PIP IMPLANTS



SERIOUS & AVOIDABLE HARMS

PUBLIC INQUIRY • ACCOUNTABILITY • CLINICAL RESET

OCTOBER 2026

Contents

Submission to the Prime Minister and Dame Diana Johnson

PIP Action Campaign seeks a statutory public inquiry and an urgent national PIP Clinical Reset. The three parts bring together the harms evidence, the accountability case and the clinical action proposed by the Campaign.

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The serious and potential harms that require independent investigation.

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PART II The Anatomy of Institutional Self-Certification

The accountability case and the complete 49-sentence evidentiary rebuttal.

Separate document

PART III The PIP (Action) Implant Guide

The Campaign's proposed national Clinical Reset and care standard.

Separate document

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October 2026

PART I



Serious & Avoidable Harms to Women and Children

Documented injury, unresolved chemical and intergenerational risks, women's rights, medical misogyny and the case for a statutory public inquiry

Serious harm is not a future hypothesis. It is already recorded in explant studies, regulatory surveillance, pathology, surgery, cancer reporting and women's lived experience.

Jan Spivey on behalf of PIP Action Campaign

October 2026

PUBLICATION NOTE

Purpose, scope and evidential discipline

This report is submitted in support of the PIP Action Campaign's call for a statutory public inquiry into the United Kingdom's regulation and management of Poly Implant Prothèse (PIP) breast implants. It is Part I of this three-part report. Part I addresses harms to women and their rights. Part II addresses regulatory conduct, accountability and the institutional case for inquiry. Part III sets out the PIP Action Campaign's proposed national Clinical Reset through the PIP (Action) Implant Guide.

The report distinguishes between: (1) documented PIP-specific harm; (2) documented breast-implant harm directly relevant to women with a history of PIP exposure; (3) serious potential harm for which the State did not create the evidence needed to give a safe answer; and (4) consequential institutional harm caused by delay, fragmented care, inadequate records, dismissal and the transfer of uncertainty back onto women.

Language and evidence rule

The evidence speaks for itself. This report records documented injury, exposure and harm in published research, regulatory data, pathology, surgery, cancer reporting and women's lived experience. The evidence is presented cumulatively and in context. Gaps created by absent registries, fragmented records, inadequate follow-up and failures to investigate are evidence of systemic failure. They cannot be converted into reassurance or used to diminish the harms experienced by women and children.

Image notice

Several figures were supplied by affected women and the PIP Action Campaign. Some show explanted devices, bodily changes and surgical injury. They are included because the physical reality of harm should not be sanitised.

Citation format

References appear in square brackets. The bibliography prints complete plain-text web addresses so that sources remain visible. Access dates are September 2026 unless otherwise stated.

Report structure

Part	Purpose
Executive finding	The documented harms and the action required
1. The originating wrong	Fraudulent manufacture and uncontrolled exposure
2. Mechanical failure and chemical movement	Rupture, gel bleed, permeability and migration
3. Documented clinical harm	Inflammation, siliconomas, saturated lymph nodes, pain and tissue damage
4. Surgical and reconstructive harm	Complex removal, repeated operations and loss of tissue
5. Implant-associated cancers	BIA-ALCL, BIA-DLBCL and BIA-SCC: distinct implant-capsule malignancies requiring specialist pathology, reporting and lifetime implant histories
6. Pregnancy, breast feeding and children	Credible exposure questions left unresolved
7. Systemic, psychological, social and economic harm	Whole-life consequences
8. Medical misogyny and institutional gaslighting	How uncertainty was weaponised against women
9. Women's and children's rights	Safety, dignity, information, bodily integrity and remedy
10. Australia as a warning	Disproportionate BIA-ALCL reporting and the shared response pattern
11. Why a statutory public inquiry is required	Serious and potential harms and urgent measures
Annexes	Evidence matrix, chronology, recommendations and sources

SECTION —

Executive finding

PIP harm was not simply “rupture”. It was exposure to fraudulently manufactured implantable devices, followed by tissue contamination, inflammatory disease, difficult surgery, cancer risk, unresolved reproductive questions and institutional abandonment.

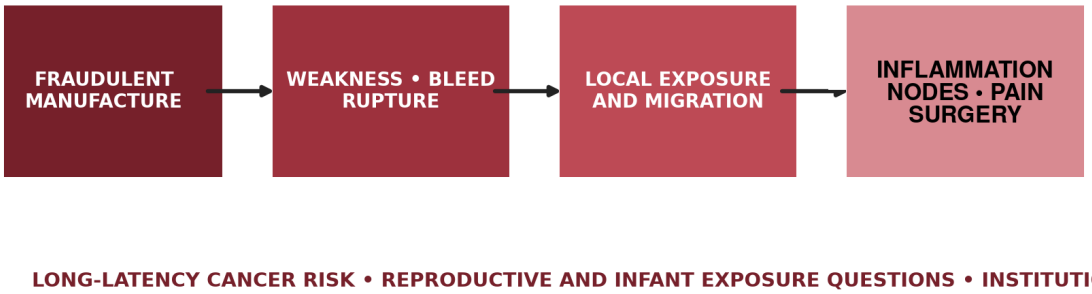


Figure 1. The cumulative chain of PIP harm. Each stage is independently relevant to patient safety; together they require a whole-system investigation.

The conclusion

Serious harm to women is established. PIP implants were fraudulently filled with unauthorised material. Published studies and regulator datasets record premature device failure, disintegration, gel escape, inflammatory reactions, capsular contracture, siliconomas, lymph-node disease, implant and other cancers, pain, lumps, seroma, repeated and technically demanding surgery, and psychological injury. PIP-specific uncertainty remains about long-term systemic, reproductive and intergenerational outcomes because the UK government failed to build the cohort, exposure and follow-up systems capable of answering those questions.

The State may say that a particular outcome has not been proved. It cannot honestly convert a failure to investigate into proof that the outcome did not occur. That distinction is decisive for women who were exposed without informed consent and then told that the absence of long-term evidence should reassure them.

Seven core findings

- **Fraudulent exposure is itself a patient-safety wrong.** Women consented to a regulated medical implant, not to unauthorised industrial raw materials and uncontrolled chemical heterogeneity.
- **PIP devices failed, leaked and disintegrated.** France’s month-by-month national vigilance evidence recorded 3,290 women with ruptures and 1,957 with inflammatory reactions by October 2012; 21–22% of preventive explantations revealed abnormalities despite no clinical signs. French explant studies documented early “perspiration” or gel bleed. This was leakage and device failure—not rupture alone. [3][4][5][8][12]

- **The contents do not remain neatly inside the implant pocket.** PIP-derived material and silicone-associated inflammation have been documented in capsule, periprosthetic fluid and regional lymph nodes. Chemical work described a silicone/serum microemulsion capable of lymphatic migration. [9][10]
- **The burden extends beyond a device exchange.** Women may require capsulectomy, debridement, granuloma or lymph-node surgery, reconstruction and repeated procedures, with no guarantee that migrated material can be recovered.
- **Cancer surveillance must follow the woman's lifetime implant history.** BIA-ALCL is a recognised malignancy associated predominantly with textured implants. PIP devices included textured and microtextured models. BIA-DLBCL, BIA-SCC and other capsule cancers are separately emerging. A count restricted to the implant present at diagnosis obscures prior PIP exposure. [18][21]
- **Pregnancy and breast feeding questions were not responsibly answered. Limited Swedish sample testing found materially elevated cyclic siloxanes in samples classified as PIP2 and showed that small hydrophobic molecules can move across the shell. D4, D5 and D6 have also been measured in human breast milk. The evidence establishes a chemical exposure pathway and an urgent duty to investigate harm to babies and children. [13][14][15]**
- **Dismissal compounded physical harm.** The Women and Equalities Committee recorded limited long-term research, inadequate follow-up and women's reports of dismissal. It expressly rejected the logic that lack of a definitive link means there is no connection. [1]

Immediate demand

A statutory public inquiry is required

Only a statutory inquiry can compel and test the complete record across government, regulators, manufacturers, notified bodies, clinicians, private providers and the NHS; reconstruct what was known and when; examine why conflicting international evidence was discounted; establish the true clinical cohort; and recommend treatment, surveillance, research and redress.

SECTION 1

The originating wrong: fraudulent manufacture

PIP women were not exposed to an ordinary product complication. They were exposed to a medical-device fraud.

PIP substituted unauthorised material for the approved medical-grade gel used to obtain CE conformity marking. The fraud defeated informed consent, traceability, risk assessment and post-market surveillance at the starting point. The exposure itself was non-consensual and outside the certified product specification.

What the Swedish Medical Products Agency found

The Swedish Medical Products Agency (national regulator) had access to more than 600 *unused* implants and acquired 46 explants, still the chemical testing was limited: 14 unused implants were tested, and its D4/D5/D6 table reports five samples classified as PIP-Nusil and six classified as PIP2. The Agency defined PIP-Nusil as based on NuSil MED3-6300—the 'medical-grade' raw material specified in PIP's CE-marking file. Its testing ***did not identify the PIP2 base raw material***; the Agency stated that, **if** NuSil was used, other raw materials had been added. ***These classifications do not establish separate product populations or a compliant PIP manufacturing stream***. [13]

The explanted gel could change character: rather than remaining cohesive, it could disintegrate into smaller particles and incorporate material derived from body fluids. The Agency also found cholesterol within the gel, supporting movement across the shell. It concluded that chemical molecules could move into—and consequently out of—the implant. [13]

Evidence	What it establishes
Fraudulent substitution	The implanted product was not the product women were told had been approved.
Unauthorised and variable gel chemistry	PIP devices were outside the certified specification; limited sample tests cannot define every implant or every woman's exposure.
Elevated D4/D5/D6 in limited PIP2 samples	The tested samples contained markedly elevated cyclic siloxanes and required exposure assessment.
Movement through the shell – PIPs Leak	Intact appearance does not eliminate exposure through diffusion or gel bleed.

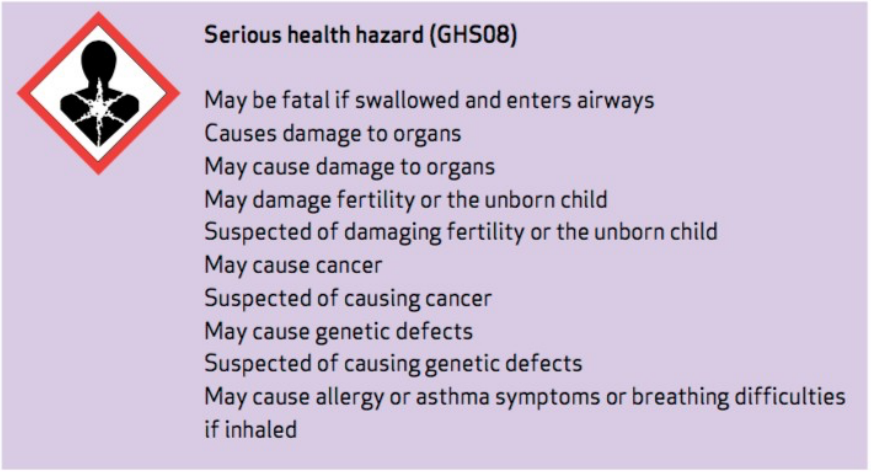


Figure 2. GHS08 serious-health-hazard pictogram: hazard communication for D4 found at elevated levels.

D4: Octamethylcyclotetrasiloxane
CAS number: 556-67-2. ECHA

D4 has a harmonised European classification as suspected of damaging fertility. Elevated D4 in the limited samples classified as PIP2 created a foreseeable duty to investigate exposure, dose, pregnancy, breast-feeding and long-term health. [15]

A 2012 European Commission letter to PIP Action Campaign recorded D4 as Reproductive Toxicity Category 2 (H361f: suspected of damaging fertility). It stated that the updated SCENIHR opinion on PIP implants should assess the potential risk presented by D4, and recorded the UK competent authorities' proposal that D4 could meet the REACH Annex XIII criteria for both a persistent, bioaccumulative and toxic (PBT) substance and a very persistent and very bioaccumulative (vPvB) substance. [39]

The Swedish Medical Products Agency table reports a limited sample set: five implant or explant samples classified as MX (PIP-Nusil) and six classified as TX (PIP2). PIP-Nusil denotes material based on NuSil MED3-6300, the 'medical-grade' raw material specified in PIP's CE-marking file. PIP2 is the Agency's analytical classification label; it is not evidence of a separate legitimate PIP product line.

LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Table 1 shows the amount in ppm of cyclosiloxanes, with four, five and six dimethylsiloxanes groups in the ring (D4, D5 and D6) found in gels and shells of PIP implants / explants.

	Gel - MX (PIP-Nusil)			Shell - MX (PIP-Nusil)		
Sample LOT	**D4 ppm**	**D5 ppm**	**D 6 ppm**	**D4 ppm**	**D5 ppm**	**D6 ppm**
Implant 06707	nd	nd	nd	nd	nd	nd
Implant 02707	nd	nd	39	14	28	48
Explant 02707 ruptured	nd	18	30	nd	nd	nd
Explant 02707 non-ruptured	nd	8	13	nd	4	nd
Explant 12108 non-ruptured	nd	55	71	nd	23	nd
	Gel -TX (PIP2)			Shell-TX (PIP2)		
Sample LOT	**D4 ppm**	**D5 ppm**	**D 6 ppm**	**D4 ppm**	**D5 ppm**	**D6 ppm**
Implant 36309	107	499	777	73	375	531
Implant 42307	73	310	436	50	218	304
Explant 68707 Non-ruptured	77	362	534	25	125	189
Explant 68707 ruptured	106	435	614	38	160	223
Implant 57707	120 (8.4)	427 (5.8)	570 (2.8)	66 (11.5)	270 (2.0)	380 (1.0)
Explant 57707 ruptured	134 (4.9)	457 (8.0)	604 (7.1)	95 (7.4)	332 (13.9)	431 (12.2)

Table 1. Amounts in ppm of cyclosiloxanes (D4, D5 and D6) in gels and shells of PIP implants and explants (Table C and F). "nd "stands for not detected. Numbers within brackets: RSD, relative standard deviation on triplicates. Yellow marked rows show results from samples matched from same LOT numbers

Figure 3. Swedish Medical Products Agency Table 1: limited testing of five samples classified as PIP-Nusil and six classified as PIP2, reporting D4, D5 and D6 in gel and shells. Yellow rows are samples matched by LOT number. The labels are analytical classifications, not patient subgroups or proof of a compliant PIP production stream. [13]

SECTION 2

Mechanical failure and chemical movement

All PIP implants leak irrespective of rupture. Low-molecular-weight chemicals pass through even an apparently intact shell by gel bleed and diffusion; the question is not only where that material goes, but also what tissues are exposed to it, what effect it has on different tissues, on the reproductive systems of biological men and women and their children, what are the long term effects and what remains in the body.

As early as 2013, a published PIP series repeatedly reported rupture, disintegration and clinically occult failure. Quaba and Quaba reported 144 ruptured implants among 676 explanted devices in 338 women: 21.3% per implant and 35.2% per woman at a mean 7.8 years. [7] Chummun and McLean found 17 ruptures among 78 implants (21.8%); and 15 were totally disintegrated. [6]

France counted, published and acted nationally. On 23 December 2011, the French Health Ministry instructed regional agencies to offer every woman preventive explantation even without clinical signs. [58] ANSM then published cumulative national findings month by month: preventive explantations rose from 7,511 in June 2012 - 10,042 in October - 12,599 in September 2013 and 13,073 by April 2014. ***In the later national reviews, implant dysfunction and/or adverse effects not detected before surgery were found in 20% of preventive explantations. France treated intact PIP implants as a national preventive-health problem.*** The UK decided against routine preventive removal, substituted the narrower 'NHS Offer', and did not establish equivalent national reporting of rupture, inflammation and findings at explantation. [3][4][5][16][17] [41][42][43]

Date of French national update	Cumulative preventive explantations
June 2012	7,511
October 2012	10,042
September 2013	12,599
April 2014	13,073

Where do the chemicals go?

- **Into the implant pocket and capsule.** Escaped gel contacts the fibrous capsule and surrounding breast tissue, where it can provoke inflammation, granuloma and contracture.
- **Along lymphatic drainage pathways.** Silicone-containing material can reach axillary, internal mammary and more distant lymph nodes. PIP periprosthetic fluid has been chemically characterised as a silicone/serum *micro-emulsion* capable of lymphatic migration. [9]
- **Into tissue that cannot simply be "washed out".** Microscopic droplets and particles can infiltrate tissue planes. Surgery may remove an implant and the capsule but it cannot guarantee removal of all migrated material.
- **Across an intact shell.** Gel bleed and diffusion of low-molecular-weight compounds occur irrespective of rupture. Swedish testing and later shell analysis document the mobility of low-molecular-weight silicones in PIP material. [11][13]
- **Into an evidence gap**. The failure to map the distribution and persistence of escaped PIP chemicals is separate from the recognised toxicity of D4. Serial imaging, tissue chemistry, lymph-node pathology, biomonitoring and long-term follow-up—including surveillance for BIA-ALCL, BIA-SCC and BIA-DLBCL—were and are required. [15][18][22][40]

The answer in one sentence

Escaped chemicals in PIP material can accumulate in the capsule, breast tissue and lymph nodes, travel through lymphatic pathways, become incorporated into inflammatory lesions and remain in the body long after explantation.

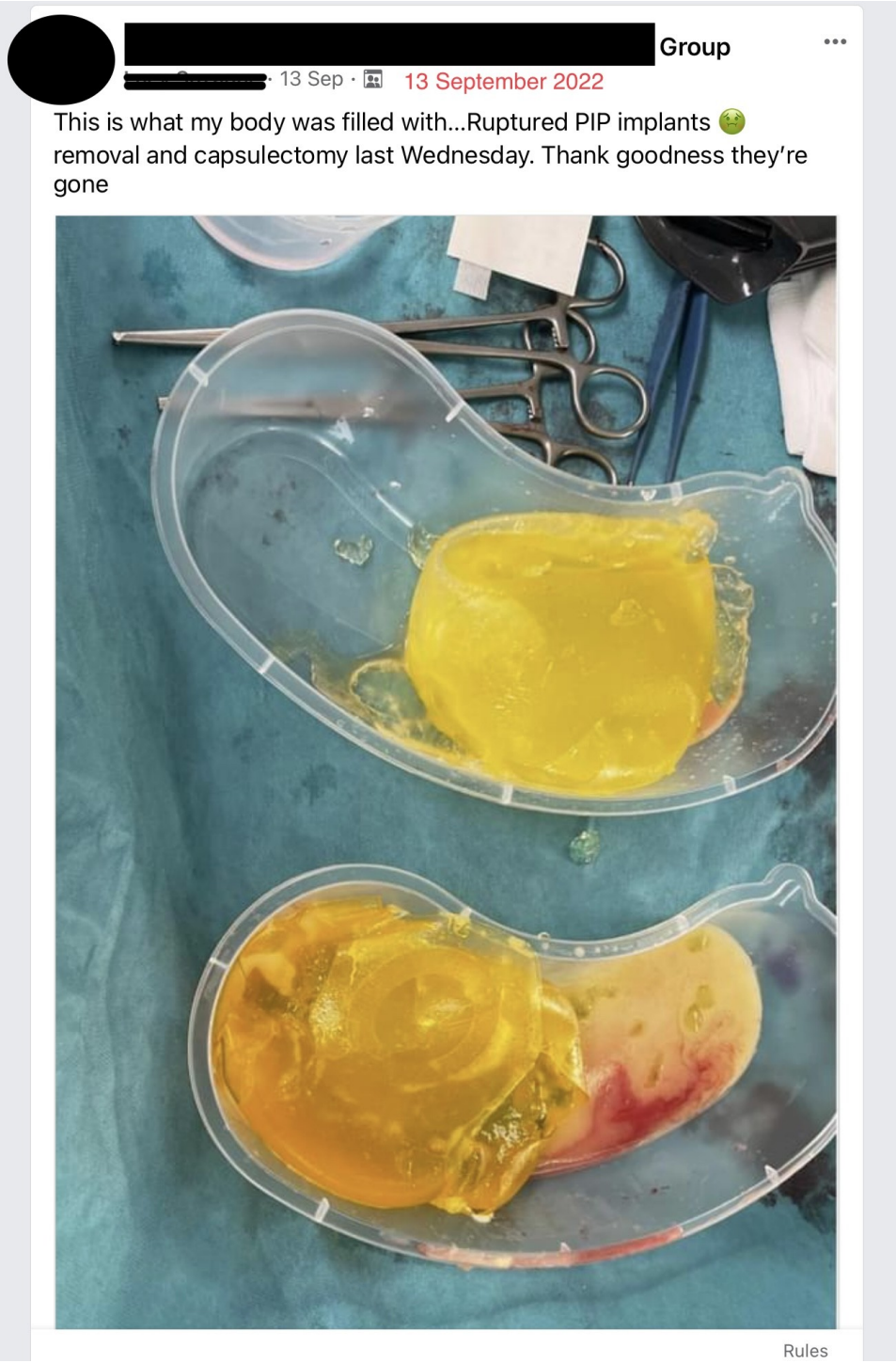


Figure 4. Campaign-supplied image of explanted PIP material and device deterioration. Characteristic "milky" peri-prosthetic fluid associated with PIP implants. Referred to by Keogh Final Expert Report (2012) as "a suspension of silicones in water", paragraph 9. [16]



Figure 5. Campaign-supplied clinical image of a ruptured/disintegrated explant. Device removal does not establish that all migrated material has been removed.

SECTION 3

Documented clinical harm

French surveillance recorded thousands of women with rupture and inflammatory reactions, including women without warning symptoms.

By October 2012, the French regulator ANSM reported 3,290 women with rupture, 1,957 women with inflammatory reactions, and 4,647 women with rupture and/or inflammatory reaction. Reported local complications included severe capsular contracture, siliconoma, inflammation or infection, adenopathy, lymphorrhoea and necrosis. [3][4][5]

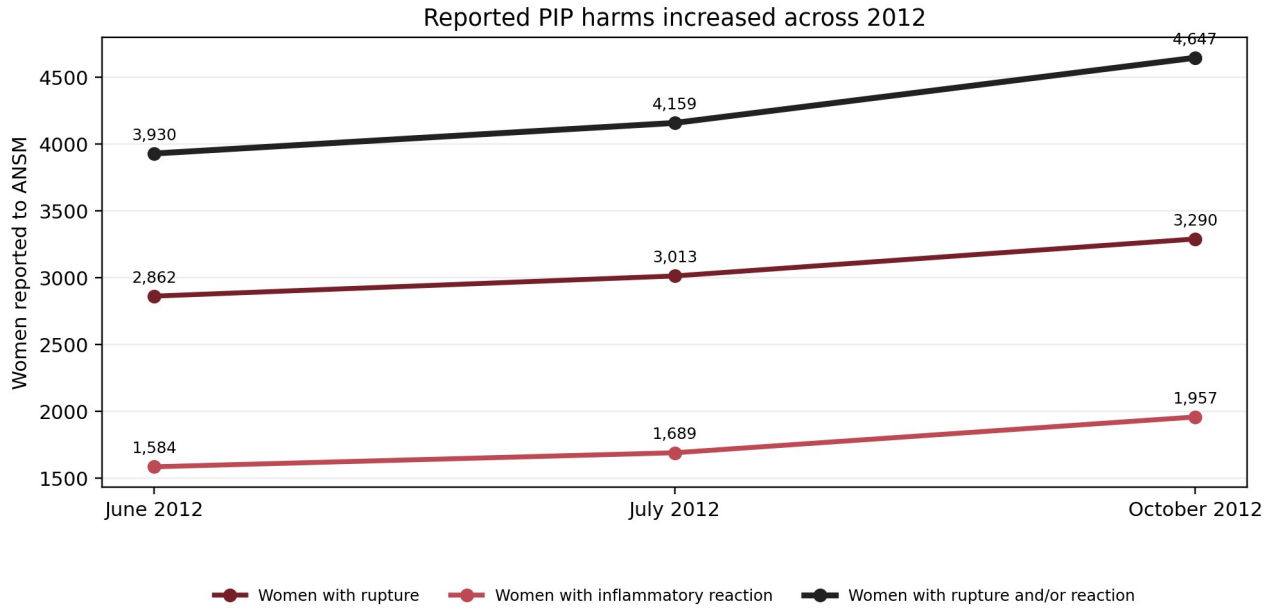


Figure 6. Cumulative reports in ANSM updates supplied to the Campaign, June–October 2012. These are surveillance counts, not population incidence estimates.

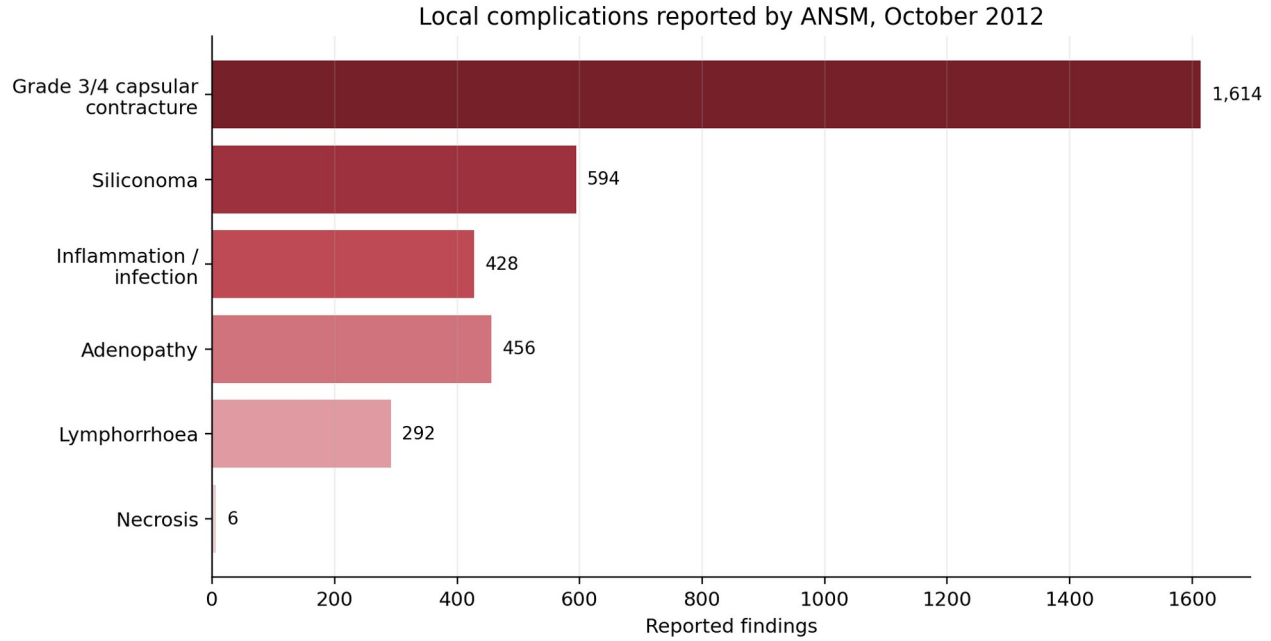


Figure 7. Local complications recorded by ANSM in October 2012. Categories may overlap within the same woman.

ANSM reported median intervals of approximately six years to rupture and 5 years 9 months to inflammatory reaction. By October 2012, preventive explantation found an abnormality or local inflammatory reaction in 21% of women without clinical signs. [5]

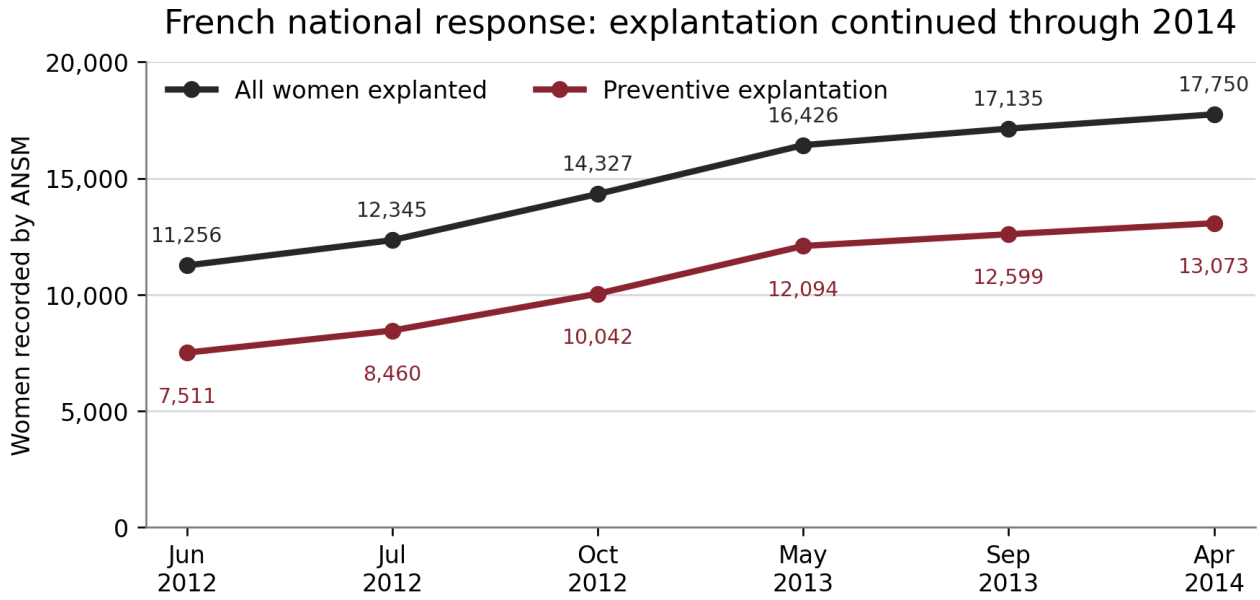


Figure 8. ANSM national surveillance: cumulative women explanted and preventively explanted, June 2012-April 2014. Later national reviews found previously undetected implant dysfunction and/or adverse effects in 20% of preventive explantations. [3][4][5][41][42][43]

The harm categories

Harm	Clinical expression	Consequences
Rupture / disintegration	Loss of shell integrity, fragmented gel, altered breast	Exposure, imaging, explantation, uncertainty about residual material
Inflammation / granuloma	Pain, swelling, nodules, erythema, seroma, tissue reaction	Biopsy, pathology, surgery; lesions may mimic malignancy
Capsular contracture	Hardening, distortion, pain; severe grades 3 –4	Functional and aesthetic injury; capsulectomy or revision
Silicone lymphadenopathy	Enlarged or painful nodes containing silicone-associated material	Diagnostic work-up; possible node excision; altered cancer assessment
Infection / necrosis / wound injury	Local infection, tissue breakdown, impaired healing	Antibiotics, debridement, hospital care, scarring
Persistent pain and sensory change	Breast, chest-wall, axillary or scar pain; hypersensitivity or numbness	Reduced sleep, work, mobility, intimacy and quality of life

The body is evidence

Women's photographs are contemporaneous evidence of lived bodily harm that should be linked to clinical notes, imaging, operative findings, explant analysis and pathology—not dismissed because the regulator failed to construct a national dataset.

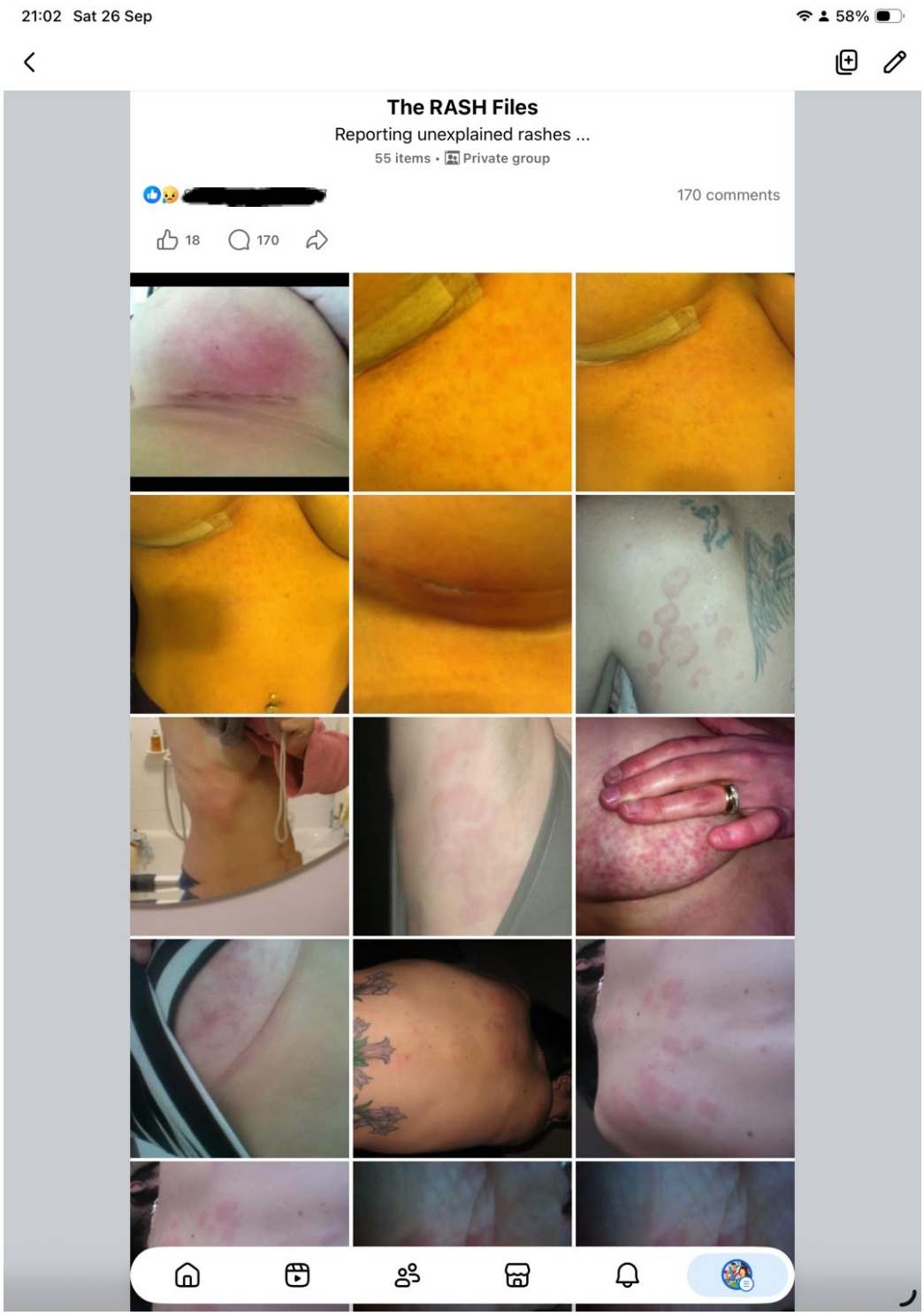


Figure 9a. Campaign-supplied clinical image. It illustrates bodily change and injury reported by affected women.



Figure 9b. Campaign-supplied clinical image. The public inquiry should establish a protected process for matching such evidence to medical records and outcomes.

SECTION 4

Surgical and reconstructive harm

“Remove and replace” understates the operative burden created by contamination, inflammation, scarring and lost tissue.

PIP injury can transform implant removal or exchange into difficult revision surgery. Surgeons may encounter peri-prosthetic fluid, fragmented gel, adherent capsule, granuloma, calcification, cancer, tissue infiltration and lymph-node disease. Total capsulectomy, debridement, lavage, granuloma excision, node biopsy or excision and reconstruction may be considered according to individual findings. Published reports describe technically demanding and prolonged surgery. [7][9][10]

- **Multiple operations.** Initial implantation, investigation, explantation, revision, reconstruction and later cancer or lymph-node procedures can produce a lifetime surgical burden.
- **Irrecoverable material.** Explantation removes the device; it does not guarantee complete removal of gel, microscopic silicone, granuloma or material in distant nodes.
- **Loss of tissue and sensation.** Capsulectomy and debridement can remove or damage healthy tissue, alter the breast envelope, and affect nipple or skin sensation.
- **Reconstruction inequality.** Women implanted after cancer surgery and women who paid privately may face different access routes, costs and thresholds for removal and reconstruction.
- **Pathology failure.** If capsule, fluid and nodes are discarded, incompletely sampled or not tested under an appropriate cancer pathway, both the woman and the surveillance system lose evidence.

A public-health response cannot depend on the MHRA for clinical leadership

The MHRA is a product regulator, not the national clinical service women require. Women need a nationally commissioned, clinically led pathway that includes complete operative records, implant identification, imaging, pathology, symptom follow-up, reconstruction, pain management, cancer vigilance and a funded route back into specialist care.

The FDA illustrates possible changes to breast appearance following implant removal without replacement. Fear of disfigurement, distress about body image and existing mental health difficulties must be addressed within the removal pathway, with access to psychological support and discussion of reconstructive options.

SECTION 5

Implant-associated cancers

Cancer risk must be analysed by a woman's entire implant history—including PIP—not only the device present on the day of diagnosis.

BIA-ALCL: a recognised serious harm, outdated reassurance and PIP erasure

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BIA-ALCL: a recognised serious harm. Missed and late diagnoses

Breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) is a lymphoma arising around a breast implant, commonly in the surrounding fluid or capsule. It can extend to lymph nodes and other organs and has caused deaths. Women's risk information and diagnostic assessment must include their entire implant history, including previous PIP exposure. [18][19]

Howe's chronology records that, on 6 December 2011, AFSSAPS formally notified competent authorities of an ALCL death in a woman with PIP implants and urgently requested information on adverse effects and lymphoma. The same chronology records an MHRA official advising against publishing its position because women might conclude that there was a link. [58]

France recommended preventive removal of PIP implants on 23 December 2011. AFSSAPS surveillance dated 28 December explicitly recorded malignancies in women with current or previous PIP implants, including one breast ALCL report. Emerging cancer concerns formed part of the national response alongside rupture and inflammatory complications. [58][59]

Keogh acknowledged lymphoma risk in a footnote. The June 2012 final report mentions anaplastic large cell lymphoma once, in footnote b on printed page 4. It acknowledges a slight excess risk associated with breast implants while stating that there was no evidence of an additional risk from PIP compared with other implants. That comparison does not exclude women with PIP implants from the acknowledged lymphoma risk. [16]

WHO formally recognised BIA-ALCL in 2016; the revised classification volume was published by IARC in 2017. Yet the NHS article captured on 14 February 2020 retained the headline "PIP implant breast cancer link ruled out" and described the ALCL death as "just a tragic coincidence". The capture documents the persistence of this reassurance after formal recognition of the disease. [60][61]

PIP-specific reassurance was allowed to persist without the clear updates women and their health professionals needed.

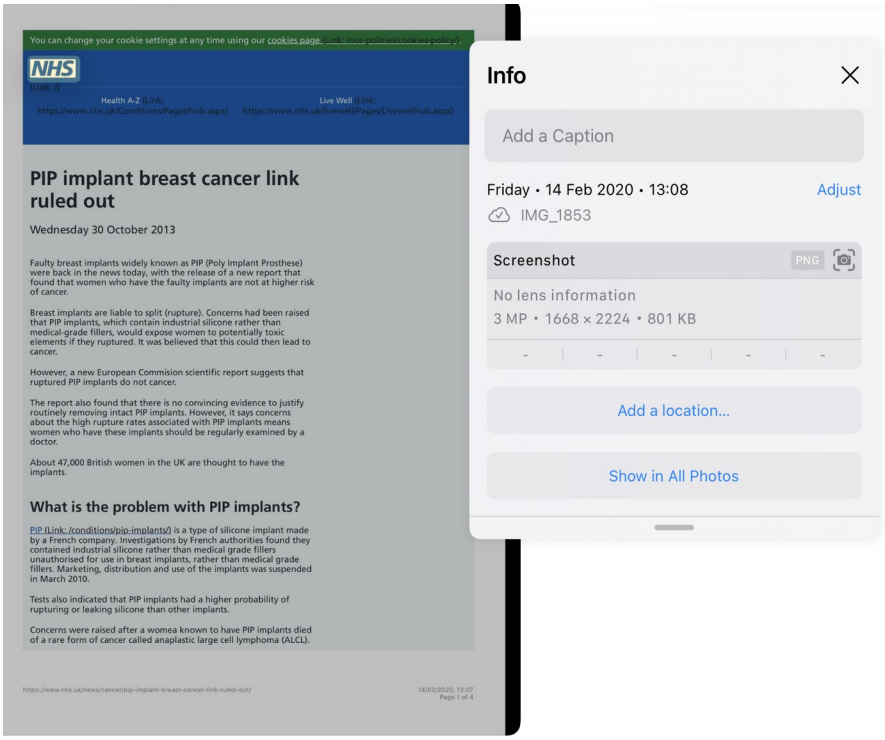


Figure 9c. NHS "tragic coincidence" reassurance retained into 2020. The NHS Choices (the only official PIP information) dated 30 October 2013 and captured on 14 February 2020, described an ALCL death in a woman with PIP implants as "just a tragic coincidence". This dismissal persisted even after WHO formally recognised BIA-ALCL in 2016. Source: Campaign-held NHS article capture.

Latency makes previous exposure essential. The Campaign-supplied PROFILE presentation records multiple-device exposure in 63% of its 238 cases, with mean exposure of 9.2 years to the current implant and 12.8 years to any implant. A woman diagnosed after replacement surgery may therefore have an exposure history extending well before the implant present at diagnosis. [44]

The separate Matros study, published in March 2021, projected a possible case peak in 2026 or thereafter from textured-implant use and an assumed median ten-year interval. Its relevance here is the need for sustained surveillance over long periods, rather than treating the end of sales or an implant exchange as the end of the diagnostic question. [62]

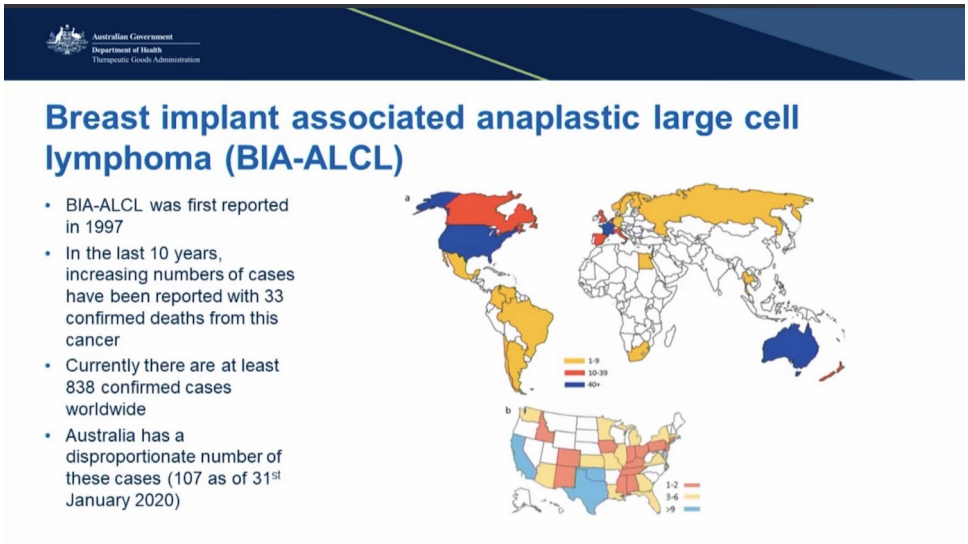
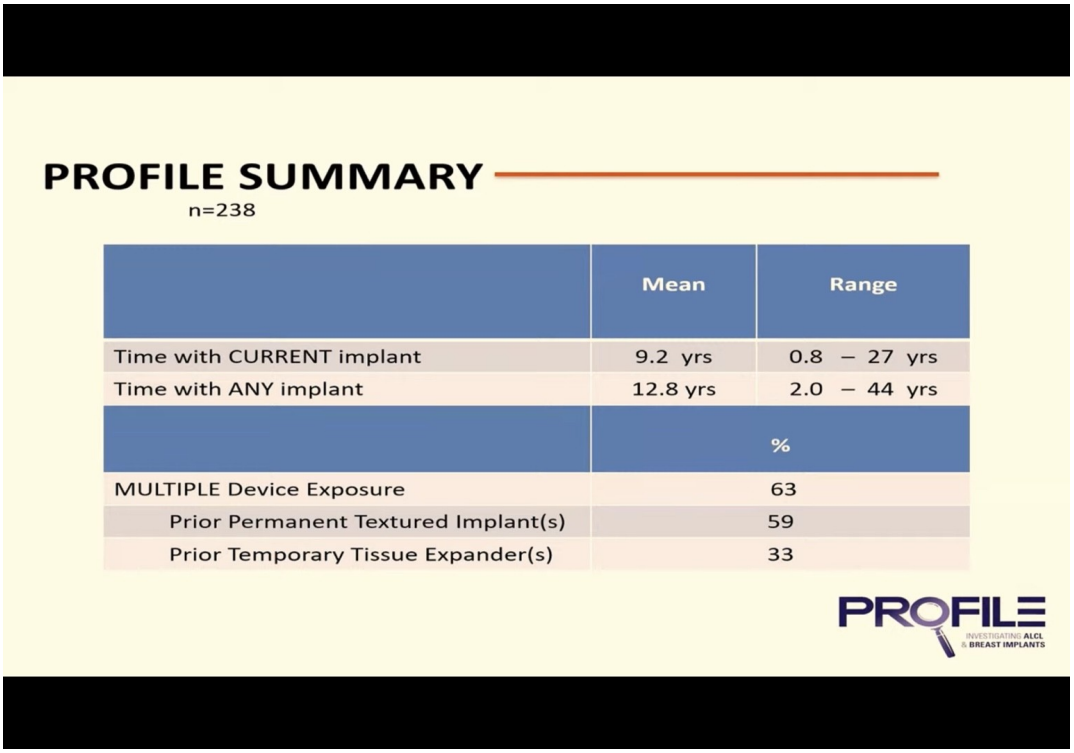
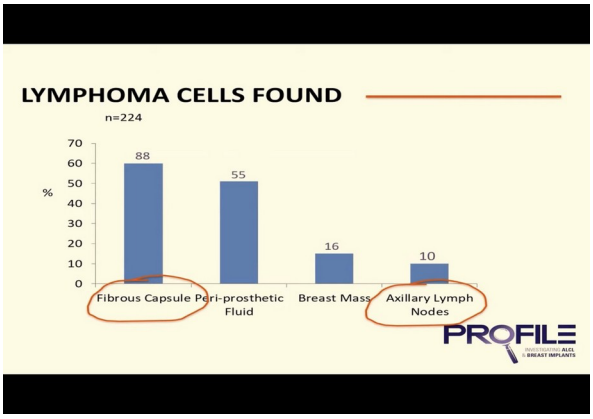


Figure 10. TGA presentation slide supplied by the Campaign: 107 Australian BIA-ALCL cases as at 31 January 2020, against 838 confirmed cases worldwide at the time. The slide illustrates Australia's disproportionate reporting burden; current totals require live regulator data. Australia has a large PIP exposed cohort.

BIA-ALCL exposure, presentation and projected burden





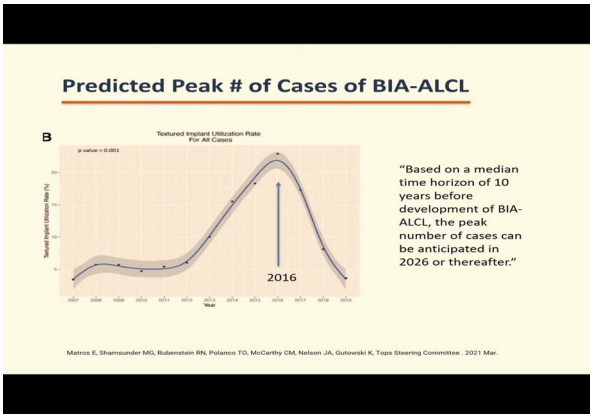


Figure 11. FDA's PROFILE BIA-ALCL evidence supplied by the Campaign: 63% multiple-device exposure; mean exposure of 9.2 years to the current implant and 12.8 years to any implant; lymphoma cells identified in fibrous capsule, peri-prosthetic fluid, breast mass and axillary lymph nodes. [44] The separate projection of a possible case peak in 2026 or thereafter, based on a median ten-year time horizon, is from Matros et al. [62]



Figure 12. MHRA presentation slide supplied by the Campaign, data to 31 December 2023: 117 reports meeting WHO diagnostic criteria, estimated UK incidence 1:16,500 implants, average time to diagnosis 8 years 11 months, and one reported fatal outcome.

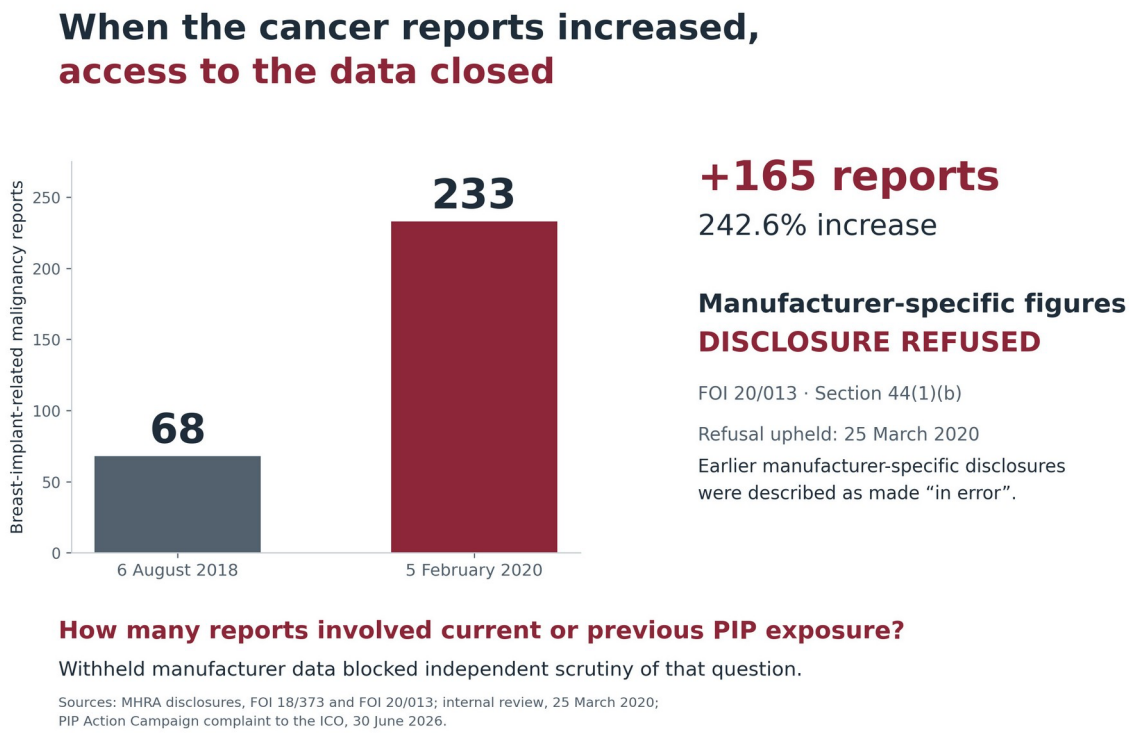
The MHRA position to the Women and Equalities Committee

The Department of Health and Social Care/MHRA evidence to the Women and Equalities Committee stated that there was no evidence that PIP implants presented a greater BIA-ALCL risk than other breast implants. [2] DHSC acknowledges seven confirmed BIA-ALCL reports in women who previously had PIP implants, yet offers reassurance by stressing that no confirmed reports involved women who had “only ever” had PIP. The Campaign calls this a redefinition of “multiple exposure” risk intended to erase women’s previous PIP implant exposure history once they have received another brand.

A cancer diagnosed after a later implant may still follow a lifetime history that includes PIP texture, PIP rupture, chronic inflammation or PIP-derived material.

When the cancer reports increased, access to the data closed

When the Campaign requested the updated manufacturer-specific figures under FOI 20/013, the MHRA refused disclosure under section 44(1)(b) of the Freedom of Information Act. Its internal review of 25 March 2020 upheld the refusal and stated that earlier manufacturer-specific disclosures had been made in error. [57]



The refusal prevented women, clinicians and researchers from determining whether current PIP exposure, previous PIP exposure, retained PIP capsules or multiple-device histories were represented within the increased cancer reports. It blocked scrutiny of the signal by manufacturer and lifetime implant history. This is not an absence of evidence. It is the denial of access to the data required to examine a public-health signal.

Access to the underlying evidence is part of the harm. The withheld data must be available so the increase in malignancy reports can be examined by manufacturer, current and previous exposure, retained capsule and lifetime implant history, and so its consequences for warnings, surveillance and diagnosis can be established.

The denominator problem: the real-world groups at risk

Risk does not end when an implant is removed. Any PIP-specific assessment must include:

- Some women have had their PIP implants removed.
- Many women have had PIP implants removed but still retain PIP capsules.
- Women still have PIP today - most because NHS explant-only is unacceptable, private remove-and-replace is unaffordable, and they will not accept separate NHS removal and private replacement operations.
- Many women had PIP removed and replaced after breast-cancer reconstruction or privately, often paying more for longer, more complex surgery under anaesthetic. They belong within the multiple-exposure group.

All of these women require lifetime exposure recording and cancer surveillance.

BIA-SCC, BIA-DLBCL and other capsule cancers

BIA-SCC and BIA-DLBCL are distinct from BIA-ALCL. In 2023 the US Food and Drug Administration reported 19 published cases of capsule SCC, including deaths, involving textured and smooth, saline and silicone implants, often after long implantation periods. Clinical evidence has also identified EBV-positive BIA-DLBCL arising around breast implants. A 2023 review described 19 cases after a median 10-15 years; 2026 diagnostic guidance warns that overlapping CD30 positivity can cause BIA-DLBCL to be misidentified as BIA-ALCL unless B- and T-cell markers and EBV testing are used. Other capsule lymphomas and mesenchymal tumours have been reported. [22][45][46]

The Campaign has received information concerning the first UK BIA-SCC diagnosis in a woman with a history of PIP exposure.

Preventing late and missed diagnoses requires direct information for every woman with a current or previous breast implant; published and actively communicated symptoms; complete lifetime implant, capsule and replacement histories; and national clinical guidance for GPs, breast services, radiology, pathology, haematology and oncology. Late seroma, swelling, pain, breast or capsular mass, capsular change or lymphadenopathy must trigger prompt investigation, correct sampling and appropriate capsule, fibrin, fluid and lymph-node pathology. Linking cancer registries, pathology and hospital records, implant registries and MHRA reports is essential so BIA-ALCL, BIA-SCC, BIA-DLBCL and other implant-associated cancers are not missed or diagnosed late.

SECTION 6

Pregnancy, breast feeding and children

The government cannot claim that babies were not harmed when it failed to conduct the studies required to know.

Women were pregnant, gave birth and breast fed while carrying PIP implants—ruptured, permeable and fraudulently manufactured. Breast implants are high risk, surgically implanted medical devices used in reconstruction and augmentation; **implants are not cosmetics.** PIP exposed women to an undisclosed chemical mixture released from an implanted device. The concern is not confined to D4.

PIP chemical exposure: what the authorities failed to answer

1. **Women were implanted with a mixture whose composition varied.** Swedish testing found markedly higher concentrations of D4, D5 and D6 in samples labelled PIP2 than in PIP-Nusil samples and comparator implants. The Agency also found that implant labelling could not reliably identify which PIP formula had been used. Women could not establish what was inside their implants from their implant records. [13]
2. **An intact implant did not prevent exchange with the body.** The Swedish MPA found cholesterol from the body inside removed PIP implants and concluded that small chemicals could move through the shell in both directions. Beretta and colleagues also identified cholesterol inside intact removed PIP implants. This directly challenges reassurance based on whether an implant had ruptured: the shell was not an impermeable barrier. [13; Beretta et al., 2013]
3. **The "milky fluid" showed silicone mixing with material from women's bodies.** Beretta's analysis identified silicone, blood-derived proteins, cholesterol and uric acid in fluid surrounding ruptured PIP implants. The researchers described an emulsion—a mixture of silicone, water and blood-derived material—not simply silicone suspended in water. Their subsequent research found that small silicone chemicals in PIP filler moved more readily at body temperature than those in an approved comparator implant. These findings demanded investigation of exposure in breast tissue, lymph nodes and elsewhere in the body. [11; Beretta et al., 2013]
4. **The MHRA breast-milk test did not answer the chemical-exposure question.** Its September 2012 exercise measured total silicon in one human milk sample. It could not identify or separately measure D4, D5, D6 or the wider PIP mixture. The laboratory described the method as unvalidated, approximate and vulnerable to contamination. Cows' milk was used to develop the test, expressly not to provide comparative data; the MHRA nevertheless used that result comparatively in its public summary. That exercise could not establish the safety of PIP chemical exposure through breast feeding. [14][47][48]
5. **The Government must answer for the mixture, the exposure and the missing investigation.** D4 is officially classified as suspected of damaging fertility. European authorities have also identified serious persistence and accumulation concerns for D4, D5 and D6. Assessing selected chemicals separately does not answer what happens when women are exposed to the whole PIP mixture over years. Where is the assessment of that mixture during pregnancy and breast feeding? Where are the investigations of the children? No safe exposure level for the PIP mixture has been established for developing embryos, foetuses or breast-fed infants. A public inquiry must examine how reassurance was issued and maintained without answering these questions. [15][34][49]

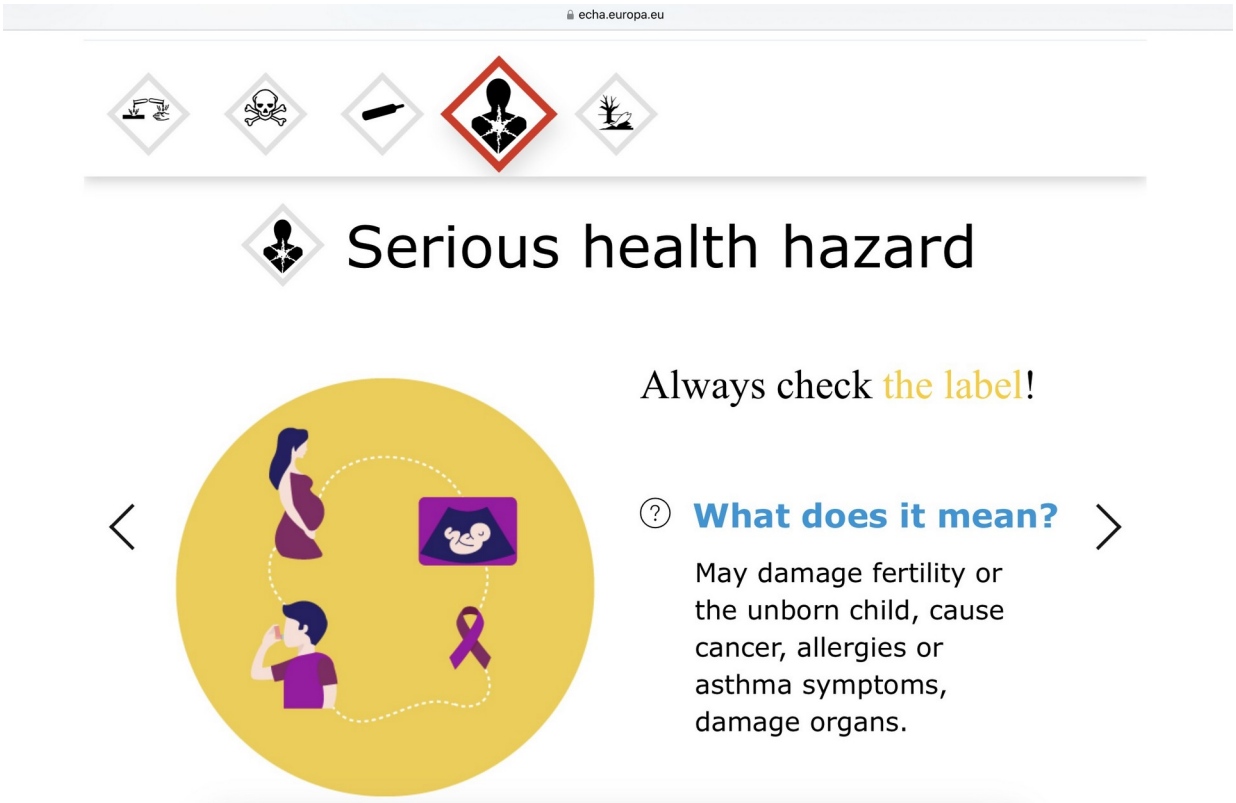


Figure 13. European Chemicals Agency general reproductive-hazard illustration. D4's harmonised classification is Repr. 2, H361f: "Suspected of damaging fertility." [15]

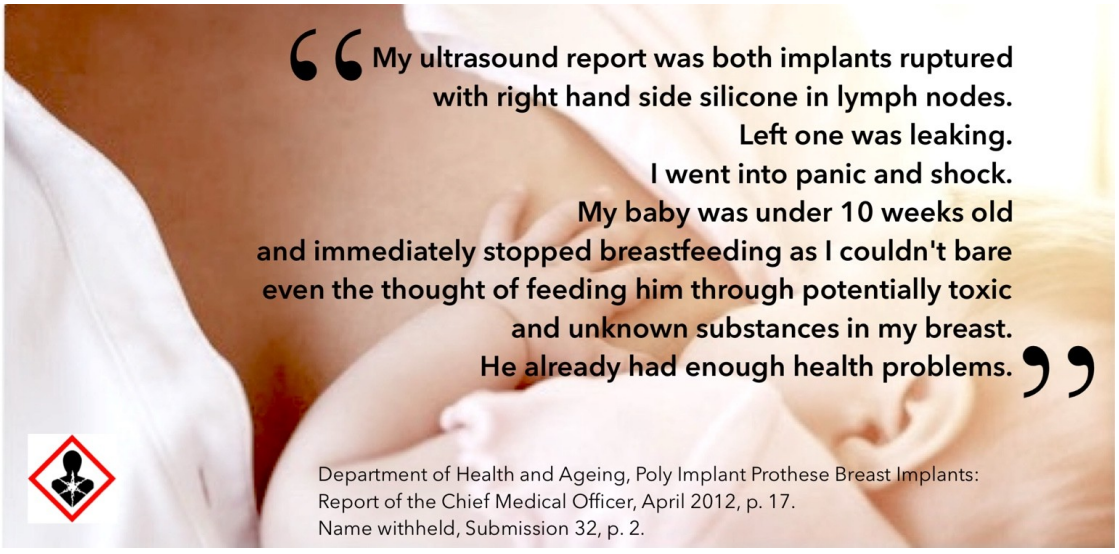


Figure 14. Campaign-supported testimony from a woman whose rupture and leakage were identified while she was breast feeding. It records maternal distress, the decision to stop breast feeding and the infant health concerns reported by the mother.

Exposure across the whole implant history

Pregnancy exposure can have occurred at any point in a woman's implant history: while a PIP implant was in place and leaking through an apparently intact shell; before or after rupture was identified; during pregnancy or breast feeding after replacement; and after explant where a capsule or migrated material remained. Assessment must therefore record the complete PIP history—including implant and replacement dates, rupture or suspected rupture, gel bleed, explant, retained capsule, migration, pregnancy, miscarriage, birth and breast-feeding dates.

What the PIP Action Mums survey records

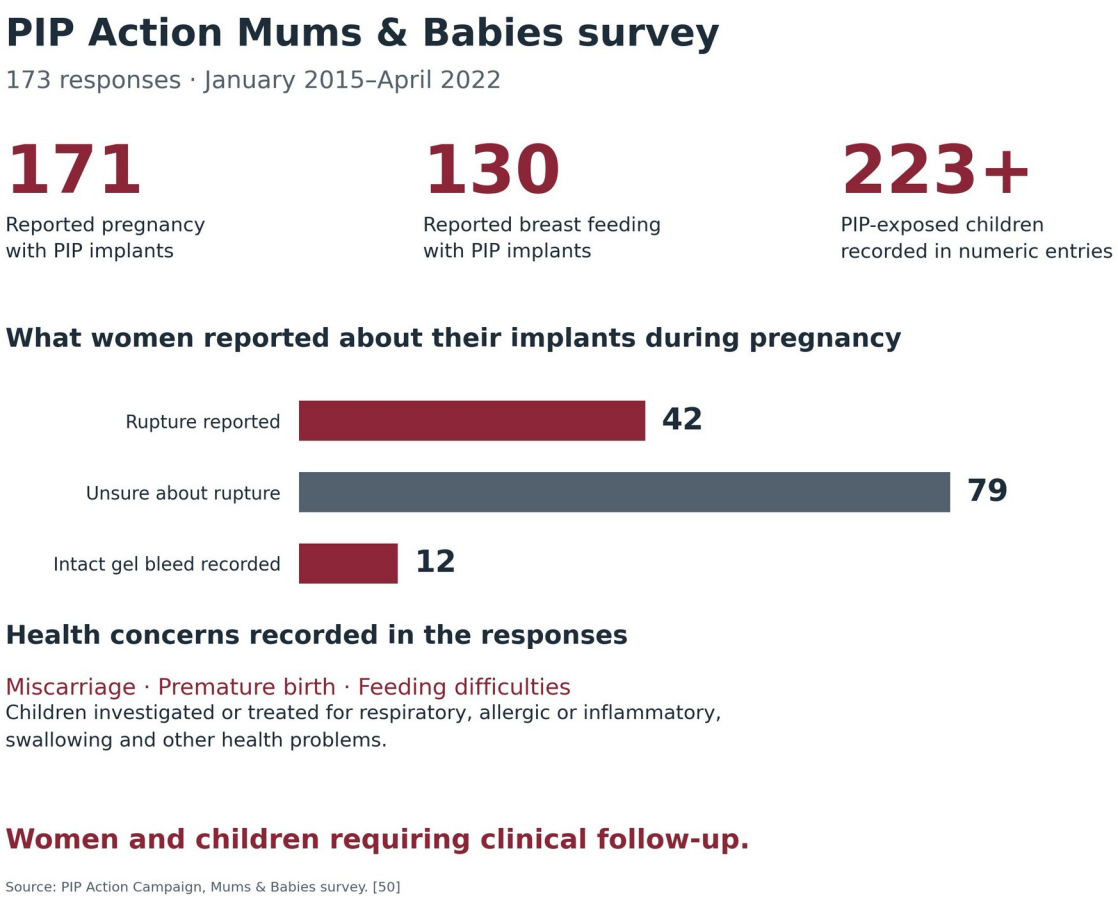


Figure 15. PIP Action Mums & Babies survey, January 2015–April 2022. Responses record pregnancy and breast feeding with PIP implants, rupture and gel bleed, at least 223 exposed children, and health concerns requiring clinical follow-up. [50]

D4 reproductive and endocrine evidence

D4 is officially classified as suspected of damaging fertility. The European Union's 2023 dossier records implantation losses, fewer implantation sites, reduced live litter size and fewer pups in animal studies, and identifies possible disruption of the hormonal control of reproduction. It also records oestrogenic and anti-oestrogenic activity and the Danish Centre on Endocrine Disrupters' conclusion that D4 is an endocrine disruptor. These findings are direct grounds for investigating exposure during pregnancy, foetal development, breast feeding and childhood. [49]

Women may have been diagnosed with oestrogen-receptor-positive breast cancer. The official evidence concerning D4's endocrine and oestrogenic activity was therefore clinically relevant to their lifetime PIP exposure history. These women, along with other PIP-exposed men, women and children, require specialist assessment rather than dismissal.

In August 2013 Sir Kent Woods replied to the Campaign's warning about D4 by describing it as "actually a very weak endocrine disruptor" and maintaining that the levels found in PIP did not represent a human-health risk. The European Union's 2023 dossier records D4's reproductive-hazard classification, endocrine-disrupting concern, oestrogenic and anti-oestrogenic activity and adverse reproductive findings. The MHRA reassurance did not establish a safe human exposure level for cancer survivors, embryos, foetuses or breast-fed infants. [49][51]

Harm to babies and children from D4 and other chemical exposures

There is no adequate UK PIP pregnancy and offspring cohort linked to each woman's complete implant, rupture, explant, capsule, migration, replacement, pregnancy and breast-feeding history; nor to maternal biomarkers, birth outcomes and child development. The State failed to identify and trace the cohort, preserve explants and samples, establish exposure biomarkers, link maternal and child records, or fund long-term independent research. The Campaign's own survey demonstrates that women and children who require follow-up can and most certainly should be identified. [50]

Government failed to investigate a known exposure pathway

PIP implants leak and release an undisclosed chemical mixture. Tested PIP2 samples contained D4, D5 and D6 at elevated levels; D4 carries an official reproductive-hazard classification and endocrine evidence; and D4, D5 and D6 have been measured in human breast milk. MHRA's one-sample total-silicon proxy and cows'-milk method development did not identify the PIP chemicals, measure the mixture or establish safety for embryos, foetuses or breast-fed infants. No safe exposure level has been established for the PIP chemical mixture in these developing groups. [13][47][48][49]

Removal and long-term monitoring

Pregnancy and breast-feeding exposure strengthens the case for timely removal of PIP implants with clinically appropriate reconstruction or replacement options, and for long-term monitoring of women and children exposed during pregnancy or breast feeding. **Follow-up must continue after explant because retained capsules, migrated material and the accumulated exposure history do not disappear when an implant is removed. Total Clinical Reset is needed urgently.**

Research and clinical duties now

1. Trace and clinically follow the national PIP pregnancy and offspring cohort, including women identified through the PIP Action Mums survey and Campaign, with ethically governed, women-led research and retrospective record linkage where consent and law permit.
2. Offer lifetime exposure assessment and specialist counselling to women who are pregnant, have been pregnant, are planning pregnancy or are breast feeding and who carry or previously carried PIP implants.
3. Clinically assess and monitor children whose mothers carried PIP during pregnancy or breast feeding, with appropriate paediatric referral and long-term follow-up.
4. Provide reproductive, endocrine and oncology review where indicated, including for hormone-responsive disease, fertility problems, miscarriage or pregnancy loss.
5. Analyse archived explants, capsule, lymph nodes, serum and—where voluntarily provided—breast milk using validated methods able to distinguish relevant siloxanes and silicone-associated material.
6. Provide evidence-based, individual pregnancy and breast-feeding guidance that states the known PIP exposure pathways and official D4 hazards and supports informed decisions.
7. Publish clinical guidance and all findings, methods and detection limits; **absence of State-collected evidence must not be presented as evidence of safety.**

SECTION 7

Systemic, psychological, social and economic harm

A narrow search for one diagnostic label misses the cumulative burden carried by women and families.

Systemic symptoms and documented harm beyond BII

Women report fatigue, difficulty thinking clearly, joint and muscle pain, rashes, disturbed sleep and neurological symptoms, often grouped under “breast implant illness” (BII). The Women and Equalities Committee recognised evidence of immune-system overactivity and called for stronger research and surveillance. [1] But PIP harm extends beyond this label. Published PIP reports document silicone-contaminated lymph nodes, inflammatory lumps, breast swelling and fluid collections, painful capsular tightening, persistent skin damage and a case of chronic silicone embolism affecting the lungs. Further surgery brings additional risks, including infection, wound problems and painful scarring.

For women with PIP implants, these concerns arise from fraudulent devices with higher rupture rates, variable chemical contents and documented movement of material through the shell. Authorities must investigate the full range of harm: trace women with current or previous PIP exposure, record their symptoms and diagnoses consistently, investigate tissue and lymph-node involvement, and follow what improves or persists after removal or replacement. Comparison with women without PIP exposure and testing for relevant chemicals are needed to answer the questions left unresolved. A public inquiry must establish why this follow-up was not organised despite the accumulating evidence.

PIP harm extends beyond BII

Specific health problems recorded in published PIP clinical reports

Silicone in lymph nodes	Enlarged and inflamed nodes; silicone confirmed by biopsy, including deeper axillary nodes. [10]
Siliconomas and granulomas	Inflammatory lumps formed around escaped silicone in breast tissue and affected lymph nodes. [10][A]
Breast inflammation and swelling	Pain, asymmetric enlargement and fluid collections around the implant. [A]
Capsular contracture	Hardening and tightening around the implant, with pain and breast distortion. [B]
Persistent skin damage	Severe inflammation and channels through tissue to the skin; disease continuing after implant removal. [C]
Lung involvement	Chronic silicone embolism syndrome reported in a woman with leaking PIP implants. [D]
Complications of further surgery	Wound infection, fluid collections, hypersensitive scars and abnormal wound healing. [E]

Clinical follow-up must address the full range of PIP harms.

Sources: [10] PIP complications report, 2013, PMID:23480085. [A] PIP clinical/histology report, 2013, PMID:23943050.
[B] ANSM PIP situation reports, 2012–2013. [C] Casey & Kelly, 2021, doi:10.1016/j.jpra.2021.03.002.
[D] Gopinath et al., 2015 (online 2014), doi:10.1111/his.12518. [E] Chummun & McLean, 2013, PMID:23499229.

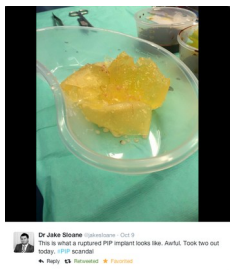
Psychological injury is not “just anxiety”

Women’s distress must be understood alongside the physical harm and institutional failures they have experienced. Discovering that an implanted product was fraudulent, that its contents could escape into the body, and that reliable records and follow-up were unavailable creates fear with concrete reasons. Women face pain, further surgery, possible disfigurement and unanswered questions about cancer, pregnancy and breast feeding. Psychological injury is part of the harm requiring care.

Dismissing these concerns as anxiety compounds the injury. Anxiety can coexist with physical disease; it must not replace investigation of symptoms. Women also need support when considering removal, particularly where previous breast cancer, reconstruction, traumatic surgery or body-image difficulties make the prospect of further surgery distressing.

1. **Physical injury and its consequences**. Pain, fatigue, restricted movement, disturbed sleep, scarring, changes in breast appearance, altered sensation and sexual difficulties can affect daily life, independence and identity.
2. **Psychological injury.** Fear, anger, shame, grief, trauma and loss of trust can follow device failure, repeated surgery, dismissal of symptoms and uncertainty about future health.
3. **Family consequences**. Illness and treatment disrupt parenting, relationships and caring responsibilities. Unanswered questions about pregnancy and breast feeding leave families carrying concerns about children’s health.
4. **Financial consequences**. Consultations, imaging, surgery and travel bring costs alongside lost earnings, reduced ability to work and difficulties obtaining treatment or insurance cover.
5. **The burden of securing accountability.** Women have spent years obtaining records, challenging misinformation and organising evidence while living with the consequences of the fraud.

A public inquiry must examine both the original harm and how the official response compounded it. **Clinical care must address physical disease, psychological injury and women’s fears about removal and disfigurement together.**



Clinician-supplied image



Campaign-supplied image



Campaign-supplied image

Figure 16. Clinician- and Campaign-supplied photographs of ruptured and disintegrated PIP implants removed at surgery. The physical condition of these devices is relevant to operative complexity, tissue damage, reconstruction and the information women need before explantation.

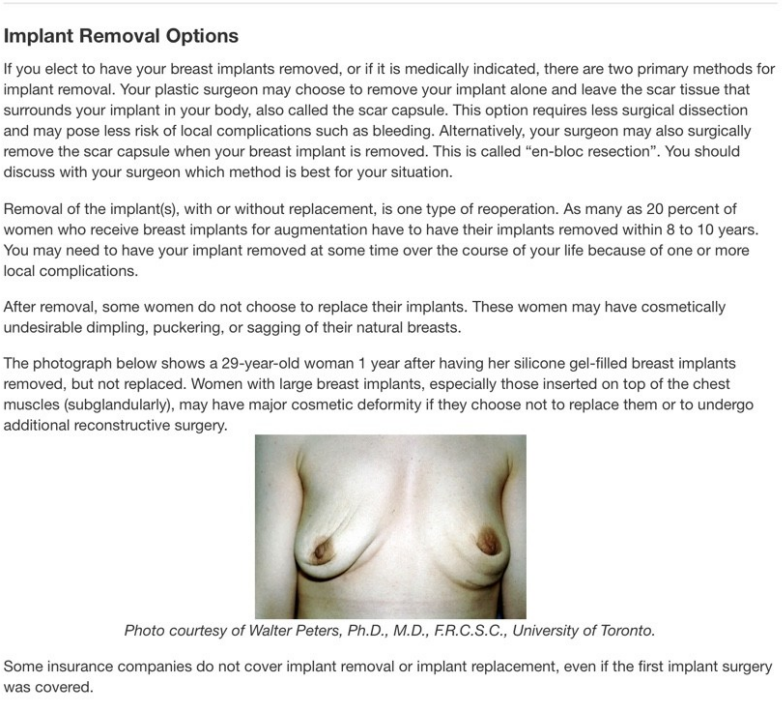
Body image, disfigurement and the realities of explantation

Body image is not a trivial or merely cosmetic issue. For women whose breasts were altered by augmentation or reconstructed after cancer, removal can affect bodily integrity, identity, sexuality, intimacy, clothing, confidence and the result of earlier cancer treatment. Disfigurement, asymmetry, contour collapse, scarring and loss of a breast reconstruction are harms in their own right.

Women with PIP were placed in an intolerable position: retain fraudulent implants; accept explantation without replacement; pay privately for removal and replacement; or undergo two operations—NHS removal followed by private replacement or reconstruction. The Women and Equalities Committee recorded evidence that the absence of replacement left women choosing between ongoing symptoms and radically changing their appearance. An explant-only offer is not a meaningful option for a woman who cannot accept or fund the resulting disfigurement. [1]

Information before explantation must cover implant-only removal and partial or total capsulectomy according to clinical need; the condition and planned management of the capsule; rupture, gel spread, migration and tissue damage; anaesthetic and bleeding risks; pathology of capsule, fluid and any mass; expected scars, asymmetry, chest-wall concavity, puckering, wrinkling and breast-tissue loss; realistic immediate or delayed replacement and reconstruction options; and the monitoring that continues after surgery.

The FDA tells women that removal without replacement can result in dimpling, chest-wall concavity, puckering, wrinkling, breast-tissue loss, sagging and major deformity. It also distinguishes implant-only removal from partial or total capsulectomy and states that ruptured silicone gel may be difficult to remove. This information is material to informed consent. UK PIP women required the same direct explanation, together with a funded route that made safe removal practically available. [52]



Implant Removal Options

If you elect to have your breast implants removed, or if it is medically indicated, there are two primary methods for implant removal. Your plastic surgeon may choose to remove your implant alone and leave the scar tissue that surrounds your implant in your body, also called the scar capsule. This option requires less surgical dissection and may pose less risk of local complications such as bleeding. Alternatively, your surgeon may also surgically remove the scar capsule when your breast implant is removed. This is called “en-bloc resection”. You should discuss with your surgeon which method is best for your situation.

Removal of the implant(s), with or without replacement, is one type of reoperation. As many as 20 percent of women who receive breast implants for augmentation have to have their implants removed within 8 to 10 years. You may need to have your implant removed at some time over the course of your life because of one or more local complications.

After removal, some women do not choose to replace their implants. These women may have cosmetically undesirable dimpling, puckering, or sagging of their natural breasts.

The photograph below shows a 29-year-old woman 1 year after having her silicone gel-filled breast implants removed, but not replaced. Women with large breast implants, especially those inserted on top of the chest muscles (subglandularly), may have major cosmetic deformity if they choose not to replace them or to undergo additional reconstructive surgery.

Photo courtesy of Walter Peters, Ph.D., M.D., F.R.C.S.C., University of Toronto.

Some insurance companies do not cover implant removal or implant replacement, even if the first implant surgery was covered.

Figure 17. FDA information on implant-removal options and possible disfigurement after explantation without replacement. The current FDA information continues to warn of dimpling, chest-wall concavity, puckering, sagging, breast-tissue loss and major deformity. [52]

SECTION 8

Medical misogyny and institutional gaslighting

When a predominantly female patient group reports pain, inflammation, bodily change and fear, dismissal is not neutral. It is a gendered patient-safety failure.

Victims of crime without a victim pathway

PIP women were harmed by a criminal product fraud. The Victims' Code sets the minimum standard for the treatment of victims of crime: respectful, sensitive and professional treatment without discrimination, together with rights including tailored support, information about compensation and a route to complain when rights are not met. **Against that standard, the UK response to PIP is a profound failure.** There was no joined-up pathway to identify and contact women, assess their needs, preserve evidence, explain routes to compensation and coordinate medical, psychological and practical support. [53]

Product liability without effective redress

Part I of the Consumer Protection Act 1987 was intended to provide consumers with a route to compensation for harm caused by defective products. Yet PIP's insolvency, fragmented responsibility between the manufacturer, clinics, insurers and the notified body, missing records, cross-border litigation and the cost of individual claims left many women without effective redress. The Law Commission now records that the product-liability regime has not always provided a straightforward route to compensation and that successful claims can be difficult. [54]

The result was abandonment by fragmentation. Crime was treated as a matter for the French courts; product liability as a private legal problem; removal and reconstruction as a question of who paid for the original surgery; and continuing illness as an individual clinical complaint. Each system narrowed its remit until no institution accepted responsibility for the whole harm.

This is where abandonment becomes medical misogyny and institutional gaslighting. Women's accounts are treated as emotionally excessive, cosmetic regret or anxiety; appearance is prioritised over health; private treatment is used to justify abandonment; and the failure to research women's injuries is cited as the reason no action can be taken. Institutional gaslighting occurs when authorities present uncertainty created by weak surveillance as reassurance, minimise contradictory evidence and require each woman to prove a population-level failure from fragmented personal records.

The repeating pattern

Institutional move	Effect on women	Required correction
Define the issue as rupture only	Chemical movement, gel bleed, migration, chronic inflammation and cancer surveillance disappear from view.	Assess the entire exposure pathway.
Require obvious local signs or an imaging-confirmed rupture	Women's pain, inflammation and other reported symptoms are dismissed when rupture is not visible or palpable. The label 'silent rupture' wrongly turns absence of clinical detection into 'no symptoms', although imaging may be required to identify rupture.	Record symptoms separately from rupture status; use risk-based MRI or ultrasound and specialist review.
Describe distress as anxiety	A foreseeable injury becomes a reason to disbelieve the woman.	Treat mental and physical harms together.
Count only the implant at diagnosis	Prior PIP exposure is erased from cancer data.	Record complete lifetime implant histories.
Say 'no evidence'	Failure to study is presented as proof of safety.	State what was studied, with what power, and what evidence the State failed to collect.
Divide NHS and private patients	Access depends on who implanted the device rather than clinical need.	Provide one national pathway based on harm and risk.
Fragment crime, product liability and clinical care	Each institution treats the harm as someone else's responsibility; women are left without one route to treatment, evidence preservation, support and redress.	Create one national pathway joining victim support, clinical care, evidence and redress.

The 2026 Women and Equalities Committee report materially changes the public record. It noted official assurances alongside limited long-term research; recorded women's reports of physical and psychological harm compounded by inadequate follow-up and dismissal; highlighted the absence of data on who still has PIP implants; and stated that absence of a definitive link does not mean there is no connection. [1]

The abandonment question

Why were women harmed by a criminal product fraud left to navigate fragmented clinical care, private costs and individual litigation when the State held the powers, records, laboratories, reporting systems and statutory duties needed to identify the cohort, investigate the harm and organise redress?

SECTION 9

Women's and children's rights

The PIP scandal engages rights to safe products and care, information, bodily integrity, equality, dignity, family life, participation and effective remedy.



Figure 18. WHO Patient Safety Rights Charter: ten rights relevant to PIP women, including safe products, information, records, dignity, being heard, fair resolution and family engagement.

The WHO Patient Safety Rights Charter provides a clear contemporary framework for assessing the response. PIP women are entitled to safe medical products, timely and appropriate care, information and supported decision-making, access to records, dignity and non-discrimination, a voice in resolution and family engagement. [23]

Right / principle	How PIP engages it	Potential inquiry finding
Safe medical products and care	A fraudulent implant entered women's bodies; follow-up and removal pathways were fragmented.	Whether regulation and clinical response protected women from avoidable harm.
Information and informed consent	Women could not consent to undisclosed non-approved filler; later advice often concealed the limits of evidence.	Whether warnings were timely, complete and intelligible.
Bodily integrity and private/family life	Implantation, contamination, surgery, pregnancy choices and sexual/reproductive life engage autonomy and Article 8 interests.	Whether positive duties to protect and inform were met.
Equality and non-discrimination	The affected population was overwhelmingly women; harms were sexualised, cosmeticised or psychologised.	Whether gender bias altered thresholds for evidence, care and redress.
Health	CEDAW Article 12 requires measures to eliminate discrimination in health care; ICESCR Article 12 protects the right to health.	Whether women had equal access to investigation, treatment and recovery.
Children's health and best interests	Unresolved pregnancy and breast feeding exposure questions affect children and parental decision-making.	Whether Article 24 research, prevention and information duties were adequately discharged.
Records, truth and remedy	Women cannot establish exposure or secure care when device, batch, pathology and operative records are missing.	Whether record systems and complaint routes delivered accountability.

Relevant legal frameworks include CEDAW Article 12, the International Covenant on Economic, Social and Cultural Rights Article 12, the UN Convention on the Rights of the Child Article 24, and Article 8 of the European Convention on Human Rights. The inquiry should examine whether the system respected the substance of these obligations. [24][25][26][64]

SECTION 10

Australia is a warning—France was producing evidence

Australia's disproportionate BIA-ALCL burden shows what active ascertainment can reveal. France shows what a national surveillance response can produce: cumulative evidence of rupture, inflammatory reactions and abnormalities identified during preventive explantation.

The TGA (Therapeutic Goods Administration) has stated that Australia's BIA-ALCL case numbers were much higher than expected from population size and at one stage represented roughly one in seven reported global cases. Australian investigators linked the disease predominantly to textured-surface exposure, and the TGA suspended or cancelled some devices. [19][20]

A national series published in 2019 identified 104 Australian and New Zealand cases by May 2019 and analysed 149 implant exposures, with a mean interval of 6.8 years from implantation to diagnosis. The scale of the burden reflects active clinical recognition and case ascertainment, reflecting the importance of awareness, diagnostic practice, registry quality and active case finding. [20]

A regulator receives more reports when clinicians are looking, pathology is standardised and cases are captured. That is case ascertainment, not 'over-reporting'. The safety question is whether another jurisdiction is under-detecting or under-linking cases. The UK cannot use a lower count as reassurance while reporting completeness, lifetime exposure histories and denominators remain incomparable.

The PIP-specific Australian gap

Australian data cannot answer the PIP question without complete lifetime device histories. Women who exchanged PIP for another implant fall into multiple-exposure groups, and a cancer recorded only against the implant present at diagnosis can erase the earlier PIP exposure. The Australian registry pilot found that only 3.4% of known PIP implants were captured. [27][28]

Comparison point	Australia	United Kingdom	Inquiry significance
Case burden	Disproportionately high reported BIA-ALCL burden.	MHRA-reported cases with estimated implant denominator.	Test ascertainment, not just headline counts.
Historic texture use	TGA reported very high textured use before 2016.	Brand/surface history incompletely recorded.	Reconstruct product-market exposure.
Lifetime PIP exposure	Cancer counts are uninterpretable without every prior implant and exchange.	'Only ever PIP' formulations exclude women whose PIP implants were exchanged.	Audit complete lifetime device histories in every cancer case.
Registry	Pilot showed profound under-capture of known PIP implants.	No complete national PIP cohort.	Registry absence is an evidence failure, not reassurance.

France was producing evidence

By April 2012, AFSSAPS had recorded 2,252 women with at least one rupture and 1,380 with inflammatory reactions. Surveillance ultrasound and pre-operative imaging were detecting rupture. By December 2012, ANSM had recorded 14,990 explanted women; among 10,900 preventive explantations, 2,259 women had implant failure and/or adverse effects identified despite no previous clinical or ultrasound sign. France was collecting and publishing the evidence while UK reassurance continued. [55] [41]

SECTION 11

Why a statutory public inquiry is required

Serious harm is established, critical risks remain unresolved, and ordinary processes have failed to produce truth, care or accountability.

The public-inquiry tests are met

Test	Evidence in the PIP case
Serious harm	Thousands of reported ruptures and inflammatory reactions; surgery, lymph-node disease, pain, disfigurement, psychological injury and implant-associated cancer surveillance.
Scale	Tens of thousands of women in the UK and hundreds of thousands globally were exposed; the remaining UK cohort is not known.
Systemic failure	Fraud passed through conformity assessment, market surveillance, adverse-event systems, clinical governance, records and redress.
Protracted uncertainty	Sixteen years after withdrawal, the UK still lacks complete exposure, outcome, cancer and maternal/child datasets.
Conflicting official responses	France and Sweden adopted preventive-removal positions while the UK emphasised reassurance; the evidential basis must be tested.
Loss of trust	Women report dismissal, fragmented follow-up and being required to prove harms the State did not monitor; manufacturer-specific adverse-event disclosure was then withdrawn.
Need for compulsion	Key records and restricted datasets span regulators, departments, private companies, laboratories, clinicians, notified bodies and foreign authorities.
Risk of recurrence	Breast-implant cancers, registry gaps and continuing disputes about systemic symptoms show that the lessons are live.

The first essential basis is established

This report establishes the first essential basis for a statutory public inquiry: serious and potential harms to women and children. The evidence records direct device harm, chemical exposure, surgery and reconstruction, implant-associated cancers, pregnancy and child-health concerns, psychological, social and economic harm, and continuing risks created by failures of surveillance, diagnosis, treatment and follow-up. The wider regulatory and institutional history is addressed in Part II.

Urgent measures pending inquiry

- **National PIP clinical reset.** Write to every identifiable woman, offer specialist review, and reopen pathways irrespective of original private or NHS provider.
- **Complete cohort reconstruction.** Link regulator adverse-event data, provider, hospital, imaging, pathology, cancer and mortality records under an independent, lawful protocol.
- **Lifetime implant history.** Make brand, batch, surface, dates, rupture and all prior devices mandatory fields in every implant-cancer report.
- **Standard diagnostic pathway.** Issue national protocols for late seroma, mass, lymphadenopathy, capsule disease, BIA-ALCL, BIA-SCC and other tumours.
- **Funded treatment and reconstruction.** Offer clinically appropriate removal, capsulectomy, pathology, pain care, psychological support and reconstruction without financial discrimination.
- **Independent research and biobank.** Fund long-term PIP-specific clinical, chemical, immune, reproductive and offspring research with women in governance.
- **Evidence-preservation notice.** Prevent destruction of government, regulator, provider, laboratory, notified-body, insurer and corporate records and retained samples.
- **Truth and redress scheme.** Create a simple route to records, acknowledgement, costs, compensation and continuing care, without forcing each woman into adversarial litigation.
-

Final finding: 47,000 women are owed truth, care and accountability

The PIP scandal began with manufacturing fraud. It was prolonged by an official response that failed to trace women, establish their lifetime exposure, investigate the full range of harm and keep risk information current. The evidence assembled in this report challenges a pattern of institutional behaviour: reassurance maintained despite unanswered questions; data withheld from scrutiny; previous PIP exposure excluded from narrow manufacturer counts; and women left to assemble the evidence that public authorities should have collected. “No evidence” became a defence while the systems needed to produce that evidence were missing.

For approximately 47,000 UK women, the consequences have been lived in their bodies and homes: pain, migrated silicone, damaged tissue, repeated operations, disfigurement, lost earnings and fear about cancer and children’s health. Women have faced these consequences while struggling to obtain records, secure investigations and have their concerns taken seriously. An implant exchange does not erase previous exposure. Removal does not necessarily remove material already dispersed through the body. Neither closes the authorities’ responsibility to investigate what happened.

This is precisely the institutional conduct that the Hillsborough Law’s commitment to candour and accountability must confront. The Public Office (Accountability) Bill seeks to require public authorities and officials to act with candour, transparency and frankness, and cooperate with inquiries and investigations. That commitment must reach women harmed by PIP. Authorities cannot be allowed to control the evidence, define away the affected population and then rely on the resulting gaps to resist scrutiny.

We therefore demand a statutory public inquiry with powers to compel documents and testimony, examine who knew what and when, and establish how official decisions affected women’s health, diagnosis and access to care. Records must be preserved, women must have the resources to participate effectively, and an urgent PIP Clinical Reset must proceed alongside the inquiry. Its findings must identify responsibility and provide a basis for redress.

The Government’s commitment to public accountability will be measured by whether it opens this record to independent examination—and acts for the 47,000 women who have carried the consequences.

CLOSING STATEMENT

The PIP scandal did not end in June 2012. The harm continued. So did the failure to account for it.

PIP's manufacturers made money through deception. Women received fraudulent implants under the protection of official checks and certification. When the fraud was exposed, those protections had already failed them. What followed demanded an honest, preventive and accessible public-health response. Instead, an official narrative of reassurance took hold while fundamental questions about exposure, injury and long-term health remained unanswered.

Women brought the evidence: damaged tissue, disintegrating implants, contaminated lymph nodes, repeated operations, photographs and medical records. They raised concerns about pregnancy, breast feeding and their children's health. The authorities' responsibility was to connect that evidence, investigate it and organise care. Women have been left to do that work themselves, while living with the consequences.

"No evidence" became a defence for institutions that had failed to collect the evidence. Cancer reports increased, but access to manufacturer-specific data was refused. Previous PIP exposure disappeared from published manufacturer tables when women had received another brand. Removal and replacement fragmented their histories without resolving what remained in their bodies. These decisions restricted scrutiny and left women without the answers needed for their care.

Approximately 47,000 UK women have been exposed; children and men have also been exposed. Our lives cannot be reduced to implant counts or government reports concluded in less than six months after the scandal was publicly announced. Especially when the consequences impact on breast cancer survivors, pregnant mothers and babies and formerly healthy women of reproductive age. Especially not when the consequences include physical injury, traumatic surgery, chemical exposure, disfigurement, psychological distress, financial loss and disrupted family life. **Women with PIP histories have died. Others are living with cancer and serious illness.** Their deaths, diagnoses and complete exposure histories demand investigation.

The PIP Action Campaign and its members call this institutional abuse: women harmed by a regulated product have then had to fight the institutions responsible for protection, information and care. A public inquiry must establish whose interests were served, whether financial considerations displaced prevention and compassion, and how official decisions prolonged suffering. Government has been alerted. Citizens have suffered and continue to suffer serious harm. Continued inaction is a decision for which it must answer.

The promise behind the Hillsborough Law must reach PIP women. Institutional defensiveness, control of evidence and years of resistance to affected families are precisely the behaviours that public accountability must confront. ***The lesson of Hillsborough and infected blood is that institutions must never be allowed to preserve their own account at the expense of people harmed.*** Candour means opening the records, confronting inconvenient evidence and answering publicly for decisions and failures.

The Government must stop defending an unresolved public health scandal as a closed episode. It must protect the women and families still living with its consequences—and make the institutions responsible answerable.

In loving memory of Susan, Paige, Lydia, Dawn and Tracey.

On behalf of all the members of the

PIP ACTION CAMPAIGN

Part I of III • Serious & Avoidable Harms To Women and Children • October 2026

SECTION ANNEX A

Evidence-status matrix

A strong case depends on saying exactly what is established, what is plausible and what must still be investigated.

Issue	Status	Evidence basis	Proper conclusion
Fraudulent non-approved filler	Established	Criminal/regulatory record; regulator analyses	Consent and product-safety breach
Higher/premature rupture and disintegration	Established	PIP explant series; ANSM surveillance	Direct device harm and exposure
Gel bleed / movement of small molecules	Established mechanism	Swedish MPA; shell chemistry studies	Exposure can occur without obvious rupture
Local inflammation, contracture, siliconoma	Established	ANSM and clinical series	Serious direct morbidity
Lymphatic migration / silicone lymphadenopathy	Established	Chemistry, imaging, pathology and case series	Material does not remain local
Complex surgery / repeated intervention	Established	Clinical literature and operative experience	Secondary iatrogenic burden
BIA-ALCL after textured implants	Established association	WHO/regulator and epidemiological evidence	PIP women require inclusion and history audit
PIP-specific BIA-ALCL excess	Unresolved	No adequate denominator or lifetime-history dataset	Cannot be ruled in or out responsibly
BIA-SCC around implant capsule	Rare, documented emerging harm	FDA literature review and reports	Urgent audit; PIP-specific causation unresolved
Systemic symptom causation	Unresolved but credible clinical signal	Patient reports and developing research	Requires prospective PIP-specific study
PIP pregnancy and offspring outcomes	Not investigated	No adequate UK PIP pregnancy/offspring cohort; exposure histories and outcomes were never linked	The State created the evidence gap and cannot assert safety
D4 reproductive hazard and infant exposure	Official European reproductive-hazard classification	D4 is classified Repr. 2, H361f—suspected of damaging fertility; D4 was elevated in PIP2 and cyclic siloxanes were measured in human breast milk	The official hazard and maternal/infant exposure required direct biomonitoring and child-health research
Psychological and social harm	Established	Studies, WEC evidence and lived experience	Must be treated as harm, not dismissal tool
Gendered dismissal / medical misogyny	Strong institutional evidence	WEC findings and recurrent response pattern	Within inquiry remit

SECTION ANNEX B

Key chronology

A non-exhaustive chronology of exposure, regulatory action and the continuing evidence gap.

Date	Event
1997–2010	PIP silicone breast implants received their European CE mark in 1997 and became available in the UK. [redacted], PIP manufactured and distributed implants using unauthorised filler. [56]
30 March 2010	French inspection discovers the fraud. AFSSAPS suspends the marketing, distribution, export and use of PIP silicone implants and begins public and professional updates.
21 December 2011	21 month delay before 1st Public Announcement by MHRA spokesperson stating PIP Implants are “no cause for concern”.
23 December 2011	France announces its national preventive-explantation policy: removal is to be systematically offered even without clinical signs of implant failure.
24 December 2011	Howe Review evidential cut-off date. [58]
January – June 2012	UK Government closes PIP case.
February–October 2012	AFSSAPS/ANSM publishes successive national surveillance reports documenting ultrasound-detected rupture, inflammatory reactions and abnormalities identified during preventive explantation. [55]
2013–2014	ANSM continues publishing cumulative national PIP surveillance, including explantation, rupture, adverse effects, lymph-node findings and reported cancers. [41][42][43]
2013	Swedish MPA reports limited chemical testing, markedly elevated cyclic siloxanes in samples classified as PIP2, and movement of small hydrophobic molecules through shells; recommends preventive removal.
2013–2015	Large clinical and analytical studies publish rupture, migration, lymph-node and shell findings; the EU scientific committee updates its opinion.
2016 onward	BIA-ALCL recognition and case reporting accelerate internationally; Australia reports a disproportionate burden.
6 August 2018	MHRA discloses PIP manufacturer-specific adverse-incident metrics under FOI 18/373, including 68 breast-implant-related malignancy reports. [57]
2019	TGA acts on higher-risk textured implants. International regulators strengthen cancer warnings.
5 February–25 March 2020	The Campaign requests updated data under FOI 20/013 after malignancy reports increase to 233. MHRA refuses manufacturer-specific disclosure; its internal review upholds the refusal and states that earlier disclosures were made in error. [57]
2022–2023	FDA warns about BIA-SCC and other capsule cancers distinct from BIA-ALCL.

Date	Event
2024	WHO publishes the Patient Safety Rights Charter.
2026	Women and Equalities Committee records limited long-term research, inadequate follow-up, dismissal and absence of a complete PIP cohort; calls for action.
30 June 2026	PIP Action Campaign submits its complaint to the Information Commissioner, challenging the refusal and seeking access to the PIP adverse-incident and malignancy data. [57]
14 July 2026	Andy Burnham MP Commons Debate Public Office (Accountability) Bill – the Hillsborough Law. Names PIP amongst other ongoing “treatment disasters”. [63]
5 September 2026	DHSC Enquiries Unit Response to PIP Action Campaign’s 25 July 2026 letter to the Prime Minister. Repeats and entrenches unsupported safety narrative.
21 October 2026	Scheduled meeting with The Rt Hon **Dame Diana Johnson DBE MP** **Minister of State (Minister for Public Health and Patient Safety)** Department of Health and Social Care, and Fleur Anderson MP

SECTION ANNEX C

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