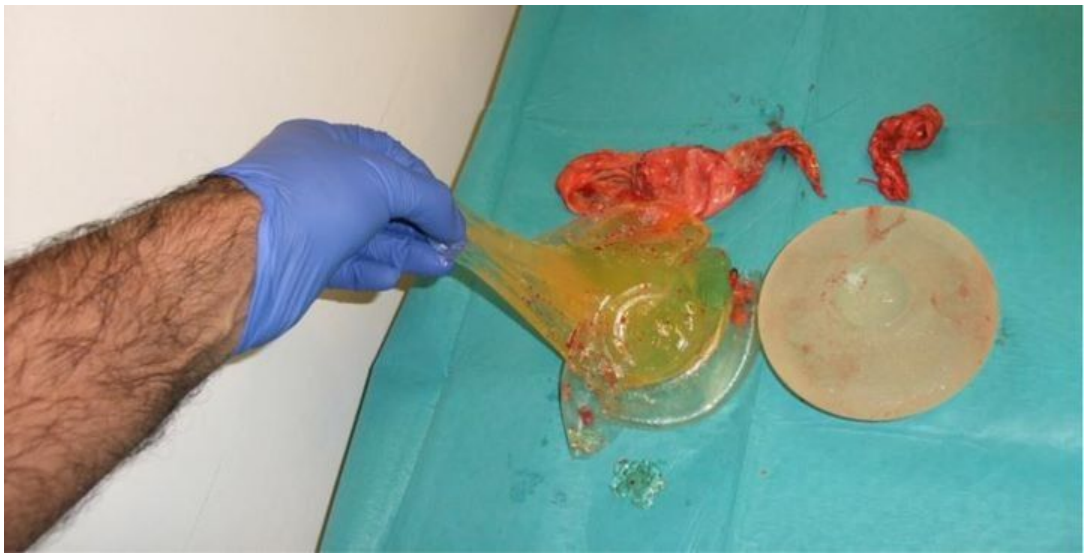
YES	190	59.2%
NO	131	40.8%

Hair thinning or hair loss [Have you experienced any of the commonly reported general symptoms linked to PIP implants?]

YES	182	55.5%
NO	146	44.5%

1.6 Generic Risks & Benefits

There are no safety assurances or protections for women with non-compliant PIP breast implants.



Further Work Recommended by SCENIHR Report

The SCENIHR identifies the need for:

a) Information to breast implants recipients The SCENIHR stresses the importance that recipients of breast implants are informed of possible risks, including that of device failure, which increases with time. Therefore, a significant percentage of women can be expected to experience a ruptured implant within their life span.

Women with financial or mental health reasons have not been advised to have leaking PIP implants removed but instead wait for a rupture which involves more risks from a longer more complicated removal surgery. **This is unacceptable.**

b) Improved data on for breast implants Implementation of a registration system of breast implantations on a national or European level is of utmost importance for collecting and analyzing data for research and risk assessment purposes. The questionnaire developed for this opinion could provide a valuable tool for this purpose. There is still a need for better reporting of breast implant failures, in particular of ruptures, through the mandatory vigilance reporting system to identify potential design problems earlier.

There is no evidence of data collection or analysis on a European level.

c) Explant analysis A retrieval study, focusing on an adequate sample of explanted devices, would enable identification of causes of implant failures, rupture mechanism, and individual body- device interaction for better understanding and safer device design.

Women with PIP implants are made part of unethical human research into the safety of other implants.

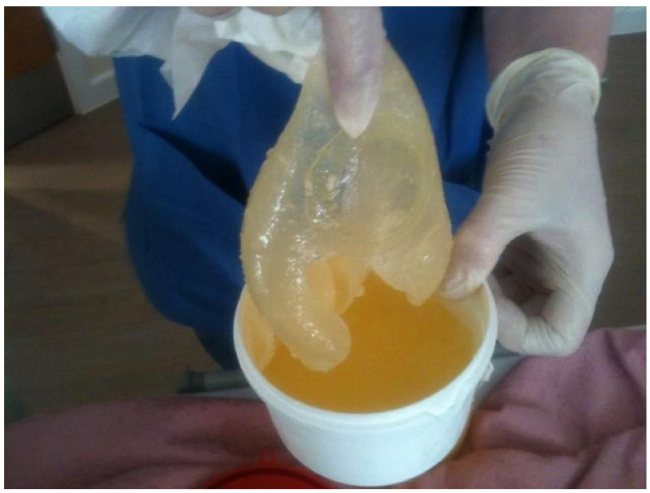
d) Information on factors causing inflammation A better understanding of the causes of the local inflammation/irritancy is needed. This includes the impact of the device/tissue interface of the shell on the development and characteristics of the tissue capsule.

Experimental Human trials are unacceptable data collection methods.

e)Future clinical examinations Women with silicone breast implants have a need for regular screening for potential leakage. Currently the most accurate mode of detecting ruptures is by medical imaging, namely Magnetic Resonance Imaging (MRI). There is a need for low cost reliable diagnostic methods, suitable for routine use, to identify implant status (leakage, rupture) in patients. It is also important to improve the understanding of inter-individual differences in vulnerability to the effects of a leaking/ruptured implant since the available data indicate substantial variations.

It is incredible that “potential leakage” of PIP has not been recognised by Scenihr as a risk associated with PIP implants.

f) Qualification of practitioners Although the SCENIHR has been unable to investigate the impact of poor surgery on implant failure it is concerned that implant operations may be carried out by individuals who are poorly qualified/experienced to conduct breast implantations.



None of the recommended actions relate specifically to inform, advise, support or provide access to healthcare or appropriate diagnostics or testing for women exposed to PIP implants.

Women's own experiences, symptoms and medical notes are the authentic measure of the extent of the damage PIP implants can cause.

The effects of PIP implants on the average woman are devastating.

5. PHYSICOCHEMICAL PROPERTIES OF PIP IMPLANTS (Scenihr)

The SCENIHR report identifies, what it refers to a "considerable amount" of literature as well as "considerable research" in the hunt for clues for the higher rate of rupture of PIP implants. And in particular, references a 2002 study[32] from the USA relating to the lack of cohesion found in silicone gels.

In the USA, at that time, there had already been a ban on silicone breast implants for more than a decade.

The Scenihr committee uses this study to draw more inappropriate comparisons between approved implants which, based on a "paucity" of safety data, were banned in the USA for 14 years.

According to more recent research (2016): "Chemical structure of the compound, as well as particle size, should be taken into account in safety evaluation of the use of siloxanes. These two factors determine the physico-chemical properties, which strictly correlate with the ability to interact with the human organism, as well as the ability to pass through cellular barriers."

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[32] Silicone gel breast implant failure: evaluation of properties of shells and gels for explanted prostheses and meta-analysis of literature rupture data.

"The rate of diffusion is dependent on the size of the space formed between cross-linked chains and chains density (degree of cross-linking)."[33]

Explanted PIP Implants

In 2013, at which point no testing of used and explanted PIP implants had been undertaken, Dr Beretta at the University of Milan, requested samples of **explanted PIP implants for analysis**.

Dr Beretta provided PIP Action Campaign members a brief report of his preliminary findings:

> Dear Ladies
>
> In the following you will find a brief report in which I have combined the results from the studies conducted by myself (Chemist, Italy), Matteo Malacco (Surgeon, Italy) and Adrian Richards (Surgeon, England) and the first preliminary but relevant observations from the experimental/clinical survey done in collaboration with those of you that kindly agreed to send specimens to my lab at the Univ of Milan.
>
> The first preliminary analyses done on PIP implants specimens provided by some donors (for reasons that you can understand, I will not reveal their number, identities and nationalities) shown features that may help understand the complicated picture of the health effects of PIPs.
>
> I will go by points and try to be as brief and clear as possible.
>
> 1) In previous studies we have shown that PIP filler silicone is only scarcely cohesive (according to what found by the French ANSM in 2010 when they found PIP was using a mixture of industrial silicones instead of the approved components).
>
> 2) In a subsequent study, we have also shown that in case of silicone bleeding from the implant(s), this silicone is incorporated under the form of very small particles into a fluid called "late periprosthetic fluid", a serum fluid that sometimes (rarely) appears also with other implants brands as a response to a inflammatory body reaction.

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[33] Direct Human Contact with Siloxanes (Silicones) - Safety or Risk Part 1. Characteristics of Siloxanes (Silicones).

The main difference between PIP and other approved brands is that commonly the late periprosthetic fluid is a clear fluid, while in the case of PIP it appears as a turbid, viscous fluid (due to the presence of silicone with a yellow to orange colour (haemoglobin).

3) We proposed that if this fluid is absorbed by the breast lymphatic system, the silicone particles may move outside the breast, in first place to the axillary lymph nodes, that if involved become more swollen than in the cases of lymphadenopathy associated to other implants brands.

4) There is a question that still needs to be answered: Why some implants do not show any problem during many years of implantation while others are found ruptured or “exploded” after even few months of implantation ?

5) We know half of the answer. **PIP implants are not filled with cohesive silicone gel (at least many of them, the first PIP silicone we analysed was from a implant manufactured in 2001 and it was not cohesive gel).** So we hypothesized that the other half of the answer was to be searched in the implants shells.

6) First indications from the evaluation of PIP shells from intact explanted prostheses sent to the lab. Originally, PIP was supposed to use a multilayer implant shells in which a anti-bleed barrier to limit the diffusion of silicones (a solution adopted by most of the manufacturers). Based on the microscopical analyses of the shells and on the informations provided by the patients, we have observed that when the shells were multilayer and thick enough (1.0-1.2 mm) there were no problems of silicone bleeding established observable by MRI, USS or at explantation (with disappearance of the toxic reactions or at least a significant improvement of the health status after explantation).

Silicone bleeding problems start to appear when the shell is not multi-layer (single layer) or thinner than normal (with more problematic management of toxic signs and symptoms).

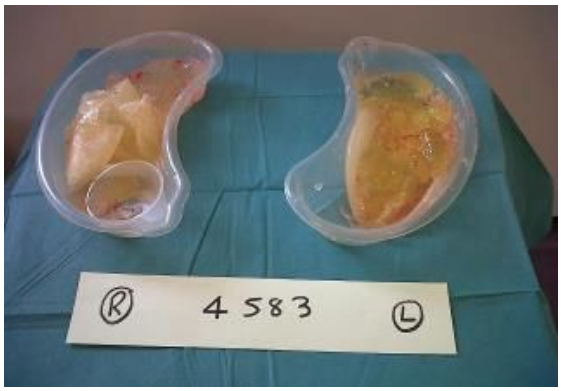
7) One observation: **The EU group SCENIHR published the information the PIP removed the barrier layer in 2007. We have evidence of single layer shells implants manufactured in 2001**.

So while the Scenihr Committee was caught up in the erroneous belief retrospective studies produced in 2000[34] are in someway useful in understanding the 'physicochemical' properties of criminally manufactured PIP. Actual studies of explanted PIP go some way to provide an explanation for the higher incidence of PIP implant rupture.

Evidence: SIngle layer and thin textured layered shells of uncertain material and uncertain manufacturing procedures account, in part, for higher rupture rate in PIP implants.

Protective (anti-bleed) barriers are missing in PIP implants

In a UK news item: ***Breast implants 'need checking'***[35] published on the 18 June 2010, the BBC reported: "A French inquiry has found that Poly Implant Prostheses - or **PIPs** - are filled with an **unapproved gel and are missing protective barriers**."



The articles goes on:"**The inquiry by the French association of plastic surgeons reported that the company (PIP) had from 2005 dispensed with the protective barrier and was also using a gel with a composition different from that approved."**

To determine how the altered version might react with the human body, BAAPs says French colleagues contacted the gel manufacturers for any studies. **There were none**, **as they had understood the substance to be intended for use in mattresses."**

Dr Beretta's analysis of explanted PIP implants showed absence of protective barrier in PIP implants manufactured in 2001. The explanted **intact** PIP implants were donated by British woman who had reconstructive surgery following breast cancer diagnosis in 2002.

Evidence: Intact PIP implants are leaking.

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[34] Silicone Gel–Filled Breast Implant Integrity: A Retrospective Review of 478 Consecutively Explanted Implants

[35] Breast implants 'need checking' BBC News Report 18 June 2010

While the Stromberg 2012 & 2013[36] investigations, referenced by the SCENIHR, concluded ***"The reason for the failure of the material could not be established"***, the variability in PIP manufacturing is clear from their results: ***"These results indicate that even though the implants had the same LOT they had different surface properties from the manufacturing process".***

Evidence points to impure raw materials and highly dangerous manufacturing experiments in **polymerisation, cross-linking and curing.**

Medical Devices Regulations : TÜV Rheinland Notified Body

Regulations of high-risk, Class III medical devices provide regulatory authorities full range of resources to facilitate them in their public duties and obligations. These resources were not utilised by the Notified Body in the PIP case. When questions were raised by the UK authorities following reports from Senior NHS consultant, the notified body provided reassurances that all was well at PIP.

How was PIP able to operate for so long without being questioned about **essential requirements** of the medical devices regulations? The notified body, TÜV Rheinland subcontracted CE Mark Quality Management Systems duties to another local agent, not licensed for auditing Class III devices.

Essential Materials checks, invoices for raw materials, unannounced inspections, appropriately qualified audit staff, product testing all evidence regulatory negligence.

Unlike the TGA, the Australian health regulator, TÜV Rheinland the Notified Body & private company has not made any key documents on PIP available for scrutiny.

The TGA has responded to the Australian Senate Inquiry and has released a number of critical documents via Freedom of Information requests from members of the public.

[36] Analysis of 17 breast implant samples by Fourier-Transform Infrared Spectroscopy (FTIR) and Field Emission Scanning Electron Microscopy (FE- SEM)

TÜV Rheinland, who were selected for EC certification by PIP, have hidden behind Article 20 of the MDD 93/42/EEC which was originally intended to protect sensitive patient data which are part of any adverse event reporting, not 'trade secrets' of Notified Bodies with public duties.

URGENT: The Medical Devices Directive requires Notified Bodies have public liability insurance. This insurance should be activated as a priority to help women into the care, treatment, compensation and future monitoring they need.
Annex XI to Directive 93/42 Section 6

Making The Needs of PIP Exposed Women a Priority

Women exposed to PIP require assurances:

Health Monitoring & Research

Dr A Menache

1. The EU requirements for biological evaluation of 'higher risk' medical devices such as breast implants (e.g. ISO 10993-1) undergo urgent revision in order to include modern toxicology testing methods, based on human genome cell data and other methods that are directly relevant to humans.
2. Effective quality control should keep in step with scientific progress as well as technical specifications, such as those described for ISO, HACCP and GLP. This is especially relevant with respect to implanting devices into the body, whose contents may leach or leak regionally or systemically over time. Several scientific studies, confirmed by magnetic resonance imaging, have indicated that many women have lived for a long period with ruptured implants without knowledge thereof. In these situations, the leaked chemicals could not only invade surrounding tissues but also spread systemically either via the lymph or the blood.
3. A programme of biomonitoring of women with breast implants should be implemented as part of an overall epidemiological health monitoring scheme. This should include the periodic analysis of blood and urine samples, using 'omics' technologies to detect biomarkers of early pathology, well before the manifestation of clinical disease. It would be advantageous to consider the cost effectiveness of such a programme.

4. Any review panel or body should uphold transparency and public accountability and be free of conflicts of interest. Its composition therefore should include more than one toxicologist and those who are without conflicts of interest. Greater transparency would also reduce the impact of conflicting messages to the public.

The Scenihr reports on the findings of both the TGA and the MHRA. **All claim "no volatile organic compounds could be detected". This is false**. See MHRA GC-MS data in LGA report[37].

Evidence: Several substances have been found in PIP implants which are not directly associated to polydimethylsiloxanes: besides different silylated organic compounds, there are also other chemical substances, of which one **NALOXONE**, a pharmaceutical drug, CAS number 000465-65-6, has been identified in all PIP batches.

(Scenihr 6.1) Human exposure to siloxanes

Low Weight Molecular Cyclic Siloxanes in PIP implants

Molecular weight of D4= 296.61576 g/mol and D5=370.7697 g/mol

"Generally, siloxanes (silicones) ... are commonly regarded as non-toxic to humans and the environment, or toxic to a very small extend. However, **there is a number of publications in which the scientists and experts question this opinion. Many authors demonstrated that the degree of polymerization and the structure affect the ability to overcome cellular barriers, including *stratum corneum* of the skin and absorption into the organism, migration in the living organism, ability to accumulate, degradability and toxicity. This particularly applies to low molecular weight siloxanes.**"

"The bioavailability and also permeation of compounds through the skin layers is possible, when they meet the following conditions (Lipinski, 2000; Lipinski et al., 2001; Mojsiewicz-Pieńkowska, 2014):

[37] https://www.gov.uk/government/publications/poly-implant-prosthese-pip-implants-toxicology-testing

(1) there are less than 5 hydrogen-bond donors (Expressed as the sum of hydroxide groups OHs and amine groups NHs);
(2) **molecular Weight is less than 500**;
(3) the Log P is less than 5;
(4) there are less than 10 hydrogen-bond acceptors (expressed as the sum of nitrogens and oxygens).

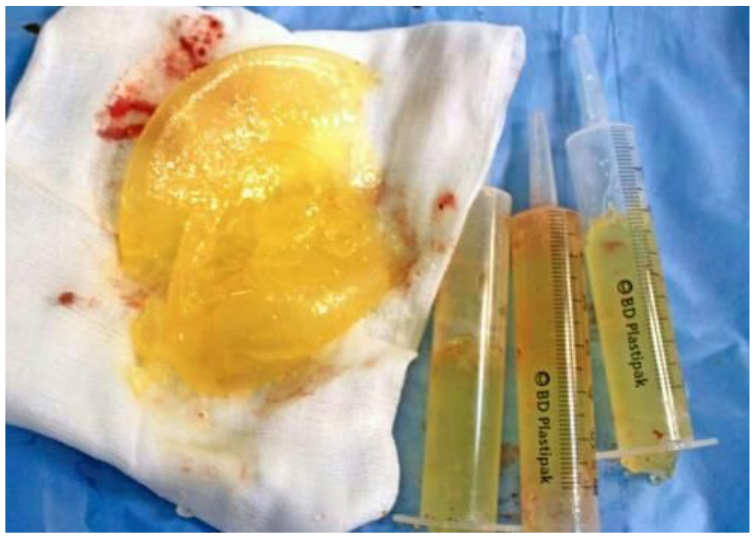
... **"low molecular weight silicones can change the structure of lipid bilayer, by the fluidization or even extraction of the lipids** (Glamowska et al., 2015; Mojsiewicz-Pieńkowska et al., 2015; Yang and Guy, 2015). This effect can weaken the natural barrier of cell membranes (Glamowska et al., 2015; Mojsiewicz-Pieńkowska et al., 2015). **Low molecular weight silicones can accumulate in the organism, and affect the organs in the long-term perspective** (Wang et al., 2013). **The least safe are cyclic siloxanes** and low molecular weight linear siloxanes (Flassbeck et al., 2001; Gaubitz et al., 2002; Papp et al., 2004; Tran et al., 2015; Xu et al., 2015).

"In conclusion, considering the safety of the direct application or contact by humans with siloxanes, the polycondensation reaction is preferred, due to lower contamination with low molecular weight siloxanes of cyclic structure. The literature indicates that they exhibit toxic effects, for example: cancerogenicity, modifications in proteins conformation, influence on the immune system, genotoxicity, skin irritations, intraocular pressure increase and teratogenicity (Wang et al., 2013; Mojsiewicz-Pieńkowska, 2014)."

Since the publication of the SCENIHR final report, a public consultation into D4 and D5 by UK competent authority for REACH, has been undertaken and referred to ECHA (European Chemicals Agency). **Both D4 and D5 are REACH substances of very high concern (SVHC). Echa has proposed a restriction (BAN) on both substances. By ignoring exposure data from women with PIP, EU chemical regulators have limited the ban to environmental exposures and shampoo.**

On the 17th March 2016, the President of the European Commission, on behalf of the European Union, nominated D4 as a **Persistent Organic Pollutant** or POP to the United Nations Stockholm Convention[38] whose mandate exists to protect human health and the environment.

Evidence: Women and children exposed to repeat-dose toxins and POPs contained in PIP have been placed at unnecessary risk as a result of the failure to recommend preventative removal in all women.



6.2. Issues to be addressed (Scenihr)

The Scenihr asks : "Do PIP implants represent an increased risk to human health compared to *conventional medical grade implants*?"

Evidence: Unregulated, non-conforming, surgically implanted, untested, **unsafe PIP implants** prone to rupture, manufactured without required cross-linking, curing, or protective barrier, decomposing, leaking and rupturing in women's bodies and seeping into lymph nodes around the body and triggering an immune response, **clearly represent a risk to health.**

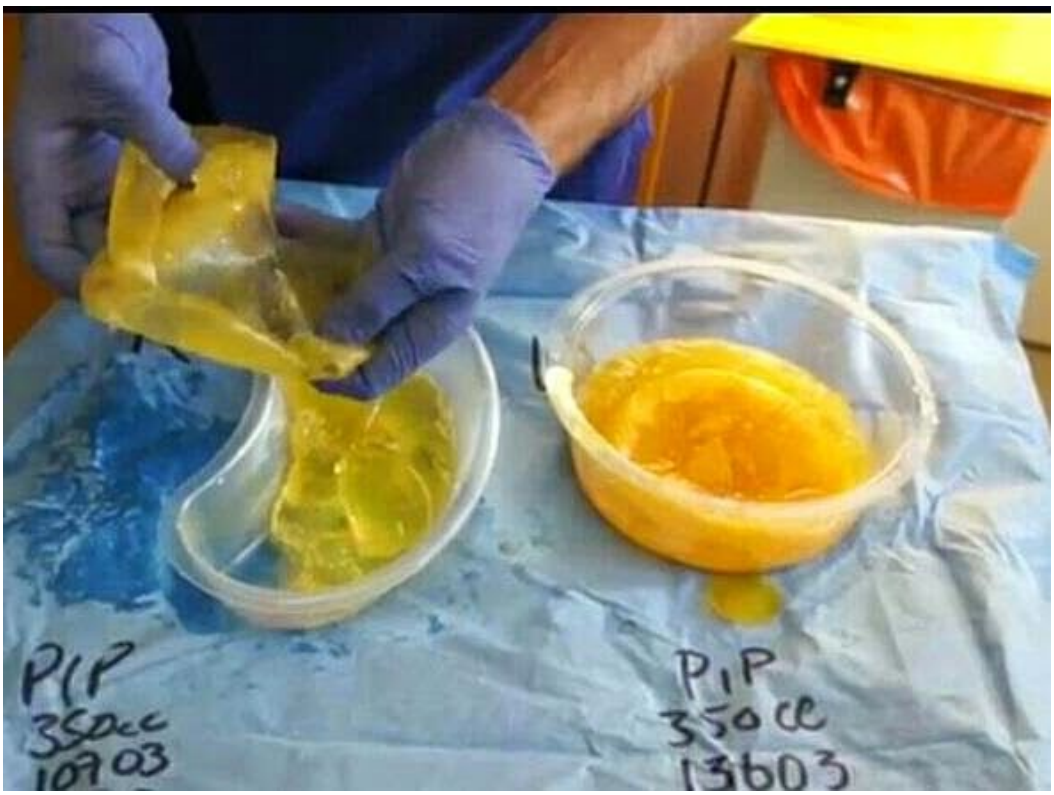
The Scenihr and the European Commission have been remiss in ignoring the Medical Devices Regulations regarding Class III implantable Medical Devices as well as their duties and responsibilities to the women affected.

There is no such thing as 'medical grade' implants. Breast and other silicone implants are **Medical Devices subject to Medical Devices Regulations. PIP is a banned Class III Medical Device.**

[38] https://ec.europa.eu/transparency/regdoc/rep/1/2016/EN/1-2016-154-EN-F1-1.PDF

The undisputedly high rate of implant rupture, the chemical cocktails, unknown raw materials and unknown manufacturing deviations and experiments all represent excess risks to women's health, particularly amongst the most vulnerable groups: mothers, women recovering from cancer, women with mental health issues, developing foetuses, breastfeeding infants and children.

Evidence: political and economical risk assessments that favour governments, businesses and industries, are failing women and children exposed to harmful PIP.

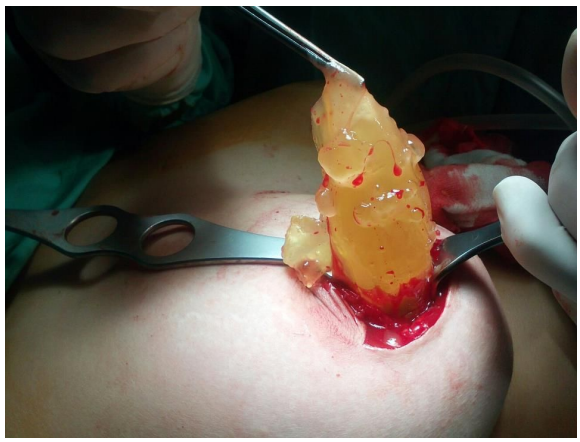


"Politically motivated 'risk assessments' such as the Scenihr opinion on PIP implants, pose very serious and unacceptable threats to women's health and well-being." pipactioncampaign.org

Scenihr 7.3.6. Case reports about unusual complications in patients with PIP implants

> An increasing number of case reports with PIP implantation and primarily significant clinical adverse reactions have been published recently. A common reporting is serious inflammation within the implant pocket, thickened fibrous capsule, enlarged and silicon containing regional lymph nodes – both in the axilla and neck region. For a summary of these findings, please go to appendix II. (Scenihr)
>
> "Is it possible that PIP silicone (either the polymeric material or the low molecular weight siloxanes) is associated with the increased incidence of local inflammatory reactions that have been reported with PIP implants compared with medical grade implants? (NB The use of data on implants from other manufacturers is very important in order to identify anything that appears unusual about PIP implants)."

Of course it is possible that PIP gels, of unknown raw materials, unknown manufacturing processes by unqualified staff are increasing inflammatory reactions in women with PIP implants. However, the focus of the Scenihr concern shows it's manufacturer's data rather than the incidence of local inflammatory reactions in women with PIP which is of particular significance.



Evidence: PIP Action Campaign submitted seven zip files of full-text peer reviewed research and case reports in response to the SCHEER Committee's Call for Information. The number of women with PIP implants seen by medical professionals with 'significant clinical adverse reactions' continues to grow.

NB: the term "medical grade implants" is a fabrication. All compliant silicone implants should conform to the Medical Devices regulations and contain "Silicones for Healthcare Application". PIP implants were manufactured using D4, D5 and D6 (as well as others in the D series) without necessary purification, cross-linking, polymerisation or curing.

The paragraphs summarizing the conclusions reached on toxicity (Scenihr 6) are predicated on limited testing by regulatory authorities and the SCCS 2010 opinion on cyclic siloxanes.

Siloxanes - Consumption, Toxicity and Alternatives[39] is a 2005 report by the Danish Environmental Protection Agency it addresses major concerns for women with PIP implants, namely, exposure to high concentrations of D4, D5 and D6.

Carcinogenicity

"Very little information is available on carcinogenicity of siloxanes. The only information identified is a report from Dow Corning received by EPA with preliminary results from a two-year chronic toxicity and carcinogenicity study in rats exposed to vapour concentrations of 0, 10, 40 or 160 ppm of D5 for 6 hours per day, 5 days per week, for 24 months. **The preliminary results show that female rats in the highest dose group had a statistically significant increase of uterine tumours. These findings may indicate that there is a potential carcinogenic hazard associated with D5 (EPA. 2003)."**

Reproductive toxicity

"D4 is classified in the EU as Toxic for Reproduction. Cat. 3; R62 (Possible risk of impaired fertility). D4 has been evaluated based on information on toxic effects on the parent animals, toxicity to fertility and developmental toxicity/teratogenicity."

Endocrine disruption

"In a uterotrophic assay in immature rats receiving oral doses of D4 and HMDS for 4 days, **D4 exhibited weakly estrogenic effects** (dose-related increase in uterine weight and epithelial cell height) in both SP and F-344 rats. **The substance also showed weak antiestrogenic properties by partially blocking EE (ethinyl estradiol) induced uterine weight increases (competitive inhibition of estrogen receptor binding or D4 acting as a partial estrogen agonist).** When co-administered together with EE, HMDS produced a slight, but statistically significant reduction in absolute uterine weight."

[39] Siloxanes - Consumption, Toxicity and Alternatives

Lassen et al 2005 at 3.3 of ***Siloxanes - Consumption, Toxicity and Alternatives*** Concludes: "Based on the reviewed information, the critical effects of the siloxanes are impaired fertility (D4) and potential carcinogenic effects (uterine tumours in females) (D5). Furthermore there seem to be some effects on various organs following repeated exposures, the liver (D4), kidney (HMDS) and lung (D5 and HMDS) being the target organs. (page 50)

Lassen et al 2005 notes: "Other relevant information is related to silicone in breast implants, where IARC has evaluated that there is evidence suggesting lack of carcinogenicity in humans of breast implants, made of silicone, for female breast carcinoma (IARC 1999)."

IARC is the World Health Organisation's International Agency for Research on Cancer.

Evidence: The current IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Report of the Advisory Group to Recommend Priorities for IARC Monographs during 2015–2019[40] provides an important update on carcinogenicity linked to breast implants::

4.10. Breast implants

Breast implants were evaluated by IARC in 1999 (Volume 74) and placed in Group 3 (*not classifiable as to its carcinogenicity to humans*). **The Working Group at that time stated that there was evidence suggesting a lack of carcinogenicity in the female breast. Since this evaluation, new information has caused the focus to switch from cancer of the breast to anaplastic large cell lymphoma (ALCL).**

And goes on "Silicone gel from commercially available breast implants increased the incidence of plasmacytoma in genetically susceptible mice."

Concerns over the safety of silicone implants are not new, in the USA they resulted in a 14 year ban, in France the ban lasted 6 years. Twenty ten, was not the first time PIP compromised women's health with its implants.

[40] IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Report of the Advisory Group to Recommend Priorities for IARC Monographs during 2015–2019

7. CLINICAL FINDINGS (Scenihr)

Reports of government committees and agencies

UK data (estimated number of women affected 28,000)

More than 47,000 women in the UK are believed to have had PIP implants.

The UK have not provided any figures for PIP ruptures, bleeds, lymphadenopathies, breast cancer or BIA-ALCL. At the time of PIP Action Campaign's most recent Freedom of Information Request (FOI) the MHRA **confirmed 17 BIA-ALCL cases in the UK**. The MHRA has yet to acknowledge the association between textured breast implants and ALCL.

(photo) Susan Grieve with daughter Alix. Susan had ruptured PIP implants and died from BIA-ALCL in 2012. Susan's death is the first recorded BIA-ALCL death in the UK.

French data (estimated number of women affected 30,000)

A poor approximation of roughly 2000 is made by the Scenihr, for the number of (French) women (~2000) who had experienced ruptured PIP implants but no apparent adverse effects. There is no reliable evidence for this. The evidence from the French authorities relates specifically to the many 1,000s of women who did experience serious health problems.

The Scenihr reports on the French data:

"A total of 70 cases of breast cancer in women with PIP implants were reported, and one patient died from ALCL (Anaplastic Large Cell Lymphoma).

> No additional cases of ALCL have been reported. **This number is not considered exceptional since a certain number of breast cancers are to be found among such a large female population.**

By 2014, seventy-four (74) cases of breast cancer were found in French women with PIP implants. At the time of the Scenihr Opinion, the Scenihr reported a single case of BIA-ALCL. Edwige Ligoneche, (see page 8) died at the age of 53 with ruptured PIP breast implants and a diagnosis of BIA-ALCL.

> "The French National Cancer Institute has been consulted and has agreed on the above interpretation: **there are no data, to date1, to evidence any additional risk of ALCL or breast adenocarcinoma specifically linked to PIP Protheses compared with other implants**." Scenihr May 2014

French Data page 37, Footnote 1 "To the date of the preliminary opinion (September 2013).

PIP Action Campaign members are naturally concerned why the Scenihr final report - published in May 2014, after a long delay, is referencing figures from the preliminary document produced by the French Authorities in September 2013 especially as more recent data had been published in December 2013.

Australian Data (Scenihr estimated number of women affected 5,000)

> "The TGA has not published information about local reactions after PIP implant ruptures."

We presume this is because data is not being collected by TGA

> "A limitation of the Australian explant data is that reporting of ruptures increased markedly in 2012 due to a request by the TGA for surgeons to make reports about PIP implants. "

The most likely reasons there are so few adverse events reported to the TGA prior to 2012 are: (1) Women and health professionals are unaware of adverse reporting procedures (2) TGA has discharged its duties to monitor adverse events in PIP implants.

Spanish data (Scenihr estimated number of women affected 18,500)

Spanish Health Authorities AEMPS issued a recommendation to Spanish women to remove PIP implants on the 30th October 2013: the day the Scenihr report preliminary findings were published.

ACTUALIZACIÓN DE LA INFORMACIÓN Y DE LAS RECOMENDACIONES SOBRE PRÓTESIS MAMARIAS POLY IMPLANT PROTHÈSE (PIP)[41] Fecha de publicación: 30 de octubre de 2013

Swedish data (Scenihr estimated number of women affected 4,082)

The Swedish Authorities were the first to conduct studies on explanted PIP. **Until that time only unused sterile PIP implants had been reviewed.** The Swedish investigations found D4 to be irritant and respecting the precautionary principle, recommended prophylactic removal of all PIP implants in Swedish women. The Swedish MPA published their findings.

Summary of National Data & Scenihr Opinion

French, Spanish and Swedish authorities amongst others, including Germany, Hungary and Czechoslovakia have evoked the precautionary principle and taken steps to protect women from harm by recommending removal of all PIP implants.

Breast cancer is one of the most terrifying and challenging diagnosis women usually have to face in their lives.

[41] https://www.aemps.gob.es/informa/notasInformativas/productosSanitarios/seguridad/2013/NI-PS_18-2013-poly-implant.htm

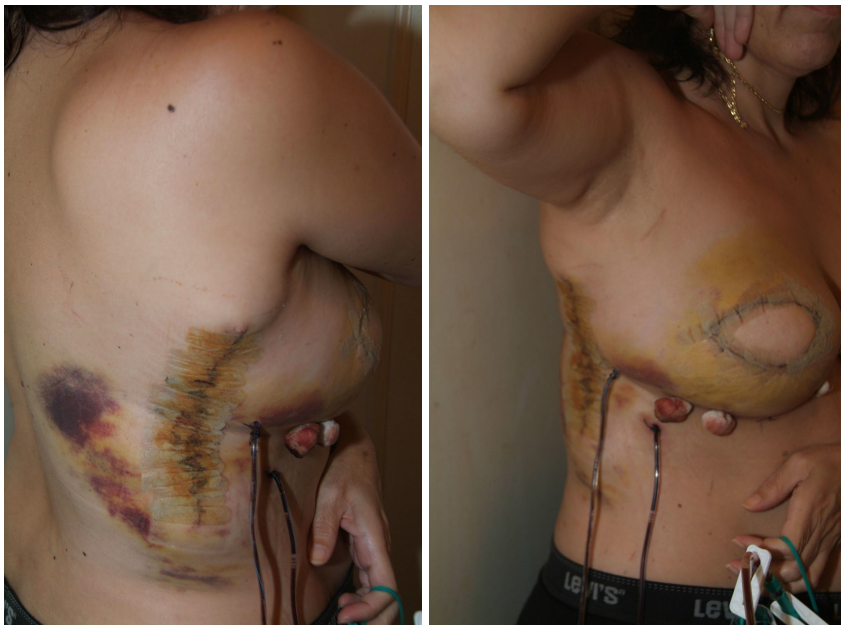
Breast Adenocarcinoma in women with PIP implants

In 2014 the French authorities (ANSM), monitoring the cohort of French women with PIP implants, reported **74 new cases of breast adenocarcinoma**.

"Un total de 74 cas d'adénocarcinomes mammaires a été signalé à l'Agence à fin décembre 2013 chez les femmes porteuses de prothèses en gel de silicone PIP (soit aucun cas de plus qu'à fin septembre 2013)."[42]

According to the Scenihr opinion, the French National Cancer Institute had agreed *"This number is not considered exceptional since a certain number of breast cancers are to be found among such a large female population."*

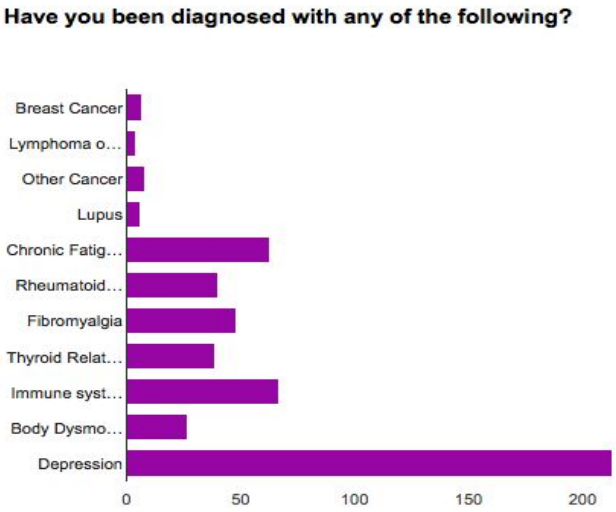
However, it is a large number of individual women. These women will have presented themselves to their doctors because of PIP to be told they have breast cancer.



One of PIP Action Campaign members, ruptured PIP, simultaneously diagnosed with breast adenocarcinoma, pictures show patient following reconstructive surgery.

[42] http://ansm.sante.fr/var/ansm_site/storage/original/application/1b95e9217dd4d5443ccbbaaec86643b4.pdf

We asked women with PIP about breast cancer diagnoses:



Breast Cancer	7	2.7%
Lymphoma or ALCL	4	1.5%
Other Cancer	8	3%
Lupus	6	2.3%
Chronic Fatigue Syndrome	63	24%
Rheumatoid or Inflammatory Arthritis	40	15.2%
Fibromyalgia	48	18.3%
Thyroid Related illness	39	14.8%
Immune system illness	67	25.5%
Body Dysmorphia	27	10.3%
Depression	213	81%

We discovered just seven women have reported a breast cancer diagnosis when responding to our Health Survey. French experts' have already stated 74 cases is in line with the expectation. This means there may still be significant numbers of women with PIP implants with undiagnosed breast cancer.

Evidence: failing to recommend the precautionary removal of banned PIP implants is putting women at unnecessary risk. The sooner breast cancer is detected the better the prognosis for the patient.

> "**...there are no data, to date**[1]**, to evidence any additional risk of ALCL or breast adenocarcinoma specifically linked to PIP Protheses, compared with other implants**." Scenihr May 2014 relying on French data from September 2013

Evidence: In May 2014, the ANSM published an *"Evaluation of the use of silicone breast implants (other than PIP) in France 2010-2013". It states:*

> "At the end of October 2013, **22 cases of breast adenocarcinoma** had been reported to the agency in women with silicone breast implants (more than 300,000 women) between 2001 and 2013.

"These tumour lesions were observed whatever the reason for implantation (aesthetic breast augmentation or breast reconstruction)"[43]

EVIDENCE: additional risk of breast adenocarcinoma in women exposed to PIP implants. According to French data, women with banned PIP implants are more than three times more likely to be diagnosed with breast cancer compared to other implants.

Scientific publications on PIP implants and Case reports about unusual complications in patients with PIP implants

A detailed submission was made by PIP Action Campaign to the SCHEER committee's **Call for Information** and attached here as Appendix A.

7.4.1. Update on Anaplastic Large Cell Lymphoma (ALCL)

A submission was made by PIP Action Campaign to the SCHEER committee's **Call for Information** Appendix B.

BIA-ALCL : Breast Implant Associated Anaplastic Large Cell Lymphoma (ALCL)

BIA-ALCL : Breast Implant Associated Anaplastic Large Cell Lymphoma (ALCL) as the name suggests is proven to be linked directly to textured silicone implants. The majority of the 100,000EU women have been exposed to PIP textured implants. Women with PIP implants have died from BIA-ALCL.

[43] http://ansm.sante.fr/var/ansm_site/storage/original/application/7fd4f94f69f8a07befd7f1e2753187ab.pdf

Anxiety, Depression and Suicide : implants and excess risk

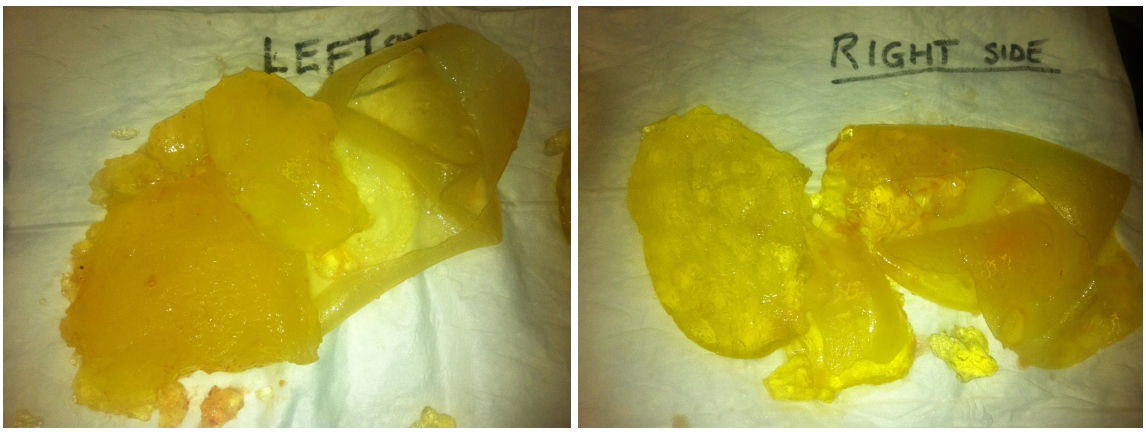
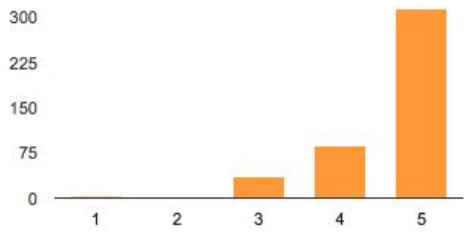


Photo: ruptured PIP removed in this condition from a woman's body

Stress and anxiety are recognised risks to women's health. Not only the worry of inevitable PIP leaks and ruptures; the symptoms of leaks and ruptures; fear of permanent injuries and disfigurement; long and complicated surgical operations and financial implications of removal surgery but also concerns surrounding pregnancy, breastfeeding as well as the future developmental health of their PIP exposed children and infants.

How anxious are you about PIP implants?



Not at all: 1	**3**	0.7%
2	**1**	0.2%
3	**36**	8.2%
4	**87**	19.7%
Extremely Anxious: 5	**314**	71.2%

Evidence: It should not be surprising that the large majority of women exposed to PIP are extremely anxious.

7.4.2. The psychological impact of the PIP implants

"Suicide and psychological issues: It is a consistent observation that the population of women with breast implants for cosmetic reasons exhibits a two- to three-fold higher rate of suicide than similar-aged women in the general." Scenihr

The psychological impact of PIP implants is a major concern particularly for voluntary support groups, like PIP Action Campaign, having to provide help and information for very distressed and frightened women.

The first concerns linking excess risk of suicide to silicone breast implants was identified by US pathologist Louise Brinton, in 2001: "We undertook a retrospective cohort study of 13,488 women receiving cosmetic implants and 3,936 patients with other types of plastic surgery at 18 plastic surgery practices".

"...findings indicate that patients seeking plastic surgery are in general healthier than their peers. Implant patients, however, experienced excess risks of death compared with the general population for brain cancer (SMR = 2.45) and suicide (SMR = 1.54)[44]".

A later study, updating the original 2001 paper, was published by Brinton in 2006. Brain and lung cancers, highlighted with excess risk in the original study, were "attenuated by additional follow-up", but the elevated risk of suicide persists according to the update.


Mirror NEWS
Real news, real entertai
FRONT PAGE | NEWS | SPORT | 3AM | TV | LIFESTYLE | MONEY | PLAY
Search
News · UK News · PIP breast implants
By Richard Smith | 2 Comments | 25 Apr 2012 12:48
"It's killing me... I'm so worried": Young mum found dead in suspected suicide after fearing faulty breast implants would rupture
Paige Goldup, 24, was fitted with faulty PIP implants and admitted on Twitter that she was stressed by fears they could rupture
Tweet 0 Like 9 Send
Terrified: Paige Goldup lived in fear that her implants would rupture and kill her
WNS
A young mum has been found dead after living in fear that her breast implants would rupture.
Civil servant Paige Goldup, aged 24, was fitted with faulty silicone implants which were due to be removed and replaced by surgeons.
Paige, mum of a nine-month-old baby girl, was found unconscious by relatives at home. She never came round and died in hospital from a suspected drug overdose.
Paige was fitted more than two years ago with implants made by the French firm PIP at the centre of the boob job scandal.
The mum admitted on Twitter that she was stressed by fears that the implants could rupture.

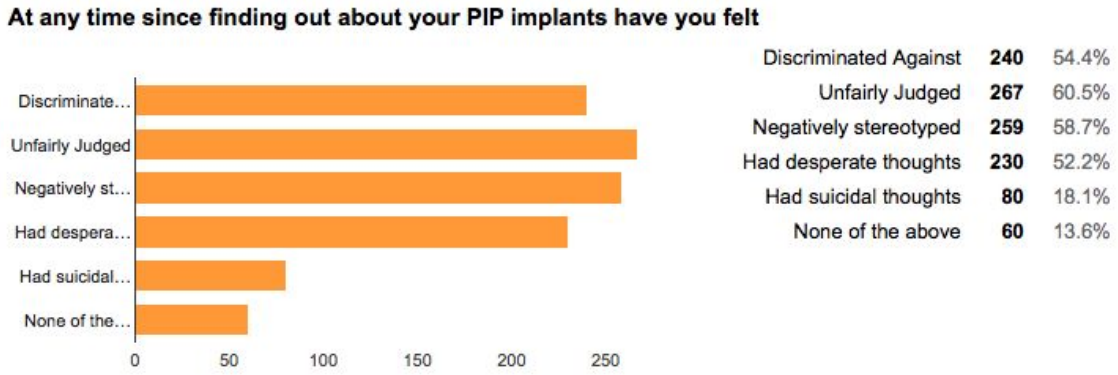
[44] Mortality among augmentation mammoplasty patients

The Scenihr Opinion references a conference paper "The Psychological Impact of the PIP Breast Implants Scandal on a Cohort of UK Women[45]", published in Plastic & Reconstructive Surgery 130 · October 2012. Its "Conclusions: The reported costs of the scandal to the British government could run to over £150 million.

"The cost to the mental health of all who have been involved is impossible to calculate. **The medical community has a responsibility to limit the psychological impacts of this traumatic event by arranging appropriate counselling and timely intervention to support these women.**"

The Scenihr opinion devotes 3 sentences to the issue of the psychological impact of PIP implants and references suicide twice at 4.1.4 Possible adverse health consequences (f) yet no recommendations for further research or funding for any kind of psychological support is identified.

We asked members about desperate and suicidal thoughts:

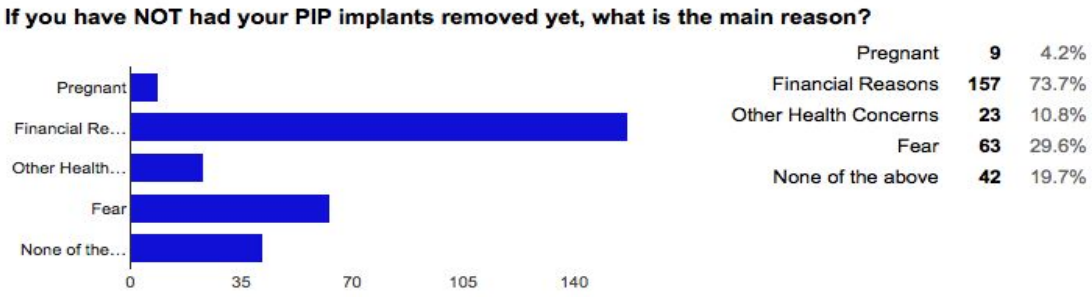


The financial implications of the PIP scandal for the British government are referenced in the Conference paper mentioned by the Scenihr committee, but not the financial implications for women with PIP implants.

Evidence: Financial reasons are given as the main reason for not removing PIP implants.

[45] https://www.researchgate.net/publication/267353261_The_Psychological_Impact_of_the_PIP_Breast_Implants_Scandal_on_a_Cohort_of_UK_Women

We asked women why they have not had banned PIP implants removed:



For some women, mental health illness is linked to the original surgery. Women with slight to extreme cases of body dysmorphia, eating disorders, self-esteem issues are not receiving help, information, support or understanding to deal with implanted PIP implants.

Evidence: vulnerable groups including women with mental health illness and women with cosmetic / medical need have been deeply affected by the PIP health fraud. As with other crime victims, PIP victims should not be denied access to appropriate care and treatment. We have yet to see any real concern for the physical and mental well-being of these vulnerable women.

7.4.3. Update on breast cancer detection

Lavigne et al 2013 warns caution in interpreting conclusions in research paper [Breast cancer detection and survival among women with cosmetic breast implants: systematic review and meta-analysis of observational studies][46] but adds

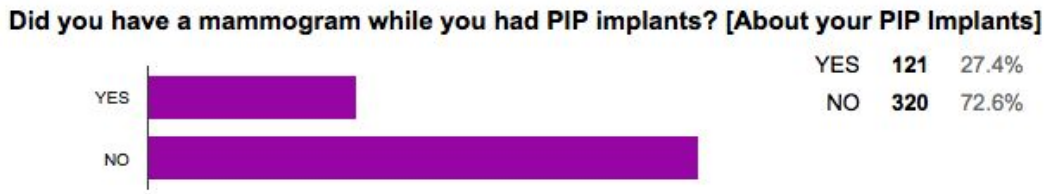
> "The accumulating evidence suggests that women with cosmetic breast implants who develop breast cancer have an increased risk of being diagnosed as having non-localized breast tumors more frequently than do women with breast cancer who do not have implants. Moreover, current evidence also suggests that cosmetic breast implants adversely affect breast cancer specific survival following the diagnosis of such disease.

[46] http://www.bmj.com/content/bmj/346/bmj.f2399.full.pdf

> Further investigations are warranted into the long term effects of cosmetic breast implants on the detection and prognosis of breast cancer, adjusting for potential confounders. "

The scenihr committee has recognised the call for further investigation but has not recommended more research.

Here, however, the Scenihr committee has, in focusing on the author's' concern for caution, overlooked the importance of providing guidance in the use of mammograms for women with PIP implants as well as dismissing very serious concerns raised by Lavigne et al regarding the effect of breast implants on detection and prognosis of breast cancer.



Mammograms & Breast Cancer Screening in women with PIP breast implants

http://www.bmj.com/content/bmj/346/bmj.f2399.full.pdf

> *"The fact that implants may interfere with the early detection of breast cancer is particularly relevant and carries with it important clinical and public health implications.*[47]**"**

Continues

> *"...silicone and saline implants create radio-opaque shadows on mammograms, which impair the visualization of breast tissue. The amount of parenchymal breast tissue obscured at mammography by the implant is known to be between 22% and 83%.*

[47] Breast cancer detection and survival among women with cosmetic breast implants: systematic review and meta-analysis of observational studies

Insufficient compression of the breast to visualize the parenchyma and the production of implant related artifacts on the film can also make interpretation of mammographic examinations difficult in women with augmented breasts. Additionally, capsular contracture, which develops in about 15-20% of women with implants, has been shown to reduce mammographic sensitivity by 30-50%. Furthermore, specific characteristics of breast implants might affect the detection of breast cancer. Specifically, implants placed under the breast glands (subglandular placement), because of their proximity with breast tissue, are suspected to obstruct mammographic visualization of the breast more than those with submuscular placement."

Breast Cancer UK In-utero exposures

"**How are in-utero exposures linked to breast cancer?** There is increasing evidence that in utero exposure to certain EDCs may increase the risk of developing breast cancer later in life. EDCs may delay or inhibit postnatal breast development and cause a lack of response to hormones (16).

They may also cause an increase in breast tissue density, a known risk factor in breast cancer, or increase sensitivity of the breast to carcinogens, thereby increasing breast cancer risk following carcinogen exposure (17). Some EDCs bind to oestrogen receptors and mimic the action of natural oestrogens (18). Binding of oestrogens to their receptors results in increased breast cell division which is thought to explain why lifelong exposure to elevated levels of oestrogens is a known breast cancer risk (19). Furthermore, oestrogen metabolites (breakdown products) may increase mutations and promote cancer (20)."

Breast Cancer UK position: "**Breast Cancer UK is calling for the Government and NHS advice services to publish a comprehensive guide for pregnant woman which explains the potential risk of in utero environmental exposures and their possible effects on the unborn child."**

Biofilm is a major cause of capsular contracture

The opinion, at 7.4.4., postulates "Textured surfaces could cause less contracture than smooth surfaces as a consequence of restricting the influence of fibroblasts." The Scenihr final opinion arrives at several premature and injudicious conclusions, including the now established link between textured implants and biofilm contamination.

> "Previous studies led by Associate Professor Anand Deva of Macquarie University's Australian School of Advanced Medicine have found that bacteria which live in clumps attached to breast implants (termed **biofilm), is a major cause of capsular contracture. Contracture is a painful hardening of the tissue around the implant that can cause physical deformity, pain and is the most common cause for revision surgery following breast augmentation.**
>
> **"Professor Deva's latest study has found that the chronic infection around these infected implants can also lead to an activation of the immune system and the patient's lymphocytes. Long-term stimulation of lymphocytes by this infection may be the stimulus for the transformation of these cells into BIA-ALCL. The infection was shown to be highest around textured breast implants and this may provide an explanation as to why BIA-ALCL seems to be more commonly seen in patients with textured implants.**
>
> "Our previous research has shown that 24 hours after bacteria come into contact with breast implants, textured implants had 72 times the number of bacteria attached to their surface as compared with the smooth implants," said Deva.
>
> "This latest study has shown that the textured implants with the highest numbers of bacteria also had the highest number of activated lymphocytes around them.

> This finding is important and has now become even more relevant since the reporting of BIA-ALCL as it provides us with a possible biological explanation of how this rare cancer could arise."[48]

The Scenihr opinion once again implies that PIP implants are no worse than other CE Marked implants "capsular contracture in PIP implantation does not seem to be excessive compared to other implants"

48

http://www.mq.edu.au/newsroom/2014/11/11/link-found-between-textured-breast-implants-and-rare-cancer/#ixzz4K5RVrpHT

What is in PIP?

This question is posed at several points in the Scenihr report. At ***1.2. Chemical composition of PIP implants***, ***5.2 Composition of Shells***, ***5.3. The contents: Chemical composition and physical properties of PIP implant gels*** and at ***6. TOXICOLOGICAL PROPERTIES OF PIP IMPLANTS***

According to documents obtained from the TGA, PIP claimed it used these products to manufacture its implants:

- Nusil MED6 6400 - for all layers of the envelope
- Nusil MED 6640 - very first glue layer applied to inside of envelope (applied on the mould before dipping)
- Nusil MED 2245 - so called glue - used to form a closure patch
- Nusil MED3 6300 (highly cohesive gel/filling) polydimethylmethylvinylsiloxane **Suppliers curing conditions 5hrs**
- Applied Silicone PN 40076 - used to close filling holes before final gel curing step
- Xylene PURCHASED FROM ANOTHER SUPPLIER (adjust dispersions viscosity)
- Heptane viscosity adjustment and as a solvent for the glue)
- Ethanol (envelopes cleaning)
- Isopropanol (stamp patches cleaning)
- Texturing Agent calibrated saccharose/purified cane sugar
- Hydrogen Peroxide (finished product washing)
- Teflon film (strip to create a filling hole during the closure patch assembly)

The chemical composition of PIP is largely unknown.

In addition to the low molecular weight cyclic siloxanes of the D-series

- C**aesium** (0.3 ppm) was found in PIP silicone but not found in other CE marked brands
- **Platinum** levels in PIP silicone (0.1ppm) lower than levels found in other CE marked brands
- **1,1 ,2,2-Tetrachloroethane** widely used in the production of solvents and pesticides. Its production ended in the 1990s, but it is a major component of waste sites. 1,1 ,2,2-Tetrachloroethane has been found in PIP. In tests "1,1,2,2-tetrachloroethane at doses greater than 590 ppm in the feed was toxic to the liver of male and female rats. **In mice, 1,1 ,2,2-tetrachloroethane was already known to cause cancer after long-term exposure. In these 14-week studies, 1,1 ,2,2-tetrachloroethane was toxic to the livers of male and female mice."**
- **Ethylene Oxide**
- **Cyclic Siloxanes**
- **Xylene**
- **Toluene**
- **DEHP** di-2-ethylexyl phthalate
- **Teflon**
- **Heptane**

European Commission's Role in PIP Health Scandal

Because the findings of the SCENIHR committee have compromised access to diagnostics, care, treatment and monitoring, we believe the European Commission is responsible for putting women and children exposed to PIP at unnecessary risk. It is our firm belief that by using politically motivated 'risk assessments', the European Commission has denied EU women their rights enshrined in **Article 152 of the EC Treaty.**[49] **The European Commission has failed to recognise women's rights and protections.**

If the European Commission again fails to respond to safety concerns raised by peer-reviewed and real-world evidence, and recommend the precautionary removal of all dangerous PIP implants, the European Courts must act to protect the rights of EU women and of other especially vulnerable groups, such as women recovering from or diagnosed with breast cancer, premature babies, women with mental health problems and children.

Women need expensive surgical operations which carry risks to remove leaking and ruptured PIP implants and these operations should be carried out by properly qualified surgeons, in appropriate hospital or clinic settings.

Urgently facilitated financial resources are necessary for some women to access the medical services they still urgently need, but cannot afford.

Others should be urgently reimbursed for costs already incurred. Financing PIP related surgeries has put many families under intolerable financial pressure.

Funding should be made available for cognitive therapies, for on-going research and future monitoring.

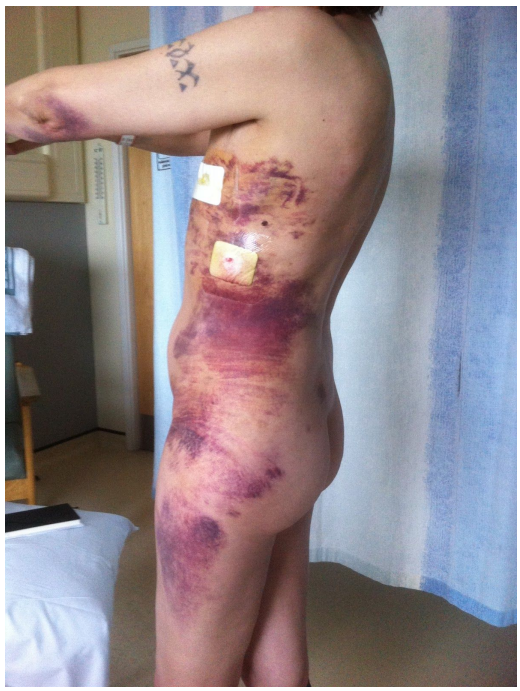
Women exposed to toxic PIP implants need urgent compensation, for the pain and injuries they have suffered and, in some cases, continue to endure.

(photo: breast cancer patient with PIP following capsule removal surgery, internal bleed, hematoma, second emergency surgery, 3 blood transfusions and life threatening pulmonary embolism)

[49] Article 152 of the EC Treaty

Women have rights as consumers, as patients and as victims of a global hate crime. We will expect the European Courts of Justice to ensure women's rights and order redress, accountability and justice for all women exposed to dangerous PIP implants.

PIP was operating with a CE Mark, issued by a European Notified Body which has not invoked its public liability cover. The manufacturer is still appealing criminal conviction.



The failure of the Scenihr committee to enact the 'precautionary principle' to protect exposed women and their children from the unknown present and future consequences of fraudulent PIP implants is a matter of great concern.

From the time of the publication of the Scenihr Opinion, it was immediately obvious that it had been compiled deliberately and cynically, under the strong political influence of the UK Competent Authority and Health Regulator, to imply PIP implants have a clean bill of health, to avoid accountability and spending in respect of the damages and the dangers to the women and children exposed to them.

European Community & Public Health

> "Treaty establishing the European Community (Amsterdam consolidated version)[50]
>
> Article 152
>
> 1. A high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities."

[50] http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A11997E152

The standard of inquiry into the dangers of PIP implants by the Scenihr committee has been an enormous disappointment, not only to women exposed to PIP but to the healthcare professionals treating them.

The findings of the Scenihr have resulted in obstacles to healthcare, lack of information or updates for women and medical professionals treating them. No research or monitoring of women with PIP was included in the Scenihr opinion recommendations. Nor recommendations for guidance or information or any financial support for PIP revision or removal surgery or therapies.

In 2012, the European Parliament in adopted texts[51] made clear reference to **"the need for a system of collective redress designed to help consumers and patients to obtain compensation".** More than 100,000 EU Women exposed to toxic PIP implants are consumers, patients and victims of PIP health fraud, they should be able to expect redress, compensation and access to justice.

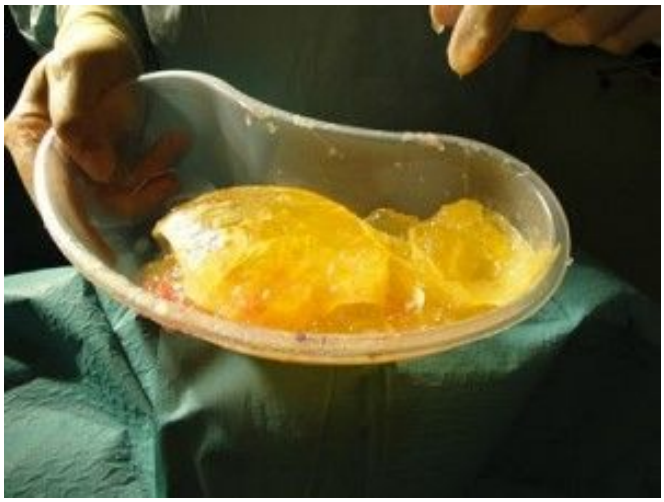
[51] http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P7-TA-2012-0262+0+DOC+XML+V0//EN

In the Public Interest

Detailed information about PIP and the production methods' must never be withheld from review. Women and children's lives are at stake!

> "A court trial against the owner and director of the PIP factory is ongoing and as a consequence **certain detailed information about the PIP implants and production methods is part of this trial and therefore not available in the development of this opinion."**

Women and children exposed to PIP implants are being treated differently throughout the EU. A Public Inquiry into the lack of help, support, information, advice and financial resources for PIP exposed women, is necessary to deal with the past mistakes while urgent action is still needed in the present and future contexts. Many thousands of women and their families have been affected by dangerous PIP implants.



Women who have been suffering unnecessary physical and mental consequences for the six years since the PIP factory was closed by the authorities, need immediate access to professional and medical help, they need fully-funded and resourced facilities to help, advise, support and monitor them and their PIP exposed children.

All dangerous leaking and ruptured PIP implants must be removed as a precaution and urgent action to help, focused on the exposed women and children, is necessary.

PIP Action Campaign's 'REAL WORLD' evidence is a call to the European Parliament to act without further delay to protect all those exposed to PIP implants.

Women with PIP expect the Notified Body in this case, TÜV Rheinland, to enact civil liability insurance without further delay.

Now the European Commission must act to protect all those exposed to PIP implants and respect the rights of all the women under Article 152 of the EC Treaty to ensure access to: diagnostics, care, treatment and to the financial resources women need to preventatively remove **all banned PIP implants**. There is a clear requirement for ongoing research and monitoring of women and children exposed to criminal PIP implants and an urgency to provide all EU women an accessible route to redress and compensation. There is an urgent need for truthful and reliable information to be communicated to the women affected.

The past 4-6 years will have been the most traumatic and challenging in the lives of many young women and mothers. It is a scandal that the European Commission have nothing to help, inform, or support women affected. When a mother is sick, the family suffers. Women and children are suffering. The time for action is now.

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Ends

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APPENDIX A

Call for information on PIP Implants

APPENDIX B

Call for information on BIA-ALCL

APPENDIX C

Public Consultation on D4 and D5

http://pipactioncampaign.org/PIPActionCampaignECHAsubmission.pdf

APPENDIX D

Summary of Responses from PIP Mums

http://pipactioncampaign.org/PIPMumsResults.pdf