We apologise that Data collected by PIP Action Campaign's Health Survey is currently unavailable on our website.

You may have arrived here, concerned about recent press reports implying women, seriously injured by PIP Implants, with on going legal claims, have "suffered a legal blow". Reuters put it like this:

*"BRUSSELS (**Reuters**) - Victims of defective breast implants made by French company Poly Implant Prothese (PIP) may only get compensation if they had the procedure in France, an adviser at Europe's top court said on Thursday, in a potential blow to thousands of women worldwide."*

If Reuters had any knowledge of Article18 (discrimination) of the Treaty establishing the European Union, this news items would never have seen the light of day. So the question is this: what's the real implant story behind this week's FAKEnews?

The report of the independent inquiry into the issues raised by jailed NHS Breast Cancer consultant Ian Paterson, published this week, highlights some of very serious public safety issues for women with breast cancer in the UK. The opening lines of Bishop Graham James' 230+ page report gets straight to the point:

*"This report is not simply a story about a rogue surgeon. It would be tragic enough if that was the case, given the thousands of people whom Ian Paterson treated. But it is far worse. **It is the story of a healthcare system which proved itself dysfunctional at almost every level when it came to keeping patients safe..."***

Breast cancer patients need to understand their treatment options, to be able to provide their informed consent, to be aware of the guidelines for diagnostics, biopsies, histologies and treatment, monitoring, including any risks they may need to consider or safety issues or complications they may face. So where is the information for these and other women considering or living with breast implants?

Breast cancer patients are still being offered reconstructive surgeries that may lead to a life-time of pain and illness, endless corrective surgeries and cancer. Evidence shows breast implants cause cancer and can kill.

In late 2018, breast implant brand leader Allergan was refused CE licensing in Europe, bans quickly followed in France, Canada, Australia and finally in the USA when the FDA wrote “inviting” Allergan to withdraw its Natrelle/Biocell implants, the company, while disagreeing with a “recall” took the implants off the global market. By 2018 a clear link had been made between textured and polyurethane implants and cancer: Breast Implant Associated Anaplastic Large Cell Lymphoma, BIA-ALCL or Breast Implant Cancer.

So how risky are breast implants?

And, What do we need to know about Breast implants?

The guidelines for Breast Screening with breast implants published by Public Health England in 2017, say this about mammogram screening with implants:

- Breast Implants represent an important imaging challenge
- Breast Implants may interfere with accurate imaging of breast tissue
- Risk factors of the procedure may include implant rupture during screening (*apparently, there is no current reliable evidence for this*).
- An experienced radiographer reduces the likelihood of rupture and other complications during the mammogram procedure

Earlier this week the Daily Mail (6 Feb 2020), would have us all believe concerns over breast implant safety might be in "women's heads"

" many doctors put the symptoms (of breast implant poisoning frequently referred to as BII) down to a combination of factors, ranging from separate autoimmune conditions to depression, menopause and what's known as 'mass sociogenic illness', where stress and fear about the potential harm caused by implants lead women to believe, and quite genuinely feel, that they are experiencing terrible pain.”

The culture of denial and lack of accountability in the medical devices industry is shrouded in secrecy, protected by the very same organisations charged with protecting patient safety. So whose interests are regulators serving?

If we are to believe Bishop James, the system is dysfunctional. Why aren't regulators taking appropriate regulatory action?

Who watches the Watchmen?

A recall without removal policy guarantees a cosmetic surgery bonanza as well as an unacknowledged health crisis amongst the sickest, poorest and most vulnerable women. What exactly makes the recall of an implanted medical device so different from any other regulated product? When is a breast implant recall not a recall?

In Europe, a few things have hindered regulatory action and/or health research and evaluation of evidence essential to patient safety:

- Manufacturers of breast implants are not required to disclose list of ingredients used in their products
- Manufacturers of breast implants are not required to inform patients about chemicals in their products
- To date, manufacturers have not produced any evidence of any serious health consequences linked to the use of their breast implants
- All evidence of safety required by the regulators for market approval is produced and funded by the breast implant manufacturer or their sponsor.

UK Regulatory authorities practices and over reliance on Section 44 (withholding important medical devices surveillance data) combined with pathological inertia, results in lack of information for concerned health professionals and obstructing patients from accessing correct and timely care.

- MHRA failure to monitor and secrecy over the number of PIP adverse event reports,
- The first public statement on the CE license removal from Allergan, from British authority, the MHRA in April 2019, on behalf of its expert group PRAESAG and three of Britain’s Surgeon’s associations, states recall is a new form of product recall. The advisory is 5 paragraphs in length.
- MHRA failure to provide accurate details of month-on-month increases in reports of BIA-ALCL in the UK, despite claims of close monitoring. *(BIA ALCL is just one of the potentially deadly cancers linked to breast implants.)*
- Department of Health, has, so far, resisted making known the true cost of PIP implant health crisis to the NHS.
- The British Breast Implant Register (introduced in 2016) does not record PIP patients or their surgeries.
- According to the MHRA, Allergan patients on the British Implant register have not been alerted about CE withdrawal
- PIP and Allergan are not the only brands of textured and polyurethane implants to have been banned in France and Australia.

So, what has sparked the recent ban on leading brands of breast implants around the world?

In 2016, the French national regulator the ANSM (now required to consider a broader range of evidence to before licensing: On the Court of Auditors' investigation into the National Agency for the Safety of Medicines and Health Products, called upon an independent panel of medical doctors, scientists, researchers, biochemists, oncological and biomaterials experts to review the evidence supplied by manufacturers of breast implants.

That's when independent experts dropped the bombshell :manufacturers of have consistently failed to provide ***relevant*** or ***substantiated*** arguments on breast implant safety in the following areas:

- General biocompatibility
- Carcinogenicity
- Immunotoxicity
- Reproductive and Developmental toxicity
- Teratogenicity
- (Toxicokinetics, Implantation and Biodegradation)
- Acute System Toxicity
- Specific Organ Toxicity

Australian Authorities also ran limited tests:

"***The TGA identified a number of deficiencies in the evidence submitted by sponsors and manufacturers to demonstrate an acceptable level of safety and quality of the materials used and/or the long term effects of the implants in the body.***" The TGA stated in its safety advisory published the week before Christmas on the 19 December 2019: **manufacturers** failed to demonstrate that their textured and polyurethane implants **did not**:

- result in harm to reproductive organs or fertility or affect offspring
- cause cancer
- Or cause harm, or elicit an altered response from, the body's immune system.

The TGA has given manufacturers six months to address the deficiencies (or until 24 April 2020).

Where is the evidence for the safety of breast implants?

Despite research payments of around $250m (between 2013-2018), another $300million over the same period in free lunches/jollies for implanting US surgeons, Allergan managed to secure leading US surgeons' association recommendation for their biocell / Natrelle range right up to the 2018 product withdrawal.

Large numbers of sick and frightened PIP patients desperate to remove their dangerous and defective, ruptured and leaking PIP implants, including recovering breast cancer patients, were guided to choose Allergan the ''safer, better, high quality" alternative. Many thousands are still living with PIP. What are the numbers of women with Allergan or one of the other banned brands that doesn't meet regulatory standards? Is this a public health emergency?

Hundreds of thousands more breast cancer patients and potentially millions of previously healthy women around the globe are currently suffering from implant poisoning. So why hasn't a single regulatory authority issued a product recall? Why would regulatory authorities consider carcinogenic implants unused in boxes on clinic shelves more dangerous to women's health than the same product implanted and decomposing in their bodies?

Where can women with PIP, Allergan and other brands of implant that have failed safety standards, find help and information about their rights?

And, Where is Allergan now?

Allergan is in $63 BILLION merger with pharmaceutical giant Abbvie.

What has REUTERS to say about it?

Read the latest here: BUSINESS NEWS JANUARY 27, 2020 / AbbVie-Allergan $63 billion deal aided by Nestle, AstraZeneca buys