



House of Commons
Health Committee

PIP Breast implants and regulation of cosmetic interventions

Sixteenth Report of Session 2010–12

*Report, together with formal minutes and oral
and written evidence*

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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.

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Additional written evidence may be published on the internet only.

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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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Summary

Following the PIP breast implant scandal, the Government has announced a number of reviews. Specifically: Sir Bruce Keogh will continue to assess the evidence relating to the risks of PIP implants; Earl Howe is conducting a review into the actions of the MHRA and the Department of Health; and Sir Bruce Keogh will also conduct a wider review into the regulation of cosmetic interventions in general.

Our Committee's evidence session on PIP breast implants raised a number of issues that we feel ought to be considered by these reviews.

In particular, we recommend that Sir Bruce Keogh's continuing review of the scientific evidence must gather all possible data, including patient-reported experiences, and, if new evidence still does not allow for a conclusive view on the safety of PIP implants, we expect the Department to bring forward a proposal for gathering the data. We recommend that the Department's policy take into account new data on the inflammatory properties of PIP implants.

We recommend that Earl Howe's review of Department of Health and MHRA actions considers both whether the MHRA had information that should have led it to take action prior to the withdrawal of PIP's CE mark in March 2010, and also whether the MHRA and DH took sufficient action in the period between March 2010 and December 2011. In particular, the review ought to address why a high-profile policy response was not adopted sooner, and whether sufficient effort was made to contact affected women.

With regard to the current policy response, the Committee agrees that, in general, private clinics have an obligation to provide care and should adopt the same strategy as the NHS offer. Nevertheless, Earl Howe's review ought to consider how well this policy fits with the capacity of private clinics to provide treatment. The NHS must recoup any additional costs incurred in the course of a procedure that ought rightly to have been carried out by a private provider.

The reviews must establish a clearer regime of responsibility and give a clear statement of the extent of the legal obligations on private clinics. The argument of a moral imperative may be compelling, but it is difficult to enforce.

The Committee agrees that replacement implants for private patients should only be provided on the NHS where there is a clinical need. However, the Committee invites the Department of Health to propose a framework that would allow women in certain circumstances to combine NHS removal of implants with paid-for private surgery to insert replacements.

We recommend that Sir Bruce Keogh's review into the regulation of cosmetic interventions considers how the CE mark system can be strengthened, not only to ensure that changes in products are assessed, but also to ensure that the concerns of national regulators regarding implants manufactured and certified elsewhere are acted upon.

We welcome the review's consideration of how to establish an effective national register of implants. There should also be a firm statement on the position regarding insurance and an assessment of cosmetic surgery advertising.

The Committee believes that the events surrounding PIP prompt some serious concerns which need to be addressed both by provider organisations and the medical profession, and by their professional regulators. In terms of provider organisations, the review should assess the quality and consistency of record keeping and reporting of adverse incidents, and should review the actions taken to communicate with patients following the withdrawal of the CE mark in March 2010. The review should also examine how to ensure organisations meet their responsibilities to inform patients of the risks and commitments involved in their surgery.

For medical professionals, both Sir Bruce's review and the GMC should examine how well surgeons are respecting their obligations to report adverse incidents and to only provide treatment where a patient has given fully informed consent. They should also review the ways in which information about risks related to medical devices is drawn to the attention of surgeons who are not members of the relevant professional associations.

1 Introduction

1. In March 2010 the French regulator AFSSAPS² found that the French company Poly Implant Prothèses (PIP) had been using non-authorised silicone in the manufacture of breast implants. The CE mark for PIP implants was consequently withdrawn and the Medicines and Healthcare Products Regulatory Agency (the MHRA, the UK regulator of medical devices) signalled that the implants should no longer be used in the United Kingdom. It was estimated that some 40,000 UK women had received PIP implants prior to their withdrawal from the market.³ Only 3,000 of these women received their implants through the NHS.⁴

2. Then, in December 2011, following an increase in the number of reported ruptures of PIP implants and fears that the unauthorised silicone could pose a risk of cancer, the French Ministry of Health advised the routine removal of PIP implants on a precautionary and non-urgent basis. The MHRA advised that there was no basis for routine removal of implants in the absence of symptoms.⁵ The Department of Health appointed an Expert Group, chaired by Sir Bruce Keogh, Medical Director of the National Health Service in England, to review existing evidence on the risks associated with PIP implants. The Expert Group published its report on 6 January 2012, concluding that: there was no causal link between PIP implants and cancer; evidence on rupture rates was inconclusive; and that there was no clear evidence that a rupture of a PIP implant posed any greater risk than that of any other implant.⁶ On 1 February 2012 the European Commission's Scientific Committee on Emerging and Newly Identified Health Risks (SCENHIR) published its own report on the matter, which reached much the same conclusions.⁷

3. On 11 January 2012 the Secretary of State for Health made a statement to the House, outlining the support that the NHS would be providing to women with PIP implants, and his expectations for the treatment that ought to be provided by private clinics.⁸ Private clinics made a variety of offers to affected women.

4. In addition to Sir Bruce Keogh's ongoing assessment of evidence relating to the risks of PIP implants, the Department of Health announced on 24 January the terms of reference for two further reviews to be carried out into the actions of the MHRA and the Department of Health (to be led by health minister Earl Howe and to report by the end of March 2012)

2 Agence Française de Sécurité Sanitaire des Produits de Santé

3 Department of Health, *Poly Implant Prothèses (PIP) Breast Implants: Interim Report of the Expert Group*, 6 January 2012, p6. In March 2012 French authorities advised that implants used prior to 2001 might also have contained unauthorised silicone, in which case a further 7000 UK women could have been affected. See Department of Health press release, *Update on PIP implants*, 15 March 2012.

4 Written Parliamentary Question, Mr Macshane (asking), Mr Simon Burns (answering). HC Deb, 17 January 2012, col 778W

5 MHRA press release of 23 December 2011

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

7 European Commission Scientific Committee on Emerging and Newly Identified Health Risks (SCENHIR), *The Safety of Silicone Breast Implants*, 1 February 2012.

8 HC Deb, 11 January 2012, cols 181–98

and into the regulation of cosmetic interventions (to be led by Sir Bruce Keogh and to report within 9 to 12 months).⁹

5. On 7 February 2012 the Committee heard oral evidence from Sir Bruce Keogh, Sir Kent Woods, Chief Executive of the MHRA and two members of the Expert Group: Dr Anne-Marie Slowther, Associate Professor of Clinical Ethics at Warwick Medical School, and Simon Withey, Consultant Plastic Surgeon.

6. This Report sets out those issues arising from our evidence session that we believe should be considered by the reviews announced by the Department of Health.

⁹ Department of Health Written Ministerial Statement, *PIP breast implants and regulation of cosmetic interventions*, HC Deb, 24 January 2012, cols 14–15WS

2 Evidence on the risks of PIP implants

7. Recommendations in this section are relevant to Sir Bruce Keogh's continuing review of scientific evidence.

8. The most striking aspect of the interim report of the Expert Group is the way in which the Group repeatedly comes up against an absence of evidence. Although the suggestion that PIP implants pose a higher cancer risk than silicone implants in general has been refuted by the Expert Group and the French National Institute for Cancer,¹⁰ there was not enough evidence to rule conclusively on other key questions such as the rupture rate of PIP implants and the post-rupture health effects of PIP implants.¹¹ This lack of evidence is compounded by uncertainty over the composition of silicone used in any particular batch of implants.¹² Without positive evidence of safety, the Expert Group has had to hedge its conclusions.

9. On the question of whether the PIP implants were more likely to rupture than other implants, the Expert Group said that “the statistical evidence on the rate of ruptures for PIP implants compared with other implants is incomplete and this risk cannot be assessed accurately”.¹³ Two additional points are worth noting. First, that the cumulative risk of rupture increases over time. The Group therefore noted that “quoting a ‘rate of rupture’ for an implant, without specifying the time since the original implant, is unhelpful and potentially misleading”.¹⁴ Second, the Group noted that perhaps as many as two in three ruptures can only be detected by scanning or following explantation (that is, removal). This may go some way to explaining the higher rupture rates reported from France, where routine removal has been recommended.¹⁵ This makes it difficult to compare French and UK figures.

10. Nor did the Expert Group make any firm judgement on the nature of the particular silicone used by PIP, noting simply that as an un-authorized material it “cannot be guaranteed to have been submitted to the same rigorous toxicological testing as is required to meet the essential requirements of the Directive”.¹⁶ The Group noted that the gel used in PIP implants appeared to be less cohesive than that used in other implants. It said that this caused “a greater tendency to interface with the local tissue and a greater potential to generate an inflammatory response”.¹⁷ The Group also noted anecdotal reports from

10 Department of Health, *Poly Implant Prothèses (PIP) Breast Implants: Interim Report of the Expert Group*, 6 January 2012, pp 6–7

11 *Ibid*, pp 7–8

12 Agence Française de Sécurité Sanitaire des Produits de Santé (AFSSAPS) [the French Regulator], *État des lieux des contrôles opérés par les autorités sanitaires sur la société Poly Implant Prothèse*, 1 February 2012. The French regulator's report concluded that it was not possible to trace exactly what type of gel had been used in each batch of implants due to many different compositions of gel that had been used, and because of discrepancies between PIP's own records for each batch and the type of gel found in analysed samples of affected implants.

13 Department of Health, *Poly Implant Prothèses (PIP) Breast Implants: Interim Report of the Expert Group*, 6 January 2012, p8

14 *Ibid*

15 Department of Health, *Poly Implant Prothèses (PIP) Breast Implants: Interim Report of the Expert Group*, 6 January 2012, p8

16 *Ibid*, p7.

17 *ibid*

surgeons that “when a PIP implant ruptures, silicone gel is more widely dispersed in surrounding tissue and the resulting explantation is more difficult and more involved. This could result in a more prolonged hospital stay with additional risks”.¹⁸

11. In the absence of evidence the policy response has become one of judgement and caution, rather than scientific imperative. As Sir Kent noted, “we were all looking at the same data, but different decisions were made in different places”.¹⁹ Sir Bruce echoed this comment: “even those countries that, at first glance, appear to have simply recommended routine removal of these implants are not functioning on any more evidence than we have”.²⁰ The UK Government took the decision that the absence of evidence of danger meant that it would be wrong to recommend routine removal, while the French Government presumably reached its decision to recommend routine removal on a precautionary basis as the appropriate action in the absence of positive evidence of safety.

12. Sir Bruce told the Committee:

What we are saying is that the absence of evidence is not the same as evidence of safety. We need more evidence. [...] What we seek is hard evidence that will enable us to give [affected women], the NHS and other providers, sensible advice that is irrefutable. [...] There is enough of an international endeavour now to help us get that evidence and probably put us in a place where a number of countries can adopt the same approach with a level of security.²¹

13. **All possible evidence, including patient-reported experiences, must be gathered and analysed in order to inform the policy response to this issue. We look forward to seeing what new evidence has been made available to the Expert Group since the publication of its interim report. If this new evidence does not allow for a conclusive view on the safety of PIP implants, we recommend that the Department brings forward a proposal for gathering the necessary data.** Since the publication of the Expert Group’s Report, further evidence has emerged about the risk of inflammation and the complications involved when removing ruptured PIP implants. The British Association of Aesthetic Plastic Surgeons (BAAPS) have reported that the inflammatory response can include lumps in the breast and engorged lymph glands, both of which may require removal.²² In a letter of 24 February to Sir Bruce Keogh, Pierre Guillot, Managing Director of the Harley Medical Group, provided preliminary information on the Group’s experiences of removing PIP implants, noting that his surgeons had “noticed phenomena that they never observed with other implants”. The phenomena encountered in some cases of ruptured implants had included the presence of pus, “redness and lumpy, granular tissue”, and silicone in the lymph nodes in “one-in-four to one-in-five cases”. Mr Guillot also noted that, when removing a non-ruptured PIP implant “in one-in-four to one-in-five cases, there is the presence of a milky secretion. In some cases this secretion has seeped inside the

18 *ibid*

19 Q 8

20 Q 69

21 Q 105

22 British Association of Aesthetic Plastic Surgeons (BAAPS) press release, *Clinics ‘do not have the skills’ to treat implant victims*, 16 February 2012.

non-ruptured implant, suggesting permeability of the shell; in other cases, there is the same pus as observed with ruptured implants, suggesting that non-ruptured implants leak, triggering inflammatory reactions”.²³

14. Since the publication of the Expert Group’s Report some further evidence has been emerging about the inflammatory properties of the PIP implants whether ruptured or not, and the increased difficulty of removing ruptured PIP implants. Evidence on these issues should be examined carefully and urgently—if it is found that the removal of ruptured PIP implants involves significant complications, then this would be an argument for recommending early removal of PIP implants.

²³ E-mail from Pierre Guillot, Managing Director, Harley Medical Group, dated 24 February 2012, to Sir Bruce Keogh (copied to Stephen Dorrell MP).

3 Actions of the Department of Health and the MHRA

15. Recommendations in this section are relevant to Earl Howe’s review of Department of Health and MHRA actions.

Action before March 2010

16. Concerns had been raised about the quality of PIP implants prior to March 2010. In 2008, following an increase in reports of adverse incidents, the MHRA raised concerns with the German Notified Body and with PIP itself. The MHRA was informed that the increase in adverse incident reports was due to an increase in sales and improvements in PIP’s reporting criteria.²⁴ According to the Expert Group report, the MHRA raised further concerns in 2009.²⁵

17. PIP implants appear to have been significantly cheaper than alternatives. Simon Withey told the Committee that he was “aware there were reports of a very significant price differential”,²⁶ and estimated that PIP implants may have cost anything between one third and one fifth of the price of other implants (although this may take into account discounts for buying in bulk).²⁷ Certainly Mr Withey noted that PIP implants predominated in the “heavily commercial end of the private sector”²⁸ where procedures were price-sensitive.²⁹ Mr Withey also suggested that where surgeons were in a position to select implants themselves, they tended not to choose PIP implants.³⁰ He said:

If you are running a business on a commercial basis and do not have sound clinical input into helping you make these decisions, the importance of some of the decisions can be less obvious than it might be to a clinician who is very aware of what he has to put in, what he is doing, and what his responsibilities are to his patients.³¹

18. A survey by the British Association of Aesthetic Plastic Surgeons (BAAPS) found that only 8% of BAAPS surgeons, who must have significant NHS experience to gain membership, had ever used PIP implants. Former BAAPS President and consultant plastic surgeon Nigel Mercer stated: “very few of our surgeons ever handled these controversial implants as they were known to be the cheapest option (though used in good faith)”.³²

24 Department of Health, *Poly Implant Prothèses (PIP) Breast Implants: Interim Report of the Expert Group*, 6 January 2012, p6

25 *Ibid*

26 Q 10

27 Q 44

28 Q 39

29 Q 45

30 QQ 42–43

31 Q 41

32 BAAPS press release, 13 January 2011, <http://www.baaps.org.uk/about-us/press-releases/1026-survey-reveals-95-of-surgeons-believe-clinics-not-the-taxpayer-and-hospitals-should-pay-for-defective-implant-removal>

19. The Committee is concerned that, given what was known about PIP implants and the issues raised by the MHRA, there wasn't greater vigilance, especially when PIP implants were significantly cheaper and were not the implant of choice for surgeons. Earl Howe's Review should seek to address whether the MHRA had information that ought to have prompted them to act sooner.

Action between March 2010 and December 2011

20. It was in March 2010 that it was discovered that PIP had been using industrial grade silicone. At that point, according to the report of the Expert Group

the French regulator Agence Française de Sécurité Sanitaire des Produits de Santé (AFSSAPS), discovered that the manufacturer had been using industrial grade silicone instead of the medical grade specified for the CE mark. AFSSAPS revoked the CE mark and the MHRA promptly issued a medical device alert to all UK clinicians and cosmetic surgery providers, asking them to cease using the implants.³³

Toxicology tests on samples of filler material in both France and the UK suggested that there was no significant health risk to women who had already received the implants.

21. The NHS was alerted to the withdrawal of PIP implants via a medical device alert, where recipients of the alert must respond within a given deadline to say that they have received the alert and acted upon it. Sir Kent told us that “penetration into the private sector is less certain. The other route that we used was the professional surgical associations, to ensure that those practitioners who were going to be using implants would have the information immediately”.³⁴ But although all doctors would be registered with the GMC, not all doctors would be a member of the professional associations.³⁵ Mr Withey also noted that engagement with clinical governance issues was “perhaps, not as strong as it might be” for some doctors that work on a part-time basis or in various locations. Mr Withey also said:

There is a huge variability in both record keeping and levels of personal responsibility—forgetting the NHS—across the private sector. There are individual clinicians who are clearly responsible and keeping a close eye on what they are doing. Then there are larger, more commercial organisations where the clinician is perhaps distanced from the executive decisions made and, as a result, does not feel quite as responsible in some cases.³⁶

In evidence, Sir Kent Woods was asked whether he could be certain that private clinics had not used PIP implants after March 2010. He told us:

33 Department of Health, *Poly Implant Prothèses (PIP) Breast Implants: Interim Report of the Expert Group*, 6 January 2012, p6.

34 Q 13

35 Q 16 (Mr Withey)

36 Q 31

I am afraid I cannot give you that assurance. [...] I honestly cannot say that no PIP implant was moved from store into an operating theatre after that date. One sincerely hopes that it did not happen, and I think the combined effects of the different routes of communication that we used were the best that could be done to make sure that it did not happen.³⁷

22. “Sincere hope” is not an adequate basis for regulation. There needs to be a more reliable method of communicating Medical Device Alerts to the private sector, that requires a positive response that the instruction has been received and acted upon in the same way as in the NHS. Sir Bruce Keogh’s review into the regulation of cosmetic interventions must set out how this could best be achieved. Using the professional associations as channels of communication will not cover all surgeons.

23. After March 2010, there was no significant activity until December 2011. On 20 December 2011, following a large increase in the number of reported ruptures and concerns over a possible cancer risk, the French regulator wrote to the European competent authorities alerting them to new data.³⁸ Then on 23 December 2011 the French Ministry of Health advised women to consider having their PIP implants removed, as a precautionary measure. The MHRA advised at that point that there was no scientific basis for recommending routine removal of implants in the absence of symptoms.³⁹

24. Sir Kent told us that in the period between March 2010 and December 2011 the MHRA commissioned toxicology research on the nature of the silicone used to fill the implants, and worked with European counterparts to collate data on rupture of PIP implants.⁴⁰ Further action only happened after the French Government recommended routine removal of implants.

25. Sir Kent told us that he believed the MHRA’s actions had been “appropriate” on the basis that the “consistent position” throughout the period (and confirmed by the Expert Group and SCENHIR) had been that there was insufficient evidence that PIP implants posed a greater risk to health than any other type of implant. Yet the very fact that evidence was insufficient ought to have been a prompt to gather further evidence, and urgently.

26. It is surprising that urgent action to gather evidence and communicate with affected women only gathered pace in December 2011, following the announcement of the French Government. Given the fact that 40,000 women were known to have received sub-standard implants, the very scale of the problem alone should have provoked a high-profile policy response much sooner, including urgent action to gather evidence that would allow the risks of these implants to be properly assessed. Earl Howe’s review must examine why action was not taken sooner.

27. Sir Kent told us that in the period between March 2010 and December 2011 “there had been a continuous communication of risk information as we had it, but the advice had not

37 Q 14

38 Department of Health, *Poly Implant Prothèses (PIP) Breast Implants: Interim Report of the Expert Group*, 6 January 2012, p6

39 MHRA press release, 23 December 2011

40 Q 2

changed”.⁴¹ The MHRA’s advice during this period was that women “should seek to consult expert advice and be examined”.⁴² But the question is, how many women were aware of the problems with PIP implants? In the absence of a register of breast implants for private patients, the MHRA has no way of communicating directly with individual private patients, so it must instead seek to publicise the issue as widely as possible. Sir Kent told us “We use all the routes available to us. We have put out press releases, medical device alerts and we have worked through the professional associations”.⁴³ This approach was used in March 2010 and later as toxicology results were published.⁴⁴ Sir Kent told us that the approach used in December 2011, when the issue was picked up by the media, was no different.⁴⁵ Sir Kent said that he believed the MHRA’s communications had been “appropriate”⁴⁶ and noted that, ultimately, the responsibility for follow-up care sat with the healthcare professional who had carried out the procedure.⁴⁷

28. The action taken to communicate with affected women after March 2010 was inadequate. The Committee recognises that private clinics had a duty to contact their patients directly, but the MHRA and the Department of Health also had a duty to raise public awareness. A more creative approach should have been used. Earl Howe’s review should determine when the Department of Health and the MHRA contacted NHS patients directly, and the adequacy of strategies to communicate with the far greater body of private patients.

The NHS offer

29. On 11 January this year, the Secretary of State made a statement to the House outlining the support the NHS would offer to women who had received PIP implants on the NHS. He said:

All those patients will receive the highest possible standard of care. First, they will be contacted to inform them and give them all the relevant information and advice. Women who wish to will be able to speak to their GP or the surgical team that carried out the original implant to get advice on the best way forward for them. If the woman chooses, that could include an examination by imaging. If, when informed by an assessment of clinical need of the risks involved and the impact of any unresolved concerns, a woman decides with her doctor that it is right to do so, the NHS will remove and replace the implants, if the original operation was done by the NHS.⁴⁸

30. Statistics released by the Department of Health on 16 March 2012 show that the latest estimate of women with NHS PIP implants *in place* is 748, of whom 743 have been

41 Q 6

42 Q 6

43 Q 19

44 Q 21

45 Q 20

46 Q 9

47 Q 29

48 Official Report, 11 January 2012, cols 181–183.

contacted. 37 scans had been completed. 112 women had decided to have their implants removed and 18 removal operations had taken place. 30 women “had completed their NHS offer”.⁴⁹

31. The vast majority of women who received PIP implants in the UK (37,000 of 40,000) were treated by private clinics. In March 2012 French authorities advised that implants used prior to 2001 might also have contained unauthorised silicone, in which case a further 7000 UK women could have been affected.⁵⁰ These women have been advised to seek treatment from their original clinics in the first instance, only turning to the NHS if the private clinic no longer exists or refuses to carry out treatment.

32. Sir Bruce told the Committee “we have taken a very clear view that the private sector should match that offer. We believe it has a moral duty of care to match that offer”.⁵¹ This echoed what the Secretary of State had said in the House of Commons in January.⁵² Simon Burns MP, Minister of State for Health, had stated that the Government had “made clear that we expect private providers of cosmetic surgery to make the same provision [as the NHS], without cost, for their patients”.⁵³ Sir Bruce told us that “by maintaining a very clear view about the moral imperative that we believe should be met by these providers, a number of providers have started to come into line”.⁵⁴

33. Sir Bruce told us, when we suggested that there was a legal obligation on private providers, that “We will be looking at that. Our early indications are that there are some opportunities for legal redress”.⁵⁵ There is a notable uncertainty as to the legal obligations on private providers in these cases.

34. At the time of the Secretary of State’s statement on 11 January, eight private health care companies, including Nuffield Health, Spire Healthcare and BMI, had confirmed that they would remove the implants without charge. Two private companies, Transform and The Hospital Group, had originally said they would charge for removal of the implants, but later announced they would only charge for the replacement implants.⁵⁶

35. The Harley Medical Group (13,900 PIP patients) initially offered to pay the cost of new implants but only if the NHS paid the bill for surgery. It later changed its policy to an offer to remove ruptured implants free of charge (if implanted in the last 10 years). Ruptured implants fitted in the last six years would be replaced without charge, while ruptured implants fitted between six and ten years ago would be replaced at cost price.⁵⁷

49 Department of Health statistical press notice, *PIP breast implants*, 16 March 2012.

50 Department of Health press release, *Update on PIP implants*, 15 March 2012.

51 Q 51

52 Official Report, 11 January 2012, cols 181–183

53 Written Answer, *Breasts: Plastic Surgery*, 91256. (asked by Jonathan Edwards, answered by Simon Burns).

54 Q 56

55 Q 66

56 Health Service Journal, *More private clinics to treat implant patients for free*, 27 January 2012.

57 Harley Medical Group, statement, 17 January 2012. <http://www.harleymedical.co.uk/breast-enlargement-pip-implant-patient-advice/>

36. Press reports have suggested that some women are being asked to pay for scans and that there is general confusion over whether private clinics are charging for removal or replacement, or what criteria will have to be met for implants to be removed.⁵⁸

37. Sally Taber, director of Independent Healthcare Advisory Services, the trade body representing many of the companies involved, said that the companies were “as much a victim of this fraud as the NHS and its patients” and that “if there is any moral or ethical obligation outstanding it lies with the government’s regulatory agency, the MHRA”.⁵⁹ There is also a question as to whether private clinics can provide treatment on the scale required. The Harley Medical Group, which provided implants to some 14,000 of the 40,000 women affected, and normally carries out 4,000 breast augmentation operations a year, said it simply did not have “enough hospitals, surgeons and staff to manage this alone. Nor does it have scanning facilities”.⁶⁰ **Private clinics used PIP implants in good faith because of the CE mark. Nevertheless, the Committee agrees with the Department of Health that private clinics have an obligation to provide care and should mirror the NHS offer.**

38. **The Department of Health has been very clear about the moral imperative—it would have been welcome to have had a clearer statement of the extent of the legal obligation on private clinics. The argument of a moral imperative may be compelling, but it is difficult to enforce. Sir Bruce’s review should provide a clear statement of the legal responsibility of providers to meet their duty of care and to supply an appropriate product. The situation must be clear and consistent. It is unacceptable that there should be uncertainty when it comes to responsibility for a device implanted into the body.**

39. **The NHS offer must take into account matters of capacity. The overall number of women affected is significant, and single providers are responsible for a significant proportion of that number. There is no point having a policy stance if it cannot reasonably be carried through. The capacity to undertake the surgery must be assessed and the policy response tailored accordingly. The Committee asks the Department of Health to identify how to make the best use of any spare capacity, whether public or private.**

40. In the case of women who received their implants outside the NHS, the Secretary of State for Health told the House:

It is right that those who received their care privately should also receive a similar level of service and reassurance from their care provider. However, I do not think it fair to the taxpayer for the NHS to foot the bill for patients who had their operation privately. [...] However, I want to be absolutely clear that the NHS will continue to be there to support any woman. If a clinic that implanted PIP implants no longer exists or refuses to remove the breast implants, where that patient is entitled to NHS

58 See, for example, BBC Newsbeat, ‘No more tests’ for women with PIP breast implants, 23 January 2012, or BBC News, *PIP breast implants women protest at Manchester clinics*, 21 January 2012

59 BBC News, *PIP Breast implants: Pressure mounts on Lansley*, 12 January 2012

60 Harley Medical Group, letter to patients, 8 January 2012 <http://www.harleymedical.co.uk/breast-enlargement-pip-implant-patient-advice/index.php>

services, the NHS will, in consultation with their doctor, support the removal of PIP implants in line with the guidance that I have just outlined. Any NHS service in that instance would cover only the removal of the implant, which would not include the replacement of private cosmetic implants. In such cases the Government would pursue private clinics to seek recovery of our costs.⁶¹

41. Statistics released by the Department of Health on 16 March 2012 showed that 4,872 women with private PIP implants had been referred for NHS treatment. A total of 2,393 scans had been completed. A total of 252 women had decided to have their implants removed, and 64 removal operations had taken place. 1,303 women “had completed their NHS offer”.⁶²

42. The Chief Medical Officer wrote to GPs on 27 January with the following instructions:

If a GP is consulted by a woman who originally received an implant from a private provider, they should encourage them in the first instance to go back to the original provider for advice, scanning if appropriate, and removal or replacement of the implant if desired. However, if the original provider has gone out of business, or is unwilling to help, the GP should carry out a clinical examination and refer onwards to specialist NHS services [...] They should make clear that the NHS is not offering to pay for a replacement implant.⁶³

43. The advertisement published in national newspapers in order to advise members of the public stated more bluntly: “If your private clinic no longer exists or refuses to remove your PIP implants, speak to your GP. The NHS will remove your implants if your doctor agrees, but the NHS will not replace implants unless it is clinically necessary”.⁶⁴

44. The Chief Medical Officer goes on to say that for those patients who received their original implants from a private provider, “the criteria for replacement at NHS expense should be the same as for a request for primary breast augmentation”.⁶⁵ Again, she notes that “such patients should be encouraged wherever possible to go back to the original provider”.⁶⁶ The Expert Group supported the policy of not replacing private implants.⁶⁷

45. As Sir Bruce told us, unless there is “a very significant clinical need” for replacement,⁶⁸ “the aim of the NHS offer is to restore somebody to their pre-implant condition as best as possible”.⁶⁹ The panel did not agree with the view voiced by Lesley Griffiths, the Welsh Minister for Health, that there would invariably be a clinical need for replacement on the

61 Official Report, 11 January 2012, cols 181–183

62 Department of Health statistical press notice, *PIP breast implants*, 16 March 2012.

63 Letter from the Chief Medical Officer, Professor Dame Sally C Davies, dated 27 January 2012, to General Practitioners, NHS Medical Directors, and Cancer and Plastic Surgeons.

64 Department of Health, newspaper advertisement, *The NHS will support women with PIP breast implants*, January 2012

65 Letter from the Chief Medical Officer, Professor Dame Sally C Davies, dated 27 January 2012, to General Practitioners, NHS Medical Directors, and Cancer and Plastic Surgeons.

66 *Ibid.*

67 Expert group report, para 25.

68 Q53

69 Q 76

basis that not replacing the implants “could result in unsightly scarring, loose skin, and potentially the accumulation of fluids, needs for drainage and risk of infection”,⁷⁰ and that the NHS should therefore provide replacements as a matter of course.⁷¹ Sir Bruce stated that such a view “overestimates the problem and underestimates the quality of surgery offered by consultant NHS surgeons”.⁷²

46. On the other hand, the British Association of Aesthetic Plastic Surgeons (BAAPS) had suggested that the increased irritation caused by PIP implants means that immediate replacement may not always be advisable.⁷³

47. The Committee agrees that replacement implants for private patients should only be provided on the NHS where there is a clinical need. Nevertheless there is a particular problem for women whose original clinic no longer exists or refuses to provide treatment.

48. The Chief Medical Officer notes in her letter of 27 January:

We have received a number of queries from patients with PIP implants supplied by private providers where the provider has failed in its duty of care, causing these patients to turn to the NHS for removal of the implants. They have asked whether they can pay for the additional costs of a replacement as part of a single operation in which the NHS pays for the costs of removal.⁷⁴

49. The CMO does not give a clear line for GPs to take in this situation, referring them instead to general guidance on top-up payments which states that private care should be carried out at a different time and in a different place to NHS care, and that it is only appropriate to divert from these principles “where there are overriding concerns of patient safety, rather than on the basis of convenience”.⁷⁵

50. In addition to the existing rules on separating NHS from private care, Sir Bruce told the Committee a number of reasons why it would not be possible to allow a procedure of this kind:

- The fitting of replacement implants in this instance was an optional, cosmetic procedure, not one of clinical need.⁷⁶
- If the NHS fitted a replacement implant, it would then become responsible for a lifetime of care for the patient, which may include subsequent operations and surveillance.⁷⁷

70 NHS Wales press release, *Wales offers further support to women with PIP implants*, 11 January 2012 <http://www.wales.nhs.uk/news/21527>

71 QQ 54 and 55

72 Q 54

73 . BAAPS press release, *Cross-selling to breast implant scandal victims “immoral”*, 10 February 2012 <http://www.baaps.org.uk/about-us/press-releases/1136-cross-selling-to-breast-implant-scandal-victimes-immoral>

74 Letter from the Chief Medical Officer, Professor Dame Sally C Davies, dated 27 January 2012, to General Practitioners, NHS Medical Directors, and Cancer and Plastic Surgeons.

75 Letter from the Chief Medical Officer, Professor Dame Sally C Davies, dated 27 January 2012, to General Practitioners, NHS Medical Directors, and Cancer and Plastic Surgeons, Annex D.

76 Q 76

- “Many women who have been let down by the private sector will see the NHS now as their preferred option. If they can have an operation at a vastly reduced cost in the NHS, that will impose a significant burden on the NHS. It will also have knock-on implications and opportunity cost for other patients”.⁷⁸
- If the NHS were to facilitate the fitting of replacement implants in this way “why would any of the private providers feel the need to address their duty of care for that patient, except for purely commercial reasons for those patients who could afford it?”⁷⁹

51. We understand the argument the Department put forward. Nevertheless the Committee feels that because of the scale of the problem, the NHS must find a way round this issue in the case of women whose original clinic no longer exists or refuses to provide treatment. **Given the number of women likely to find themselves in this situation, and the potential risks for women undergoing two surgical procedures in rapid succession, a framework must be developed to allow women whose original clinic no longer exists or refuses to provide treatment to be able to pay for private fitting of privately-paid for implants in the course of the same surgery that begins with the NHS removal of the implants. It must be made clear to the patient that the implants are being fitted under a private procedure and that the NHS bears no responsibility for their future care. Such a procedure should, of course, not be carried out if the PIP implant has left the breast cavity in such a condition that it is not advisable to replace the implants immediately.**

52. We appreciate that this step will need to be carefully thought through if it is to fit within existing structures and in order to avoid setting unhelpful precedents, but we invite the Department of Health to propose how it could be achieved. Barriers posed by accounting and administration should not be the cause of women putting themselves through two operations in quick succession.

53. Any additional costs incurred by the NHS in the course of this, or any other procedure that ought rightly to have been carried out by a private provider, must be recouped from that provider.

77 Q 76

78 Q 78

79 Q 80

4 Regulatory issues

54. Recommendations in this section relate to Sir Bruce Keogh’s review of the regulation of cosmetic interventions.

CE Mark

55. PIP breast implants received a CE mark in 2000 via the German Notified Body TUV Rheinland. The BMJ reported that “some time in 2001” “the PIP implant went on to differ in two key respects from its original regulatory application: the company dispensed with the protective outer skin and replaced the silicone contents with lower grade material”.⁸⁰

56. The interim report of the Expert Group noted that concerns about the performance of PIP implants began to emerge in 2006.⁸¹ Following an increase in reports of ruptures, the MHRA raised concerns with PIP and the notified body, and was told that the trend was due to an increase in sales of the implants and improvements in PIP’s reporting criteria. The MHRA raised further concerns in 2009.

57. In March 2010 the French regulator discovered that PIP was using non-authorised silicone, in violation of the CE mark. The CE mark was consequently revoked. The MHRA issued a medical device alert to cease use of the implants.

58. An editorial in the *Lancet*, 18 January 2012 accused the MHRA of having “been well aware of the risks of serious device failures for some time” and described the PIP implant scandal as “an inevitable result of MHRA’s paralysis and inability to correct the failings of a severely flawed system”. It accused the MHRA of operating under the principle of “do nothing until something goes wrong”.⁸² Sir Kent Woods refuted the accusations, stating that “the evidence which has emerged in France in the course of legal investigations is a deliberate, economically motivated breach of the regulatory requirements. The challenge [...] is whether any feasible reform of the regulatory system could adequately guard against such incidents”.⁸³

59. Although the MHRA conducts periodic audits of Notified Bodies, it does not conduct its own assessment of data on safety and effectiveness of devices. The MHRA has stated that “our responsibility [in the PIP case] was to investigate adverse incidents as part of our post-market surveillance role. We did this and we have continually monitored the safety of these breast implants”.⁸⁴

60. The real issue here is the failure of the CE mark to provide adequate assurance that the product—the PIP implant—was appropriate to use. Sir Kent told the Committee:

80 BMJ vol 344 p10, *The saga of Poly Implant Prothèse Breast Implants*, Carl Heneghan, 14 January 2012

81 Department of Health, *Poly Implant Prothèses (PIP) Breast Implants: Interim Report of the Expert Group*, 6 January 2012, p6

82 The *Lancet*, 18 January 2012, *Offline: The scandal of device regulation in the UK*

83 Sir Kent Woods, Chief Executive, MHRA, letter to the editor of the *Lancet*, 24 January 2012

84 MHRA, *MHRA response to the Harley Medical Group position on the replacement of PIP implants*, 11 January 2012.

It is very important to look extremely closely at the circumstances of the particular situation here: how this arose and how it was possible that this manufacturer was able to produce a non-authorised product for so long. One of the issues that have very much concerned regulatory authorities—and, indeed, the Commission—is the question of how spot checks can best be targeted and made use of. The broad framework for medical devices regulation is generally held to be a good one, but, clearly, there are lessons to be learned in the specific instance of the relationship between the manufacturer and the notified body that was responsible for auditing the factory in this instance.⁸⁵

61. A February 2012 *Times* article quoted Sir Kent: “Sir Kent defended the regulatory system, saying that it could not be expected to detect fraud, was basically sound and needed only “incremental improvements”.”⁸⁶

62. Recent concerns about the safety of metal-on-metal hip implants suggest there is further cause for strengthening CE mark requirements more generally.⁸⁷

63. Procedures for the follow-up of the CE mark certification have been shown to be inadequate by what has happened in this case. Sir Bruce’s review should examine how to strengthen the CE mark system—for example by ensuring that certified devices are subject to routine review. There must be a procedure whereby the concerns of national regulators regarding implants manufactured in another European country can be acted upon and investigated.

Register of implants

64. The MHRA were not able to contact private patients directly,⁸⁸ instead they had to go through the UK supplier:

That is a route we have used: going back to the UK supplier for PIP implants to find out where those implants were sold by hospital name. [...] They are, essentially, sales volumes data. They do not allow us to get down to patient level, of course, but knowing the organisations into which those PIP implants were sold, we can then pursue our inquiries through that organisation and ask them to provide us with the follow-up data.⁸⁹

65. Sir Kent told us that “in terms of the ability to identify and track patients, what one would like to see for the future is a proper registry system for breast implants [where] the fact of an implant and the identity of the recipient were centrally recorded and the outcomes of those procedures were analysable over time”.⁹⁰

85 Q 100

86 *The Times*, Implant scandals ‘cannot be prevented’, 17 February 2012.

87 See, for example, MHRA Medical Device Alert on metal on metal implants, issued 28 February 2012. <http://www.mhra.gov.uk/Publications/Safetywarnings/MedicalDeviceAlerts/CON143782>

88 Q 19

89 QQ 36–37 (Sir Kent Woods)

90 Q 30

66. Between 1993 and 2006 the MHRA funded a National Breast Implant Registry, set up following a review by a Department of Health Expert Advisory Group. That Group had recommended a register to be used as a basis for future research projects into the long term outcomes associated with silicone gel breast implants. The register was voluntary and only small numbers of women were willing to take part in the scheme. The register was closed in 2006 because the data was considered inadequate.

67. Sir Kent noted that the particular problem with the previous attempt at a register had been the “striking reluctance of women who had breast implants to give follow-up information” and that “for breast implants, there are particular difficulties with the population and the clinics in which this is done, which made our attempt to run an implant registry come to nothing”.⁹¹

68. The Secretary of State told the House:

I would expect [Sir Bruce’s second] review also to include consideration of an outcomes-based register of frequently implanted devices, covering everything from breast implants to heart valves and replacement joints, in order to provide the United Kingdom with a valuable asset for further innovation and safety improvement. There is already considerable clinical support for such a comprehensive register.

69. Sir Bruce’s review should pursue the creation of a register of implants, to improve reporting of adverse incidents, allow better monitoring of outcomes, and allow swift communication with affected parties in the event of a problem being found. Inclusion on the register should be compulsory.

Responsibilities of provider organisations and medical professionals

70. Time and again during our evidence session the matter was raised of the responsibilities of both private clinics as organisations carrying out medical care, and of surgeons as medical professionals. On a number of issues it was not certain that either provider organisations or surgeons had met the ethical and professional standards that we expect of those carrying out medical treatment of any kind, whether in the NHS or private care.

71. For example, both provider organisations and medical professionals should have an obligation to report incidents which may give rise to concerns about the performance of implanted devices. Secondly, both providers and medical professionals are under an obligation to ensure patients only commit to treatment following informed consent.

Adverse incident reporting

72. The Expert Group’s report concluded that, in terms of data on risk of rupture:

Much of the available information is subject to potential under-reporting. Although the manufacturers are required to report all serious adverse events (including rupture), notifications from providers in the UK to the regulator are voluntary.

Cosmetic surgery providers will only be aware of problems if patients come back to them for follow-up, and many patients may seek advice elsewhere (including the NHS). We believe that under-reporting seriously affects the validity of current PIP data and some comparative data about similar implants.

73. The Secretary of State told the House:

The adverse incident centre has had 478 reports of ruptures over the whole period, which extends back many years. One of the things we want to understand as part of our review is why, if there were ruptures and, more to the point, adverse health effects associated with these implants, they were not disclosed to the adverse incident centre.

74. The Secretary of State described the safety information provided by the industry to the regulator as being “of variable quality”. Sir Kent told us:

The difficulty has been that most of the information on this subject has been by the nature of individual case reports coming to the regulator, the manufacturer, or the notified body. That will give a proportion of the implants that have been reported to have ruptured but, since time itself is a determinant of rupture, one really needs to be able to plot, as it were, the durability of these implants under conditions of use.⁹²

75. This has made it difficult for the MHRA to identify clear early warning signs, and to give advice once a difficulty has been identified. Witnesses were also unable to tell us how, when, or if private clinics had contacted their patients following the withdrawal of the CE mark.⁹³

Informed consent

76. The Chief Medical Officer, in her letter to GPs of 6 January 2012, noted that she remained concerned “at the high level of cosmetic implants in young people. In particular, the apparent lack of real understanding by recipients of the associated risks”.⁹⁴ The MHRA advice leaflet for women considering breast implants sets out that breast implants are a long-term commitment, and reminds women that “breast implants do not come with a lifetime guarantee. They are likely to need replacing with consequent further surgery and expense. A young woman who has implants may expect to have further operations in her lifetime to maintain the beneficial effects of the implants”.⁹⁵

77. Simon Withey told us:

A number of patients who have had implants put in elsewhere have come to see me with worries, asking whether they can have their implants removed. It has become clear that, in some instances, these women are not aware that implants will

92 Q 3

93 QQ 23–25

94 Letter from the Chief Medical Officer, Dame Sally C Davies, dated 6 January 2012, to General Practitioners, NHS Medical Directors, Cancer and Plastic Surgeons.

95 MHRA, *Information for women considering breast implants*, April 2011.

occasionally rupture. They are not aware that, inevitably, there will be some further implications down the line of having had surgery.⁹⁶

78. Mr Withey noted that a contract between a surgeon and his patient could only be an “understood contract if the patient has adequately consented”.⁹⁷ He also told us:

There has been a tendency for commercial pressures to override what we know is sound clinical judgement and sense. It is vital that those who are not appropriate for or will not benefit from surgery are made aware of that beforehand and that anyone who is felt to be appropriate is also made aware of the implications of surgery.⁹⁸

79. **In the light of these issues, the Committee believes that these events prompt some serious concerns which need to be addressed both by provider organisations and the medical profession, and by their professional regulators.**

Responsibilities of provider organisations

80. **Sir Bruce’s review should look into how to improve reporting of adverse incidents and examine the procedures in place in provider organisations for the reporting of such incidents. All providers in both the public and private sectors should have consistent and obligatory procedures for reporting adverse incidents to the MHRA. Sir Bruce’s review should assess the quality and consistency of record keeping in the both the public and private sectors; and should review the actions taken to communicate with patients following the withdrawal of the CE mark in March 2010. Providers also have a responsibility to ensure that their patients are aware of the risks and commitments involved in their procedures. Sir Bruce’s Review should assess the quality of consent procedures and investigate how it can be ensured that patients have been given the time and information they need to reach an informed decision.**

Professional responsibility of medical professionals

81. **Medical professionals should be alert to adverse incidents and ought to ensure that these are reported to the MHRA. They ought also to satisfy themselves that treatment is only provided to a patient who has given fully informed consent.**

82. **Sir Bruce’s review should look at how well surgeons are respecting these professional obligations. The Committee also believes that the GMC should review medical professionals’ performance of these obligations in the light of these events.**

83. **The Committee believes that both Sir Bruce and the GMC should review the ways in which information about risks related to medical devices is drawn to the attention of surgeons who are not members of the relevant professional associations. The fact that many of these operations are taking place in the private sector does not change the nature of the professional obligation on medical professionals.**

96 Q 74

97 Q 74

98 Q 75

Insurance

84. The situation regarding insurance is unclear. The Harley Medical Group has said that the advice it has received is that it would not be possible to claim for the cost of pre-emptively removing PIP implants because it had not been proven that the product was faulty (the Expert Group itself having found inconclusive evidence) and because, even if a risk were to be proved, insurers would only pay out subsequent damage or injury (as opposed to simply rupture) had occurred.⁹⁹

85. Mr Withey noted:

There is a clearly a statutory obligation for medical indemnity—professional indemnity insurance—of the surgeon. But I do not think any surgeon put this implant in knowing that he was putting in anything other than a reasonable and regulated product. If it was clear that they had been professionally negligent in choosing an implant, the situation would be very different. That, clearly, is not the case. There is not an obligation, as far as I am aware, for the providers to have any sort of second tier of insurance.¹⁰⁰

86. Sir Bruce stated that his review would look into the extent of existing arrangements and whether there was a need for an additional statutory obligation on private providers.¹⁰¹

87. Sir Bruce told BBC Radio 4 programme *The Report* that his review would consider an insurance protection scheme for private cosmetic surgery patients. He said that the review would look at “something like the ABTA arrangement, which means that when a company runs into trouble for whatever reason, the consumer is covered”.¹⁰² Sir Bruce said that this model “captured the flavour of where we want to go”.¹⁰³

88. Sir Bruce’s review must look into how existing insurance arrangements in the sector, which apply to both providers and medical professionals, protect the interests of patients and how such insurance arrangements may need to be strengthened for the future.

Advertising for cosmetic surgery

89. Finally, Simon Withey agreed that there had been trivialisation of cosmetic surgery in some areas.¹⁰⁴ He also noted that advertising often promised unrealistic results from cosmetic surgery:

99 E-mail from Pierre Guillot, Managing Director, Harley Medical Group, dated 24 February 2012, to Sir Bruce Keogh (copied to Stephen Dorrell MP).

100 Q 57

101 Q 57

102 ABTA, the Association of British Travel Agents, offers financial protection for its members and customers should something go wrong. Companies pay a subscription to become members of Abta, which then provides a fund for people to fall back on should there be a problem.

103 BBC News, *PIP implant review could result in new insurance scheme*, 20 January 2012.

104 Q 87

Suggestions that it makes a dramatic difference to your job prospects, your life prospects or your prospects with the other sex is something that, clearly, must be considered as advertising that is unreasonable. But there are very strong data about the positive effects in well-selected patients.¹⁰⁵

90. In certain cases, cosmetic surgery has been commercialised and trivialised. Advertising is sometimes inappropriate and fails to make clear the commitment and aftercare involved. Advertising should not be targeted at under-18s, and the Review should consider how to ensure this.

Conclusions and recommendations

Evidence on the risks of PIP implants

1. All possible evidence, including patient-reported experiences, must be gathered and analysed in order to inform the policy response to this issue. We look forward to seeing what new evidence has been made available to the Expert Group since the publication of its interim report. If this new evidence does not allow for a conclusive view on the safety of PIP implants, we recommend that the Department brings forward a proposal for gathering the necessary data. (Paragraph 13)
2. Since the publication of the Expert Group's Report some further evidence has been emerging about the inflammatory properties of the PIP implants whether ruptured or not, and the increased difficulty of removing ruptured PIP implants. Evidence on these issues should be examined carefully and urgently—if it is found that the removal of ruptured PIP implants involves significant complications, then this would be an argument for recommending early removal of PIP implants. (Paragraph 14)

Action before March 2010

3. The Committee is concerned that, given what was known about PIP implants and the issues raised by the MHRA, there wasn't greater vigilance, especially when PIP implants were significantly cheaper and were not the implant of choice for surgeons. Earl Howe's Review should seek to address whether the MHRA had information that ought to have prompted them to act sooner. (Paragraph 19)

Action between March 2010 and December 2011

4. "Sincere hope" is not an adequate basis for regulation. There needs to be a more reliable method of communicating Medical Device Alerts to the private sector, that requires a positive response that the instruction has been received and acted upon in the same way as in the NHS. Sir Bruce Keogh's review into the regulation of cosmetic interventions must set out how this could best be achieved. Using the professional associations as channels of communication will not cover all surgeons. (Paragraph 22)
5. It is surprising that urgent action to gather evidence and communicate with affected women only gathered pace in December 2011, following the announcement of the French Government. Given the fact that 40,000 women were known to have received sub-standard implants, the very scale of the problem alone should have provoked a high-profile policy response much sooner, including urgent action to gather evidence that would allow the risks of these implants to be properly assessed. Earl Howe's review must examine why action was not taken sooner. (Paragraph 26)
6. The action taken to communicate with affected women after March 2010 was inadequate. The Committee recognises that private clinics had a duty to contact their patients directly, but the MHRA and the Department of Health also had a duty to raise public awareness. A more creative approach should have been used. Earl Howe's review should determine when the Department of Health and the MHRA

contacted NHS patients directly, and the adequacy of strategies to communicate with the far greater body of private patients. (Paragraph 28)

The NHS offer

7. Private clinics used PIP implants in good faith because of the CE mark. Nevertheless, the Committee agrees with the Department of Health that private clinics have an obligation to provide care and should mirror the NHS offer. (Paragraph 37)
8. The Department of Health has been very clear about the moral imperative—it would have been welcome to have had a clearer statement of the extent of the legal obligation on private clinics. The argument of a moral imperative may be compelling, but it is difficult to enforce. Sir Bruce’s review should provide a clear statement of the legal responsibility of providers to meet their duty of care and to supply an appropriate product. The situation must be clear and consistent. It is unacceptable that there should be uncertainty when it comes to responsibility for a device implanted into the body. (Paragraph 38)
9. The NHS offer must take into account matters of capacity. The overall number of women affected is significant, and single providers are responsible for a significant proportion of that number. There is no point having a policy stance if it cannot reasonably be carried through. The capacity to undertake the surgery must be assessed and the policy response tailored accordingly. The Committee asks the Department of Health to identify how to make the best use of any spare capacity, whether public or private. (Paragraph 39)
10. The Committee agrees that replacement implants for private patients should only be provided on the NHS where there is a clinical need. Nevertheless there is a particular problem for women whose original clinic no longer exists or refuses to provide treatment. (Paragraph 47)
11. Given the number of women likely to find themselves in this situation, and the potential risks for women undergoing two surgical procedures in rapid succession, a framework must be developed to allow women whose original clinic no longer exists or refuses to provide treatment to be able to pay for private fitting of privately-paid for implants in the course of the same surgery that begins with the NHS removal of the implants. It must be made clear to the patient that the implants are being fitted under a private procedure and that the NHS bears no responsibility for their future care. Such a procedure should, of course, not be carried out if the PIP implant has left the breast cavity in such a condition that it is not advisable to replace the implants immediately. (Paragraph 51)
12. We appreciate that this step will need to be carefully thought through if it is to fit within existing structures and in order to avoid setting unhelpful precedents, but we invite the Department of Health to propose how it could be achieved. Barriers posed by accounting and administration should not be the cause of women putting themselves through two operations in quick succession. (Paragraph 52)

13. Any additional costs incurred by the NHS in the course of this, or any other procedure that ought rightly to have been carried out by a private provider, must be recouped from that provider. (Paragraph 53)

CE Mark

14. Procedures for the follow-up of the CE mark certification have been shown to be inadequate by what has happened in this case. Sir Bruce's review should examine how to strengthen the CE mark system—for example by ensuring that certified devices are subject to routine review. There must be a procedure whereby the concerns of national regulators regarding implants manufactured in another European country can be acted upon and investigated. (Paragraph 63)

Register of implants

15. Sir Bruce's review should pursue the creation of a register of implants, to improve reporting of adverse incidents, allow better monitoring of outcomes, and allow swift communication with affected parties in the event of a problem being found. Inclusion on the register should be compulsory. (Paragraph 69)

Informed consent

16. In the light of these issues, the Committee believes that these events prompt some serious concerns which need to be addressed both by provider organisations and the medical profession, and by their professional regulators. (Paragraph 79)

Responsibilities of provider organisations

17. Sir Bruce's review should look into how to improve reporting of adverse incidents and examine the procedures in place in provider organisations for the reporting of such incidents. All providers in both the public and private sectors should have consistent and obligatory procedures for reporting adverse incidents to the MHRA. Sir Bruce's review should assess the quality and consistency of record keeping in the both the public and private sectors; and should review the actions taken to communicate with patients following the withdrawal of the CE mark in March 2010. Providers also have a responsibility to ensure that their patients are aware of the risks and commitments involved in their procedures. Sir Bruce's Review should assess the quality of consent procedures and investigate how it can be ensured that patients have been given the time and information they need to reach an informed decision. (Paragraph 80)

Professional responsibility of medical professionals

18. Medical professionals should be alert to adverse incidents and ought to ensure that these are reported to the MHRA. They ought also to satisfy themselves that treatment is only provided to a patient who has given fully informed consent. (Paragraph 81)
19. Sir Bruce's review should look at how well surgeons are respecting these professional obligations. The Committee also believes that the GMC should review medical

professionals' performance of these obligations in the light of these events. (Paragraph 82)

20. The Committee believes that both Sir Bruce and the GMC should review the ways in which information about risks related to medical devices is drawn to the attention of surgeons who are not members of the relevant professional associations. The fact that many of these operations are taking place in the private sector does not change the nature of the professional obligation on medical professionals. (Paragraph 83)

Insurance

21. Sir Bruce's review must look into how existing insurance arrangements in the sector, which apply to both providers and medical professionals, protect the interests of patients and how such insurance arrangements may need to be strengthened for the future. (Paragraph 88)

Advertising for cosmetic surgery

22. In certain cases, cosmetic surgery has been commercialised and trivialised. Advertising is sometimes inappropriate and fails to make clear the commitment and aftercare involved. Advertising should not be targeted at under-18s, and the Review should consider how to ensure this. (Paragraph 90)

Formal Minutes

Wednesday 21 March 2012

Members present:

Mr Stephen Dorrell, in the Chair

Rosie Cooper
Andrew George
Barbara Keeley

Chris Skidmore
David Tredinnick

Draft Report (*PIP Breast implants and regulation of cosmetic interventions*), proposed by the Chair, brought up and read.

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

Paragraphs 1 to 90 read and agreed to.

Summary agreed to.

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

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

Ordered, That embargoed copies of the Report be made available, in accordance with the provisions of Standing Order No. 134.

Written evidence was ordered to be reported to the House for printing with the Report.

Written evidence was ordered to be reported to the House for publishing on the Internet.

[Adjourned till Tuesday 17 April at 10.00 am

Witnesses

Tuesday 7 February 2012

Page

Professor Sir Bruce Keogh KBE, NHS Medical Director, **Professor Sir Kent Woods**, Chief Executive of the Medicines and Healthcare products Regulatory Agency, **Dr Anne-Marie Slowther**, Associate Professor of Clinical Ethics at Warwick Medical School and Consultant Clinical Ethicist at University Hospitals, Coventry and Warwickshire NHS Trust, and **Mr Simon Withey**, Consultant Plastic Surgeon, Member of the Council of the British Association of Aesthetic Plastic Surgeons and Member of the Steering Committee looking at Standards in Aesthetic Plastic Surgery.

Ev 1

List of printed written evidence

Department of Health supplementary

Ev 17

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.

Session 2010–12

First Report	Appointment of the Chair of the Care Quality Commission	HC 461-I
Second Report	Public Expenditure	HC 512 (Cm 8007)
Third Report	Commissioning	HC 513 (Cm 8009)
Fourth Report	Revalidation of Doctors	HC 557 (Cm 8028)
Fifth Report	Commissioning: further issues	HC 796 (Cm 8100)
First Special Report	Revalidation of Doctors: General Medical Council's Response to the Committee's Fourth Report of Session 2010–11	HC 1033
Sixth Report	Complaints and Litigation	HC 786 (Cm 8180)
Seventh Report	Annual accountability hearing with the Nursing and Midwifery Council	HC 1428 (HC 1699)
Eighth Report	Annual accountability hearing with the General Medical Council	HC 1429 (HC 1699)
Ninth Report	Annual accountability hearing with the Care Quality Commission	HC 1430 (HC 1699)
Tenth Report	Annual accountability hearing with Monitor	HC 1431 (HC 1699)
Eleventh Report	Appointment of the Chair of the NHS Commissioning Board	HC 1562-I
Twelfth Report	Public Health	HC 1048-I (Cm 8290)
Thirteenth Report	Public Expenditure	HC 1499 (Cm 8283)
Fourteenth Report	Social Care	HC 1583-I
Fifteenth Report	Annual accountability hearings: responses and further issues	HC 1699
Sixteenth Report	PIP Breast implants and regulation of cosmetic interventions	HC 1816

Oral evidence

Taken before the Health Committee on Tuesday 7 February 2012

Members present:

Mr Stephen Dorrell (Chair)

Andrew George
Barbara Keeley
Grahame M Morris

Dr Daniel Poulter
David Tredinnick

Examination of Witnesses

Witnesses: **Professor Sir Bruce Keogh** KBE, NHS Medical Director, **Professor Sir Kent Woods**, Chief Executive of the Medicines and Healthcare products Regulatory Agency, **Dr Anne-Marie Slowther**, Associate Professor of Clinical Ethics at Warwick Medical School and Consultant Clinical Ethicist at University Hospitals, Coventry and Warwickshire NHS Trust, and **Mr Simon Withey**, Consultant Plastic Surgeon, Member of the Council of the British Association of Aesthetic Plastic Surgeons and Member of the Steering Committee looking at Standards in Aesthetic Plastic Surgery, gave evidence.

Q1 Chair: Good morning. Thank you for coming to what is intended to be a single-session review of where we are in the light of the events just before Christmas regarding breast implants. We propose to handle the session in four stages, if we may. We will begin by looking at the factual background to what happened. Secondly, we will look at the treatment implications for the women concerned. Thirdly, we will look at the future regulatory lessons that may be appropriate for these specific devices. Fourthly, we will look at the broader issues relating to the cosmetic surgery practice as a whole. If we can try to stick to that progression, we will get a reasonably orderly discussion.

With that background, could I ask you, very briefly, to introduce yourselves so that we know exactly who we are talking to?

Professor Sir Bruce Keogh: Good morning, Chair. My name is Bruce Keogh. I am the NHS Medical Director.

Dr Slowther: I am Anne Slowther. I am Associate Professor of Clinical Ethics at Warwick Medical School.

Professor Sir Kent Woods: I am Kent Woods. I am Chief Executive of the Medicines and Healthcare Products Regulatory Agency.

Mr Withey: I am Simon Withey. I am a Consultant Plastic Surgeon at the Royal Free and University College Hospitals. I have been an expert adviser to Sir Bruce Keogh.

Q2 Chair: Thank you very much. Could we begin by asking Sir Bruce and Sir Kent to summarise for us what the timelines were from the point at which there was known to be a problem with the PIP implants? Our understanding is that that was first reported to the French authorities in March 2010, and it seems an extraordinarily long time between that notification of a substandard product and the policy response.

Professor Sir Kent Woods: You are right. The immediate precipitant to current concerns was the report circulated from the French regulatory agency at the very end of March 2010 that an unannounced

inspection of the PIP plant revealed the company was using an unauthorised silicone filler which was not that specified in the CE marking assessment and that, therefore, the product was not of the quality approved for the market. On the basis of that information, we and other regulatory agencies, immediately took steps to make sure that PIP implants were no longer being used.

The history with PIP is a little longer, but I would emphasise that the immediate cause of the present concerns was that finding of what appears to have been—and this is, at the moment, subject to a criminal investigation—a deliberate, sustained and well-concealed economic fraud to use a cheaper filling material in the implants than the one approved a decade earlier. That brought matters to a head.

Our concern as a regulator, at that point, was threefold: first, to stop the PIP implants being used, and for that we communicated both with the health profession and with the professional associations and in public; secondly, to find out what we could about the properties of this improper filling material—in other words, the risks that it might carry for patients; and, thirdly, to look at the evidence available on the rates of rupture of these implants, again as a marker of the likelihood of women being exposed to this unauthorised material. Subsequently, our efforts were directed towards, among other things, commissioning some toxicology research on that filler material and also collating—and, indeed, our colleagues across Europe collating—all the information available about rupture with that particular type of implant.

Q3 Chair: I am struck that, even at the very beginning, you thought rupture was an issue from that evidence. Does that imply there were already stories in circulation that these products were subject to a higher rate of rupture than would be regarded as acceptable?

Professor Sir Kent Woods: That has been a point of some debate. The basic facts of the matter are that all breast implants will wear out and will have a predictable—or, rather, a slightly unpredictable—rate

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of rupture over time. In this respect, PIP implants appear to be no different. The question is whether the rate of rupture with these implants diverges from what one would expect of other products over time. The difficulty has been that most of the information on this subject has been by the nature of individual case reports coming to the regulator, the manufacturer or the notified body. That will give a proportion of the implants that have been reported to have ruptured but, since time itself is a determinant of rupture, one really needs to be able to plot, as it were, the durability of these implants under conditions of use. So it is a complex issue.

The current state of understanding—not only in the Expert Group that Sir Bruce chaired but also in the European Expert Group which reported to the Commission a few days ago—is that, on present evidence from the data that we have, there does not appear to be an increased rupture rate. This is of limited reassurance because, of course, the data are not as comprehensive as we would like.

Q4 Chair: I will come on, if I may, to the question of the data. Pausing for a second on the period between March 2010 and December 2011, do you recognise that it is surprising to an onlooker that the regulatory authorities were told in March 2010 that products that would not have passed if they had been submitted for test had been implanted routinely until March 2010, but it took over 18 months for there to be any significant policy response, either in this country or, apparently—and is this right?—in other European countries as well?

Professor Sir Kent Woods: Can I respond to that directly? We put out advice immediately, as soon as we had that information in March 2010. As I say, our advice then was that the implants should not be used and that we were collecting further data, and—

Q5 Chair: Can I interrupt you? I accept that you stopped further use, but currently a population of, we understand, about 40,000 women have had these products implanted, and as of March 2010 the regulators knew that those products would not have passed tests.

Professor Sir Kent Woods: Yes.

Q6 Chair: Do you think, in retrospect, that 21 months was an appropriate time to take to conclude whether some further response directed to those 40,000 was necessary, accepting that there were no further implantations after that time?

Professor Sir Kent Woods: Our advice over that time has not changed. Our knowledge, as toxicology results have come in, has been strengthened. As new information has accumulated, we have put that out into the public space, both by medical device alerts and by press communications. What changed on 23 December 2011 was the stated decision of the French Government to advocate explantation. That was the new feature. The background to that in the preceding 18 months was that there had been a continuous communication of risk information as we had it, but the advice had not changed. Our perception remained

that there was not a case for advising routine explanation, but that these women should seek to consult expert advice and be examined. If they had symptoms to suggest rupture, then they should be investigated with explantation in mind. The thing that changed in December 2011 was the announcement by the French Government that they wished to adopt a policy of recommending routine explantation.

Q7 Chair: Did you know that the French authorities were contemplating that announcement?

Professor Sir Kent Woods: We had intimations of that three days earlier.

Q8 Chair: It does not suggest that the European authorities are working very closely together, does it?

Professor Sir Kent Woods: It is fair to say that we had quite good exchanges of information with the French regulator, AFSSAPS. The origin of this statement was essentially a policy statement coming from the Ministry of Health. It is true that we would have very much wished to have had clearer sight of the way the French authorities—and indeed the French Government—were thinking of moving. Since then, we have been trying to ascertain precisely what new data there were underpinning that decision. I have to say, particularly in view of the European report—the report by the Scientific Committee on Emerging and Newly Identified Health Risks—which came out a few days ago, that it appears we were all looking at the same data, but different decisions were made in different places.

Q9 Chair: Looking back over that period, is it still your view, knowing what you knew at the time, that the MHRA did what was appropriate? Given your time again, would you have done it differently?

Professor Sir Kent Woods: No. I believe our actions were appropriate and I think the communications were appropriate. Indeed, the view that has been taken by the SCENIHR expert group reporting to the Commission a few days ago aligns very closely with the conclusions reached by Sir Bruce Keogh's Expert Group that "there is no clear evidence at present that patients with a PIP implant are at greater risk of harm than those with other implants." That was Sir Bruce's report on 6 January. The SCENIHR expert committee reported to the Commission on the 1st of this month that there is "insufficient evidence to warrant a conclusion that women with PIP silicone breast implants have a greater risk to their health than women with breast implants from other manufacturers." That is the consistent position, and I do not think that the events of December 2011 alter that perception.

Q10 Andrew George: I will not skirt over the first of your three objectives in March 2010; you said that the first objective was to stop the use. I understand that that was advice rather than a mandatory instruction. I want to get the background as to what might have motivated clinics, and indeed the NHS, as I understand it, to have used the unauthorised—not known to them, but unauthorised—silicone implants.

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What is the market like in silicone implants? In other words, are the unauthorised implants significantly cheaper than those that are authorised? As I understand it, the majority of the implants used within the NHS were authorised and, obviously unbeknown to them, in a minority of cases it seems that unauthorised PIP implants were used. Is that the case? I want to get a picture of what the drivers are within the plastic surgery field and why surgeons were using them.

Professor Sir Kent Woods: I am not best placed to answer that question as regards surgical practice, except to say that, at the time of use, all these were considered authorised and CE marked.

Andrew George: Of course, yes.

Professor Sir Kent Woods: I understand there was a significant price differential, but I cannot give you any more detail than that.

Professor Sir Bruce Keogh: Simon may be best equipped to answer that question.

Mr Withey: I am aware there were reports of a very significant price differential. You would hope that everyone would put the best implant into the patient—the implant that was most suitable for them. Probably there were commercial pressures, in some instances, to use PIP as opposed to other implants. Initially when they were brought out, although they were cheaper, they were felt by certain people to be as strong and robust as anything else. I know that some surgeons, subsequently, felt perhaps they did not meet their needs and stopped using them, but that probably happens with a lot of products. I suspect you are correct that, in some instances, the choice of these implants was driven by price, but it does not take away from the fact, as Sir Kent says, that these were all legitimate implants. No one who bought them, even if they were buying them at a cheaper price, was aware that they were anything but a CE-marked and legitimate implant.

Q11 Andrew George: Of course. By and large, these were used in most cases in the private sector, but rarely in the NHS. Is that a fair characterisation?

Mr Withey: Yes. I think about 3% were used in the NHS and the remainder in the private sector.

Q12 Andrew George: Is that 3% of all the implants used or 3% of the whole market?

Mr Withey: It is 3% of these implants. They were used for a variety of procedures. They were used for reconstructive procedures, for balancing asymmetric breasts and, in some cases, for primary breast augmentation for women with amastia—with small breasts.

Q13 Andrew George: I come now to the point of March 2010 and your advice. You do not, as I understand it, have the power to stop use of a device, so it was advice at that stage. You said—and indeed the Chairman implied—that was it, and one assumes that all clinics will have followed that advice immediately. How do you know that that is the case and that—with, perhaps, their storerooms of PIP

implants—they were not continuing to use them until those stores ran out?

Professor Sir Kent Woods: First, I will deal with the question of powers to remove from the market. This was a French manufacturer based near Toulon. Therefore, it was in the authority of AFSSAPS—the French regulatory body—to suspend and then withdraw the CE marking, which had been approved by a German-notified body. That action was rapidly put in hand by the French agency.

In terms of your second question about how we know that our advice in this country is being acted on, when we send out a medical device alert it goes through a central alerting system that requires a response from the recipients to indicate, by a given deadline, first, that they have received the information and, by a second deadline, that they have acted on the information. That system certainly runs throughout the NHS. Penetration into the private sector is less certain. The other route that we used was the professional surgical associations, to ensure that those practitioners who were going to be using implants would have the information immediately.

Q14 Andrew George: But Mr Withey has said that this is something that is commercially price-driven, particularly, no doubt, in the private sector. Can you say that you are absolutely confident that, in the private sector clinics, these PIP implants will not have been used after your advice was issued in March 2010?

Professor Sir Kent Woods: I am afraid I cannot give you that assurance. I can only say that we used every route available to us to get that information out to where it was needed. I honestly cannot say that no PIP implant was moved from store into an operating theatre after that date. One sincerely hopes that it did not happen, and I think the combined effects of the different routes of communication that we used were the best that could be done to make sure it did not happen.

Q15 Andrew George: Mr Withey, you are a professional and know what the professional standards are among your colleagues. Are you confident that all 100% of them will have acted on that advice immediately and will not have been tempted, due to commercial pressures, to use the cheaper, unauthorised implants after that date?

Mr Withey: I can be confident that members of the two main professional associations will have taken that view. I cannot comment on some of the commercial organisations who are, perhaps, less aligned to the professional associations. I would have thought that any doctor who uses these, knowing they have been withdrawn from the market, would be immediately under the scrutiny of the GMC. It is something that is unacceptable in clinical practice. If you know something is not fit for practice, you should not be using it.

Q16 Andrew George: I am going to expose my ignorance here. Are there any circumstances in which a breast implant might be placed by someone who

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is not within the medical professions that you have described—not registered with the GMC?

Mr Withey: No. Everyone putting them in will be a doctor registered with the GMC. Not all of them will be a member of one of the professional associations, which have a certain set of codes of ethics and standards of care.

Q17 Grahame M Morris: I would refer to an answer that Professor Woods gave a little earlier in relation to the advice of the Chief Medical Officer—the fact that a decision was made, based on advice from the Expert Group, that where there was a clear clinical imperative the NHS would undertake replacements. I want to ask your opinion, or perhaps Mr Withey’s opinion, about anxiety issues for individuals who have had these PIP implants. Surely, that is a significant health risk in itself. Is there anything we should learn from what is happening in Wales, where they seem to have given greater emphasis to this anxiety issue, and should that, in itself, be cause for the NHS to replace these PIP implants?

Mr Withey: I do not think anxiety alone is a reason to remove an implant. If a patient is anxious, there is very good reason for them to see a surgeon—or a professional—who can give them advice on the relative risks and benefits of removing that implant. Getting access to a professional to have that discussion is very important, and that is certainly something on which the Expert Group have advised and has been generally accepted as good practice. I do not think that necessarily means that you should be taking out every implant from every anxious woman. You can generally allay a lot of the anxiety when you discuss the reality of the situation with them.

Q18 Grahame M Morris: Where should the NHS draw the line in that regard? Is it not a material factor when we are considering the health and well-being of patients? A constituent has contacted me who is distraught at the prospect and has had some difficulty contacting the private clinic that originally carried out the procedure. Is that anxiety not a legitimate concern that the National Health Service should be addressing?

Mr Withey: Currently, it is addressing it. If a patient is anxious and they contact their private provider and their private provider is unwilling to help them, they cannot remember who it was or they fail to make communication, they are able to go to their GP. Their GP will refer them to a specialist service and they will see a professional, either a breast cancer surgeon, if there are lumps and a reason for worry beyond simply having these implants, or a reconstructive breast surgeon in the NHS, and the risks and benefits will be discussed with them. If they feel they would like to go ahead with removing the implant, the NHS will undertake that work. It has already started doing that.

Chair: Before we move on to the rest of NHS services, Barbara, you wanted to come back to the factual position.

Q19 Barbara Keeley: It is important that we take on board not only ruptures—which you have talked

about, Professor Woods—but the Expert Group’s note that there is a greater tendency with these PIP implants to interface with the local tissue and a greater potential to generate an inflammatory response. That may be the basis of other countries recommending routine removal because, on the same balance of evidence, other countries are coming up with different conclusions.

I want to ask you two questions. First, it appears, from a lot of the information milling about, that this may not have come out of the blue. There seem to have been concerns about this company PIP. It had earlier issues with a different sort of implant, many cases have been talked about and there has been much communication about this. I cannot believe that this did come out of the blue, given there were already levels of concern and what those levels of concern were.

Secondly, I am concerned by what you say about communication. You say that the medical device alert system runs through the NHS. Most of the 40,000 victims of these faulty products were not seen in the NHS—I think only a very small proportion was seen in the NHS—so, possibly, 37,000 or 38,000 women. It does seem to me, and I think most Members would agree, that many only became aware of this from December onwards. You may have used a system that runs through the NHS, but what communication did you think about making with the people affected? Given what the Expert Group is saying, whether or not these products rupture, they have the tendency to cause this inflammation and, clearly, materials can get into the body. That is a real worry. Once it was realised that these products were faulty in this way, surely the right thing to do would have been to communicate, in some way, very directly with the 38,000 women, who then have to decide for their own health what to do about it.

So there are two things. Did it come out of the blue—what was known about this firm before and what were the concerns—and why was there not communication directly with the women involved?

Professor Sir Kent Woods: Perhaps I can answer the second one first. We are not in a position to communicate directly with the patients because we do not have the identity of the patients. We use all the routes available to us. We have put out press releases, medical device alerts and we have worked through the professional associations.

Q20 Barbara Keeley: Can I stop you there? That had impact in December. Clearly, protests started, and people became very concerned and started contacting their Members of Parliament. Time was lost—this 18-month period—when health could be affected and it does not seem as if you were putting out effective enough communications to alert 38,000 people to the fact that they had something that could be harming their health.

Professor Sir Kent Woods: No, but exactly the same processes were used in March 2010. We used press notices and medical device alerts. We used nothing different, but there is no doubt that the level of media interest in the subject rose sharply in December 2011.

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We had used exactly the same efforts to communicate with the wider public in March.

Q21 Barbara Keeley: Does that not suggest that you did not get through to the wider public? It is not the wider public but the 38,000 people who were affected. Surely there is a way of putting out a communication that will alert the very people affected. It should be very clear and very direct.

Professor Sir Kent Woods: We can only go through the general media and through the profession—in other words, through those who have treated these women. There is no other route available to us. Therefore, we made, as I say, every effort to put that information out at that time. Also, in June and September of that year, as more results came through from toxicology testing that we had commissioned, we went through exactly the same route of public communication. I understand what you are saying, but there is no possibility of our directly contacting the patients concerned because we do not have their identities.

Q22 Barbara Keeley: Indeed. What I am questioning is the effectiveness of the press releases you put out. Clearly, press releases can reach this audience, and they did, once the alerts were being put across the press in a more effective way. I am questioning the effectiveness of what you did.

Professor Sir Kent Woods: We have a fully committed communications division within the agency. We have a 24-hour-a-day press office working 365 days a year. We have a website, and all this information is on our website. We communicate with the media. We talk to journalists. We do everything we can to make sure—

Q23 Barbara Keeley: Do you not think it might be appropriate that you look at this? What I am saying is, do you not think you should look back—

Chair: May I add another suggestion? Do you not think it would have been appropriate for the doctors who implanted these proven substandard products to have communicated with their patients? Presumably, they did know who they were.

Professor Sir Kent Woods: That would seem to us to be the appropriate route of communication because there needs to be a discussion. Simply telling a lady the facts is only a prelude to an informed discussion with their healthcare professional. Therefore, I totally agree with you, Chair. It is up to the healthcare professional who implanted these devices to communicate with their patients, whom they know, and to take matters forward.

Q24 Chair: Did they?

Professor Sir Kent Woods: Unfortunately I have no data on that.

Q25 Chair: Was it something the Expert Committee looked at?

Professor Sir Bruce Keogh: No. It is something that we will consider under the forthcoming review. May I, please, answer one other aspect of your question?

You wondered why some other countries might have taken a different view.

Q26 Barbara Keeley: No, I do not wonder. I do not wonder at all. I think that is a sensible response. I commented that they had done that. They are probably taking into account the worries of the 38,000 women involved, and I think that is quite a reasonable response. I am more at odds with our response than that of other countries.

Professor Sir Bruce Keogh: I am sure we will come to that at some point—I hope.

Chair: David has been straining at the leash.

Q27 David Tredinnick: I want to ask Sir Kent a simple question on terminology and clarity about what we are discussing. You have used the word “explantation”. Does it have any difference in meaning to “removal”, please?

Professor Sir Kent Woods: No.

Q28 David Tredinnick: Then why can we not use “removal”? It is a much clearer and simpler word and would be understood by everybody. There is a degree of obfuscation in “explantation”.

Professor Sir Kent Woods: There is no intention to obfuscate, but I entirely accept your view that we should use a simpler common word.

Q29 Dr Poulter: I want to pick up on the points made by the Chair and Barbara Keeley. If there were concerns for NHS-treated patients over, for example, smear tests being taken or proper treatment being given, those patients could be very easily picked up on and called in by the hospital, the physicians or the medical team concerned. Is not one of the key problems, picked up two years ago in your own response, that there is no way of making the private cosmetic providers contact patients and you are very much relying purely on good will, and was this not an issue that perhaps should have been more effectively dealt with two years ago?

Professor Sir Kent Woods: I would not call it good will. I would call it good clinical practice, to be honest.

Dr Poulter: I would agree.

Professor Sir Kent Woods: The responsibility sits with the healthcare professional who has carried out the procedure to take responsibility for follow-up. I do not think that this is a responsibility that can be moved elsewhere, to be honest.

Q30 Dr Poulter: I agree that it is good medical practice and a GMC requirement, effectively, to do this, but would you say that the record keeping and audit trail—which is something I am sure we will pick up on later—is adequate among private providers? Are those records made freely available to support you in your work when things go wrong, as they have done here?

Professor Sir Kent Woods: I can give two answers to that. One is that I am not sufficiently familiar with the way in which all the different private providers go about their business. I know there are some very large

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private providers and some very small ones. There is diversity there. Perhaps Simon Withey can expand on that.

In terms of the ability to identify and track patients, what one would like to see for the future is a proper registry system for breast implants. The model here is the National Joint Registry for knee and hip prostheses. One would like to get to a situation where the fact of an implant and the identity of the recipient were centrally recorded and the outcomes of those procedures were analysable over time.

You may be aware that the Department of Health and the MDA, as it was then—the MHRA, as it is now—set up a breast implant registry in the middle 1990s, which ran for over a decade. The reason it had to be dismantled in 2005 and 2006 was a striking reluctance of women who had had breast implants to give follow-up information. There is a general principle that, whenever an implant is placed in the body, one would like to know that there was full documentation and follow-up so that one has the totality of experience. That is exactly what we are seeing now coming out of the National Joint Registry. But, for breast implants, there are particular difficulties with the population and the clinics in which this is done, which made our attempt to run an implant registry come to nothing.

Q31 Dr Poulter: At the moment, there is an acceptance that there is great variability, potentially, in the quality of record keeping. The women concerned here were very much at the mercy of the private clinics as to how they dealt with safety concerns as and when they have arisen—in terms of how they were communicated to the women over the past two years.

Professor Sir Kent Woods: I cannot speak from personal experience because I spent my entire clinical career in the NHS, but that is a reasonable supposition from what I know. Perhaps Sir Bruce or Simon Withey can say more.

Mr Withey: You are absolutely right. There is a huge variability in both record keeping and levels of personal responsibility—forgetting the NHS—across the private sector. There are individual clinicians who are clearly responsible and keeping a close eye on what they are doing. Then there are larger, more commercial organisations where the clinician is perhaps distanced from the executive decisions made and, as a result, does not feel quite as responsible in some cases. I cannot speak for individual clinicians, but you get the sense that that can happen in those big organisations. If you are running a business on a commercial basis and do not have sound clinical input into helping you make these decisions, the importance of some of the decisions can be less obvious than it might be to a clinician who is very aware of what he has put in, what he is doing and what his responsibilities are to his patients.

Q32 Chair: Can I pick that up? All these doctors—because that is what they all are—whether they work in the NHS or in a private clinic, and different forms

of private clinic, have the same obligations to the GMC, do they not?

Mr Withey: They all have exactly the same obligations to the GMC.

Q33 Chair: They all have the same professional obligation, if they are aware of an implantation that does not meet standards, to do something about it, do they not?

Mr Withey: They do, yes. There has been a history of some of these doctors working on a part-time basis for some of the clinics. There is a group of doctors who tend to be slightly peripatetic, who work in a number of places and come from abroad for a short time. Their engagement with some of the clinical governance issues, perhaps, is not as strong as it might be. This is clearly one of the things that will have to be looked at after this.

Q34 Chair: I know Sir Bruce's Expert Group has a further round of review processes—a short-term review. I think it is a month that you have given yourselves. Is this question of professional obligation one of the things you will be looking at in that context?

Professor Sir Bruce Keogh: There are two reviews we are involved in at the moment. The first is simply a scientific and clinical review of the evidence underpinning the advice that we have given with respect to how these implants should be dealt with. The second longer-term review will be to look at the aspects of regulation, governance and behaviours that pertain in the cosmetic surgery industry. That will be a much longer review, which will probably take a year.

Q35 Chair: As to these issues of professional obligation, it is not a question of how one might change regulatory structures for the future. It is simply a question of whether existing obligations are being respected and enforced, is it not?

Professor Sir Bruce Keogh: Yes. We had not proposed to look at that in the course of the next month, but we look forward to guidance from the Committee.

Q36 Chair: It is an issue on which the Committee has expressed views in the past in different contexts. We might do so again.

Can I put one other factual question to Sir Kent about accepting that it would be a better world, possibly, if we had a national registry? Could you be clear with the Committee what, in fact, currently exists in terms of an audit trail, whether it is kept centrally, by the provider, the doctor or the commercial provider of the implant? What records currently exist about which women have breast implants? "Surely there should be an obligation" is the thought behind my question. If you are selling a regulated product for implantation into the human body, whether or not there is a national register, the people who sell the product should be able to tell the regulator where it has gone.

Professor Sir Kent Woods: They should certainly be able to tell us where it has been sold on to in terms of which healthcare organisations have purchased it.

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That is a route we have used: going back to the UK supplier for PIP implants to find out where those implants were sold by hospital name.

Q37 Chair: Are those records robust?

Professor Sir Kent Woods: They are, essentially, sales volumes data. They do not allow us to get down to patient level, of course, but knowing the organisations into which those PIP implants were sold, we can then pursue our inquiries through that organisation and ask them to provide us with the follow-up data, which we are now analysing.

Q38 Chair: There is nothing that links the supplier to the patient other than the service provider.

Professor Sir Kent Woods: No.

Q39 Andrew George: I want to come back to the commercial side of this because there may be parallels in other areas. It would be useful for me to understand the extent of this particular activity. After the PIP implants got their CE status 12 years ago and came on to the market, did they swamp the market? In the private sector, were they the implant of choice, for example, of most of the private clinics? In other words, do you know how many procedures were completed each year within the private sector and what proportion of them would have been PIP implants during that period?

Mr Withey: In the heavily commercial end of the private sector, in retrospect, it seems that for a certain time they did predominate. Among individual surgeons carrying out private practice, who probably account for only about 10% of the private sector in this area, they were used relatively rarely. There are instances of surgeons using them, but they are few and far between. In the commercial sector they were used much more.

Q40 Andrew George: How many procedures do you understand are completed each year, on average, in terms of aesthetic enhancements, in the private sector?

Mr Withey: About 25,000.

Q41 Andrew George: Of those 25,000 a year, taking an average year, you would say that up to half might be PIP implants; so it would be about 40,000 over that period.

Mr Withey: This is current activity. Obviously, over the years it has increased quite dramatically. Five or 10 years ago it was significantly less, but on average between 80% and 90% of breast augmentation is undertaken through the large commercial organisations.

Q42 Chair: Could we be clear about this? You are seeking to draw a distinction between surgeons and large commercial undertakings, but even in large commercial undertakings implants are inserted, presumably, by surgeons.

Mr Withey: They are inserted by surgeons.

Q43 Chair: And those surgeons are subject to the professional obligations we were discussing.

Mr Withey: Yes. It is a question of who makes the decision as to what is used. I think that was what the point was getting to.

Q44 Andrew George: Yes. I was also trying to get to the driver behind this. If these are significantly cheaper than the alternatives that were available in the market—I wanted to find out—is this half price? Is it 10% less? How much less expensive were the PIP implants in contrast to their rival?

Mr Withey: I cannot tell you exactly. There are discounts for buying in bulk, I suspect, but there are reports that it is anything between one third and one fifth. Some people have said 10% of the price, which is probably an exaggeration, but I think one third and one fifth of the price of others.

Q45 Andrew George: Was that then reflected in the cost of the procedure? In an answer a moment ago, you said that of course there has been a large increase in breast augmentation in recent years. I was not aware of that, but has that been driven by the fact that the cost of the procedure has come down because the PIP implants brought the cost of the procedure down, or has the cost of the procedure remained the same and have the private clinics simply reaped that cost difference in surplus?

Mr Withey: There is clearly a part of the market, if you like to call it that, that is price-sensitive. It seems to be this part of the market that the PIP implants were largely used in. I think, almost certainly, in most cases where a PIP implant was used the price of surgery was at the lower end of a scale. Whether it changed with the use of PIP implants, I am not entirely sure. I do not think it would have, but whether the difference in price was passed on to the consumer completely, I would have no idea.

Q46 Andrew George: You said a figure of about 25,000 breast augmentations per annum in the private sector. Is that in recent years? What was it, say, 10 years ago?

Mr Withey: Again, I cannot tell you. The data are sometimes very difficult to get hold of.

Andrew George: Quite, yes.

Mr Withey: It largely comes from the providers of breast implants because individual clinics will not release their data, as previously happened. I would have thought that over the last 10 years there has been an increase of 80% or 90% in the amount of breast surgery undertaken.

Q47 Barbara Keeley: Can we come back to the question about where an explantation or removal will happen? My colleague has already talked about the extent of concern and worry, and about that stress and anxiety being a cause for the NHS helping with removal. There have been numerous cases of protest groups, and women who were left by a clinic—perhaps a clinic that had gone into administration. There was one such case in south Manchester where the women had nowhere to get a solution to their difficulty with PIP implants. In fact, the 25 women protesting and wanting a solution wore T-shirts that

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said “PIP Implant Warning. I Am a Time Bomb.” If you think about it, that is how they feel about themselves. They feel they now have something that they have learned quite recently is a ticking time bomb. That type of thing has happened. There are stories up and down the country, but that one was close to me.

Can we come back to the question of what on earth happens? The women were protesting in south Manchester because the medical group that had dealt with them—the clinic—had gone into administration and been taken over by another company who now will not have anything to do with this. There are individual surgeons who are letting people down and clinics that respond in that way. What can be done for those people in that stressful situation? As my colleague drew out the point earlier, there is a feeling that the NHS ought to be able to draw the line around that group of women and, if the stress and anxiety is going to make them ill, deal with it.

Professor Sir Bruce Keogh: One of the major problems here is that we are dealing with significant uncertainty. It is that level of uncertainty that creates the anxiety relating to the ticking time bomb. The first review, which I have chaired and which has still to deliberate fully, is an attempt to quantify the extent of that. We have looked at several things. We have looked at whether there is a cancer risk. The answer appears to be no. We have looked at whether there is an elevated rupture risk. The evidence on that is still unclear, and I will come back to that in a moment. We have looked at what the toxic risk, if you like, of this silicone is, both in terms of genotoxicity—the effect on the genes in the cells—and also what we call cytotoxicity—damage to the cells themselves. We have also looked at the risk of re-operation, which, frankly, in a group of young women is very small. So we are left with uncertainty as to the potential damage from the silicone itself.

Barbara Keeley: Can I stop you there, if I may?

Professor Sir Bruce Keogh: May I finish this, please? This has to be tempered with a significant component of compassion. It was that element of compassion that drove the deliberations that led to what I will call the NHS offer, which specifically addresses the issues you raise. The NHS offer is pretty clear. We have advertised it in newspapers with full-page adverts; we have used Facebook and Twitter to communicate it; it is on NHS Choices and there is direct advice available from NHS Direct. If you are an NHS patient and you have had a PIP implant under the NHS, the NHS will remove the implant and replace it.

Q48 Barbara Keeley: That is a small percentage.

Professor Sir Bruce Keogh: Yes. It is a very small percentage.

Q49 Barbara Keeley: How small?

Professor Sir Bruce Keogh: So far we have identified 745 patients in the NHS.

Q50 Barbara Keeley: That is out of 40,000.

Professor Sir Bruce Keogh: Yes.

Q51 Barbara Keeley: It is not a large number.

Professor Sir Bruce Keogh: With respect to the private sector, we have taken a very clear view that the private sector should match that offer. We believe it has a moral duty of care to match that offer. When you embark on treating a patient, you embark on treating them in their totality and you do not desert them in their time of need. There will be some organisations that have gone out of business, there will be others where the surgeons have retired and there will be others where the organisations themselves, as Simon Withey has alluded to, are simply recalcitrant in the way they want to offer their duty of care. In that case—let me be absolutely clear—the NHS is there to help any woman in this country. By that, we mean that women who have anxiety can go and see their GP. As Simon Withey has quite clearly stated, their GP will assess that level of anxiety, assess the woman physically and, if appropriate, will refer them on to receive more specialist advice from people who conduct this sort of surgery.

I believe that anxiety is a very significant issue. But, again as Simon has said—and he deals with many of these women—when they understand the facts and some of the issues and that there is somebody there to help them and keep them under surveillance, their anxiety can be attenuated. Of course, some of the evidence we have, which underpins that advice, is changing and will continue to change. That is why our final offer has been, quite simply, a personalised package for women whereby they can engage with either their general practitioner or their surgeons so that they can have a private, informed discussion that is tempered to their requirements, their anxiety and their needs. I think the NHS offer meets the issues that are causing you concern.

Q52 Barbara Keeley: It runs on to questions of capacity, which I would like to come to.

Professor Sir Bruce Keogh: Absolutely.

Q53 Barbara Keeley: It is important to convey that—from a number of contacts there have been with Members—there is a pool of women who are very, very anxious. There are a number of situations that have been reported to me and to others, like the protest group in Northenden, where the firm went into administration and the new firm will not deal with them. In some of the cases reported, women will not even be seen. They are being spurned by receptionists in clinics and told that, unless they come up with money for a scan and for a consultation, they cannot be seen. Of course, depending on when this surgery happened, people may already be in debt for the original surgery and have taken out loans for that. That question follows too.

That leads to the question about the capacity of the NHS to respond to a surge. What is the situation as to that? You have mentioned 745 women who were treated in the NHS, but we know the numbers are 40,000. If many thousands of women present to take up that offer in the coming months, what will the

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situation be? Is there the capacity to cope with such a surge?

Professor Sir Bruce Keogh: The first thing to say—and I would like to reiterate this, Chair—is that, as Medical Director of the NHS and in consultation with colleagues, I have a very clear view that there is a moral and social duty upon those commercial organisations that have embarked on this to meet their requirements for duty of care. Having said that, there will be some women who are let down by that particular system. We do not have a clear view yet what the magnitude is, but we are in the process of collecting some information. So far, about 1,000 women have presented to the NHS. We will be offering them the same sort of consultation. We will be offering removal of their breast implants, but not routine replacement unless there is a very significant clinical need for that.

Q54 Barbara Keeley: There is a difference with the NHS offer being made in Wales, is there not? The consideration there was that there may be loose skin, accumulation of fluids, a need for drainage and risk of infection. On that basis, patients in Wales are being offered replacement as well. Is there not then the question of putting people through two procedures, if removal is one, and they have to go through further surgery later?

Professor Sir Bruce Keogh: The advice I have had from plastic surgeons is at odds with the advice that Wales has received. It overestimates the problem and underestimates the quality of surgery offered by consultant NHS surgeons. I do not want people to think that this is an inevitable consequence of the removal of breast implants. Of course, in some cases there will be some residual deformity. Much of that deformity will correct over time. Frankly, that published advice is at significant odds with the views of the plastic surgical community at large.

Q55 Barbara Keeley: Mr Withey, would you like to add to that?

Mr Withey: Yes. There is no evidence that there is an increased risk physically to a woman having an explantation compared to having an explantation and a re-implantation—removal, sorry. There is clearly an aesthetic impact. That is something that, I am sure, women will be considering when they discuss it.

Going back to your question about the impact on services, there will obviously be a huge impact on the service if every one of 30,000 women decided they wanted to use the NHS as their provider of choice. We have thought very carefully about the stream these patients should take to avoid them ending up taking up spaces in breast oncology clinics, for instance. We have a very clear pathway through which these women should be directed, and the GPs have been advised appropriately on this. The idea is to try and minimise the impact but accept that the impact may be significant, depending on what the response of the private providers is.

Q56 Barbara Keeley: Can we come back to my final point about the moral duty that you have tended to

stress? It seems from the cases that have been brought to Members that there is a whole variety of offers. Some private clinics are dealing with it, either just with removal or some with removal and replacement. It is clear, is it not, that some private clinics—the case of being in administration and, as you mentioned, surgeons coming from abroad and surgeons who are not traceable—are failing to meet their duty of care? Is it acceptable to have the current situation, in which there is a variety of levels of assistance causing the confusion, worry and stress that we have? Should it not be that, if there is an NHS offer, you proceed on the basis of an NHS offer and then take legal action against those organisations who did not meet their duty of care?

Professor Sir Bruce Keogh: That is a very reasonable comment. However, by maintaining a very clear view about the moral imperative that we believe should be met by these providers, a number of providers have started to come into line. Of the 12 major providers in this area, seven now match the NHS offer, three are very close to it and two are some distance away. So we are making progress.

Q57 David Tredinnick: Presumably there is a statutory obligation on these providers to have proper insurance. Is that right? Do we know that?

Professor Sir Bruce Keogh: I am not clear at this stage. There are two things I am not clear of that we will be looking at in the review. One is whether there is a statutory obligation and, secondly, whether insurance would cover a clear act of criminal activity.

Mr Withey: There is clearly a statutory obligation for medical indemnity—professional indemnity insurance—of the surgeon. But I do not think any surgeon put this implant in knowing that he was putting in anything other than a reasonable and regulated product. If it was clear that they had been professionally negligent in choosing an implant, the situation would be very different. That, clearly, is not the case. There is not an obligation, as far as I am aware, for the providers to have any sort of second tier of insurance.

Q58 David Tredinnick: Is this not the nub of the problem here? You have 30,000 implants out there, as Barbara said, and the Secretary of State has said, yes, these companies have a moral obligation. But they may be looking at their books and saying, “We are going to go bust if we do this.” If they have no insurance, it may well happen.

Professor Sir Bruce Keogh: Again, that is a very reasonable point. I had hoped to consider, as part of the review of the governance of the cosmetic surgery industry, the options available for that kind of insurance—in the same way, for example, that travel agents are covered by ABTA.

Q59 Chair: But there is no requirement for that now.

Professor Sir Bruce Keogh: Not that I am aware of.

Q60 Chair: It would be a future requirement.

Professor Sir Bruce Keogh: Yes.

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Q61 Grahame M Morris: Could I develop that and ask this of Professor Woods? You may have given the answer earlier in relation to the timeline, but, for clarity, of the 38,000 women who have had PIP implants, how many had the procedure after the warnings of 2010? Do you have that from the data set, both in the NHS and the private sector?

Professor Sir Kent Woods: I do not have any such data. We gave pretty explicit guidance in March 2010 when the problem was first brought to light. I am not aware of any implantation of PIP implants beyond that point.

Q62 Grahame M Morris: Is that only in the NHS or in the private sector as well?

Professor Sir Kent Woods: I do not have data, I am afraid.

Q63 Grahame M Morris: Returning to the answers that Professor Keogh gave to my colleague, we are aware that private clinics have a variety of offers, and some are charging for the replacements. You were quite categorical, quite unequivocal, when you said that these private providers or commercial organisations have a moral and social duty of care to the women who have had PIP implants. How does that translate in terms of what Government can do? How do Government enforce a moral obligation? It is a bit like bankers' bonuses. What mechanism do they use to enforce that moral obligation on those listed providers who are not co-operating, still imposing charges and not doing the right thing by their patients?

Professor Sir Bruce Keogh: I am not sure I am the best person equipped to answer that, but it is the sort of thing I hope we would consider in our subsequent review. The stance that we have taken this time is simply to emphasise that moral duty through a number of communication channels, the sorts of channels that I have outlined earlier.

Q64 Grahame M Morris: In truth, we do not have any mechanism or powers over private sector providers.

Professor Sir Bruce Keogh: I think the answer would be no.

Q65 Chair: In this respect. We have one or two powers, but not—

Professor Sir Bruce Keogh: Yes.

Q66 Chair: In that connection, did your group consider whether this was not only a moral requirement but a legal requirement? I should have thought a woman who has had a breast implant from a private sector provider that did not meet the standard that was implied in the original contract would have had redress against the private provider anyway in the straight law of contract.

Professor Sir Bruce Keogh: We will be looking at that. Our early indications are that there are some opportunities for legal redress.

Q67 Grahame M Morris: Can I come back on this? We are looking specifically at the PIP breast implants

here, but are there any analogies with, say, eye surgery where situations like this arise and the NHS has to take corrective action? What is the legal position there in seeking redress against a private provider who is offering eye surgery? Is there a legal obligation in that situation?

Professor Sir Bruce Keogh: I do not think the situation is any different.

Q68 Grahame M Morris: It would not be cosmetic in that case.

Professor Sir Bruce Keogh: No. I am not an expert in legal things, and I hope that we will cover that in our review, which will be relatively comprehensive.

Q69 Dr Poulter: I want to come back to the issue of insurance. There was the case of Trilucent breast implants, which happened 10 years ago now. What sort of lessons could be learned from that? There were 8,000 women affected but, it seems to me, one of the key issues was that the implants actually caused damage. It may well have been the case that the providers of the cosmetic surgery were insured because their insurance would have covered the fact damage was caused to the women. Therefore, that situation was much more easily dealt with.

In this case, on the facts, there is not an issue that the implants have any carcinogenic properties. There is not necessarily good evidence to support the fact that, in terms of causing immediate damage, these implants are any less safe than other implants. On that basis, it may be very difficult for private sector providers to invoke any insurance to enable them to act in a way that we may consider to be morally right, which is that they should replace the implants in women. If they cannot invoke their insurance, it may be incredibly cost-prohibitive. We may not have huge sympathy for that on a human and moral level, but it may be impossible for some private cosmetic providers to replace these implants. Is that something you have looked at?

Professor Sir Bruce Keogh: We have not looked at that specifically, but you raise an interesting point in the sense that the response from an insurer will need to be based on evidence. Equally, I am convinced that any decisions that we take that relate to the NHS, not only for PIP implants but across the board, need to be based on evidence. We are in the process of trying to accrue that evidence at the moment and we are working with colleagues around the world to help us accrue that evidence. But it is also clear that even they have very little evidence. Even those countries that, at first glance, appear to have simply recommended routine removal of these implants are not functioning on any more evidence than we have. When we look specifically at those countries, we find that their offer, in practice, is very similar to what we are offering in England. Denmark, the Netherlands, Portugal, Spain and Australia are all doing pretty much the same as us. I will ask Simon to comment on where the French surgeons are at the moment, but I think their behaviour is closer to ours. Germany has recommended removal, but it seems that the cost of that is at the discretion of the insurer. We are a little

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unsure about what is happening in the Czech Republic.

To add to that, in terms of the growing evidence base, you will be aware that the Scientific Committee on Emerging and Newly Identified Health Risks, as part of the European Commission, has come to the view—similar to ours—that the evidence is incomplete, that further work needs to be done to understand the chemical composition of the implants and its biological effects, and also to try and establish simple tests to identify a rupture. They have explicitly stated, along with others, that there is no urgency in dealing with this. So we have time to collect the evidence. The urgency comes from the anxiety imposed by the uncertainty of evidence.

To get back to your original question, the evidence underpins the insurance. The robustness of that evidence will also underpin the advice that we need to give to citizens of this country who have had PIP implants, and to Ministers.

Q70 Dr Poulter: But the issue is this. If the evidence says, at the moment, that these implants are safe—although we obviously have a very big issue of public concern, with a lot of women who are very distressed because of all that has happened with these implants—there may be a question about how some of these private sector cosmetic providers can support women or whether they are in a position to replace implants. If they cannot invoke insurance, on a cost basis they are not necessarily in a financial position to do that. If we are looking at the whole picture of how we are going to make things better in the future, how some of these providers are insured is something that perhaps needs to be looked at in more detail.

Professor Sir Bruce Keogh: Dr Poulter, you are absolutely right, and it is something that I will be keen we look at in some detail in the second review. Ultimately, this is about protecting consumers who are otherwise very vulnerable.

Q71 Dr Poulter: What this also drew out was that, if something goes wrong for an NHS patient, generally speaking the law of tort applies. There is a duty of care, and if there is a breach of that duty of care and it was foreseeable and so on, there is a general duty of care. But even though we are dealing with invasive bodily procedures and procedures that can be carried out on the NHS, once we move away from NHS-funded care—be it by the NHS directly or by a private provider doing NHS procedures—into the private sector performing these procedures for cosmetic reasons rather than direct healthcare reasons, we move to the law of contract, which is somewhat different. Is it the case, when we are dealing with invasive bodily procedures, that, if we accept that there is a duty of care under tort, this is not really about a contract but about healthcare, duty of care and those sorts of things, and that this is one of the fundamental problems that faces the cosmetic industry, if you like?

Professor Sir Bruce Keogh: Dr Poulter, you are a lawyer. I am not.

Q72 Dr Poulter: I have a law degree, you meant.

Professor Sir Bruce Keogh: Forgive me. This is something that we will want to look at in the second review. Any guidance that the Committee can give us on this would be more than welcome.

Chair: I do not think the Committee will stray into free legal advice, but my understanding of the law of contract is that if you pay for something you are entitled to be supplied with it.

Q73 Dr Poulter: What I was driving at on that theme, following what the Chairman just said, is that when we are dealing with procedures that are bodily invasive, that can change the way someone looks and may have long-term impacts upon their health as well as their psychological well-being, there is a discussion as to whether that is a contractual arrangement in its entirety or a duty of care arrangement and whether we should be looking at the cosmetic industry and how it functions in the general context of healthcare rather than in a consumerist way. Perhaps these issues to do with insurance that we were talking about flag up a fundamental problem with the way the industry operates in some cases.

Professor Sir Bruce Keogh: Thank you. That is helpful. I will take that as a statement rather than a question, if I may.

Q74 Dr Poulter: Indeed. I was asking whether it is perhaps something you will be looking into.

Professor Sir Bruce Keogh: Thank you very much.

Mr Withey: May I make one addition to that? One thing that has become clear to me regarding the contract is the process of adequate consent of patients when they are considering these operations. A number of patients who have had implants put in elsewhere have come to see me with worries, asking whether they can have their implants removed. It has become clear that, in some instances, these women are not aware that implants will occasionally rupture. They are not aware that, inevitably, there will be some further implications down the line of having had surgery. One of the critical things that should be considered is the consent process and the adequacy of consent across the board because, at the end of the day, it is a contract between two people, but it is only an understood contract if the patient has adequately consented.

Q75 Dr Poulter: Clearly, there you have a concern. But in terms of taking that consent and speaking to and engaging with patients, there are some people who come to the cosmetic industry who have underlying body dysmorphic concerns and problems. Are you convinced that, in all aspects of the cosmetic industry—and specifically looking at breast implants, because some women come back for repeated breast implants—the industry has become consumerist-driven rather than looking at the whole patient in some cases?

Mr Withey: That is a perfectly valid comment to make. There has been a tendency for commercial pressures to override what we know is sound clinical judgment and sense. It is vital that those who are not

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appropriate for or will not benefit from surgery are made aware of that beforehand and that anyone who is felt to be appropriate is also made aware of the implications of surgery—the limitations of what it can and cannot do and the potential complications. Unless that role is clearly fulfilled, the contract is rather meaningless.

Q76 Chair: Can I come back to one aspect of what Sir Bruce has called the “NHS offer”, which concerns the case in which a patient qualifies for removal under the NHS but does not want to have a replacement implant? If that case was dealt with under the moral obligation in the private sector, it would clearly be one procedure. If it was dealt with as for an NHS patient, pure and simple, it would be one procedure. As I understand it, the current NHS offer is that, for an NHS patient, where removal is under the NHS but re-implantation is under the private sector, that would be two procedures. Are we not in a position where the rules are defying common sense and good medical practice? It cannot be good medical practice to subject a patient to two procedures where only one is necessary.

Professor Sir Bruce Keogh: As to the first bit, if there is a compelling and good clinical reason, the NHS will put implants in. Otherwise, the aim of the NHS offer is to restore somebody to their pre-implant condition as best as possible. One of the reasons why we say that is because these operations, as Dr Poulter has pointed out, are cosmetic and optional. The moment that the NHS puts a replacement into a young woman, we commit the NHS to a lifetime duty of care for her, which may mean several subsequent operations and continued surveillance.

Q77 Chair: But that woman, under the current position, could easily turn up in the same operating theatre with the same team as a private patient a month later and pay for it. Would it not be both better medicine and better economics to allow that woman to pay for the implantation while she is there for the removal?

Professor Sir Bruce Keogh: If that is done in the NHS under those circumstances—in an NHS hospital by NHS surgeons in an NHS environment—then the NHS has to pick up the long-term duty of care. If it is done by those surgeons who are conducting private practice in a private organisation under rules of private practice, then those surgeons and that organisation pick up the duty of care rather than the NHS.

Q78 Chair: I understand the theology, but I do not understand the practical consequence from the woman’s point of view. Would it not be more sensible to allow the NHS to deliver the NHS offer to remove the privately-implanted device and then allow the woman to pay the same team, while she is there in the operating theatre, to have a replacement implant put in at her own expense?

Professor Sir Bruce Keogh: This also comes back to Barbara Keeley’s issue of capacity. I will ask Anne Slowther to come in, in a minute, on this. There are some complex interactions here. As you will have

seen from the Chief Medical Officer’s report, we allow women, under certain circumstances, to pay a top-up fee, if you like, to pay for the implant. One of the problems with this is, quite simply, that many women who feel that they have been let down by the private sector will see the NHS now as their preferred option. If they can have an operation at a vastly reduced cost in the NHS, that will impose a significant burden on the NHS. It will also have knock-on implications and opportunity cost for other patients, given the capacity issues to which you have already alluded. Perhaps I could ask Anne to come in on that.

Dr Slowther: The other thing that is important to remember in terms of an ethical justification in this case is fairness across all patients within the NHS. If we are offering, say, a woman the opportunity to pay for a new breast to be put in at her own cost while she is having the NHS offer, then, as Sir Bruce has already pointed out, the long-term care for any problems with that breast would fall to the NHS in their normal duty of care.

Q79 Chair: If the implant is put in as a private procedure, surely that becomes a paid-for relationship. It may be a relationship with the NHS, but it is a paid-for relationship, not a tax-funded relationship.

Professor Sir Bruce Keogh: We need to be clear that we are not talking at cross-purposes. A privately-conducted procedure is where the patient pays for the totality of the procedure, so they pay—

Q80 Chair: I understand the problem you have, which is that if NHS resources and staff are going to be used to deliver private medicine, they have to be done at a separate time and place from tax-funded care. However, it seems to me, particularly bearing in mind that women in these circumstances in the private sector will have it done that way and if they are NHS patients with these implants for NHS reasons they will have it done that way, that in this specific set of circumstances they will not because of the principle. I understand the background, but I think we should be looking for ways round it.

Professor Sir Bruce Keogh: It may not be conventional, but perhaps I could pose a question. If we were to adopt that approach, why would any of the private providers feel the need to address their duty of care for that patient, except for purely commercial reasons for those patients who could afford it?

Chair: If we did what I am suggesting and the private provider was still around, I would certainly hope that the NHS would go to the private provider to recover the cost. There would be no gain to the private provider in not doing what they are contractually obliged to do. Maybe it is an issue for further work.

Q81 Barbara Keeley: I think there is some difficulty if we start raising issues of fairness across types of patient, as you have done. There are burdens on the NHS from people doing stupid things like dangerous sports, drinking too much and overdoses of drugs. Do we turn them away? If somebody turns up who has OD’d, do we turn them away? Those are issues. There

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was even—I raised it when we had the debate in the Chamber here—some selling of what turned out to be a toxic vodka product before Christmas that was illegally made and not as it seemed. There is a similarity here. We have explored, in the first part of this session, what really amounts to a failure of regulation. That has to be taken into account here. These questions are too big for us to get into today, but there are issues there.

Going back to the point about having privately-implanted implants removed and then having a replacement, is there a difference with patients who were treated privately after breast cancer? They would have been entitled to primary breast augmentation in the NHS but, if they had had that done privately and now find themselves in the same position as others, is there a difference? Clearly, that is a different case? I do not know how many people that applies to, but the Breast Cancer Campaign is concerned to reassure patients about their position. What would it be? Would they be in a different position?

Professor Sir Bruce Keogh: The position is that we would remove them and replace them.

Q82 Barbara Keeley: Even if it had been done privately.

Professor Sir Bruce Keogh: Yes, because we are dealing with patients there who are in terrible personal circumstances, who have a significant disease process and have sought treatment for that in the private sector rather than people who have chosen optional surgery.

Dr Slowther: Could I come back on the issue of fairness? There is a distinction between saying we would treat people differently because of the reason they are in the position they are, which would be unfair. For people who are coming to use the NHS service, for whatever reason, the NHS should respond to their need—whatever the reason for that need. If someone has had an accident while mountain climbing, or they have had the PIP implant put in or they have a disease that is causing a particular problem, the NHS would respond to that. In terms of fairness across the NHS, it would be a response irrespective of the reason for that need.

In terms of the response being fair to all people across the NHS, the example of the patient who had breast cancer, who had her operation done in the private sector and then comes to the NHS to have her PIP implant removed and replaced, demonstrates that the NHS treats all patients consistently and fairly. If that woman had gone to the NHS in the first instance, she would have had an implant put in. So we are responding in the way that we would to women in that particular situation with that particular problem.

Q83 Barbara Keeley: I would add, Chair, that that position does not seem clear to organisations like the Breast Cancer Campaign. Perhaps it could be clarified after today.

Professor Sir Bruce Keogh: Thank you. We will do.

Q84 Chair: Can I ask another detailed point? The principle is that, if a woman cannot get her position

dealt with by her private sector provider, then the NHS offer is available. What about the case in which a woman is told by her private sector provider that she is to be charged additionally, for example for a scan to establish whether the implant has ruptured or should be replaced? What is the attitude of the NHS in that case?

Professor Sir Bruce Keogh: Our attitude would be that they should not be charged, but we would also see that as a derogation of responsibility, if you like, by that private provider, and the NHS would help.

Q85 Chair: If a scan was clinically required and the private sector provider was proposing to charge for it, it would be available free on the NHS.

Professor Sir Bruce Keogh: I do not think we have been absolutely clear about that. We would need to reflect on the potential impact that that would have on scanning services in the NHS. Let me be clear; I do not want to offer an easy route out for those providers.

Q86 Chair: My question is linked to the principle that I offered five minutes ago. If the Health Service has to do anything to put women back in the position they thought they were going to be put in by their private sector provider, I would certainly hope—and I think the Committee would hope—that the NHS will pursue any remaining private sector provider for the cost of meeting their obligations.

Professor Sir Bruce Keogh: Yes. We will take that away and look at it, Chairman. Thank you.

Chair: I am not sure that I have the authority to say that on behalf the Committee, but I am sure it will object if it does not agree. David wants to move on to the broader issues of the sector as a whole.

Q87 David Tredinnick: Yes. I want to talk about attitudes to cosmetic surgery. I am concerned about the advice given to people coming to cosmetic clinics—whether they are getting the right advice—and regulation and, following on from that general introduction, the way in which advertising portrays this kind of cosmetic surgery. I was in a waiting room the other day and I read an article in a magazine that said a girl now could expect, if she wants to be smart, to have blonde hair extensions, a toy dog—meaning a small breed—and enlarged breasts. If this kind of procedure has become so trivialised, there must be something very wrong with the way it is being presented. I would ask you to comment on that, please.

Mr Withey: That is a very fair comment and a concern that members of the professional associations have. The codes of advertising, some of the portrayal in the media and—your phrase—“trivialisation” is something that I think we have all experienced. We have patients coming in on a regular basis who are surprised they are going to have a scar for an operation and that they are going to be off work for a few days, and patients who have sat in consultations with some of the commercial providers—I know it is a phrase you did not particularly like, but with some doctors where there is strong commercial pressure—who have come away very unaware of the

implications of surgery. It is very important to get back to a position where we have a degree of understanding and maturity of conversation on this subject. There would be considerable applause for any proposals that would reduce the trivialisation and increase the awareness of the level of risk and of what people are getting into.

Q88 David Tredinnick: For example, would advice given to a teenage girl include the fact that, if she has a child, her breasts would probably enlarge naturally as they carry milk? Is that the kind of advice that is often—

Mr Withey: You are obliged to discuss the options for treatment. Many teenage girls will not be interested in hearing that, if they are potentially going to have children 10 years from the time you are having that discussion, but these are reasonable discussions to have. There should be a very lengthy and involved discussion about all of the implications and the implications of having had implants, or whatever cosmetic surgery you choose in the future, when you become pregnant or as you age. There are considerable and lengthy discussions that need to be had.

Q89 David Tredinnick: Concerns have been expressed about young babies having cow's milk, and that that can cause some medical conditions that would not occur if they were fed with their mother's milk. What impact does a silicone implant have on the mother's milk if she wants to feed her baby?

Mr Withey: In theory, none. If it is a well-regulated product—the product you would expect to be used—there is no risk in breast feeding.

Q90 David Tredinnick: Does it have any impact on the capacity of the breast to feed a child?

Mr Withey: Not necessarily. It may have some impact. You may find that there is a certain percentage reduction in the ability to produce.

Q91 David Tredinnick: Will a woman who is pregnant or has had a child and is lactating get a further breast enlargement because the natural process will not take account of the breast implant that has already been placed in her breast?

Mr Withey: She will get a further enlargement, yes.

Q92 David Tredinnick: She will get an enlargement beyond that which she had expected when she contracted or agreed to have that operation.

Mr Withey: She will.

Q93 David Tredinnick: She is getting something she did not want.

Mr Withey: But, as would normally happen, the breast will then reduce in size. The implications of that should be discussed. Normally, lactating women will find that their breasts enlarge and then, as time goes on, reduce in size and there is a degree of deflation. That should be discussed and the implications of that, in the context of augmentation, should be discussed. I

completely agree that these are things which are very important for patients to be aware of.

Q94 David Tredinnick: Thank you for that. This is the last line of questioning here. Earlier on, I think Sir Bruce or Sir Kent—one of you—talked about genotoxicity and cytotoxicity, the toxicity potential for genes and the toxicity potential for cells in the body. Is this something that needs further research or do you feel that the research has established the parameters of the problems already?

Professor Sir Kent Woods: Perhaps I can reply to that. Studies have been done in three countries—in the UK, France and Australia—of both of those aspects of the filling material in PIP implants. The results for genotoxicity and cytotoxicity have been consistently negative using a variety of systems. The difficulty comes not so much in whether those tests should be repeated using different test systems, but in being confident that we have tested all the possible variants of filler which were used during the 10 years of manufacture. I am reassured to an extent that the Australian samples, for instance, were different from the French samples and different from the UK samples. But there is no way, retrospectively, in which we can, as it were, confirm the toxicological properties of every possible permutation of the filler used over that 10-year period. We will do further research. We will do further studies, and indeed there is a toxicology working group looking at this at the moment. The data we have—and they are, as I say, coming from several sources—are negative on both of those things.

Q95 David Tredinnick: Do you think there is a tendency for surgeries to target those in poorer areas where a person, who is possibly not as well educated as someone else, might be encouraged to have a breast implant? I am thinking of the targeting of poor areas by short-term loan companies. A couple have moved over from America specifically. I know one has set up in Lambeth, which is not seen as an affluent area, and there are other locations in the midlands where this is taking place—and I represent the midlands. Do you think that is true?

Mr Withey: I am afraid I cannot comment on that. I would be surprised, given the cost of the procedure, that they would be targeting the same people as the payday loans companies, but there may be a tendency to look and try and decide who your patient demographic was. I honestly cannot tell you.

Q96 David Tredinnick: Do you think there should be any attempt to influence male opinion of breast implants? There seems to be a tendency in the industry to encourage women to have these because they will be more attractive to men, when in fact the consequences of the procedure—I have been told in correspondence—could be quite the opposite?

Mr Withey: There is good psychological research and quality-of-life data on the positive benefits of breast augmentation surgery when it is undertaken in the right person, who is adequately informed and suitably consented. Clearly, things are different if patients do

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not know what they are having and if they have been led to believe that the operation may achieve something that, ultimately, it does not—that it may change their life in a way that it does not. Suggestions that it makes a dramatic difference to your job prospects, your life prospects or your prospects with the other sex is something that, clearly, must be considered as advertising that is unreasonable. But there are very strong data about the positive effects in well-selected patients.

Q97 Chair: Presumably, these are issues of regulation both of the providers and of the professionals working within the providers. You said that I did not like the phrase “commercial pressures”, but I recognise commercial pressures. My concern is that professional people should be professionally independent of those commercial pressures. Those seem to me to be the issues, both for the regulation of providers and the regulation of the professions. Are these going to be the issues that your future review on regulation of the cosmetic surgery industry will focus on?

Professor Sir Bruce Keogh: Yes.

Q98 Chair: Is that in both areas—regulation of the institutional providers and of the professionals?

Professor Sir Bruce Keogh: Yes. We will be looking at both of those.

Q99 Barbara Keeley: I have a small point, going back to the group of breast cancer patients having implants for augmentation. Is anything being done, or should and could anything be done, to reassure those patients—patients who have had to get augmentation to get back to the situation they were at before cancer treatment—who are still worried about implants other than PIP implants, where this whole thing has caused them to have a level of concern? Once you hear that implants leak and people have immune system problems, when you have had cancer treatment and have been through the mill, it is natural that you might think, “It might not be just those implants. I have had to have these implants. How safe are mine?” Is general reassurance needed for breast cancer patients?

Professor Sir Bruce Keogh: That general reassurance is best coming from the people who have undertaken the surgery. Patients who have undergone surgery for cancer are under close follow-up, both in the private sector and in the NHS, so they will have the opportunity to have that personal discussion with either their surgeon or oncologist. I would advise them to do so if there is any level of anxiety whatsoever.

Q100 Barbara Keeley: There is bound to be, is there not? But there is something specific that goes both to the Expert Group and to regulation. Clearly, there was a failure here. It seemed to be an unannounced inspection that found this problem. There are questions that people may have. Should there be spot checks? Should there be more checks? Should everything be much more detailed in terms of ensuring quality so that people do not end up having been implanted and left with a fear they cannot get rid

of? It seems to me there are some issues left hanging. That is all I am saying.

Professor Sir Kent Woods: You used the phrase “regulatory failure” earlier and I think it is very important to look extremely closely at the circumstances of the particular situation here: how this arose and how it was possible that this manufacturer was able to produce a non-authorized product for so long. One of the issues that have very much concerned regulatory authorities—and, indeed, the Commission—is the question of how spot checks can best be targeted and made use of. The broad framework for medical devices regulation is generally held to be a good one, but, clearly, there are lessons to be learned in the specific instance of the relationship between the manufacturer and the notified body that was responsible for auditing the factory in this instance. I think, even within the existing regulatory framework of European law, there are things which can be done, learning from this experience, to minimise the risk of recurrence. Ultimately, there is no certain way of ensuring that fraud will not be perpetrated around the regulation, whatever it is.

Q101 Barbara Keeley: But spot checks of anything that is to be implanted into people sound like a good idea, don’t they?

Professor Sir Kent Woods: Indeed.

Q102 Chair: This question occurred to me. Is it not odd and is there an explanation why a French manufacturer based in Toulon chose a German regulator for their registration process?

Professor Sir Kent Woods: Under the Medical Devices Directives, the manufacturer can go to any notified body in Europe, of which there are something like 80.

Q103 Chair: Were there no notified bodies closer to Toulon?

Professor Sir Kent Woods: There is a French notified body, but I do not know the answer to your question. It might be that this is to do with the areas of specialism of notified bodies because they do not all assess every type of product. This is a class 3 device. Therefore, they may have had some particular reason for going to a German notified body, but I am speculating. I honestly do not know. It would not strike me as strange that that should happen, at first sight, because it is a pan-European recognition and there is a degree of specialisation among the notified bodies as to the types of device they assess.

Q104 Chair: I understand and agree with the principle of pan-European regulation, but if we have a system that relies on occasional spot checks—I forget where it is in Germany—I know this place is a long way from Toulon.

Professor Sir Kent Woods: Indeed. Many of the larger notified bodies—I have no reason to doubt the credibility of this particular German notified body—will frequently have offices in multiple countries, and the larger ones are multinational in their approach. I

do not know the specific factors that influenced the choice here.

Q105 Chair: More importantly, from our point of view, I was struck, when reading the report of the Expert Group, by how often the conclusions were qualified by the phrase “on the available evidence”, or, “we need more evidence.” Effectively, it seemed to me that, very often, the Expert Group was saying, “We found no evidence of a problem”, but that is not saying there is not a problem.

Professor Sir Bruce Keogh: What we are saying is that the absence of evidence is not the same as evidence of safety. We need more evidence. All our deliberations were tempered by a recognition that there are a lot of very anxious and worried women out there. What we seek is hard evidence that will enable us to give them, the NHS and other providers, sensible advice that is irrefutable. Of course, that was labelled an interim report and we were not in a position to do that at that time. There is enough of an international endeavour now to help us get that evidence and probably put us in a place where a number of countries can adopt the same approach with a level of security.

Q106 Chair: Would it be reasonable to conclude, both from your report and from the answer you have given, that you regard the improvement of the quality of evidence on which regulation is based as a priority?

Professor Sir Bruce Keogh: Yes, I do. Also, it is this kind of evidence that is important for vigilance and surveillance. There are a number of issues we have to look at in the context of the next review. There are issues as to the sort of evidence that regulators may look at. There are considerations such as how we encourage professionals to report what they deem to be failures of a device, how we marshal and collect information on devices and how we not only make that kind of information available to the public but give it utility for the professional organisations, individual surgeons and the regulator. The greater utility that any of this information has, the more likely it is that everybody will buy into it.

Q107 Chair: It is worth reminding ourselves, is it not, that this issue as to regulation of devices happened to arise in the cosmetic surgery sphere? Many of these issues arise in the rest of medical devices, not exclusively in the cosmetic sphere.

Professor Sir Bruce Keogh: Yes. May I perhaps give you a pen picture of where I think some of this could lead? I hope you will understand that many of the answers that certainly I and my colleagues have given during the course of this have necessarily been phrased in such a way that we do not pre-empt our conclusions or are seen to prejudice the outcome of either review, and we look forward to your guidance, as a Committee, to help us frame some of our considerations.

It seems to me that there is a great demand in the NHS for us to focus on clinical outcomes at the moment. That is clear in the philosophy underpinning the current Bill going through Parliament. I have also

had some experience with developing clinical outcomes databases that have been of use to surgeons. So it seems to me that we have a number of devices that are put in in big numbers and that, potentially, have a significant impact on patients if they go wrong. If we could develop a system that provided information on clinical outcomes that was also linked to individual devices, we could do something quite unique in this country. We could provide information to clinicians about their own clinical outcomes and the outcomes of the devices they use. That same information could feed into the regulatory agencies and would help to drive clinical improvement.

We have gone some way towards that. For example, there is a good database that collects about 150 data points on everybody undergoing heart surgery. That includes size, make and model number of all heart valves that go in. We have a similar database for pacemakers and for joint replacements. It is not a big step to start to link those together in such a way that we have a good surveillance system for the commonly-used important devices that drives quality improvement and helps surgeons know how they are performing in relation to colleagues, and whether they are using the same sorts of devices.

There is a hidden benefit in that because, if we can get the surveillance right in a way that has utility and that drives quality improvement, we also have a unique resource that could help UK plc, in the sense that it would be an opportunity for manufacturers that are developing new devices to start thinking about coming to the UK first. That would ensure that our citizens got access to the more advanced devices earlier and that we were also part of a significant and innovative research endeavour. We also know that where patients are looked after in that sort of environment—where they are under the greater surveillance that research brings—we get better clinical outcomes. I can see that, if we get this right, it is a win for the patients, for clinicians and for the country.

Chair: That is a positive note, but it has prompted some more questions.

Q108 Barbara Keeley: In terms of where this goes next and next reviews, you have not mentioned patients and the public among the people you will be talking to. As Members, some of us have been rather surprised and horrified to hear of the experiences people have had—of the aggressive marketing that you have talked about and of the trivialisation of surgery—and to discover what is happening out there. Also, there is the lack of follow-up and the lack of interest in after care or the duty of care. It seems to me that this has drifted in a bit to MPs, be it from their own constituents, from others who have been in touch or from stories in the press. Surely, that is a group you should take to heart and consult with to fully understand what is going on out there. There have been some shocks in this in terms of the poor practice.

Professor Sir Bruce Keogh: I think all four of us at this table are just as shocked. I can reassure you that we will be taking the views of patients and others very

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seriously. But, ultimately, when we offer healthcare services, whether they are for disease or are optional, the person that we seek to look after is the patient. If we do not seek their views, then we fail in our aims. I am in the process, at the moment, of working out how best to conduct the review of the regulation and governance behaviours of the cosmetic surgery industry, but your remarks get really to the heart of how we should think about how we conduct the review. Thank you.

Q109 Dr Poulter: I very much agree with the comment you made, Professor Keogh, a moment ago, that there are very good examples in medicine—and urogynaecology is another example—where clinicians take a lead in very good record keeping. It is absolutely right—comments have been made by the Chair but also elsewhere—that it is good medical practice and a GMC requirement for surgeons and healthcare professionals to make sure that they look after their patients in an effective way. Good record keeping is clearly a part of that.

The only concern I flag up there is that I am sure—and the Committee generally holds this view—that medical professionals do take responsibility for the standard of care they provide and all aspects of it, including record keeping, the operation or the advice they give before surgery. However, if we are going to pursue this to the extent that part of good medical practice is keeping those online databases of care, let us say in urological gynaecology or in cardiology, we have to be a little bit careful—and I want to seek your views on this—that we do not let those private providers, those cosmetic providers, off the hook and put the onus solely on the professional. It is important, if companies are involved in healthcare, that they themselves have a compassionate and holistic view of care in the way they carry things out. One of the problems flagged up here, in the response of some private companies to this, is that there has not been, necessarily, that caring, patient-centred ethos. It is not just about the profit motive. I am trying to seek your view about that. Is it just down to the professional or does there need to be more scrutiny and pressure, or possibly regulation, of some of these companies to make sure that they take more responsibility for holistic care, audit trail and record keeping?

Professor Sir Bruce Keogh: Dr Poulter, you raise a really important point. You can encourage clinicians

to collect data and to submit it to whatever registry you have in mind. There will always be those who are keen to do so; there will be others who are less keen, for whatever reason; and there will be those who are keen, but say, “I do not have the support from my organisation.” If we are going to embark on this endeavour, it is very important that we dovetail the incentives to the individual and to their employing organisation to make sure that there is harmony of effort between the individual and the organisation. A number of levers already exist in the system that we can use to do that.

Q110 Dr Poulter: Nevertheless, the key issue is record keeping, audit trail and record of care. As I say, when things go wrong in the NHS, or there is a problem between NHS doctors about NHS care, you can get access to notes from another hospital, from a GP surgery and elsewhere. With private sector providers, there is a specific issue about audit trails, records of care, free availability of notes or even whether good record keeping has been done in the first place. It is those issues I am driving at.

Professor Sir Bruce Keogh: Yes. I think, again, you make a good point. I was referring in my last set of remarks specifically to some kind of device database, but there are issues about note keeping in the private sector and the relationship of those notes to the organisation. For example, some private organisations will have their own sets of notes that they keep. In many other parts of the private sector, the notes are kept by the operating surgeon or clinician rather than by the organisation. So there is a fracture, if you like. I imagine that that will come out during the course of our future deliberations.

Q111 Dr Poulter: What if that surgeon is over here in the UK, as Mr. Withey said, for a short period of time—there are issues about that in itself—but then leaves or retires? The notes are retired with the surgeon. In the NHS that is not the case, but in the private sector that is a very real problem.

Professor Sir Bruce Keogh: Thank you. I think you have given us another pointer. I appreciate it.

Chair: Very good. Thank you very much indeed for your attendance, and for your patience and clarity in answering our questions.

Supplementary note by the Department of Health

At last week’s evidence session, Barbara Keeley raised the issue of women who have received a PIP implant from a private provider following reconstructive surgery after breast cancer, and who now find that they need to approach the NHS for support because the private provider has gone out of business or is failing to meet its duty of care. Ms Keeley asked whether women in this position could expect replacement, not just removal, of the implant at NHS expense.

Earl Howe wrote on 1 February to Baroness Morgan of Drefelin, as chairman of the Breast Cancer Campaign, to clarify our policy on this issue, and I attach a copy of his letter. Essentially, the position is as Dr Slowther and I set out at the hearing; a woman in this position would be treated by the NHS on the same criteria as if they had applied for breast augmentation immediately after their mastectomy. These criteria, originally issued by the Modernisation Agency in 2005, explicitly allow for breast augmentation by the NHS in such

circumstances. The Chief Medical Officer also drew the attention of the NHS to the 2005 criteria in her letter of 27 January, which we sent to the Committee in advance of the hearing.

Since the hearing, we have been in touch with officials of the Breast Cancer Campaign to ask whether there is anything more we can do to make the position clear. This could for instance include amending the current article on NHS Choices or agreeing a short statement, which could be included in the Campaign's regular newsletter. I would be happy to write again, to Ms Keeley or to yourself, once we have agreed with the Campaign on the further steps to be taken.

Professor Sir Bruce Keogh
NHS Medical Director

16 February 2012

Annex

In the oral question which you asked on 12 January, you referred to the concern of women who have received a PIP breast implant privately following surgery for breast cancer, and who now find that their original provider has gone out of business or is refusing to help. You suggested in discussion after the question that the number of women in this position was likely to be small, and asked whether I could enlarge on the answers I gave in the House.

The government's position, as you know, is that private providers—like the NHS—owe a duty of care to their patients and, in these distressing circumstances, have a moral and in many cases legal duty to remove and replace the PIP implants free of charge, if that is the woman's choice after taking clinical advice. Nevertheless, we recognise that some women will in the end need to come to the NHS as the provider of last resort, and we have said that in these circumstances the NHS will offer clinical advice, a scan if the woman desires, and removal of the implants if the woman and her doctor agree.

If the woman in this scenario were to ask for replacement of the implants (as well as removal), the decision would be taken locally by the commissioner—at present this would be the Primary Care Trust. In general, the NHS only provides treatments such as breast enlargement if there is a genuine clinical need. Guidance on the clinical criteria was issued by the former Modernisation Agency in *Action on plastic surgery: Referrals and guidelines in plastic surgery—Information for commissioners of plastic surgery services* (2005). An extract of the relevant section is annexed,¹ and you will see that they include “women with an absence of breast tissue unilaterally or bilaterally, or in women with of a significant degree of asymmetry of breast shape and/or volume” as a result of previous mastectomy. Our view is that the local criteria for replacement of breast implants should be the same as those for the initial breast enlargement.

I hope this is helpful, and thank you again for raising this issue with me. I am copying this letter to all peers that spoke during the Oral Question.

Earl Howe

31 January 2012

¹ The British Association of Plastic, Reconstructive and Aesthetic Surgeons, <http://www.bapras.org.uk/page.asp?id=719>, *Action on plastic surgery: Referrals and guidelines in plastic surgery—information for commissioners of plastic surgery services* (2005), p 8.