House of Commons
Health Committee

PIP breast implants: web forum on patient experiences

Second Report of Session 2012–13
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PIP breast implants: web forum on patient experiences

Second Report of Session 2012–13

Ordered by the House of Commons
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The Health Committee

The Health Committee is appointed by the House of Commons to examine the expenditure, administration, and policy of the Department of Health and its associated bodies.

Membership

Rt Hon Stephen Dorrell MP (Conservative, Charnwood) (Chair)¹
Rosie Cooper MP (Labour, West Lancashire)
Andrew George MP (Liberal Democrat, St Ives)
Barbara Keeley MP (Labour, Worsley and Eccles South)
Grahame M. Morris MP (Labour, Easington)
Dr Daniel Poulter MP (Conservative, Central Suffolk and North Ipswich)
Mr Virendra Sharma MP (Labour, Ealing Southall)
Chris Skidmore MP (Conservative, Kingswood)
David Tredinnick MP (Conservative, Bosworth)
Valerie Vaz MP (Labour, Walsall South)
Dr Sarah Wollaston MP (Conservative, Totnes)

Powers

The Committee is one of the departmental select committees, the powers of which are set out in House of Commons Standing Orders, principally in SO No 152. These are available on the Internet via www.parliament.uk.

Publications

The Reports and evidence of the Committee are published by The Stationery Office by Order of the House. All publications of the Committee (including press notices) are on the Internet at www.parliament.uk/healthcom.

The Reports of the Committee, the formal minutes relating to that report, oral evidence taken and some or all written evidence are available in printed volume(s).

Additional written evidence may be published on the internet only.

Committee staff

The staff of the Committee are David Lloyd (Clerk), Martyn Atkins (Second Clerk), David Turner (Committee Specialist), Frances Allingham (Senior Committee Assistant), and Ronnie Jefferson (Committee Assistant).

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¹ Mr Stephen Dorrell was elected as the Chair of the Committee on 9 June 2010, in accordance with Standing Order No. 122B (see House of Commons Votes and Proceedings, 10 June 2010).
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Second Report

1. In February 2012 the Health Committee undertook an inquiry into PIP Breast implants and regulation of cosmetic interventions. This inquiry followed the announcement by the Government of the establishment of three reviews of health and regulatory issues associated with the treatment of breast implants manufactured by the French company Poly Implant Prothèse (PIP), which have been found to have been manufactured with silicone gel which was not of the required medical grade.

2. The three reviews established were as follows:

   i. a review of the actions of the Medicines and Healthcare products Regulatory Agency (MHRA) and Department of Health in relation to PIP implants, chaired by Parliamentary Under Secretary of State Earl Howe;

   ii. an Expert Group chaired by the NHS Medical Director, Sir Bruce Keogh, to review existing evidence on the risks associated with PIP implants, and

   iii. a review into the regulation of cosmetic interventions, also to be led by Sir Bruce Keogh.

3. The Committee published the report of its inquiry on 28 March 2012.\(^2\) Recommendations of the report were directed as appropriate at the three ongoing reviews.

4. An interim report of the Keogh review of the evidence on risks associated with PIP implants was issued on 6 January 2012.\(^3\) The final report of the review was issued on 18 June 2012.\(^4\)

5. The report of the Earl Howe review was published on 14 May 2012.\(^5\) On the same day, the Government issued its response to our report, which we do not comment upon here.\(^6\)

6. The second Keogh review into regulation of cosmetic interventions is ongoing: when announced, it was expected to report between 9 and 12 months from January 2012.

7. The Committee concluded in March 2012 that “all possible evidence, including patient-reported experiences, must be gathered and analysed in order to inform the policy response to this issue.”\(^7\) The timescale of the earlier inquiry did not allow us to take evidence directly from those women affected by PIP implants. We nevertheless wished to hear directly about the experiences such women had had. We therefore established a web

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\(^2\) Health Committee, *PIP Breast implants and regulation of cosmetic interventions*, 16th Report of Session 2010–12, HC 1816


\(^6\) The Government’s Response to the House of Commons Health Committee: Sixteenth Report Of Session 2010–12, PIP Breast Implants and regulation of cosmetic interventions, Cm 8351

\(^7\) HC 1816, para 13
forum where women with PIP implants could tell us how they had learned about the issues with the implants once the MHRA had issued its medical device alert in March 2010, what they had been told about their implants when they were provided, their experiences with their private providers once they had discovered they had PIP implants, and the support they received from private providers or the NHS in having the implants removed or replaced.

8. The web forum was open for comments during the month of May 2012. It was announced by means of a press notice and news was further disseminated by the social media outlets operated by Parliament’s Web and Intranet Service. By the time the forum closed to new comments on 31 May 2012, 194 women had registered with the forum and left 279 posts. By 24 June 2012 the forum had received over 4,230 page views. A summary of the main issues raised in the forum in response to the topics on which we sought comment is annexed to this Report.

9. The Committee is to sponsor a Westminster Hall debate on its March 2012 report and the Government response. The debate is scheduled to take place on Thursday 5 July. We are publishing this report and its annex now in order to place on the record a summary of the comments we have received. The full text of each response is available on the forum website.

10. We are extremely grateful to all those who took the time and trouble to submit comments to the web forum. Many have stated that they are experiencing poor health which they attribute directly to their PIP implants. While we make no judgment here on the clinical and regulatory issues covered by the Keogh and Howe reviews, we consider this first-hand testimony important to a proper understanding of the effects of regulatory failure in this case.

8 http://forums.parliament.uk/pip-implants. The text will remain accessible at this location until December 2013.
Annex: summary note on the Health Committee web forum on PIP breast implants

Introduction

1. Following the conclusion of its inquiry into PIP Breast implants and regulation of cosmetic interventions, the Health Committee set up a web forum to hear first-hand from women who have breast implants which were manufactured by the French company Poly Implant Prothèse (PIP). The purpose of the forum was to gather first-hand information about the scale of the problem and how well it is being tackled. Participants were asked to contribute their personal experiences of implant surgery from a private provider or the NHS, and how far their particular concerns about implants had been addressed where they have sought to raise them.

Practicalities

2. The forum opened on 2 May 2012 and was closed to new comments on 31 May 2012. By 24 June 2012 the forum had received over 4,230 page views.

3. The site was designed and created by the Parliamentary Web and Intranet Service. During the registration process, users agreed to a set of discussion rules. The forum was moderated by Health Committee staff. Messages were checked to ensure that they adhered to the discussion rules before they were published on the forum.

Outreach

4. The forum was announced by the Committee via a press notice. The Web and Intranet Service publicised the forum via social media outlets including Facebook and Twitter. Parliamentary Outreach also promoted the forum to their contact base. Analysis of the data on referrals to the web forum indicates that a substantial proportion of registered contributors and visitors to the forum found it through following links from PIP support groups established on Facebook.

Forum questions

5. Participants in the forum were asked to address the following questions:

- How did you first learn of the potential issues with PIP implants?
- If you have, or think you may have, PIP implants, have you experienced problems with them?
- What advice did you receive before or at the time you received your implants?
- Have you sought to have your PIP implants removed or replaced? If so, what has your experience been?
6. Following the publication on 15 May 2012 of the response to the Health Committee’s report on PIP Breast implants and regulation of cosmetic interventions and the report of Earl Howe’s Review of the actions of the Medicines and Healthcare products Regulatory Agency (MHRA) and the Department of Health, a further question for response was added to the site:

• What do you think of the Government’s response to the Health Committee’s report on PIP breast implants?

Profile of respondents

7. 194 women registered with the forum and left 279 posts. All the registered contributors had received breast implants: 189 women had received PIP implants and the remainder did not know what implants they had. 187 women had received their implants from private clinics: the remaining seven had received them from the NHS (five in England, one in Scotland and one in Northern Ireland).

8. Registered contributors to the forum received their implants in the following years:

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of contributors</th>
</tr>
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<tbody>
<tr>
<td>1992–2003</td>
<td>21</td>
</tr>
<tr>
<td>2004</td>
<td>46</td>
</tr>
<tr>
<td>2005</td>
<td>20</td>
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<td>2006</td>
<td>29</td>
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<td>22</td>
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<td>2008</td>
<td>37</td>
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<tr>
<td>2009</td>
<td>14</td>
</tr>
<tr>
<td>2010</td>
<td>5</td>
</tr>
</tbody>
</table>

Summary of responses

A summary of responses under each topic is given below. In some cases the responses have been edited for clarity. Names of identifiable clinics or medical groups have been edited from this summary. The full text of each response is available on the forum website at http://forums.parliament.uk/pip-implants.⁹

⁹ This text will remain accessible at this location until December 2013.
A. How did you first learn of the potential issues with PIP implants?

9. Contributors were asked to respond to the question above and the following sub-questions on the topic:

- When did you first discover that concerns had been raised about these implants?
- Did you receive any contact from the NHS or your clinic informing you of concerns about PIP implants?
- If you raised concerns with the NHS or your clinic about these implants, what response did you receive?
- How do you feel about the contact you have had with the NHS or with your clinic about issues with PIP implants?

Notification and communication

10. Several respondents discovered that the implant type they had been provided with had been the subject of a medical device alert, and had been subject to recall by the French medical device regulator, via the media rather than by their provider:

“I learnt about problems with PIP implants from the BBC news around Christmas 2011. I only received a letter from the company about 6 weeks after the story broke. It only told me that I had PIP implants and they would be in touch. They later told me I could go for an MRI scan in Plymouth or Republic of Ireland (I live in the Isle of Man!). I didn’t bother replying.”

“I first heard about the problem with PIPs just before Christmas 2011. I was worried sick and very upset. On phoning my clinic they seemed to dismiss my concerns and said there was no link with cancer as if this was the only thing that would cause any concern. I received a standard letter from the clinic several weeks later which just said that they would be in touch shortly and to keep checking their website and [the] MHRA website for updates. They set up a PIP helpline but this was answered by people at a call centre who had very very little knowledge of PIP implants, they seemed to be reading and quoting automatic responses from a sheet and always said that someone would call back from my clinic when available. The clinic later sent confirmation I had PIP implants. Then a couple of weeks later they said I would need an MRI scan at my own expense to see if I had a rupture in either or both implants.”

“My email and home address and phone number have not changed since my operation, yet I received no notification of the health scare with PIPs from my provider, it wasn’t until I saw it on national TV in January [2012] that I thought it may possibly relate to me. The clinic have been less than sympathetic and the emails

10 The posts can be read online at http://forums.parliament.uk/pip-implants/index.php?read,1,123
that I have received since have resembled disclaimers rather than attempts to rectify a difficult situation.”

“[I] only learnt about the scare in January 2012 after seeing a short news report. When asked for implant type advice from clinic they took 4 weeks to respond and said I had PIPs, but ok ones as [they were manufactured] pre 2001. On March 15th [. . .] MHRA stated pre 2001 [implants were] also affected – I’m still waiting to hear this news from the clinic I used.”

“I first heard about this in Dec 2011 but to be honest I didn’t think it concerned me: I just presumed it was people that went abroad for cheap operations etc. I went to a massive cosmetic surgery group and had very lengthy discussions with my surgeon to ensure I had the best possible silicone that could not leak in to my body. He assured me that there was no better/safer option and even swayed me away from going with another implant as he thought this one was safer! In Jan [2012] I went to get my hair done and got talking to a lady that revealed that she had had her implants done at the same clinic as me and that she had had them removed as they were PIP and ruptured. I called the clinic straight away to ask them, they told me it would take a few weeks (longest weeks of my life) they phoned me to inform me that I had and that I would be seen within 8 days. It’s now been 3 months and I have still not been seen!”

“It was in the New Year [2012]. I had heard about the PIP Implants, but wasn’t worried as I had cohesive implants and I hadn’t heard of PIPs. But I did look for any paperwork and I found the card that the hospital gave me and it said PIPs. I was very worried and called my clinic. I was told to leave my contact details and someone would get back to me. After 2 weeks I had heard nothing, so I called again, and was told that an appointment would take weeks to see the clinic. By calling as pretending to be a new patient I got an appointment at the clinic for a week later. To this day the clinic has still not given me anything that says that I have pips (I have had them removed so I know I had them).”

“I first discovered when the news broke in December that French authorities had recommended removal of PIP implants. I received no contact from the NHS or my clinic at all. The response from the NHS was confused: GPs were ill informed and confused as to what they are able to do and told me to go to the private clinic. I am disappointed about the response from the NHS and private clinics. I feel like I am stuck in the middle with nobody willing to take responsibility to help me.”

“I first knew something about them in Jan 2012 when I heard it on the news, didn’t think anything of it till someone told me the bigger picture so [I] decided to look into it myself. I didn’t receive anything from [the clinic].”
B. If you have, or think you may have, PIP implants, have you experienced problems with them?

11. Contributors were asked to respond to the question above and the following sub-questions on the topic:11

- When did you first discover that concerns had been raised about these implants?
- Did you receive any contact from the NHS or your clinic informing you of concerns about PIP implants?
- If you raised concerns with the NHS or your clinic about these implants, what response did you receive?
- How do you feel about the contact you have had with the NHS or with your clinic about issues with PIP implants?

**Medical issues**

12. Respondents reported a number of symptoms which they attributed to PIP implants: in many cases they reported that the removal of the implants correlated with a lessening or disappearance of the symptoms.

“I have been telling my GP for the last 2 years that I have lumps and pains in my armpits and shooting pains down my arms. My GP said it will be nerves in my neck. I also went with massive shooting pains in the sides of both breasts and I was again told this was back trouble. Since the PIP scandal broke I went back: he again examined my breasts and I was told that they do in fact look misshapen and flat, one bigger than the other and with obvious ripples. I was eventually referred for an MRI [scan] which has confirmed that I have folds in the implant and prominent axillary [lymph] nodes.”

“I had noticed that my breasts had changed over the last year or so. I thought this was just down to the ageing process as I had them in for 8 years. Around Christmas I began to experience burning pains in the left side, which got worse during the night and when I got up in the morning, gradually wearing off as the day progressed. After discovering they were PIP implants, I really noticed that their shape had changed considerably. [. . . ] I had my implants replaced at the end of March, where it was found that the left was in fact ruptured. The pain I was experiencing disappeared as soon as they were replaced, so I have no doubt that it was caused by the PIP implant rupture.”

“I had my PIP implants in 2006 [. . .]. The first I heard about it was on the news in December last year. I had my implants removed earlier in the year which I paid for myself, they had both leaked. I have suffered health problems ever since they were put in including, tiredness, underactive thyroid, anaemia, pain in head and chest, breathing problems, swollen glands for 2 years, bleeding gums. The list is endless. I

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11 The posts can be read online at http://forums.parliament.uk/pip-implants/index.php?read,1,119
have been referred to many consultants who have been unable to find the cause obviously as there is no test for silicone in the body."

“I have [a] confirmed rupture in my left breast, I also have a fluid around my right. I have experienced burning, change in size, lumps in lymph nodes, pins and needles and dull aches in my arms.”

“[I have had] pain for years in left abdomen, shoulder and upper back, raised lymph nodes underarm, (all on left hand side) chronic fatigue, unable to think clearly and anxiety. I found out upon explanting that I had a gel bleed in the left and am still suffering symptoms even after explant and not replacing as it is now in my system.”

“I have had problems following removal of my ruptured PIP implants in February 2012. It appears that it is not a straightforward procedure as there are risks of further leakage of the silicone. I had silicone in my lymph nodes prior to removal of these implants, however I know have more lymph nodes affected following the explant surgery. I have pain and discomfort daily and I am currently still under the care of the NHS Breast Clinic. I will need surgery to remove these lymph nodes but there are risks to having this surgery, especially with regards to the larger nodes that are currently affected. I may experience breast oedema and lymphoedema in my right arm. I am very anxious about this and I have not made a decision yet as to whether or not to go ahead with this surgery. But I am also not happy with having to continue taking painkillers daily to cover the pain that I experience every day.”

“I have PIP implants with serial numbers matching the recalled batches. Problems experienced are burning, tingling sensation and spontaneous sharp pains or throbbing. Noticed end 2010. Private clinic refused to acknowledge any link between symptoms and PIP; no evidence. Also said no evidence to suggest routine removal. If however I wanted my implants removed (PIP word never mentioned) then surgeon would remove under LA [local anaesthetic] only at normal cost. Surgeon felt he had no liability as implants were MHRA approved.”

“2 years after PIP implants I suffered joint pains to knees and elbow, anxiety attacks, hair loss, sensitive eyes, weak knees [and I was] spaced out [and] feeling unbalanced: the list is endless. I found out I had PIPs as I started to Google my symptoms as all blood tests showed negative but I knew something was wrong with me and stumbled against [the] PIP scandal. I had them removed and not replaced at [my] own expense as [I was] convinced [my problems were] linked to implants, and [the] joint pains disappeared within 2 weeks and [the] hair loss recovered. Unfortunately other symptoms [are] still continuing. My implants had not ruptured but I believe they sweated/bled.”

“I have never incurred pain with the implants as other women have but I knew something was wrong [in] mid-2011, as I noticed my right breast seemed to be getting larger. Over the last few months since I noticed this I have suffered hot sweats and tingling/cramps sensations - but prior to the scandal coming out I never put these issues down to the implants [ . . . ] I now have had confirmation of internal and external ruptures and silicone laden nodes in my right axilla. I do now very much believe my sensations/cramps are due to the implants.”
“I have recently found out I have PIP implants as I was experiencing horrendous pain in my chest, arms, neck and head. [ . . . ] I am now on the NHS waiting list for my scan which at the earliest will be in July - almost 2 months after I started experiencing the pain. I am in agony taking codeine prescribed from my doctor. My health, family and working life are suffering greatly and I can’t seem to get any support from anyone. [ . . . ] I have been told unless [my implants] have ruptured they will not be getting removed and replaced even though they are causing me such bad pain and anguish and are now majorly misshaped not to mention the impact it’s having on my health.”

“After I had the implants I started feeling tired all the time, pains in my muscles, cysts in my ovaries and breast, stomach problems, [a] poor immune system, dark brown discharge from [the] nipple, burning breast, memory loss. My GP is lost with all of my symptoms: he has done blood test after blood test. I have had X-rays taken to check my bones and operations to remove cysts. I was sent to a cancer ward for an ultrasound [scan] over [a] lump in [my] breast and the discharge. All this has been going on for years. I am now 34 years old and my body feels like an old woman. Only eight months ago I was diagnosed with fibromyalgia. I feel that my implants have played a big part in all my illness. I have never been the same since.”

13. Reports of responses from private clinics were generally not positive:

“[I first heard about PIP implants on the news in December 2011 but to be honest I didn’t take much notice as I knew these were cheap implants and because I had gone to a top surgeon and paid ‘top’ money for them, I assumed he wouldn’t have used these. It was only in early January that I was urged by a friend to look at the surgeon’s website and on it I saw he’d put a comment about PIP implants. I contacted his office and after about a week I received confirmation that I did have PIPs. Prior to me finding out, the clinic had not been in touch with me to advise me that I had PIPs and I’m sure they never would have as I heard they have themselves found out early last year and had put their company into liquidation to prevent them from this scandal leaking out. I was told by the clinic not to worry, but that I should pay to have them removed and replaced at a cost of £3,900. I am appalled and disgusted that they didn’t have the decency to contact everyone involved at the time, rather than each individual having to contact them to find out the devastating news. I am then appalled that they didn’t have the decency to deal with everyone involved, rather than some cases that they deemed suitable (i.e. less than 10 years old).”

“I first heard about PIP implants on the news in December [2012]. My clinic did not inform me of the recall in 2010 and failed to mention this on my 5 year check up after the recall for which they said there was no issue with my boobs even though they were sagging/misshapen. I did not think I would have PIP implants as I went to a top clinic and paid a lot of money but I phoned to check to be on the safe side on 23rd December. At first she said ‘oh, we hardly used those implants, don’t worry’, so I was relieved. I then got a phone call a couple of days later which I could not believe telling me that I had them and they only used them on 50 people [. . .]. They also said the MHRA [had] said there is nothing to worry about and it’s all media hype. I was crying on the phone and she said I should have them replaced and it would cost £4000! She offered no help whatsoever and was very rude and short and did not reply
to my emails or phone calls. It took me a month to get my records and also a letter from them confirming the situation.”

14. Women who approached GPs for referrals to NHS services reported mixed experiences:

“I also went to my GP who I have to say was very good (and this was April 2010 before people were made more aware [of] this). He referred me to the (NHS) breast clinic. The breast clinic saw me very quickly and tried to reassure me. They said the pain would be due to hormones (even though I’ve never had this problem pre implants). They asked me where the most pain was and they scanned that very small area on the right breast and said it was fine. ([I] since found out the left was leaking silicone, the one that wasn’t checked).”

“I went to see my GP who was lovely and very sympathetic. I was referred to [the NHS] breast clinic. My experience there was very different. They were horrible to me. They told me I should take problems up with clinic not them and that they were there for women with breast cancer symptoms implying I was taking [a] valuable appointment away from a cancer patient. I was refused a scan at first but on examination I had some slight thickening on left side so had an ultrasound on that side but only an area the size of a 50p. I was kept waiting three hours at the clinic and found them very rude. I ended up paying privately for an MRI scan.”

“I was that disgusted with the lack of response from the private company who put my PIP implants in initially, I refused to go back to them. I raised the problem of having the PIP implants with my GP who referred me to the breast clinic at the hospital. I received an appointment for a consultation with a surgeon 3 weeks later. I had an ultrasound exam at that appointment which confirmed ruptures in both breast implants. The surgeon told me I would have to pay privately to have implants put back in, though she could remove them only on the NHS if I wanted that. I was very pleased with the response from the NHS.”

“I contacted my clinic about these health issues only to find they had gone bust! So I contacted the hospital where I had it done, they arranged a consultation for me to see the surgeon who done my operation. The surgeon was very abrupt and rude and told me to go back to my clinic as it was not his problem. He also stated that he had no moral duty towards me. I then approached my GP who sent me to see a NHS breast consultant at my local breast clinic. The consultant arranged an ultrasound for me which showed nothing, so I asked for an MRI scan but was refused on the grounds of not worth spending the money.”

“My GP was helpful but every time I was referred for a scan the NHS breast clinic refused to see me even though I had pain and lumps in my breasts. I don’t blame the NHS for refusing to see me. But [the Secretary of State] shouldn’t promise the public we are being helped when he knows we are being turned away. I have a letter proving they refused to see me [. . .] I am appalled that the Government did not support us and make the clinics face their duty of care to us. It is shocking that we have been left like this.”
“I have lumps in my breast, hardening, pain and tenderness, I am suffering from extreme tiredness. I have raised [this] with my private clinic who were only willing to help if I paid another £2500 and £500 for a scan. I approached my GP who said I had to take it up with the clinic. I feel very worried that I have nowhere I can turn to, I cannot afford another £2500 to replace my implants, I feel the clinics are in a difficult position: because the government has not declared PIPs unsafe, the clinics cannot claim on their insurance and offer replacement, the NHS won’t replace and the women who are victims are stuck in the middle.”

“I had not experienced problems with my implants, but I raised the issue of a scan and replacements with my original clinic and my GP and neither wished to help me. I feel I hit a brick wall, and that nobody cared about the situation nor wanted to help me find a solution. I felt judged and that people saw it as a risk that I had taken and should have expected there to be a problem.”

“When I went to see my GP I was almost laughed at and rather rudely asked questions that were very upsetting. I had to save up to go private as the NHS funding I was meant to [have] got was pulled. I had to explain all my circumstances and, finally, as I had been under the GP for nearly a year with different problems that could [have] been down to the PIPs, they agreed to refer me for a scan. After weeks of waiting I got a call from the GP saying the hospital refused to scan me. In tears I had to go through it all again: the GP refused to do anything. Eventually later that day the GP called me again and told me she would refer me to plastics and they could decide what to do. I did eventually get an appointment with plastics who then put me forward to have a ultrasound scan.”

“My female GP has been supportive but sent me to a breast unit in March 2011. It was embarrassing to be there. Understandably breast oncology surgeons have cancer patients to treat. Said I had nothing to worry about and that my breasts shape were just fine [. . .] [that was] not the reason I was there, the PIP matter seemed to be completely ignored or they seemed unaware of it. As more info was released as well as [the] NHS support offer, I returned to my GP Jan 2012. I was referred to [the] plastic [surgery] unit and sympathetically treated although I feel uncomfortable having to ask for NHS support. I do not want replacement implant[s]. Surgery was scheduled and twice withdrawn due to bed shortage. The third booking went ahead for bilateral PIP explantation and capsulectomy. Treatment and care was outstanding, far better than I would have received at my private clinic even if they had agreed to explant. I am supremely grateful.”

“When I went to the GP, I was sent to [a] cancer doctor as [I was] told [that] implants could not rupture. After having a biopsy and finding silicone in my lymph nodes, [I] wasn’t happy at all when [I was] told they could not rupture, and [I] had to beg for [an MRI scan] to prove they had. [I] also had to wait another 6 months to have them removed, then needed another operation to remove more lymph nodes full of silicone. [I am] constantly being told not to stress and read info on internet. [I have been] very unhappy with [my] experience.”
C. What advice did you receive before or at the time you received your implants?

15. Contributors were asked to respond to the question above and the following sub-questions on the topic:\textsuperscript{12}

- What information were you given about the type of implant you were receiving?
- Were you told about any risks with your implants in general or about the particular implant type you were receiving?
- What information were you given about aftercare? Were you made aware of the general risks of implants reaching the end of their life span?
- If your care provider was a private clinic:
  - what promotional information and marketing was used to tell you about the surgical procedure and the implants you would receive?
  - what medical information did you receive about the surgical procedure, the risks of rupture of breast implants and the need for eventual replacement of your implants?

\textit{Information about type of implants}

16. Few of the women who responded had been given information about the manufacturer of their implants, either before or after their operation:

  “At the time, I was not given ANY information about the type of implant, apart from the fact it was silicone. I saw one and was allowed to touch it.”

  “I was also never advised on the brand of implant, it was sold by [the clinic] as a generic cohesive silicone implant which was known to be very safe and would last for 10-15 years or more. The manufacturer was not mentioned until I received my post op card.”

  “I was only told that they used silicone implants. I was given one to hold and was given a tight fitting t-shirt to put on and try a few different sized implants to decide on a size.”

  “I was not told (did not think to ask) what type of implants I would be getting. To be honest I would not have been any the wiser had he told me I was having PIPs. I was unaware that there different types.”

  “I was given no information about the brand of implant, nor any choice on the type of implant I was having. I asked why the clinic I was going with was several hundred pounds more than other clinics I had visited. The nurse looked me in the eyes and said ‘we use the best products and we will give you the best aftercare. When you are our patient we look after you.’ That is why I decided to go with them.”

\textsuperscript{12} The posts can be read online at http://forums.parliament.uk/pip-implants/index.php?read,1,121
“All [the clinic] told me was that they were silicone implants. I didn’t see one or anything, they didn’t even tell me what make or size or anything . . . . but then again why would I ask . . . . I went to a highly recommended surgeon and clinic which [was] more expense to me. I paid for the best . . . .”

“When I went for my consultation with [the clinic], they showed me, what they called ’the best silicone implant on the market’, and told me that they very rarely rupture, and if they ever did, which would usually be because of impact, they stay within the capsule. To demonstrate this they showed me an implant that had been cut in two. The nurse at [the clinic] told me that she could see no reason why I wouldn’t take these implants to my grave as they were so good. I now know this was untrue as one of mine had ruptured after only 6 years.”

“I was given no information prior to surgery other than that I was getting a top of the range recommended implant that would last me around 20 years.”

“[I] was assured that implants never need to be replaced - not like years ago when you would have to change them every 5 or so years - these were the top of the top and were super duper great!!”

“I was told that the pip implants were the safest and most durable. I was not given a choice: the surgeon said it’s all he ever used.”

“My surgeon told me that PIPs were the best and most expensive available and that they should last a lifetime. I was shown cohesive implants and was told how safe they were.”

“I was told I’d be having silicone gel implants and the make PIP, and that they were the best on the market.”

17. Several women reported similar themes used by clinics addressing the risk of rupture in cohesive silicone implants:

“I was told they were silicon cohesive gel and could not leak or break. I was told the result would most likely be permanent should there be no problems such as hardening.”

“I was also told the cohesive gel in the implants was like a ’Gummi bear’. In the very rare chance – which would need to be a car accident – that these implants ruptured the gel could not go anywhere because of this consistency.”

“[I] did not receive any advice from [my clinic] when I had the PIP implants, only that the PIP implants would last a lifetime, it would take a high impact car crash to rupture them.”

“[I was told] that you could drive a car over them and they still would not rupture.”

“I was told they were completely safe and because of their cohesive nature even if they did rupture the implant would retain its shape because of the gel like consistency of the silicone. An implant was cut in front of my eyes to demonstrate how the gel retained its shape.”
“I was told that my PIP implants would never leak, and the shell would only rupture if I were in a car or plane accident, or stabbed.”

“I was told that my implants were top quality and had a rare rupture rate & if they ever did rupture, it would be because of a very forceful impact, like a car crash, and even if this did happen, the silicone would not leak into my body because of the cohesive gel. They told me it was like cutting open a jelly baby.”

“I was shown an implant and given a demonstration of how strong they were. I was told about their outer shell and how they were medical grade silicone. I was reassured that even if they did rupture they would stay enclosed in the outer shell and would not leak into my body.”

“I was also given a demonstration of the texture and the contents - an implant was cut in half and resembled that of a 'jelly baby'. This was to demonstrate how difficult it would be for them to rupture and that there was no possibility of the contents leaking out as the texture was not liquid form.”

“All I was told is that my implants would last 20 years and they were the best on the market and if [they were] to rupture they were like a jelly baby so wouldn't leak into my body.”

“I was told that the implants were the safest you could get, that if you cut them they were like a 'jelly baby' that they would not leak. I was never told about any other implants, these were the only type they told me about.”

18. Some contributors had been persuaded of the benefits of silicone gel implants over saline implants:

“I asked my surgeon for saline implants as I was terrified of them leaking and silicone getting in to my body. The surgeon told me that saline had not been around that long and in 20 years side effects may come to light that we do not know about. He convinced me that silicone was best and especially the more expensive cohesive silicone, impossible to leak; he even cut one in half and showed me, demonstrated squeezing it and told me and my husband to squeeze it as hard as we could and the gel just oozed out and then sprung back in to the casing.”

“I went to my clinic asking for saline implants but they talked me into silicone as they said they were SAFER!”

19. Some women using private clinics recalled the medical information they had received about the surgical procedure, the risks of rupture of breast implants and the need for eventual replacement of their implants, though the information given seems to have varied from case to case:

“I was given limited information re problems and potential re operations. Aftercare was 3 years, and I was told [that the implants were] that good it would be 15 years before needing [to be] replaced. [ . . . ] No promotional info [was] ever used to tell me about the implant/surgical procedure. [The] medical info was concentrated more on the risk of a general anaesthetic. I was told the chance of rupture was minimal; it
would take a high impact car crash for example to cause them to rupture. They kinda glossed over this area to be honest.”

“My surgeon told me [that my implants] may need to be changed in the next 15 years but only if the need was there, such as hardening of the capsule, but that was very rare.”

“I was not given any promotional deal or marketing gimmicks (apart from to try them under some clothes to see the look, which obviously will sway a girl’s opinion!) I have the PIP information leaflet for both surgeon and patient. I have all the associated risks with normal implant surgery, I was told rupture was rare and that these particular implants were strong and almost impossible to rupture which was why they were a good brand and that replacement, although on average is 16.4 years, is not necessary if you have no problems and they are still relatively soft.”

“The sales advisor, who was also my surgery co-ordinator, showed us the product and the brochure which was given to me, this has no implant branding in it. I did my own homework about my surgeon but not about the implants themselves. I had no idea what size was being put inside me: [the sales advisor] did not discuss this with me; he just asked me my ideal cup size. He did not discuss aftercare with me, that was discussed after the op with a nurse on discharge or I presume she was a nurse as I was not told. I was told to leave the hospital at 7 am even though I was feeling unwell and had had my operation at 6pm the previous day, I had nothing to eat the whole time I was there and nothing was offered which is probably why I was feeling so ill. The aftercare was poor and nonexistent. I missed my two week follow up due to falling extremely ill from a canular infection from the operation. I never had a call from the clinic at all: I had to call them to arrange another appointment. I have not seen my surgeon after my operation or on the operation day, the only time I have actually seen him was for the 20 minutes he was selling me [the breast augmentation].”

“I was told all the general risks of implants i.e. rippling, breast sensation loss, pregnancy, weight gain and loss, capsular contraction and sagging, [and] that the gel does not ooze if ruptured [. . .] On aftercare I was given a instruction sheet of what to do and avoid. I was given an on call number, I was given an appointment 14 days after surgery and then another 3 weeks after. I was told [my implants] had a life span of 15 to 20 years and a long history of reliable use. I was given brochures to tell me about surgical procedures, and was given a sheet stating documentaries featuring their companies, i.e. on ITV1 and Sky Discovery Health: my surgeon actually featured in this.”

“I was given information concerning capsular contracture and was told that the only way that PIPs would rupture would be if you were in a very severe car accident or were stabbed in the breast, and even then the cohesive gel would remain together [. . .] I wasn’t given any information about aftercare other than the type you would expect following any surgery. There was no information about the implants regarding risks reaching the end of their life as that would have negated all the other things I was told.”
“I was told the implants were silicone and textured. No brand was discussed or even mentioned. I knew why [the] surgeon liked textured but had no idea of the brand choice he had or the reason for his choice. Verbal advice to wear a sports bra and to refrain from lifting heavy objects and to take it easy. No information on risks of implants in general was given. No mention was made of life span. No promotional material was provided.”

“I wasn’t given an info about rupture risks or alternative info: this section is unsigned in my paperwork which I’ve seen for the first time two weeks ago.”

“[I was given] no [medical] information, [and was] only told about incision type.”

“I was told the life span was 15-20 years but they would only need changing for the appearance as sagging may occur overtime. I was also told these implants would be safe to leave in if I wasn’t bothered about the sagginess! [I received] no medical information about the surgical procedure. [I was told that there were] no risks to them rupturing: [I could] replace if I wanted to in 15-20 years but could leave in.”

“I was told that my implants could stay in me forever. They said that after 10 years my body may have changed and I may want new implants to suit my changing shape but that they could stay inside me my whole life. I was given a booklet with minimal information and was told verbally about the slight risk of capsular contraction and rupture but was told that the chance of rupture was tiny. They also explained I may have a loss of sensation.”

“I was informed of issues such as capsular contraction and rippling, and the risks of elective surgery. I researched all other risks myself. Aftercare was to massage my implants for 5 minutes daily and to wear a sports bra as I slept. Also to always wear a bra throughout the day. I was told that the implants may last 10 or 15 years before needing replacing, or maybe 20 years, and may never need replacing. I was not told of signs to look out for that may indicate the implants needed replacing. I was hopeful I may go 15 years before needing to consider more surgery. [. . . ] The surgeon discussed the procedure with me and what to expect in terms of the operation and recovery time. I was not given any statistics regarding rupture rates, but told that it would be trauma or impact that may cause a rupture and even if it did, that the silicone would not leak from the shell.”

“Plenty [of advice] about the risks of anaesthetic and risk of infection, capsular contraction etc but was assured that implants never need to be replaced.”
D. Have you sought to have your PIP implants removed or replaced? If so, what has your experience been?

20. Contributors were asked to respond to the question above and the following sub-questions on the topic:13

- If your implants were provided by a private clinic, what response did you receive?
- If your implants were provided by the NHS, what has your experience of NHS treatment for removal been?
- Have you sought removal and/or replacement because you have experienced problems with your implants?
- Have you had PIP implants both removed and replaced? If so, was it in a single operation or two operations?
- How do you feel about the treatment you have received? Is there anything you think could or should have been done differently?

Treatment by private clinics

21. Several contributors were not impressed by the way their cases had been handled by private clinics:

“My private clinic have been totally useless unless rupture is proven at my/NHS expense, after many months in total distress I am now booked in to have these pips removed and this time replaced at a greater expense that I originally paid.”

“I decided not to go back to the private company who had put the implants in, because of their complete lack of response at first to the problem in general. They were more concerned with profit than women’s safety.”

“My Implants were provided by a private clinic, who have behaved appallingly, it took weeks for them to respond to any emails, even though I knew I had PIPs and had 4 of the symptoms which they stated on their website. I eventually received details of private providers of MRI scans in Surrey, when I live in Bucks and the charges for this. I had been in contact with my original surgeon, who told me that US [ultrasound scan] results would be sufficient, only to be told by [the clinic] that they would not. I had an U/S [ultrasound] and a mammogram in Dec 2011 (before the news broke) due to breast pain – all the symptoms which [the clinic] then posted on their website, and another in Jan 2012, both through the NHS. After both I was given a "hands on" examination, and both times I was told that my PIPs were intact. One consultant told me to go home and take painkillers, the other to take Oil of Evening Primrose – but not to quote him. I knew that these results were incorrect and have now had R&R [removal and replacement] with a different private provider. Both my PIPs had gel bleeds, one significantly. I had one procedure for my R&R and am now in debt for the first time in my life. The treatment I received from [my provider] was

13 The posts can be read online at http://forums.parliament.uk/pip-implants/index.php?read,1,117
disgraceful. I questioned why we had not been informed of the situation with PIPs back in 2010, when they were instructed to by the MHRA and their reply was "we posted the information on our website." Now that is hardly identifying, contacting and reassuring us as the Medical Device Notice stated. Thinking that we would all go onto a website looking for information when NONE of us knew there was a problem???

"The clinic were very slow to respond. At first they answered the phone and dismissed my concerns saying there is no proof PIP’s are unsafe/ no link with cancer. They then stopped answering calls at the clinic and calls diverted to a call centre where they employed useless people who quoted automated responses and could not answer many questions as they had no knowledge of implants whatsoever. The clinic have been appalling; they will only help if there is evidence of a rupture (only proven by MRI scan funded by ourselves) and only within 6 years of original implantation. They sent out a couple of generalised letters saying they do care and are doing all they can etc but have yet to put their money where their mouth is."

"I had my implants provided by a private clinic in 2001. When I heard about the PIP scandal in January this year I contacted the provider who told me as I had had the implants for over 10 years (10 years and 3 months to be precise!) there was nothing he could do as they should be changed after 10 years. This was news to me as when I had them originally done I was told they would last c.15–20 years plus if I had no problems with them. He then said he would remove and replace for £3,900."

"My original private clinic did not want to know. They would not help me at all. I struggled to get my records for a month. They tried to charge me £4K for removal and replacement and they said it was the governments fault and they would not replace for free even though I had a rupture. I had a rupture so I looked for another clinic that could replace my implants as my original clinic and the NHS could not help me. I had my PIP implants removed and Nagor implants inserted in one operation. My replacement clinic were very helpful and I researched them thoroughly having received advice and talking to other women on a Facebook support group. They put a special package together to help PIP victims and I am very happy with the clinic I chose and the help they gave me when no one else would. I had to get a loan however to pay for the replacements."

"I had my surgery with one of the biggest cosmetic groups, and felt that this was safer. I paid over £5000. [...] When I found out about PIPS I called and emailed the clinic. I was told that it would take 3 weeks to get my notes, in the end it took 3 months. And it was just the handwritten notes the consultant made in the first meeting. No mention of the word PIPs. I had a meeting with the surgeon: I was in his office for 4 minutes. He was brash and clearly didn’t care. Other ladies had said that he had walked out without seeing ladies before, so I was nervous. He even made me take my top and bra off standing next to his desk, not even the respect of behind a curtain with a nurse there. He felt my breasts and said that there was nothing wrong with the implants that they were safe. He then said to talk to the lady and book for replacement at a cost of £2900. I didn’t book. I was very unhappy with their attitude towards me. [...] I heard about a clinic that had never used PIP implants and they were prepared to remove and replace for £1895 I had a consultation with a surgeon
and was there for an hour, he explained everything and made me feel very safe and I trusted him. I had my surgery 8 weeks ago, both of my PIP implants were badly ruptured and I have silicone in my lymph nodes. It’s been 4 months and I have heard nothing from my original clinic since.”

“The experience is awful, desperate. The private clinic want me to pay up to £4000, which I can't afford. My local hospital want to remove & replace asap as I have ruptures, but the PCT will not fund it!!! I've worked hard all my life, paid my national insurance, & I can't get help in my own, disgusting.”

22. There were exceptions to these experiences:

“I am one of the lucky ones. My surgeon works for [a clinic] who have treated me very well and have removed and replaced for free.”

E. What do you think of the Government’s response to the Health Committee’s report on PIP breast implants?

23. Contributors were asked to respond to the question above and the following sub-questions on the topic:

- The Government believes that the official response to the discovery of the PIP breast implants fraud was ‘reasonable and proportionate’. Do you agree? What sort of communication did you expect?

- The Government has not accepted the Committee’s recommendation that it should find a means to allow private patients who have their PIP implants removed on the NHS to have a replacement performed as part of the same operation. This affects women who had PIP implants with private clinics who are now unable or unwilling to remove and replace the implants. How does this affect you?

24. Responses from women with PIP implants have not in general accepted the Government’s view of the MHRA’s actions:

“[The response is] reasonable and proportionate for the government. Not in the slightest for the PIP patients. Action should have focused on the patient as a priority rather than where did we go wrong and which lessons were learnt. Oh of course, there was a reasonable response for the patient. There is no evidence other than anecdotal and health care does not act on anecdotal. What evidence is wanted? They should not be in the body, end of matter. Is it really a reasonable response to sit back while we all have non-medical grade implants in a highly regulated country. There seems to be no telling who is going to end up with swollen lymph nodes. Reasonable and proportionate to have to live with this uncertainty? I hope women ending up with lymphodema are well compensated. Someone made the decision, someone slipped up.”

14 The posts can be read online at http://forums.parliament.uk/pip-implants/index.php?read,1605
“I was quite interested to see Lord Howe’s report, but was rather alarmed that it seemed to be covering the backs of everyone in the UK. What upset me was that there was no mention of the support that had been offered to women, by way of counselling or telephone help lines. I am still waiting for this support. My GP is not an expert on PIP implants or what happens to your body after they leak.”

“I think we have been very let down by our current government. The Health Committee seem to have concerns for our health and the government sees our situation from a purely financial point of view, avoiding any liability for itself. There has to be a solution in England and by publicly declaring these implants unsafe would allow women to pursue claims against their credit cards in accordance with section 75 [of the Consumer Credit Act 1974]. Because of the defensive stance that the government is taking, credit card companies are claiming PIPs are still fit for purpose.”

“My life and my family’s life have been turned upside down by this: it’s a total mess. The [Earl Howe] report has not helped us PIP VICTIMS in any way!”

“We have been let down by the Government. I have a ruptured left implant, which is leaking silicone into my body. If there is no danger from toxins in the silicone, I guess it would be ok for me to donate blood next week. The Government needs to ‘recall’ all of the PIP implants, then we will be able to move on with removing and replacing them, at no cost to ourselves. The Government’s response to this outrage hasn’t helped us at all.”

“This report was very disappointing and like many other things in this country it is all about saving money and financial costs. It is sad and embarrassing and makes me ashamed to be a part of it. Five other countries have taken immediate action in support of their women - but not the British government. It makes me very sad. Perhaps they need to think about the possible long term health implications for the women of this country.”

“The way I see it is everyone is passing the buck and no one wants the responsibility for this dreadful mess. Thousands and thousands of women have been left emotionally, physically and mentally scarred by all of this and yet there is no one helping us. Somebody has to be held responsible and fight for us and help us win to obtain our money back from the original surgery let alone having to pay again for new surgery. The goods sold were faulty and not fit to be inside humans yet there are thousands of women still walking around with these implants in them, causing illnesses and untold health problems that are ruining lives. The Government have done nothing to help us victims and all the words are empty ones, we need action and NOW to sort this out sooner rather than later.”
25. Women eligible for the NHS offer to remove implants are bemused by the Government’s refusal to develop procedures to allow NHS removal and private replacement in the same operation:

“I am very disappointed that they will not let the NHS remove and pay to have implants replaced. I don’t understand what the problem is if we are paying for the replacements.”

“A creative solution would be to use two surgeons to do the same operation: one private, one NHS. But creative thinking clearly is not an element possessed by government departments hell-bent on financial damage limitation. We are real people with a very real health dilemma, perhaps even a potential health timebomb. This will not go away and requires immediate recourse.”
Formal Minutes

Tuesday 26 June 2012

Members present:

Mr Stephen Dorrell, in the Chair

Rosie Cooper  
Andrew George  
Barbara Keeley  
Dr Daniel Poulter  
Mr Virendra Sharma

Chris Skidmore  
David Tredinnick  
Valerie Vaz  
Dr Sarah Wollaston

Draft Report (PIP breast implants: web forum on patient experiences), proposed by the Chair, brought up and read.

Ordered, That the draft Report be read a second time, paragraph by paragraph.

Paragraphs 1 to 10 read and agreed to.

Annex agreed to.

Resolved, That the Report be the Second Report of the Committee to the House.

Ordered, That the Chair make the Report to the House.

[Adjourned till Tuesday 3 July at 10.00 am]
List of Reports from the Committee during the current Parliament

The reference number of the Government’s response to each Report is printed in brackets after the HC printing number.

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