Chapter 3

High revision rates: the consumer experience

Introduction

3.1 The previous chapter focussed on the role of the TGA in regulating the quality of medical devices in Australia. This examined both pre-market regulation and post-market surveillance.

3.2 This chapter commences with a background to the DePuy ASR hip system. The chapter then turns to the experience of consumers with DePuy ASR hip prostheses and associated revision surgery. Information was also provided to the inquiry regarding the DePuy LCS Duofix Femoral Knee Replacement Component (the DePuy knee replacement). The processes in place to notify the relevant authorities and the general public of high revision rates or faulty devices are also examined here. In particular, the effectiveness of the current regime in place to ensure prostheses with high revision rates are identified and the action taken once these devices are identified, will be discussed in detail.

3.3 A consistent theme of evidence provided to the committee was a need for the TGA to improve the way that it communicates with stakeholders as part of the fulfilment of its regulatory role. The submitters' comments frequently echoed the recommendations of the TGA Transparency Review. The need for improved communication has been discussed in general terms in the previous chapter. The call for greater transparency and better provision of information assumes critical importance when identifying and acting upon the high revision rate prostheses that are the subject of this chapter.

The DePuy ASR hip system

3.4 Issues around the De Puy ASR hip system were brought to light in May 2011 when ABC current affairs program ‘Four Corners’ broadcast a program detailing allegations regarding a relatively new type of hip replacement surgery used in Australia. The technology involved using metal-on-metal technology, including the metals cobalt and chromium.[1]

3.5 Many individuals interviewed by Four Corners had received ASR, or Articular Surface Replacement, hips manufactured by DePuy Orthopaedics, part of the Johnson & Johnson company. The high revision rates of these devices, both in Australia and worldwide, eventually prompted a voluntary recall by DePuy.

1 ABC, Program Transcript, *Four Corners*, 'Joint Reaction', 16 May 2011.

Approximately 5500 people in Australia, and 93 000 worldwide, were the recipients of these metal-on-metal devices.[2]

3.6 During the course of the program, Four Corners interviewed numerous individuals who had received metal-on-metal devices, including interviews with those who had subsequently had revision surgery. Many interviewed reported systemic health problems extending beyond initial complications with the device. This included: vision impairment, tinnitus and heart palpitations. Professor Ross Crawford, an orthopaedic surgeon who has been involved with providing revision surgery theorised these complications are due to cobalt toxicity.[3]

3.7 The issues raised by the Four Corners program provided much of the impetus for this inquiry. The program also served to inform the public of something that should already have been much better known.

What is the DePuy ASR Hip System?

3.8 The hip is a ball-and-socket joint. The socket is formed by the acetabulum, which is part of the large pelvis bone. The ball is the femoral head, which is the upper end of the femur (thighbone). A slippery tissue called articular cartilage covers the surface of the ball and the socket. It creates a smooth, frictionless surface that helps the bones glide easily across each other.[4]

3.9 A total hip replacement, involves the removal and replacement of the head of the thighbone (femoral head) and the damaged socket (acetabulum) with metal, plastic, or ceramic components.[5]

3.10 Hip resurfacing is a newer technique, which does not involve the removal of the femoral head. The femoral head is instead capped, or 'resurfaced', with a hemispherical covering. The damaged bone and cartilage within the socket is removed and replaced with a shell made of metal, ultra-high molecular-weight polyethylene or a combination of polyethylene backed by metal, as in a total hip replacement.[6]

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2 ABC, Program Transcript, *Four Corners*, 'Joint Reaction', 16 May 2011.

3 ABC, Program Transcript, *Four Corners*, 'Joint Reaction', 16 May 2011.

4 American Academy of Orthopaedic Surgeons, *Hip Arthroscopy*, http://orthoinfo.aaos.org/topic.cfm?topic=A00572, accessed 12 September 2011.

5 American Academy of Orthopaedic Surgeons, *Hip Resurfacing*, http://orthoinfo.aaos.org/topic.cfm?topic=A00586, accessed 12 September 2011.

6 American Academy of Orthopaedic Surgeons, Hip Implants, http://orthoinfo.aaos.org/topic.cfm?topic=A00355, accessed 12 September 2011.

3.11 DePuy Orthopaedics, a subsidiary company of JJM, is a provider of orthopaedic devices for hip, knee, extremities and trauma, in addition to bone cement and operating room products.[7]

3.12 There are two types of DePuy hip prostheses: the DePuy ASR resurfacing hip prosthesis; and the DePuy ASR XL femoral head prosthesis. These replaced some earlier models supplied by DePuy.[8]

3.13 The DePuy ASR XL System includes two components:

- a metal femoral head connected to a stem that is inserted in the femur; and
- a one-piece metal cup that lines the acetabulum.

3.14 With an ASR XL total hip replacement, a one-piece metal component known as an acetabular cup is placed in the acetabulum. The femoral head is replaced with a metal ball which is connected to a metal stem placed inside the femur.[9]

3.15 The DePuy ASR Hip Resurfacing System includes two components:

- a metal cap is placed over the natural femoral head; and
- a one-piece metal cup that lines the acetabulum.

3.16 With an ASR Hip Resurfacing System, a one-piece metal component known as an acetabular cup is placed in the acetabulum and a metal cap is placed over the femoral head.[10]

3.17 The ASR Hip Resurfacing System was first approved by the Therapeutic Goods Administration (TGA) for use in Australia in 2004 and the ASR XL System was approved in 2005.[11]

3.18 The ASR Hip Resurfacing System was only approved for use outside the United States (US) and was not commercially available in the US.[12] The US Food and

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7 Johnson & Johnson Medical, *Press Release*, 'DePuy Orthopaedics Voluntarily Recalls ASR Hip System', 26 August 2010, http://www.jnj.com/connect/news/all/depuy-orthopaedics-voluntarily-recalls-asr-hip-system, accessed 7 September 2011.

8 Therapeutic Goods Administration, *Recall of DePuy Orthopaedics hip replacement device*, 16 May 2011, http://www.tga.gov.au/newsroom/btn-dupuy-recall.htm, accessed 25 October 2011.

9 *DePuy ASR Hip Replacement Recall Guide* at: http://www.depuy.com/asr-hip-replacement-recall, accessed 7 September 2011.

10 *DePuy ASR Hip Replacement Recall Guide* at: http://www.depuy.com/asr-hip-replacement-recall, accessed 7 September 2011.

11 Therapeutic Goods Administration, *Recall of DePuy Orthopaedics ASR hip replacement device*, 16 May 2011, http://www.tga.gov.au/newsroom/btn-dupuy-recall.htm, accessed 7 September 2011.

Drug Administration (FDA) did not approve this implant because resurfacing was then a new procedure and it required DePuy Orthopaedics to test it in a clinical trial before it could be sold in the US. In late 2007, DePuy Orthopaedics submitted the study data on the resurfacing implant to the FDA for approval; however, the process was terminated when DePuy Orthopaedics withdrew its application in 2009.[13]

3.19 The ASR hip was included on the Australian Register of Therapeutic Goods after an evaluation by the British Standards Institute, an accredited European assessment body under the supervision of the British regulator, the Medicines and Healthcare products Regulatory Agency.[14]

Recall of DePuy ASR Hip System

3.20 In December 2009, in Australia, Johnson & Johnson Medical issued a recall of the ASR XL Acetabular Hip System and DePuy ASR Hip Resurfacing System used in hip replacement surgery.

3.21 In August 2010, DePuy Orthopaedics issued a worldwide voluntary recall of the same medical devices. The recall only applied to patients who had undergone hip surgery after July 2003.[15] All components for the ASR XL Acetabular System and DePuy ASR Hip Resurfacing Platform were part of the recall.[16]

3.22 The worldwide recall followed receipt of new, then unpublished data from the national joint replacement registry in the UK that tracks implant performance and outcomes, indicating a higher number of patients than previously reported to DePuy requiring revision surgery.[17] The DePuy Hip Replacement Recall Guide elaborated on the data:

> The UK data indicated that within five years of having an ASR resurfacing device implanted, approximately 12 percent of patients had revision surgery and that within five years of having an ASR total hip replacement,

12 *DePuy ASR Hip Replacement Recall Guide* at: http://www.depuy.com/asr-hip-replacement-recall, accessed 7 September 2011.

13 Barry Meier, 'The Implants Loophole', *The New York Times*, 16 December 2010.

14 Therapeutic Goods Administration, *Recall of DePuy Orthopaedics ASR hip replacement device*, 16 May 2011, http://www.tga.gov.au/newsroom/btn-dupuy-recall.htm, accessed 7 September 2011.

15 *DePuy ASR™Hip Recall Guide*, http://asrrecall.depuy.com/countries_list, accessed 2 September 2011.

16 *DePuy ASR Hip Replacement Recall Guide*, http://www.depuy.com/asr-hip-replacement-recall, accessed 7 September 2011.

17 *DePuy ASR Hip Replacement Recall Guide*, http://www.depuy.com/asr-hip-replacement-recall, accessed 7 September 2011.

> approximately 13 percent of patients had revision surgery, which was not in line with data previously reported to DePuy.[18]

3.23 DePuy Orthopaedics also provided Australian data:

> The 2010 Australian National Joint Replacement Registry reports five years after having an ASR hip implanted 7.8% of patients (1 in 13) who had an ASR total hip replacement and 10.9% of patients (1 in 10) who had the ASR resurfacing device needed to have revision surgery.[19]

3.24 The processes surrounding the recall of the ASR hip system are discussed in detail below.

Legal action in Australia

3.25 On 28 February 2011, Maurice Blackburn Lawyers commenced a class action in the Federal Court of Australia against DePuy International Ltd, which manufactured the ASR hip implants, and against Johnson & Johnson Medical Pty Limited, which distributed and sold the DePuy ASR hip implants within Australia.

3.26 This class action is being conducted on behalf of all patients who have had one or more DePuy ASR components surgically implanted by a doctor in Australia.[20]

3.27 Shine Lawyers is also pursuing legal action against DePuy Orthopaedics seeking compensation for over 200 Australians who received an ASR hip.[21]

The consumer experience

3.28 The committee received a number of submissions, and heard evidence from, people whose lives had been deeply affected by their experience of the DePuy ASR XL Hip and DePuy ASR Hip resurfacing system, and the DePuy knee replacement, and associated revision surgery.

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18 *DePuy ASR Hip Replacement Recall Guide*, http://www.depuy.com/asr-hip-replacement-recall, accessed 7 September 2011.

19 *DePuy ASR Hip System Recall Guide for Patients*, http://asrrecall.depuy.com/aupatient, accessed 7 September 2011.

20 Maurice Blackburn Lawyers, *DePuy ASR hip implants class action*, http://www.mauriceblackburn.com.au/areas-of-practice/class-actions/current-class-actions/depuy-asr-hip-implants-class-action.aspx, accessed 8 September 2011.

21 Shine Lawyers, DePuy ASR hip replacement class action, http://www.shine.com.au/pages/depuyhipreplacement.aspx, accessed 13 September 2011.

3.29 Although the circumstances of individual patients differed, the committee received evidence from consumers of devastating health problems that required:

- revision and other surgery;[22]
- repeated or extended hospital stays;[23]
- multiple and extended courses of antibiotics;[24]
- major personal and family impact;[25] and
- significant financial loss.[26]

3.30 Health problems cited by submitters included severe pain,[27] loss of mobility[28] and a complex of physical and psychological effects due to shedding of cobalt and chromium ions from the implanted device.[29]

3.31 The majority of submitters who were recipients of either the DePuy hip or the DePuy hip resurfacing system have elevated cobalt, and sometimes chromium,

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22 Name Withheld, *Submission 22*, pp 2, 3, 5–6 ; Name Withheld, *Submission 23*, p. 2 ; Name Withheld, *Submission 24*, [p. 1] ; Name Withheld, *Submission 25*, p. 1; Mr Robert Lugton, *Submission 29*, [pp 1–2]; Name Withheld, *Submission 31*, [p. 1]; Mr Stuart Cain, *Submission 32*, [p. 1]; Name Withheld, *Submission 34*, [p. 1].

23 Name Withheld, *Submission 22*, pp 3, 5, 6, 7; Name Withheld, *Submission 23*, p. 2; Name Withheld, *Submission 25*, pp 1–2; Name Withheld, *Submission 26*, [p. 1]; Name Withheld, *Submission 31*, [p. 1]; Mr Stuart Cain, *Submission 32*, [p. 1].

24 Name Withheld, *Submission 22*, pp 6–7; Name Withheld, *Submission 25*, p. 4.

25 Mrs Therese Wood, *Submission 9*, [p. 1]; Name Withheld, *Submission 22*, pp 4, 8–15; Name Withheld, *Submission 23*, pp 1, 2, 4; Name Withheld, *Submission 26*, [p. 1]; Mr Robert Lugton, *Submission 29*, [pp 1–2 and 13]; Name Withheld, *Submission 31*, [p. 1]; Mr Stuart Cain, *Submission 32*, [p. 2]; Name Withheld, *Submission 34*, [p. 1].

26 Mrs Therese Wood, *Submission 9*, [p. 1]; Name Withheld, *Submission 22*, p. 9; Name Withheld, *Submission 25*, pp 2–3, Mr Robert Lugton, *Submission 29*, [p. 2].

27 Mrs Therese Wood, *Submission 9*, [p. 1]; Name Withheld, *Submission 22*, pp 4–8, 11–15; Name withheld, *Submission 23*, p. 1; Name withheld, *Submission 25*, p. 1; Name Withheld, *Submission 26*, [p. 1]; Mr Robert Lugton, *Submission 29*, [p. 1]; Name Withheld, *Submission 31*, [p. 1]; Mr Stuart Cain, *Submission 32*, [p. 1]; Name Withheld, *Submission 34*, [p. 1].

28 Name withheld, *Submission 22*, [p. 1]; Name Withheld, *Submission 23*, p. 2; Name Withheld, *Submission 25*, pp 1–4; Name Withheld, *Submission 26*, [p. 1]; Mr Robert Lugton, *Submission 29*, [p. 2]; Name Withheld, *Submission 31*, [p. 1]; Mr Stuart Cain, *Submission 32*, [p. 1]; Name Withheld, *Submission 34*, [p. 1].

29 Name Withheld, *Submission 22*, pp. 5, 8; Name Withheld, *Submission 23*, pp 1, 2, 4; Name Withheld, *Submission 24*, [p. 1]; Name Withheld, *Submission 25*, p. 5; Name Withheld, *Submission 26*, [p. 1]; Mr Robert Lugton, *Submission 29*, [p. 2]; Name Withheld, *Submission 31*, [p. 1]; Mr Stuart Cain, *Submission 32*, [p. 1]; Name Withheld, *Submission 34*, [p. 1].

levels.[30] Submitters stated that the excessive amounts of cobalt and chromium in their body have produced symptoms such as bone loss,[31] extensive damage to bone and soft tissues,[32] hip dislocation,[33] pus coloured fluid and pseudo tumours,[34] and depression.[35] As a result of ensuing problems and complications, one submitter's condition is now terminal.[36]

3.32 Information in the *DePuy ASR Hip Replacement Recall Guide* advised that ASR patients requiring revision surgery experienced a variety of symptoms, including pain, swelling and problems walking, on a recurrent or continuing basis. These symptoms may be caused by the following problems:

- loosening – when the implant does not stay attached to the bone in the correct position;
- fracture – where the bone around the implant may have broken; and
- dislocation – where the two parts of the implant that move against each other are no longer aligned.[37]

3.33 The Department of Health and Ageing (DoHA) provided information to the committee on the symptoms of, and limited treatment options for, cobalt toxicity. They stated that:

> Heavy metals, such as cobalt and chromium, have been associated with hypothyroidism, cardiac toxicity and nerve damage. In general, where possible, treatment involves attempting to minimise exposure to the heavy metal and treating any associated organ damage.[38]

3.34 The DePuy ASR Hip Replacement Recall Guide also advised on the effects of metal leaching into the body:

> ASR Hip is made up of ball and socket components that move against each other. These metal components wear over time and generate very small particles that can only be seen with a microscope. This is an expected process. These particles do not cause problems for most patients, but a

30 Name Withheld, *Submission 22*, p. 5; Mr Robert Lugton, *Submission 29*, [p. 2]; Name Withheld, *Submission 31*, [p. 1]; Mr Stuart Cain, *Submission 32*, [p. 1]; Name Withheld, *Submission 34*, [p. 1].

31 Mr Robert Lugton, *Submission 29*, [pp 1 and 7].

32 Name Withheld, *Submission 23*, p. 2; Mr Robert Lugton, *Submission 29*, [pp 1–2].

33 Name Withheld, *Submission 31*, [p. 1].

34 Name Withheld, *Submission 26*, p. 1.

35 Name withheld, *Submission 22*, pp 4 and 13; Name Withheld, *Submission 27*, [p. 1].

36 Name Withheld, *Submission 23*, p. 2.

37 *DePuy ASR Hip Replacement Recall Guide*, http://www.depuy.com/asr-hip-replacement-recall, accessed 7 September 2011.

38 Department of Health and Ageing, Answers to questions on notice, 25 October 2011.

> small number of patients may react to these particles, causing fluid to collect in the joint and in the muscles around the joint. While this condition may initially be painless, if left untreated, this reaction may cause pain and swelling around the joint and could damage some of the muscles, bones, and nerves around the hip.[39]

Case studies

3.35 The following cases are illustrative of consumers' experiences of the DePuy ASR hip and hip resurfacing system provided to the committee.

3.36 Case Study A received an ASR total hip replacement in January 2008 at the age of 63. He told the committee that:

> It is difficult as a victim to come to terms with the fact that, if I had received one of the many, many proven hips that are available, I would be enjoying life without the pain and suffering that will follow me for the rest of my life. It would have been that easy. No second five–hour operation, no bone grafts, no splitting of my femur open and putting it together with clamps and wire–caging, no pneumonia, no renal failure, no second stay in intensive care, no pain, no pain–killing drugs, no stress for my wife and family and no loss of what will amount to a minimum of $80, 000 to myself and the community–all because someone wanted, for whatever inducement, to use me in a medical trial, and I am one of the lucky ones. They value the quality of our lives too cheaply.[40]

3.37 Case Study B, Mr Stuart Cain, received an ASR total hip replacement in June 2007. He subsequently experienced major physical problems including pain, mobility loss, anaemia, fatigue, weakness, and cobalt and chromium toxicity. The hip was revised in November 2010. However, this was not the end of his ordeal. In a supplementary submission received by the committee he detailed the subsequent 'catastrophic failure of the right total hip replacement':

> Fortunately I was able to successfully undergo surgery on Saturday October 8 and after 4.5 hours of surgery I now have received my last possible hip replacement and have had my femoral bone wired together to repair the damage caused through the removal of the ten month old implant that had broken. The main cause of concern for me, and I think a very relevant issue for this inquiry is what the surgeons discovered upon performing the osteotomy (splitting of the bone to access the interior of it) to separate my femoral bone to remove the broken elements of my previous implant.
>
> There was an approximately 10cm area within the bone that had developed severe necrosis (tissue death) as a result of metalosis caused by the original ASR implant degrading whilst it was insitu as there was no visible degradation on the surface of the 'new' implant I received in November

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39 *DePuy ASR Hip Replacement Recall Guide* at: http://www.depuy.com/asr-hip-replacement-recall, accessed 7 September 2011.

40 Name Withheld, *In Camera Committee Hansard*, 27 September 2011, p. 1.

> 2010. This 'dead' area had not allowed my new implant to grow or adhere to the bone, this allowed the femoral stem to have flex which in the course of time caused it to snap in half. I also had to undergo 4 blood transfusions post–surgery to try to assist me to recover even a low Haemoglobin level, this was directly related to the Anaemia that I developed as a result of having the ASR implant in my hip in the first place. This was effectively a time bomb that was ticking away within my leg, it would eventually fail and as there is no other way to determine the extent of metalosis within the bone (except for regular bone biopsies which are not a standard follow up procedure for hip replacement patients), this is now a risk that I have come across, but more importantly, potentially there are many other Australian patients out there who could be unknowingly in the same situation.[41]

3.38 Case Study C received an ASR hip resurfacing device in November 2008. The consumer explained their subsequent experience to the committee:

> My recovery following the surgery was slow and painful during the first six weeks post–op. From then I became ill with a whole range of different general symptoms and my hip remained sore, the pain increasing with time and the hip began "clicking and crunching". I consulted many different Doctors over the following fifteen months as I attempted to discover what was causing my general malaise. At no time did I consider that my worsening illnesses may be attributable to the hip implant. At no time did my Surgeon suggest my illness could be related to the hip implant.
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> Following a television current affairs programme, my partner and I realised that "Heavy Metal Poisoning (Cobalt and Chromium)" seemed to account for all of the symptoms I had experienced between the day of my operation and then.
>
> I arranged for an appointment with my GP and for a Cobalt and Chromium blood test. The results revealed extremely high levels of Cobalt and Chromium toxicity in my blood. I then attended for my next scheduled follow–up appointment where I informed the replacement surgeon of my blood test results. Further blood tests were arranged and the results showed a significant increase in the already enormous level of toxicity in my blood.
>
> [Name Redacted] then refused to see me again and referred me to the [Name Redacted] for assessment and possible treatment at some time in the future. Since that time I have been refused all orthopaedic treatment in South Australia.
>
> Realising that the part needed to be revised urgently, my partner attempted to locate a Surgeon somewhere in the world who was willing to operate and remove the device. Eventually a Surgeon in Melbourne contacted us and I travelled to Melbourne, where the implant was removed on 11th November 2010.
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> The damage to my bone and soft tissues was horrendous and extensive. This meant that a Total Hip Replacement was required as described in the

41 Mr Stuart Cain, *Supplementary Submission 32*, [pp 1–2].

> operation notes. Follow–up blood tests have indicated a dramatic reduction in Cobalt levels, but Chromium levels remain extremely high and static to the present time.
>
> I am at this stage, despite medical expectations, still alive. I have been told that my death from the damage caused by the level of Cobalt and Chromium toxicity in my body will be horrific and will occur sooner rather than later. My partner and my family are extremely distressed.[42]

3.39 Consumers and their advocates were highly critical of a regulatory system that they consider has failed. Issues raised with the committee by submitters go to shortcomings at all stages of the regulatory process for medical devices. Submitters raised the inadequacy of pre-market testing of devices; potential conflicts of interest of, and inducements for, surgeons and hospitals; the lack of information provided to patients to enable them to make informed decisions prior to surgery; problems with the adverse event reporting regime; the failure of the TGA to act upon information that it had available to it; the failure of the TGA to enforce the legislation and regulations that they are responsible for administering; and the lack of information and follow up provided to patients and the public once prostheses had been identified as problematic.

Pre-market clinical testing

3.40 Many of the consumers who provided evidence to the committee questioned why their hip and knee replacements were not adequately tested prior to being listed on the ARTG, and indeed whether the TGA should have listed these devices without clinical evidence.[43] Some consumers consequently felt that they were themselves unwittingly part of an unofficial clinical trial.

3.41 Ms Karen Carey, CHF, argued that the listing, and subsequent implantation, of medical devices without adequate pre-market clinical testing meant that patients were being treated as 'guinea pigs'. She explained further:

> In a normal clinical trial, before a device would be put into common use, you would have a trial population. They would be the guineapigs and you would try it out on them. With medical devices, when a product comes to market without the clinical evidence they are really using normal patients as guinea pigs, because the evidence is not there. And they do not do it within a clinical trial environment in which those patients are closely monitored. They are simply putting the devices in, and patients are rarely told that there is only a small amount of evidence.[44]

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42 Name Withheld, *Submission 23,* [pp 1–2].

43 Mrs Therese Wood, *Submission 9*, [p. 1]; Mr Robert Lugton, *Submission 29*, [p. 6]; Name Withheld, *Submission 22*, p. 11; Name Withheld, *Submission 23*, p. 2; Name Withheld, *Submission 26,* [p. 1].

44 Ms Karen Carey, Board Director, Consumers Health Forum of Australia, *Committee Hansard*, 27 September 2011, p. 32.

3.42 Ms Carey went on to submit that this process also failed in other ways. She told the committee that:

> I have to say it does not even effectively constitute a trial, because they do not collect data and then use that data to make decisions. It is even worse than that: they trial it on patients and do not collect the data.[45]

3.43 Another consumer raised concerns that patients are unaware that they are receiving clinically untested prostheses, effectively constituting unofficial trials, and further that those who have suffered as a result don't have an avenue of complaint. This consumer explained these concerns to the committee:

> I am here because I have a duty to represent the thousands of people who have been unknowingly involved in trials with untested hip prostheses that have consequently failed and are unable to have their plight heard because of many reasons and circumstances. The vast majority of them will not even be aware that they have been part of a medical trial.[46]

3.44 This sentiment was echoed by another submitter who stated that:

> I find it hard to accept that the Australian trials for this device relied on data from overseas – and there were, in actual fact, no Australian trials and investigations into the suitability of this prosthesis. Obviously the patient was the trial.[47]

3.45 Mr Robert Lugton highlighted that the AOA have similar concerns about the adequacy of pre-market testing.[48] He drew the committee's attention to the AOA submission to the TGA Consultation on Reforms in the Medical Devices Framework. In this submission, the AOA stated:

> Currently there are no standards that define what is required for pre-market assessment of hip and knee replacement prostheses and the approach to the assessment by both manufacturers and regulators is ad hoc. It is likely that the type and amount of information that is required to undertake a pre-market assessment needs to be re-evaluated and clarified. Regulators must develop more stringent approaches to both product approval and post market surveillance. Finally it is also clear that orthopaedic surgeons need to be more discriminatory and evidence based in their approach to prostheses choice.[49]

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45 Ms Karen Carey, Board Director, Consumers Health Forum of Australia, *Committee Hansard*, 27 September 2011, p. 32.

46 Name Withheld, *In Camera Committee Hansard*, 27 September 2011, p. 1.

47 Name Withheld, *Submission 26*, [p. 1].

48 Mr Robert Lugton, *Submission 29*, [p. 6].

49 Australian Orthopaedic Association, AOA Submission, Discussion Paper– Reforms in the Medical Devices Regulatory Framework, 17 December 2010, appended to Mr Robert Lugton, *Submission 29.*

3.46 Mr Lugton drew the committee's attention to JJM's opposing position regarding pre-market scrutiny in a submission the company had made to the TGA Consultation on Reforms in the Medical Devices Framework.[50] JJM stated that:

> ...JJM acknowledges the TGA's concern about the adequacy of review of higher risk devices. However we do not believe that the proposed increase in pre-market scrutiny is the most appropriate model for ensuring the quality, safety and performance of medical devices supplied in Australia The nature of complex medical technology is that some unexpected outcomes of devices use only manifest with extensive post approval clinical use and post market surveillance is essential to identify these. [51]

3.47 Mr Lugton submitted that this statement from JJM shows that:

> ...they would like to rely heavily on "risk management" and "post market surveillance". What this actually means is that manufacturers would like to be allowed to continue supplying clinically untested devices into the market and let the patients take the risks, and then watch and see what happens.[52]

Committee comment

3.48 The committee notes the significant and substantiated concerns of patients as well as the AHIA and the AOA regarding inadequate pre-market clinical testing, which was discussed in chapter 3 of this report. The committee considers that implementing Recommendation 8c of the HTA to increase the rigour of assessment of high risk medical devices is paramount. In this regard, introducing a requirement for two years minimum clinical evidence prior to a device being listed on the ARTG would appear to have significant merit.

Informed consent

3.49 Many of the consumers who submitted evidence to the inquiry did not feel they were provided enough information to give informed consent to the implantation of these devices. They did not feel they were informed by their surgeons of the known problems that were being experienced, particularly with the DePuy ASR hip, DePuy ASR hip resurfacing device and the DePuy Femoral Component. They also did not feel that their surgeons' or hospitals' financial interest in using that specific device was disclosed to them, meaning that informed consent was not possible.[53]

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50 Mr Robert Lugton, *Submission 29*, [p. 4].

51 Johnson & Johnson Medical, Reforms in the Medical Devices Framework, Submission in Response to the TGA Discussion Paper of 25 October 2010, 7 January 2001, appended to Mr Robert Lugton, *Submission 29.*

52 Mr Robert Lugton, *Submission 29*, [p. 4].

53 Mrs Therese Wood, *Submission 9*, [p. 1]; Ms Karen Carey, Board Director, Consumers Health Forum of Australia, *Committee Hansard*, 27 September 2011, p. 33; Name Withheld, *Submission 24*, [p. 1].

3.50 Ms Karen Carey, Board Director, CHF outlined a range of informed consent issues with the committee:

> In the first instance the obligation is to tell the patient what their options are. Therefore when you are discussing options, whoever has the conflict needs to say that if in relation of one of those options they have a financial interest or a research interest that needs to be told to the patient so that they can take that into account when they are making the choice between the treatment options. If patients are properly informed, and that is that they know their treatment options, they know the potential outcomes, including complications, and they know the rates of incidence, it is a format in which proper disclosure can occur. It should always be disclosed.[54]

Product information

3.51 The CHF explained that a variety of information is available about medicines including Consumer Medicine Information (CMI), Product Information (PI) and Australian Public Assessment Reports for prescription medicines (AusPAR). However, CHF has expressed concern that the information about medical devices is currently inadequate, compared to that available for medicines. They argue that having such information available for medical devices is even more important, 'as their use cannot be ceased in the way that medications can be when a problem occurs', and that this information needs to be available prior to a device being implanted.[55]

Committee comment

3.52 The committee notes that on 23 September 2011 the TGA announced a 'proposed course of action' in relation to Proposal 4 of the *Reforms in the Medical Devices Regulatory Framework Discussion Paper*[56] which addresses this issue:

> The TGA considers that it is important to be more transparent and will explore the possibility of posting manufacturer's Instructions for Use (or an abstract thereof) and Australian Public Assessment Reports (AusPAR) equivalents on the TGA in the first instance.[57]

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54 Ms Karen Carey, Board Director, Consumers Health Forum of Australia, *Committee Hansard*, 27 September 2011, p. 33.

55 Consumers Health Forum of Australia, *Submission 2*, p. 5; Mrs Therese Wood, *Submission 9*, [p. 1].

56 Department of Health and Ageing, Therapeutic Goods Administration, *Reforms in the Medical Devices Regulatory Framework: Discussion Paper 25 October 2010*, p. 24.

57 Department of Health and Ageing, Therapeutic Goods Administration, *Reforms to the medical devices regulatory framework: Proposals, 23 September 2011*, http://www.tga.gov.au/newsroom/consult-devices-reforms-110923.htm, accessed 29 September 2011.

Disclosure of known problems

3.53 A number of submitters told the committee that if they had been informed that the prosthesis chosen by their surgeon was already known to be causing patients problems, they would not have agreed to it being implanted in their bodies.[58]

3.54 Of particular note is the patient who received an ASR hip resurfacing device in November 2008: the NJRR had reported to the TGA on several occasions since September 2007 that there was a statistically significant rate of revisions of this device.[59] Further, the minutes of the OEWG meeting held on 21 May 2008 show that the TGA noted that the manufacturer of the ASR resurfacing hip implant had approached the TGA recognising that the revision rate was unacceptable.[60]

3.55 It should also be noted that the TGA does not have access to information regarding specific patients who have received implants. When a recall of a device is undertaken, the TGA contacts industry and health professional bodies, with information about the action.

Committee comment

3.56 It appears to the committee that ASR hip devices were in use after a higher than expected revision rate had been identified. The committee believes that insufficient information was provided to consumers regarding the concerns with the device. This is regrettable.

Conflicts of interest

3.57 Some submitters believed that the choice of implants by doctors may have been subject to conflicts of interest or inducements of a financial nature.[61] Mr Richard Bartlett, First Assistant Secretary, Medical Benefits Division, DoHA addressed the issue of disclosing commercial interests between the manufacturer of the device and the doctor:

> In terms of the patient actually giving informed consent, they need to be fully informed. If the surgeon has an interest in the device and they are not told of that, they are not actually giving fully informed consent. There is

58 Name Withheld, *In Camera Committee Hansard*, 27 September 2011, p. 2; Name Withheld, *Submission 23,* p. 1.

59 Professor Stephen Graves, National Joint Replacement Registry, *Committee Hansard*, 27 September 2011, p. 20.

60 Department of Health and Ageing, Answers to questions on notice, 25 October 2011, *Minutes of the Orthopaedic Expert Working Group*, 21 May 2008, p. 5.

61 Name Withheld, *Submission 22,* p. 2.

> also a professional and ethical element to this that one would expect the relevant college to have a level of interest in.[62]

3.58 Ms Carol Bennett, Chief Executive Officer, CHF, also addressed this issue and submitted there was room for improved disclosure:

> The codes of professional conduct should cover those sorts of issues. Whether or not it happens, certainly consumers report to us that it does not often happen and they do not feel as though they have received fully informed consent. Clearly there is a limitation there, but that is around how the profession manages those sorts of conflicts, and it needs to be improved.[63]

3.59 Submitters stated that they were not given a choice of hip or knee implants. The committee also received evidence that in a number of cases the consumer had specifically asked for a different device to be implanted, however the request was refused by their doctor.[64] As one submitter told the committee:

> I was a recipient of a metal-on-metal hip replacement in January 2008. My surgeon was the partner of [Name redacted], one of the researchers into the technology and the development of the De Puy ASR XL Hip implant. [Name redacted] insisted upon fitting the De Puy device, despite my wish for [Name redacted] to use a ceramic device.[65]

3.60 Another submitter noted that JJM sponsor the fellowship programme at the hospital where the operation was performed and stated that in their view, this is why the hospital uses JJM's products.[66]

3.61 In the May 2011 Budget Estimates hearing Senator Xenophon asked the TGA two questions on this matter:

> In September 2007, De Puy Orthopaedics agreed to pay $84.7million to the US Government as part of an agreement to avoid criminal prosecution over financial inducements the company paid to surgeons for the use of their products
>
> a) Was the TGA aware of this case at the time?
>
> b) Was De Puy, or De Puy's products, subject to additional scrutiny because of this?[67]

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62 Mr Richard Bartlett, First Assistant Secretary, Medical Benefits Division, Department of Health and Ageing, *Committee Hansard*, 27 September 2011, p. 52.

63 Ms Cathy Bennett, Chief Executive Officer, Consumers Health Forum of Australia, *Committee Hansard*, 27 September 2011, p. 33.

64 Name Withheld, *Submission 24*, [p. 1].

65 Name Withheld, *Submission 24*, [p. 1].

66 Name Withheld, *Submission 22*, p. 2.

67 Senate Community Affairs Legislation Committee, Answers to questions on notice, Health and Ageing Portfolio, Budget Estimates 2011–2012, 31 May 2011, Question E11–018.

> And
>
> In addition, De Puy has recently paid 4.8 million pounds in a further settlement after De Puy's Director of Marketing, Robert Dougall, was convicted of paying bribes to secure contracts in Greece.
>
> a) Was the TGA aware of this conviction?
>
> b) What impact did this have on the TGA's dealings with De Puy?

3.62 In both cases the TGA answered it was unaware of the cases.[68]

Codes of conduct

3.63 Information was provided to the committee on a range of codes of conduct and internal guidelines that address the need to provide patients with full disclosure in the event that a doctor has a financial or other interest in a medical device.

3.64 The AOA provided the committee with information on their code of conduct:

> AOA has had a professional code of conduct for members for a number of years. However, following the USA FDA investigation of device companies during 2004/05, the AOA Code of Conduct was reviewed and strengthened.
>
> The code of conduct since at least 2006 has outlined the requirement for members to disclose any financial interest in the sale of drugs, prostheses, or appliances that he/she may have when recommending that particular item to a patient.
>
> AOA believes the previous code of conduct also outlined the same requirement but due to a change of website that occurred in that year the file format used previously is unreadable.
>
> The code of conduct has been reviewed in 2006, 2008 and 2010.[69]

3.65 The AOA also provided information on sanctions for breaching the AOA code of conduct:

> Firstly the complaint has to be a written complaint directly to AOA to initiate the process. The complaint would be referred to the AOA Professional Conduct Committee for assessment and review. Sanctions include counselling of the member through to removal of the member from the Association. If the complaint involved anything of a criminal nature it would be referred to the relevant authority (ie police,[Australian Health Practitioner Agency] AHPRA).[70]

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68 Senate Community Affairs Legislation Committee, Answers to questions on notice, Health and Ageing Portfolio, Budget Estimates 2011–2012, 31 May 2011, Question E11–019.

69 Australian Orthopaedic Association, Answer to question on notice, 17 October 2011.

70 Australian Orthopaedic Association, Answer to question on notice, 17 October 2011.

3.66 Finally, the AOA provided information on complaints made to the AOA regarding breaches of the code:

> There have been no complaints to AOA that were progressed through to invoking sanctions. AOA received one written complaint in 2010 but it was not progressed internally as it was regarded as raising issues outside AOA charter. The complainant was advised to report the matter to AHPRA.[71]

3.67 JJM provided information to the committee on their International Health Care Business Integrity Guide:

> As with other affiliate companies, Johnson & Johnson Medical Pty Limited (JJM) is required to comply with an internal International Health Care Business Integrity Guide (the Guide) that contains enterprise-wide standards for compliance with a number of legal regimes. It is intended to supplement national and international legislation and applicable industry codes.
>
> The Guide sets out how Johnson & Johnson Medical Pty Limited (JJM) interacts with healthcare professionals (HCP) including the following principles:
>
> When engaging a HCP to act on behalf of the company, the services paid for by the Johnson & Johnson Medical Pty Limited (JJM) must fill a legitimate, documented business need and such services must be obtained from individuals who possess demonstrable special knowledge or capabilities to perform the services;
>
> These services must be properly documented in a written agreement, and that agreement must specify the complete compensation arrangements. Compensation paid must be fair market value for the services provided. Johnson & Johnson Medical Pty Limited (JJM) must document how fair market value was determined;
>
> Performance of services received must be documented and invoices from service providers must have sufficient detail to enable proper recordkeeping; and
>
> The agreement must contain a representation and warranty by the HCP that, in the event the HCP is or attains a position to influence purchasing decisions by a government entity or the HCP's employer, the HCP shall notify the purchase decision-maker of the HCP's financial relationship with Johnson & Johnson Medical Pty Limited (JJM) and otherwise comply with applicable requirements of local law. In such circumstances, the agreement will also permit Johnson & Johnson Medical Pty Limited (JJM) to terminate the agreement.
>
> The Guide also sets out the requirements for arrangements under a Product Development Agreement or a licence for intellectual property rights. Again, such arrangements must be properly documented in a written contract that includes the complete compensation arrangements with the healthcare

71 Australian Orthopaedic Association, Answer to question on notice, 17 October 2011.

professional. In addition, if royalties are to be paid, the healthcare professional's contribution to the development of the product at issue must be documented. Further, the Guide requires that purchases by the applicable healthcare professional be excluded in the calculation of appropriate royalties to avoid the potential for improper influence.

The Guide does not require that Johnson & Johnson Medical Pty Limited (JJM) should ensure that healthcare professionals notify patients that they have a commercial relationship.[72]

3.68 In addition JJM provided information to the committee that the company expected 'the doctors and orthopaedic surgeons with whom it interacts to abide by their professional standards of conduct and ethics, including':

- The Australian Medical Council Good Medical Practice: A Code of Conduct for Doctors in Australia (the AMC Code) which applies to all doctors nationally registered within Australia. Section 8.11 sets out the requirements of a doctor to adhere to when a conflict of interest arises which may affect their care of a patient.
- The Royal Australasian College of Surgeons (RACS) has a Code of Conduct (the RACS Code), which defines the standards of professional behaviour applicable to surgeons who are fellows of RACS. Section 8.1(4) specifies that surgeons will be honest and transparent with respect to any potential conflicts of interest.
- The Australian Orthopaedic Association also has a Code of Conduct for members, which reflects appropriate professional standards and professional expectations for orthopaedic surgeons, above and beyond the requirements of the AMC Code, due to its unique discipline. Section 6.4 of the AOA Code requires that orthopaedic surgeons declare any conflicts of interest, in particular, financial relationships with prosthetic companies or hospitals and other corporate entities or persons.[73]

Committee comment

3.69 The committee notes that in the US, JJM have agreed to pay a '$21.4 million criminal penalty as part of a deferred prosecution agreement for improper payments by J&J subsidiaries to public health care providers in Greece, Poland and Romania in violation of the Foreign Corrupt Practices Act (FCPA)'.[74]

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72 Johnson & Johnson Medical, Answer to question on notice, 14 October 2011.

73 Johnson & Johnson Medical, Answer to question on notice, 14 October 2011.

74 Tom Moylan, LexisNexis, 'Johnson & Johnson, DePuy Pay $76.9M To Settle Foreign Bribery Claims', http://www.lexisnexis.com/community/corpsec/blogs/fcpa-law-blog/archive/2011/04/12/johnson-amp-johnson-depuy-pay-76-9m-to-settle-foreign-bribery-claims.aspx, accessed 25 October 2011.

3.70 Similarly, the committee notes that the UK Serious Fraud Office obtained a Civil Recovery Order against DePuy International Limited, in recognition of unlawful conduct relating to the sale of orthopaedic products in Greece between 1998 and 2006.[75]

3.71 The committee further notes that public disclosure of payments to physicians and teaching hospitals by medical manufacturers and pharmaceutical companies is now the subject of legislation in the United States. The Physician Payment Sunshine provisions were included in the *Patient Protection and Affordable Care Act* of 2009 (H.R. 3590, section 6002) which was signed into law on 23 March 2010, and will come into effect on 1 January 2012.

3.72 The committee notes with interest legislative developments in another jurisdiction, designed to address the insidious problem of the payment of inducements by pharmaceutical companies and medical device manufacturers to doctors and teaching hospitals. The practice of paying inducements in this way is anathema to principles of informed consent and improved patient safety. The committee is of the view that there is merit for Australia in developing a similar approach.

Notifying authorities, patients and the general public about faulty devices

3.73 One of the critical issues that has been raised by consumers, their advocates and industry bodies relates to the timeliness of notification of those affected by the ASR DePuy hip and ASR DePuy hip resurfacing system, and the adequacy of subsequent action.

3.74 These matters are pertinent to the TGA as regulator of medical devices in Australia, and JJM as the manufacturer of these devices. Some submitters have also raised the question of whether the NJRR could play a more active role in the provision of information to consumers and the medical profession.

Identifying the problem

3.75 It has been reported that between 2003 and 2010, surgeons implanted the DePuy ASR hip and ASR hip resurfacing device in 93 000 patients around the world – 5500 of whom were Australians.[76] The ASR hip and hip resurfacing devices were withdrawn in Australia by the company in December 2009, and worldwide in August 2010.

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75 Serious Fraud Office, 'DePuy International Limited ordered to pay 4.829 million pounds in Civil Recovery Order', http://www.sfo.gov.uk/press-room/latest-press-releases/press-releases-2011/depuy-international-limited-ordered-to-pay-4829-million-pounds-in-civil-recovery-order.aspx, accessed 25 October 2011.

76 ABC, Program Transcript, *Four Corners*, 'Joint Reaction', 16 May 2011.

3.76 The committee sought details of when the NJRR, the TGA and JJM became aware that there was a problem:– first with the ASR hip resurfacing system; and subsequently with the ASR hip replacement system itself.

3.77 The DoHA has provided a helpful timeline regarding events associated with the ASR hip. This can be found at appendix 5.

The NJRR and the TGA

3.78 The committee received evidence about how problems with joint replacements are identified by the NJRR, and subsequently reported to the TGA. Professor Stephen Graves, NJRR, informed the committee that for a device to be considered an 'outlier', or statistically significant, it must have 'at least twice the rate of revision of any other device'. He went on to provide more detail on how the NJRR identified outlier prostheses:

> Those outliers have gone through a very rigorous process of identification, which includes statistical analysis that says that they are an outlier. As part of the process, it is also reviewed by an independent group of orthopaedic surgeons. It is that independent group of surgeons that makes recommendations to the registry to identify those particular devices as being outliers.[77]

3.79 Dr Michael Armitage pointed out that a device that requires revision at at least twice the rate of revision of any other device, may in fact need revising at five or six times the rate of any other device.[78]

3.80 It is unclear to the committee how the algorithm of 'at least twice the rate of revision of any other device' was arrived at by the NJRR, and has the appearance of being somewhat arbitrary.

3.81 Professor Graves went on to explain that there are a number of ways that the NJRR provides information to the TGA including by giving the TGA direct access to the NJRR database, by providing more detailed reports on request, and through identification of outlier prostheses in the Annual Report. He noted that prior to the annual report being released detailed reports on each device are provided to the TGA.[79]

3.82 Professor Graves went on to explain what happens after the NJRR notifies the TGA that there are outlier prostheses:

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77 Professor Stephen Graves, National Joint Replacement Registry, *Committee Hansard*, 27 September 2011, p. 18.

78 The Hon Dr Michael Armitage, Australian Health Insurance Association, *Committee Hansard*, 27 September 2011, p. 1.

79 Professor Stephen Graves, National Joint Replacement Registry, *Committee Hansard*, 27 September 2011, p. 18.

> When we notify the TGA, what happens is that they then go through a process of providing that information to companies and getting responses from companies. That is then reviewed by the orthopaedic expert working group, which again is a further independent group that the TGA has gathered. That group then provides advice to the TGA about what should happen with those particular devices. That advice is then taken on board by the TGA, with the TGA then making its own decisions as to what it will do.[80]

3.83 Professor Graves emphasised to the committee that the role of the NJRR and the TGA are distinct, noting that 'the responsibility for regulation of devices rests solely with the TGA'. He explained further:

> It is important to separate the regulatory functions and the information gathering and reporting functions. There is no infrastructure within the registry to determine whether a device is suitable or not suitable for use within the Australian market. What we do is identify devices that are performing differently from other devices.[81]

3.84 The NJRR first reported higher than usual revision rates for the ASR resurfacing device in 2006, although it did not meet the threshold of twice the normal rates of revision, and thus was not considered statistically significant. Professor Graves, NJRR, explained that at that time there was no formal notification process between the NJRR and the TGA.[82]

3.85 However, in mid-September 2007 the NJRR informed the TGA that the ASR resurfacing device was experiencing revisions at a statistically significant rate. By July 2008 the NJRR was aware that the hip replacement itself was experiencing significant revision rates, and informed the TGA in September 2008.[83]

3.86 Professor Graves told the committee that in September 2008 when the NJRR informed the TGA that the hip replacement itself was a problem, they 'also re-emphasised at that point in time that the resurfacing was still an outlier as well'. He then told the committee that 'In 2009 we again emphasised that both the conventional hip and the resurfacing were outliers'.[84]

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80 Professor Stephen Graves, National Joint Replacement Registry, *Committee Hansard*, 27 September 2011, p. 18.

81 Professor Stephen Graves, National Joint Replacement Registry, *Committee Hansard*, 27 September 2011, p. 18.

82 Professor Stephen Graves, National Joint Replacement Registry, *Committee Hansard*, 27 September 2011, p. 20.

83 Professor Stephen Graves, National Joint Replacement Registry, *Committee Hansard*, 27 September 2011, p. 20.

84 Professor Stephen Graves, National Joint Replacement Registry, *Committee Hansard*, 27 September 2011, p. 20.

3.87 Professor Graves also explained that a correlation was not immediately made between there being problems with the ASR hip resurfacing device and potential problems with the ASR hip replacement. However, he explained that there is a nexus, telling the committee that 'The devices are similar in one respect, in that the acetabular or the cup is the same, but the femoral component is quite different'.[85]

3.88 Dr Hammett explained the responses of the TGA to the receipt of information from the NJRR: first regarding the hip resurfacing device, and subsequently the hip replacement itself. Dr Hammett informed the committee that as a result of the 2007 NJRR report, the TGA established the OEWG, as a subcommittee of the TGA's Medical Device Evaluation Committee, in order to 'bring in some expert independent clinical advice to review the data of the joint replacement registry and work out what regulatory action was appropriate based on that data'.[86] The OEWG met for the first time on 8 August 2007.[87]

3.89 Dr Hammett reported to the committee that the advice provided by the OEWG in 2007 was that the higher revision rate 'may be due to the technical complexity of implanting this particular joint prosthesis'. Dr Hammett further commented that the OEWG recommendation 'was that surgeons should be required to undertake additional training regarding insertion of the ASR hip'.[88] DePuy Orthopaedics agreed to provide the training.[89]

3.90 The training program on the ASR hip was instituted between 2007 and 2008.[90] Dr Hammett reported that in 2008 the OEWG was consulted again and they agreed that the monitoring and training program that had been put in place was appropriate for the ASR hip.[91]

3.91 The OEWG met on 21 May 2008, and considered the ASR resurfacing hip implant. The minutes of this meeting state that:

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85 Professor Stephen Graves, National Joint Replacement Registry, *Committee Hansard*, 27 September 2011, p. 20.

86 Dr Rohan Hammett, National Manager, Therapeutic Goods Administration, *Committee Hansard*, 27 September 2011, p. 47.

87 Department of Health and Ageing, Answers to questions on notice, 27 September 2011.

88 Dr Rohan Hammett, National Manager, Therapeutic Goods Administration, *Committee Hansard*, 27 September 2011, p. 48.

89 Therapeutic Goods Administration, *Recall of DePuy Orthopaedics ASR hip replacement device*, 16 May 2011, http://www.tga.gov.au/newsroom/btn-dupuy-recall.htm, accessed 7 September 2011.

90 Dr Rohan Hammett, National Manager, Therapeutic Goods Administration, *Committee Hansard*, 27 September 2011, p. 48.

91 Dr Rohan Hammett, National Manager, Therapeutic Goods Administration, *Committee Hansard*, 27 September 2011, p. 49.

> The TGA noted that the manufacturer of the ASR resurfacing hip implant had approached the TGA recognising that the revision rate is unacceptable The manufacturer advised that supply of the implant will no longer be possible unless the surgeon undergoes a training and mentoring program. It appears that many surgeons are reluctant to undertake this training, and the company reports that sales have decreased sharply since this measure began.[92]

3.92 At the same meeting the OEWG advised that:

> The Working Group endorsed the actions taken by the ASR resurfacing hip implant's sponsor towards requiring surgeons to undertake specific training for this implant as a condition of sale. The Working Group advised that the performance and revision rate of the ASR resurfacing hip implant should continue to be observed.[93]

3.93 The OEWG met on 18 June 2008 and again on 9 December 2009.[94] Professor Graves confirmed that the TGA were sent information by the NJRR, on higher revision rates of both the ASR hip resurfacing device and the hip replacement itself, in September 2008. Yet, the OEWG did not meet again until December 2009, a period of over a year between receiving this information and meeting again.[95]

3.94 At the December 2009 meeting of the OEWG it was noted that:

> The TGA reported that there have been approximately 30 implants identified in the 2008 and 2009 report that have a higher than average revision rate. Due to the slow response rate from the manufacturers, of the 30 implants, 10 will be discussed at this meeting and the remaining 20 will be discussed at subsequent meetings to be held early in 2010.[96]

3.95 According to additional information provided to the committee by Professor Graves, the NJRR originally provided the 2007 report to the TGA in September 2007

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92 Department of Health and Ageing, Answers to questions on notice, 25 October 2011, *Minutes of the Orthopaedic Expert Working Group*, 21 May 2008, p. 5.

93 Department of Health and Ageing, Answers to questions on notice, 25 October 2011, *Minutes of the Orthopaedic Expert Working Group*, 21 May 2008, p. 5.

94 Department of Health and Ageing, Answers to questions on notice, 25 October 2011, *Meeting Record and Outcomes of the Orthopaedic Expert Working Group*, 18 June 2008; Department of Health and Ageing, Answers to questions on notice, 25 October 2011, *Draft Meeting Record and Outcomes of the Orthopaedic Expert Working Group*, 9 December 2009.

95 Professor Stephen Graves, National Joint Replacement Registry, *Committee Hansard*, 27 September 2011, pp 20, 24; Department of Health and Ageing, Answers to questions on notice, 25 October 2011, *Draft Meeting Record and Outcomes of the Orthopaedic Expert Working Group*, 9 December 2009.

96 Department of Health and Ageing, Answers to questions on notice, 25 October 2011, *Draft Meeting Record and Outcomes of the Orthopaedic Expert Working Group*, 9 December 2009.

and then again in February 2008 when the TGA requested that the data be resent.[97] This data was not reviewed until May and June 2008, a delay of over nine months.[98] This is concerning.

3.96 Dr Hammett explained that during this period that the OEWG did not meet that 'the TGA was reviewing the processes of gathering information and responding to it from the NJRR data'. Dr Hammett went on to state:

> The NJRR data, while it is widely acknowledged as incredibly useful for post-market monitoring, has had some challenges in the interpretation of that data over the years, and not long before the period in question I think there had been questions raised about the way this information was handled and about the processing of data from the NJRR and whether the mechanisms by which that information was utilised by the regulator was appropriate and whether it accorded appropriate natural justice to sponsors of companies and to the general community. [99]

3.97 The OEWG met on 9 December 2009 and considered the ASR Acetabular Cup. The minutes of the meeting state that:

> The TGA reported that the rate of revision for this device due to metal sensitivity is high. The Sponsor is taking steps to withdraw the product from the market but wishes to retain some components on the ARTG. Approximately 4000 devices were implanted and access to components will be beneficial when revision surgery is required...
>
> A member commented on ASR being problematic and the ongoing incidents reported to the Medical Devices Incident Reporting Scheme (MDIRC).
>
> Members agreed that the ASR should no longer be available on the market, but that some components such as the femoral heads should be available for revision surgery. The TGA together with the company will make a decision as to what components will remain on the ARTG.[100]

3.98 Dr Hammett told the committee that once devices are identified as having a high revision rate it is not the case that they are just withdrawn from the market, noting that 'That actually would not help patients. There are many useful devices contained within the Joint Replacement Registry data that do have a real role'. Dr Hammett went on to explain how the OEWG conduct their considerations and why the process takes time:

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97 Professor Stephen Graves, National Joint Replacement Registry, Answers to questions on notice, 25 October 2011, [p. 2].

98 Professor Stephen Graves, National Joint Replacement Registry, Answers to questions on notice, 25 October 2011, [p. 3].

99 Dr Rohan Hammett, National Manager, Therapeutic Goods Administration, *Committee Hansard*, 27 September 2011, p. 50.

100 Department of Health and Ageing, Answers to questions on notice, 25 October 2011, *Minutes of the Orthopaedic Expert Working Group*, 9 December 2009, p. 5.

> They have to consider each of the devices that have been shown to have higher revision rates and there is a process whereby the information is conveyed to the companies, and they are asked to respond to it to try to explain what might be causing that. That is reviewed by the clinical experts, and that takes some time. There are now 76 separate devices that have been identified within the Joint Replacement Registry as having higher rates of revision. Of those 76, after they have all been considered by experts and by the regulator, only 15 have been removed from the market. There is a lengthy process of understanding what might be contributing to this data.[101]

3.99 Once the NJRR identifies prostheses being revised at greater than twice the usual rate it does not necessarily mean that those implants are removed from the market. Dr Michael Armitage pointed out that the implants may stay on the market, only to be identified once again in the following year's report. To illustrate this point Dr Armitage drew the committee's attention to the 2010 National Joint Replacement Registry annual report:

> ...there were 16 hips that needed replacement at a rate greater than a standard algorithm, at twice the rate of revision of others. It says 'more than' so it might be a five or six times greater failure rate. Sixteen were identified but seven of those had been identified in the previous report and were still being used. In the case of knee replacements, nine failed more than twice as often as another standard knee replacement but, in fact, five of those had been identified the year before. We think that is cause for action to be taken on behalf of Australians.[102]

3.100 Professor Graves gave evidence to the committee regarding the timeliness of the TGA in responding to issues about devices that have been flagged by the NJRR:

> Have I been happy with the timeliness of action over the whole period? The answer is no. Am I currently happy with the approach that the TGA is using? The answer is yes. There have been times when I have thought the timeliness could have been better.[103]

3.101 Further evidence that the OEWG also had concerns about the timeliness of the TGA's response to devices showing high revision rates was apparent in the minutes of the 9 December 2009 OEWG meeting:

> A member voiced their concerns on the slow action being taken on some of the recommendations made by the working group at previous meetings. There was robust discussion regarding timeframes and some of the prosthesis identified in previous meetings that were still on the ARTG.

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101 Dr Rohan Hammett, National Manager, Therapeutic Goods Administration, *Committee Hansard*, 27 September 2011, p. 53.

102 The Hon Dr Michael Armitage, *Committee Hansard*, 27 September 2011, p. 1.

103 Professor Stephen Graves, National Joint Replacement Registry, *Committee Hansard*, 27 September 2011, p. 22.

> The Chair expressed concern at the lack of meetings for the past 18 months of the working group and stated that this group will need to meet on a more regular basis to be of any benefit.
>
> The TGA referred the OEWG to the Out of Session Item that was distributed prior to the meeting and included with the papers for consideration, highlighting the actions already taken by the TGA on previous OEWG recommendations. Some members felt that the actions had been too weak and too slow.
>
> The TGA explained that there had been an internal review of the process for re-assessment of implants that had been identified as having higher than expected revision rates, and that the process had been halted during the review. But the process has now been cleared to continue. TGA expects to be able to process the implants that were identified in the 2008 and 2009 NJRR reports quite quickly, provided that the OEWG can meet a couple of times early in 2010.[104]

3.102 Dr Hammett responded to apparent criticisms about the TGA's timeliness:

> ...what I would say is we have worked very hard over the last couple of years to improve the timeliness of review of data from the NJRR and to improve the links with the NJRR to the point where we have access to the database and can make specific inquiries. I think...the relationship and the communications between the NJRR and the TGA currently is better than it ever has been.[105]

Committee comment

3.103 The committee notes that both the NJRR and the TGA assert that the TGA is currently responding to NJRR data with improved timeliness. The committee notes that Australia was the first country to remove the ASR devices from the market. However, the committee is of the view that response to the emerging problem could have been more timely. Additionally, more could have been done to understand the extent and nature of the problem including consumer experience post-implant of the devices. The committee also considers there could have been better communication with stakeholders as events unfolded.

The manufacturer

3.104 The committee also sought to ascertain when JJM became aware of a higher than usual rate of revision for the ASR hip resurfacing system and the hip replacement. JJM submitted answers to questions on notice but in response to the question about when the company first became aware of these issues, its reply was

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104 Department of Health and Ageing, Answers to questions on notice, 25 October 2011, *Draft Meeting Record and Outcomes of the Orthopaedic Expert Working Group*, 9 December 2009, p. 2.

105 Dr Rohan Hammett, National Manager, Therapeutic Goods Administration, *Committee Hansard*, 27 September 2011, p. 49.

decidedly opaque. In its response, JJM correctly identified that in 2006 the NJRR annual report said that 'The ASR has a higher revision rate when compared to the [Birmingham Hip Resurfacing] but it is not significant'.[106] JJM went on to note that:

> The revision rates reported in 2010 by the UK National Joint Registry were higher than expected, which resulted in DePuy Orthopaedics Inc (DePuy) issuing a voluntary recall of the ASR Hip System on 24 August 2010.[107]

3.105 The committee drew on answers to questions on notice provided by DoHA, to ascertain when JJM would have been informed that there were problems with the hip resurfacing device firstly, and subsequently the hip replacement.

3.106 DoHA provided details of contact between the TGA and JJM in relation to the ASR hip, but not documentation supplied by JJM. DoHA explained that, while the Department has no objection to the release of documentation provided by JJM to the committee, it has not been supplied because:

> ...it is claimed by J&J to be commercial in confidence. Following a recent Freedom of Information request, release of this information is currently the subject of a review by the Office of the Information Commissioner.[108]

3.107 Details of discussions between the TGA and JJM, and information provided by JJM to the TGA, were provided to the committee are as follows:

> The Therapeutic Goods Administration (TGA) met with the manufacturer, Johnson & Johnson Medical (J&J) in September 2007 to discuss high early revision rates for the ASR Surface Replacement device. J&J tabled a submission which proposed surgeons be required to undergo specific training on the ASR implant as a means of reducing the number of revisions...
>
> On 1 May 2008 the TGA received an update report from J&J on the actions undertaken in September 2007 in relation to the ASR Surface Replacement device (see preceding paragraph)...
>
> Individual early revisions (revisions that take place <10 years after implantation) are considered to be reportable adverse events. To date the TGA has received 401 adverse event reports from J&J about ASR implants. Of these:
>
> 69 were received prior to December 2009 (the date of the withdrawal of the implant in Australia)
>
> 139 were received between January 2010 and December 2010
>
> 193 were received as a batch of summary reports covering the period January - March 2011.[109]

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106 Johnson & Johnson Medical, Answers to questions on notice, 27 September 2011, p. 1.

107 Johnson & Johnson Medical, Answers to questions on notice, 27 September 2011, p. 2.

108 Department of Health and Ageing, Answers to questions on notice, 25 October 2011.

109 Department of Health and Ageing, Answers to questions on notice, 25 October 2011.

Committee comment

3.108 The committee notes that JJM did not provide clear answers to information sought by the committee about when it first became aware of a higher than usual revision rate. The committee considers it highly unlikely that the company was not aware of the issue before 2010 given that a withdrawal was issued in Australia in 2009. In particular the committee notes that the TGA was meeting with JJM on this issue from at least September 2007 onwards.

3.109 The committee is deeply disturbed by what appears to be tardiness on the part of JJM to act on known problems with these devices. Many people could have avoided considerable pain, suffering and diminished quality of life if the company had acted in a responsible manner to known problems with these devices. In failing to respond to the committee's requests for information on this matter, JJM have only served to confirm the committee's views.

Removal of DePuy ASR hip products from the Australian market

3.110 JJM, through DePuy withdrew the DePuy hip resurfacing system and the DePuy hip from the Australian market in December 2009. Ms Robyn Chu, Director, Health Outcomes, JJM, described in general terms what happens after such a withdrawal:

> ...my understanding is that when a product is withdrawn from the market there is a conversation with the TGA about what has occurred, and then the process is that the communication is drafted and approved by the TGA, and that communication is then provided to healthcare professionals who deal with patients.[110]

3.111 The TGA, on their website, advise that:

> In 2009, after ongoing monitoring of the performance of both types of ASR hip prosthesis for a reasonable period to evaluate the effects of the enhanced training program, data from the NJRR revealed that the rate of hip revisions remained of concern. The TGA took immediate action with the sponsor regarding this ongoing, higher-than-anticipated revision rate and subsequently DePuy Orthopaedics agreed to remove the ASR resurfacing hip implant from the Australian market in December 2009. [111]

3.112 Clarification on the TGA's role in the removal of the ASR device from the Australian market was sought by Senator Xenophon through the Budget Estimates 2011–12 process. Senator Xenophon asked the following question on notice:

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110 Ms Robyn Chu, Director, Health Outcomes, Johnson & Johnson Medical, *Committee Hansard*, 27 September 2011, p. 40.

111 Therapeutic Goods Administration, *Recall of DePuy Orthopaedics ASR hip replacement device*, 16 May 2011, http://www.tga.gov.au/newsroom/btn-dupuy-recall.htm, accessed 7 September 2011.

> The DePuy ASR hip device was eventually withdrawn from the market by DePuy. Dr Hammett, in an interview with Four Corners, you state that the device was withdrawn: "as a result of the TGA, and its expert clinical groups analysing data and presenting that to the company, making it quite clear that we regarded the performance of this device as no longer acceptable".
>
> a) So the TGA did not require DePuy to remove the device from the market, it merely provided information and allowed the company to make that decision?[112]

3.113 The Department of Health and Ageing answered:

> a) The TGA, through bringing the company to a point where it understood that the data was showing that there was a problem, achieved removal of this device from the Australian marketplace ten months before it had been removed anywhere else in the world.[113]

Following through

3.114 Given that it appears that so many consumers are experiencing ill health as a result of being implanted with either the DePuy hip resurfacing device or the DePuy hip replacement, the committee endeavoured to understand what actions have been taken by the TGA and the manufacturer, subsequent to the withdrawal of the devices.

3.115 The following section considers provision of information and provision of assistance to consumers. It also considers follow up of cobalt and chromium toxicity in patients.

The TGA and orthopaedic surgeons

3.116 The TGA website described what happened following the removal of the ASR implant from the Australian market. The website stated that:

> ...the TGA worked with DePuy and the Australian Orthopaedic Association (AOA) to ensure that all Australian orthopaedic surgeons were aware of the recall and the appropriate advice provided to patients.

3.117 However, consumers who provided evidence to the inquiry were not informed once problems had been identified with their particular prosthetic devices. Additionally, although both the ASR hip and ASR hip resurfacing system were withdrawn by the manufacturer in Australia in 2009, it appears this information was not conveyed to patients in a systematic or consistent manner.

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112 Senate Community Affairs Legislation Committee, Answers to questions on notice, Health and Ageing Portfolio, Budget Estimates 2011–2012, 31 May 2011, Question E11–017.

113 Senate Community Affairs Legislation Committee, Answers to questions on notice, Health and Ageing Portfolio, Budget Estimates 2011–2012, 31 May 2011, Question E11–017.

3.118 A number of submitters described how they only became aware that there was a problem with their device through the media. Mr Stuart Cain received a hip replacement in June 2007 and started experiencing major physical problems in December 2008. He visited his doctor, but as he noted, neither he nor his doctor considered his implant could be a cause. He explained how he found out that the device could be causing his problems:

> It was only when the media enlightened me to the issues around the dePuy implant and my Orthopaedic Surgeon requested that I have a blood test for Cobalt and Chromium Ion poisoning as well as a Nuclear Bone Scan to assess the integrity of the implant, that my true situation became clear.[114]

3.119 The consumer in Case Study C had a similar experience. She received a DePuy hip resurfacing device in November 2008, even though the device had been reported as having a statistically significant rate of revisions since September 2007. She told the committee that it was only following a television current affairs program that she identified the cause of her symptoms.[115]

3.120 Another consumer also commented that the only information they had received was through the media:

> Unfortunately I recently became aware of the problems that lay ahead for me when [I saw] the Australian Broadcasting Co[sic] on a Television show "4 Corners"...This programme made it quite clear what a very poor outlook [there is for] any folk who like me had a Cobalt – Metal to Metal Hip reconstruction implanted in their body.[116]

3.121 Mr Robert Lugton, described how after constantly raising symptoms with his surgeon, he finally realised the source of his ill-health, through searching on the internet. Mr Lugton explained:

> I was a fit and active 63 year old when I had a DePuy ASR total hip replacement in January 2008. In June 2010 and after 2 years of pain with continual surgery visits, I was informed by my surgeon that the ASR had been withdrawn from the market.
>
> My surgeon informed me that it was also subject to a high failure rate of around 12%. After examining my x-rays he said that everything looked good and for me to come back for another check-up in a year's time. I again, as I had many times before, asked him about my thigh and groin pains. His reply was, as before, that I must have a lower back problem. I left the surgery unconvinced and worried! I decided to look on the internet to try and determine what symptoms patients, who had already undergone revisions had experienced before having to have their ASR implants removed. Their symptoms were similar to what I was experiencing. The

114 Mr Stuart Cain, *Submission 32*, [p. 1].

115 Name Withheld, *Submission 23*, p. 1.

116 Name Withheld, *Submission 31*, [p. 1].

> amount of information on the ASR failure around the world on the internet was staggering. The Metal-on-metal hip was leaching Cobalt and Chromium into patients' bloodstreams in huge quantities.[117]

3.122 Another submitter described how, after significant ill health and a test indicating seriously elevated cobalt levels, his wife was only informed on 10 October 2010 by her original surgeon at her annual review of the DePuy ASR hip's withdrawal.[118] The submitter went on to describe the surgeon's response, prior to providing a referral to another surgeon:

> The surgeon told us not to worry about [her] blood toxicity, as this alone was not significant to warrant revision surgery. He mentioned he had twelve other patients in a similar position.[119]

3.123 Dr Michael Armitage, Chief Executive Officer, Australian Health Insurance Association was critical of the processes in place to notify the relevant authorities and the general public of high revision rates, stating:

> ...this simply does not occur, and we think that is one of the key failings. The Australian public are not stupid and they deserve to be told when there are high revision rates.[120]

3.124 In relation to the effectiveness of the current regimes in place to ensure prostheses with high revision rates are identified, Dr Armitage went on to say that:

> ...we actually believe that there should be a lot more action taken in this matter. We think there should be identified any potential problems with the devices and those should be made public for Australians to make their own decisions as to whether they want to have the device or prosthesis inserted into them.[121]

3.125 The AOA contended that in the case of high revision rates or possible faulty devices 'the ideal method of dissemination of information to patients and consumers is through the surgeons who implant the devices and informed medical practitioners'. It asserted that 'to do otherwise promotes patient, media and legal mischief and misinformation' and that 'it would appear to AOA that there is a role for TGA to advise the public directly'.[122]

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117 Mr Robert Lugton, *Submission 29*, [p. 1].

118 Name Withheld, *Submission 34*, [p. 2].

119 Name Withheld, *Submission 34*, [p. 2].

120 The Hon Dr Michael Armitage, Australian Health Insurance Association, *Committee Hansard*, 27 September 2011, p. 1.

121 The Hon Dr Michael Armitage, Australian Health Insurance Association, *Committee Hansard*, 27 September 2011, p. 1.

122 Australian Orthopaedic Association, *Submission 5*, [p. 4].

3.126 St Jude Medical noted their support for the recommendations of the TGA Transparency Review report which recommended processes:

> ...for ensuring that information related to deficiencies in the quality, safety, or performance of medical devices will be made available to health care professionals and the public as early as possible.[123]

3.127 The AOA also provided information about a recently established system of web-based linkages for early notification of hazard alerts, enabling early and rapid dissemination to AOA surgeons. They explain that 'this expediency precludes further devices being implanted during any "lag" period of notification'.[124]

Committee comment

3.128 The committee is of the view that provision of information to patients regarding the withdrawal of the ASR hip devices, and the known associated problems with the devices, has been lacking and should be addressed as a matter of urgency.

3.129 It appears to the committee that industry has been very good at promoting medical devices to surgeons and hospitals but utterly remiss in informing them in a timely manner of problems with those same devices.

The manufacturer

3.130 The committee heard from Mr Anthony Bishop, Area Vice President, Australia and New Zealand, JJM, that 'the recall has had an enormous impact upon patients, their loved ones and their healthcare professionals'. Mr Bishop went on to state that:

> ...our company profoundly and deeply regrets the impact that this recall has had on patients. We are doing what we can to minimise the impact that this recall is having.[125]

3.131 Mr Bishop explained that the company's first priority in response to the recall was 'the care and well-being of all ASR patients'. Mr Bishop told the committee that:

> We are trying to ensure that no ASR patient is without information and that they receive appropriate support during this time. We are working to ensure that no ASR patient suffers financial detriment related to this recall. To this end, Crawford and Company, an independent third-party claims processor, has been engaged to appropriately evaluate claims and reimburse individuals for the eligible expenses they incur in the course of their treatment arising from the ASR recall. At the date of this hearing, we have

123 St Jude Medical Australia, *Submission 8*, [pp 15–16].

124 Australian Orthopaedic Association, *Submission 5*, [p. 4].

125 Mr Anthony Bishop, Area Vice President, Australia and New Zealand, Johnson & Johnson Medical, *Committee Hansard*, 27 September 2011, p. 34.

> reimbursed over $21 million in approved claims, and at the date of this recall we have over 3½ thousand patients registered with Crawford.

3.132 JJM provided additional information to the committee about assistance the company is providing for patients with the ASR hip devices through the Crawford & Company Scheme. JJM explained that:

> Crawford & Company has been engaged to process the funding of reasonable and customary expenses incurred by patients for tests and treatment (including revision surgery) associated with ASR hip devices. The expenses funded include hospital charges, surgeon and anaesthetist fees, surgical assistant fees and implant costs, and out-of-pocket costs for reasonable and documented expenses, such as travel expenses, subject to review by Crawford & Company.[126]

3.133 JJM also told the committee that in some circumstances, patients who are assessed to be eligible for funding under the Crawford & Company Scheme may be considered by JJM to be eligible for additional compensation. JJM explained that:

> Such consideration is likely to be most appropriate for patients whose conditions have stabilised. Those individuals (or someone on their behalf) should approach Johnson & Johnson Medical Pty Limited (JJM) directly. Any compensation provided beyond the Crawford & Company process would be on a full and final settlement basis and covered by a settlement agreement.[127]

Monitoring and evaluating the effects of cobalt and chromium

3.134 The committee received details of cobalt toxicity in some patients who received the ASR hip. The Medical Journal of Australia has called for more research into this issue for patients with metal-on-metal hip prosthesis as a result of a recent report[128] on this issue:

> Mao and colleagues report the first Australian patients with ASR prostheses to show a potential association between high serum metal ion levels and systemic toxicity. Their report also highlights the difficulties in understanding the relevance and significance of these high metal ion levels. To date, there have only been anecdotal case reports of potential toxicity, and this is another such publication. The authors have been clear in stating that it is not possible to draw conclusions because there is not enough evidence to determine if the problems these patients have experienced are coincidental rather than causal. What this and other reports have done, however, is highlight the urgent need to undertake comprehensive research to examine the relationship between high serum metal ion levels after total

126 Johnson & Johnson Medical, Answers to questions on notice, 14 October 2011.

127 Johnson & Johnson Medical, Answers to questions on notice, 14 October 2011.

128 Xinzhan Mao, Andrew A Wong and Ross W Crawford, Cobalt toxicity – an emerging clinical problem in patients with metal-on-metal hip prosthesis, *Medical Journal of Australia*, 2011; 194(12): pp 649–651.

> hip replacement and the risk of toxicity. It is critical to determine at what concentration elevated cobalt and chromium serum levels may cause toxicity, and how the extent and severity of toxicity varies with the level. This is important because surgeons currently have no information on whether a hip should be revised based simply on the patient's serum metal ion levels. Revision surgery has significant morbidity and mortality risks and should not be undertaken without good indications to do so.[129]

3.135 The committee received evidence from Dr Hammett, of the TGA, Professor Graves, of the NJRR, and the DoHA that research and publication on the effects of cobalt and chromium in the human body is nascent.[130] Professor Graves, NJRR, told the committee that:

> At this point in time, there have been two reports of metal toxicity published in the literature. Both of those are on two patients, so we have four patients worldwide that have been reported with cobalt systemic toxicity.[131]

3.136 However, Professor Graves went on to state that cobalt systemic toxicity 'is potentially a major concern'. He explained further:

> I think that the jury remains out as to what the extent of this problem is. I am not saying it is not a problem; I am saying that we do not know the extent of it. But what we are saying is that we need to look at this quickly and we need to get an understanding of the extent of the problem.[132]

3.137 Dr Hammett appeared more equivocal on the problems posed by metal ion toxicity in patients who have received metal-on-metal implants, stating that 'We share concerns about the need to understand whether metal ion toxicity is a real thing'.[133] Dr Hammett went on to explain that:

> So if there are about a million people out there who have had these cobalt based implants and all of those have high levels of cobalt-and we do not know that, so no-one knows that-and a million of them less four are walking around asymptomatic with no problems, then it would suggest-on the balance of those numbers-that there may not be an issue. But we do not

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129 Stephen E Graves, 'What is happening with hip replacement ?', *Medical Journal of Australia*, 2011; 194(12): pp 620–621.

130 Professor Stephen Graves, National Joint Replacement Registry, *Committee Hansard*, 27 September 2011, p. 24; Dr Rohan Hammett, National Manager, Therapeutic Goods Administration, *Committee Hansard*, 27 September 2011, p. 56; Department of Health and Ageing, Answers to questions on notice, 25 October 2011.

131 Professor Stephen Graves, National Joint Replacement Registry, *Committee Hansard*, 27 September 2011, p. 24.

132 Professor Stephen Graves, National Joint Replacement Registry, *Committee Hansard*, 27 September 2011, p. 24.

133 Dr Rohan Hammett, National Manager, Therapeutic Goods Administration, *Committee Hansard*, 27 September 2011, p. 56.

> know that. As I started by saying, I am not trying to downplay this; I am just saying that there is a gap in the scientific knowledge.[134]

3.138 Professor Graves informed the committee that the NJRR has been approached by the TGA 'as to whether a study like that could be undertaken in Australia'. Professor Graves went on to recommend that:

> ...there needs to be a careful, systematic review of what is actually happening. We believe that those studies would be best undertaken by being embedded in registries, where we know what the outcome is with respect to revision.[135]

3.139 Similarly, Dr Hammett provided evidence on the TGA's plans to address the issue of metal ion toxicity:

> At this stage we are just working out what is feasible in terms of doing research on this and what the appropriate and best ways of doing it are. We are certainly talking with experts from the orthopaedic expert working group, the AOA and the joint replacement registry about whether it is possible in some way to track people who have had these metal-on-metal hips and to assess whether there are any impacts. But this is all very nascent work at present and we are still in discussions about whether there is a feasible mechanism of undertaking that sort of research.[136]

3.140 DoHA has advised the committee that 'the TGA has reviewed the scientific literature regarding blood levels of cobalt and chromium'. DoHA went on to state that:

> The TGA is not a research body but will examine research results when they become available to determine any regulatory significance.[137]

3.141 The committee endeavoured to establish what the acceptable range in Australia and internationally for the presence of cobalt and chromium in blood, and whether the range had been changed. DoHA informed the committee that:

> There is no established reference (normal) range for serum cobalt and chromium. Serum cobalt and chromium level testing is performed only in a few Australian pathology laboratories and the quoted reference ranges vary.[138]

3.142 DoHA stated that different pathology companies and the academic literature suggest different reference ranges for cobalt and chromium. DoHA explained that:

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134 Dr Rohan Hammett, National Manager, Therapeutic Goods Administration, *Committee Hansard*, 27 September 2011, p. 57.

135 Professor Stephen Graves, National Joint Replacement Registry, *Committee Hansard*, 27 September 2011, p. 24.

136 Dr Rohan Hammett, National Manager, Therapeutic Goods Administration, *Committee Hansard*, 27 September 2011, p. 57.

137 Department of Health and Ageing, Answers to questions on notice, 25 October 2011.

138 Department of Health and Ageing, Answers to questions on notice, 25 October 2011.

> For instance, one large pathology company suggests a reference range for cobalt (0–20 nmol/L) and for chromium (10–100 nmol/L). In an article published in 2011 in the Medical Journal of Australia, the reference range for chromium was 0–100nmol/L {Mao et al MJA 2011;194(12):649–651}. The Sandwell and West Birmingham Hospitals, Birmingham UK, Trace Elements Laboratory quote reference ranges of <40 nmol/L for Chromium and <10 nmol/L for Cobalt in patients without hip replacements.[139]

3.143 DoHA also submitted that:

> ...there is acceptance that serum cobalt and chromium levels will be elevated in patients who have undergone well functioning metal-on-metal hip replacement relative to those without hip replacements. As well, the metal ion levels will vary over time even in patients who have well functioning implants and no symptoms suggesting any health problem.[140]

Committee comment

3.144 The committee received compelling and distressing evidence from consumers of serious ill health and complications associated with metal toxicity, caused by the leaching of cobalt and chromium ions from the hip replacements into patients' bodies. The committee is of the view that this is being treated by health authorities and professionals with an inadequate sense of urgency. The committee recommends that a process for monitoring the levels of cobalt and chromium, and any possible health effects, should be established as a matter of urgency for all patients who have received metal-on-metal hip replacements.

139 Department of Health and Ageing, Answers to questions on notice, 25 October 2011.

140 Department of Health and Ageing, Answers to questions on notice, 25 October 2011.