Additional Comments by Independent Senator Nick Xenophon

1.1 I would like to join the committee in acknowledging the witnesses who provided evidence about their personal experiences of the regulatory failure relating to the DePuy ASR hip replacements and other devices. This evidence was vital to the committee's understanding of the real life impact of the failure of these devices, and I thank these witnesses (many of whom are in very poor health) for taking the time to provide this information to the committee.

1.2 I would also like to acknowledge the other individuals who have contacted me since the committee hearing to share their stories, not just of the DePuy ASR hips but also of other metal-on-metal devices. It is important to note that the problems caused by the ASR are not restricted to these two devices, but have also been found to occur where other types of metal-on-metal devices have been implanted in patients. I note that the committee has made reference to this in the majority report.

1.3 Australian health consumers have been subject to a serious failure of regulatory standards, not just on the part of the device manufacturer, but on the part of the Therapeutic Goods Administration. As Australia's regulator, it is not unreasonable to expect the TGA to be meticulous not only in its original approval of devices, but in the area of post-market monitoring.

1.4 Instead, evidence provided to the committee by the TGA and by Professor Stephen Graves of the Australian Orthopaedic Association and National Joint Replacement Registry shows that the TGA was unacceptably slow in examining data relating to revision rates of hip and knee replacements provided to them by the National Joint Replacement Registry.

1.5 In one instance, data supplied to the TGA by the NJRR in September 2008 was not discussed by the TGA's Orthopaedic Expert Working Group until December 2009, after the NJRR had also supplied the TGA with the 2009 report[1]. Even then only ten of the thirty devices flagged in the 2008 and 2009 reports were addressed[2].

1.6 In this same meeting, members of the OEWG, including the Chair, raised concerns about the lack of meetings and the delays in addressing some of the devices flagged in previous meetings that were still on the Australian Register of Therapeutic Goods and therefore approved for use in Australia. Concerns were also expressed in

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1 Professor Stephen Graves, National Joint Replacement Registry, further answers to questions on notice, 21 October 2011, (received 25 October 2011), pp 2-3

2 Department of Health and Ageing, answers to questions on notice, 27 September 2011, (received 25 October 2011), Minutes of the Orthopaedic Expert Working Group, 9 December 2009, p 2

relation to the TGA's lack of action in responding to recommendations made by the OEWG[3].

1.7 The TGA's response to these concerns, as stated in the minutes, indicates that that some implants identified in the 2008 and 2009 NJRR reports had still not been processed by early 2010. Given that some of these implants were identified in 2008, and some may possibly have been identified as early as 2007[4], this seems an excessive and unacceptable delay, which has compromised the health of patients.

1.8 According to additional information provided to the committee by Professor Graves, the NJRR originally provided the 2007 report to the TGA in September 2007, and then again in February 2008, when the TGA requested that the data be resent[5].The TGA's lack of timely action is unacceptable. This data was not reviewed until May and June of 2008, a delay of over nine months[6]. This is very concerning.

1.9 However, it is important to note that Professor Stephen Graves of the AOA and NJRR stated in the committee hearing that, while he was not happy with the timeliness of action over the whole period of OEWG meetings, he is now happy with the approach the TGA is currently using[7].

1.10 In relation to the ASR resurfacing device, it is also important to note the comments made by Dr Rohan Hammett, National Manager of the TGA, regarding the TGA's actions. During the committee hearing, Dr Hammett indicated that, at first, it was considered that the technical complexity of implanting this device was responsible for the higher than expected rate of revision, and that a training program for surgeons was put in place to try and address these issues.

He stated:

> Their [the expert working group] recommendation to the TGA... was that surgeons should be required to undertake additional training regarding insertion of the ASR hip. That was the advice of the clinical experts, which the TGA accepted, and a training program was put in place...[8]

He continued:

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3 Ibid

4 Ibid

5 Professor Stephen Graves, National Joint Replacement Registry, further answers to questions on notice, 21 October 2011, (received 25 October 2011), p 2

6 Department of Health and Ageing, answers to questions on notice, 27 September 2011, (received 25 October 2011), Minutes of the Orthopaedic Expert Working Group, May 2008 and June 2008

7 Professor Stephen Graves, National Joint Replacement Registry, Committee Hansard, 27 September 2011, p 22

8 Dr Rohan Hammett, TGA, Committee Hansard, 27 September 2011, p 48

> So, in fact, the utilisation of that hip was reduced by the risk mitigation that was put in place by the TGA. The Joint Replacement Registry said there was a problem. The experts said the right mitigation is to have better training and then, as a result of that, we saw a slower uptake in the use of that hip as people were required to train.[9]

The advice from the OEWR minutes, however, states:

> 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.[10]

Dr Hammett's statements seem to infer that the TGA was responsible for implementing the training program, when it fact it had already been put in place by the manufacturer.

Dr Hammett's statements also imply that the TGA acted on notification from the National Joint Replacement Registry. However, the minutes specifically state:

> The TGA noted that the manufacturer of the ASR resurfacing hip implant had approach the TGA recognising that the revision rate is no longer acceptable.[11]

1.11 Dr Hammett's evidence also states that the training program led to a drop in the use of this prosthesis. However, information provided to the committee by Professor Stephen Graves states that:

> ...a decline in use was evident prior to the company initiated focus on training, which did not commence until early 2008. The most significant decline in the use of the ASR resurfacing hip occurred in 2007.[12]

1.12 While it is understandable that Dr Hammett was simply providing evidence to the committee based on the information he had at the time, it would have been useful for the TGA to clarify Dr Hammett's statements once the OEWG minutes and Professor Graves' information showed that Dr Hammett's comments could be considered to be confusing and clouding the key issues.

1.13 Questions were also raised in relation to the TGA's withdrawal process. The current process seems to be that, if or when the TGA becomes aware of a problem

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9 Ibid

10 Department of Health and Ageing, answers to questions on notice, 27 September 2011, (received 25 October 2011), Minutes of the Orthopaedic Expert Working Group, 21 May 2008, p 5

11 Ibid

12 Professor Stephen Graves, National Joint Replacement Registry, further answers to questions on notice, 21 October 2011, (received 25 October 2011), p 1

with a device, the TGA approaches the company to discuss the withdrawal process [1314]. This process could be considered to be allowing manufacturers to make a 'voluntary withdrawal' rather than being subject to a forced recall.

1.14 In the evidence provided at the committee hearing, the Hon. Dr Michael Armitage of the Australian Health Insurance Association pointed out the important role of forced recalls as a type of sanction[15]; a withdrawal conducted by the manufacturer obviously does not have the same impact.

1.15 This relationship between the TGA and manufacturers, where the TGA allows manufacturers to 'withdraw' rather than 'recall' devices, needs to be investigated and these issues addressed as a matter of urgency.

1.16 It is also important to note that information provided by Johnson & Johnson Medical in response to questions on notice from the committee did not attempt to clarify when JJM first became aware of the problems with either of the ASR devices[16]. I endorse the committee's comments in relation to this.

1.17 Overall, the TGA's response to the failure of these devices has been unacceptable. Australians have had their health severely compromised because of a systemic failure on the part of Australia's regulator.

1.18 It remains unclear whether the TGA fully understands its failures in this area and acknowledges the need for greater action and change on its part. This raises serious concerns that this manifestly inadequate response could be replicated in the future.

1.19 If the TGA does not undertake a major systemic reform, the DOHA needs to require the TGA take action.

1.20 The DOHA needs to act on Recommendations 7, 8, 9 and 10 in the majority report within the next six months.

1.21 It is also useful to note the processes involved in approving medical devices in France. For a device to be eligible for rebates, French authorities require proof that the device will have equal or better outcomes than the devices currently approved. Evidence was given in relation to this by The Hon. Dr Michael Armitage of the Australian Health Insurance Association [17]. I note the comments made by the

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

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

15 The Hon. Dr Michael Armitage, AHIA, Committee Hansard, 27 September 2011, p 4

16 Nicholas Campbell, JJM, answers to questions on notice, 27 September, (received 14 October), pp 1-2

17 The Hon. Dr Michael Armitage, AHIA, Committee Hansard, 27 September 2011, p 3

committee in the majority report; it would also be useful for the DOHA to conduct a further investigation on the French model and any relevance it may have to the process for approving devices in Australia. Based on the evidence provided to the committee, it appears to be a stronger system that would provide better patient outcomes.

1.22 In relation to the remanufacture of devices, it is vital that the issues of patient consent and legal liability are addressed in the form of legislation or regulations. The current application for approval to remanufacture devices is the first to come close to approval in Australia, and it is vital that the TGA and the DOHA ensure that appropriate safeguards are in place.

1.23 Patients have the right to be provided with accurate, unbiased, comprehensive information about the medical device their practitioner is going to use on them. This information should include any interest (financial or otherwise) or involvement the practitioner has in the device or the company manufacturing the device. This information should also include whether the device has been remanufactured, details of the remanufacturing process, and any risks or benefits this may have. This information should also be provided in writing, so that patients are able to study it at their leisure.

1.24 There also needs to be clear regulatory or legislative guidelines in place relating to legal liability and 'ownership' of the device in case of patient injury or device failure. Stryker Australia made useful comments in relation to this in their supplementary submission to the inquiry [18]; however, it is vital that the regulatory guidelines in place are examined and tested before remanufacturing is approved.

1.25 Issues of patient consent in relation to medical practitioners' interests (financial or otherwise) in particular devices were also raised during the committee hearing. I acknowledge the committee's comments in the majority report regarding this, particularly in relation to the use of DePuy devices that had already been flagged as having higher than expected revision rates in previous NJRR reports. It is reasonable to assume that, if the patients in question had been made aware that issues had been raised in relation to these devices, they would have not consented to have them implanted.

1.26 The DOHA should act on Recommendation 18 of the committee's majority report and introduce and implement legislation within the next 12 months.

1.27 In relation to the importation of dental prostheses, the TGA should carry out Recommendations 12 and 13 of the majority report within the next six months. The lack of regulation in this area is very concerning and should be addressed as a matter of urgency.

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18 Chris Szeleczky, Stryker Australia, *Supplementary Submission 11*, p 4

Amended Recommendation 2:

The committee recommends that the Department of Health and Ageing fully implement Recommendation 8c of the Health Technology Assessment Review regarding the need for increased rigour of regulatory assessment of higher-risk medical devices within the next six months.

Amended Recommendation 4:

The committee recommends that the Therapeutic Goods Administration investigate whether allowing an increasing number of medical devices onto the Australian market actually improves clinical outcomes; and whether a more judicious approach could improve pre-market assessment and post-market surveillance of higher risk medical devices, for the ultimate benefit of patients. This investigation should include consideration of the system currently in place in France, and should be completed within the next 12 months.

Amended Recommendation 7:

The committee recommends that the Department of Health and Ageing implements Recommendations 13, 14, and 15 of the Health Technology Assessment Review in a timely manner, and in any event within the next six months. These recommendations address the need for improved post-market surveillance by increasing the rate of reporting of adverse events, including by health service providers and consumers; facilitating the expansion and use of post-market surveillance data to inform safety, effectiveness and reimbursement decisions; and establishing further clinical registers for high risk implantable devices and procedures.

Amended Recommendation 8:

The committee recommends that the Therapeutic Goods Administration put in place mechanisms to educate and encourage doctors to report adverse incidents associated with the use of medical devices. The committee further recommends that the Department of Health and Ageing introduce mandatory reporting for health practitioners to the Therapeutic Goods Administration on relevant issues, in certain circumstances including problems with medical devices. These mechanisms should be in place within the next 12 months.

Amended Recommendation 9:

The committee recommends that the Government implements the Recommendations of the Therapeutic Goods Administration Transparency Review in a timely manner, and in any event within the next six months.

Amended Recommendation 10:

The committee recommends that the Therapeutic Goods Administration consider simultaneously allocating or aligning the great variety of codes used to identify medical devices, in order to facilitate more efficient regulation and more rapid identification of devices when problems occur. This should take place within the next six months.

Amended Recommendation 12:

The committee recommends that the Therapeutic Goods Administration consider whether custom made dental devices are adequately regulated; and whether the approach used in the United Kingdom of requiring a statement of manufacture to be provided to patients, and retained by the dental practitioner, has merit. A report in relation to this should be provided to the Department of Health and Ageing by the TGA within the next 12 months.

Amended Recommendation 13:

The committee recommends that the Therapeutic Good Administration carry out an investigation to ascertain whether importation of medical devices via the internet is adequately regulated. A report in relation to this should be provided to the Department of Health and Ageing by the TGA within the next 12 months.

Amended Recommendation 15:

The committee recommends that the Department of Health and Ageing prepare, as a matter of priority, a comprehensive communications strategy to inform medical practitioners, patients and the general public about the issues associated with De Puy hip and hip resurfacing devices as well as options for treatment, obtaining further information, and reporting adverse outcomes. The committee further recommends that such a strategy be implemented as a standard process for any future adverse event reporting, and should be implemented within the next 12 months.

Amended Recommendation 16:

The committee recommends that the Department of Health and Ageing, as a matter of urgency and in any event within the next six months, consider the best way of establishing a process for monitoring the levels of cobalt, chromium, and other toxic metals; and any possible health effects, in all patients who have received metal-on-metal hip replacements.

Amended Recommendation 17:

The committee recommends that the Government consider the best mechanism for initiating and advancing research on the health effects of cobalt, chromium, and other toxic metals, on the human body. The committee also recommends that consideration

be given to ensuring adequate funding for that research is made available within the next 12 months.

Senator Nick Xenophon
Independent Senator for South Australia