



House of Commons
Health Committee

PIP breast implants: web forum on patient experiences

Second Report of Session 2012–13



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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).

Contacts

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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

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

3 Department of Health, *Poly Implant Protheses (PIP) Breast Implants: Interim Report of the Expert Group*, 6 January 2012.

4 Department of Health, *Poly Implant Prothèse (PIP) breast implants: final report of the Expert Group*, 18 June 2012.

5 Department of Health, *Poly Implant Prothèse (PIP) silicone breast implants: Review of the actions of the Medicines and Healthcare products Regulatory Agency (MHRA) and Department of Health.*, 14 May 2012.

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.⁸ 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:

Year	Number of contributors
1992–2003	21
2004	46
2005	20
2006	29
2007	22
2008	37
2009	14
2010	5

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:¹⁰

- 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].”

