COMMONWEALTH OF AUSTRALIA

Official Committee Hansard

SENATE

COMMUNITY AFFAIRS REFERENCES COMMITTEE

Regulatory standards for the approval of medical devices

TUESDAY, 27 SEPTEMBER 2011

CANBERRA

BY AUTHORITY OF THE SENATE

INTERNET

Hansard transcripts of public hearings are made available on the internet when authorised by the committee.

The internet address is:

http://www.aph.gov.au/hansard

To search the parliamentary database, go to:

http://parlinfo.aph.gov.au

SENATE

COMMUNITY AFFAIRS REFERENCES COMMITTEE

Tuesday, 27 September 2011

Senators in attendance: Senators Carol Brown, McKenzie, Moore and Xenophon

Terms of reference for the inquiry:

To inquire into and report on:

The regulatory standards for the approval of medical devices in Australia, with particular attention to devices with high revision rates, and in undertaking the inquiry the committee is to consider:

(a) the role of the Therapeutic Goods Administration in regulating the quality of devices available in Australia;

(b) the cost effectiveness of subsidised devices;

(c) the effectiveness and accuracy of the billing code and prostheses list;

(d) the processes in place to ensure that approved products continue to meet Australian standards;

(e) the safety standards and approval processes for devices that are remanufactured for multiple use;

(f) the processes in place to notify the relevant authorities and the general public of high revision rates or possible faulty devices;

(g) the effectiveness of the current regimes in place to ensure prostheses with high revision rates are identified and the action taken once these devices are identified;

(h) the effectiveness of the implemented recommendations of the Health Technology Assessment; and

(i) any other related matter.

WITNESSES

ARMITAGE, the Hon. Dr Michael, Chief Executive Officer, Australian Health Insurance Association

Evidence was taken via teleconference—

Committee met at 10:08

ACTING CHAIR (Senator Moore): The Senate Community Affairs References Committee will now commence its public inquiry into the regulatory standards for the approval of medical devices. I welcome Dr Michael Armitage of the Australian Health Insurance Association, appearing via teleconference. You have the information on parliamentary privilege and the protection of witnesses and evidence, having appeared so many times before Senate committees. We have your submission—thank you very much. I now invite you to make any opening statement you have, and then we will go to questions. This session will go through till about 10.45, if required. It is over to you.

Dr Armitage: Thank you very much. As I said, I apologise I am not in Canberra but thank you very much for the opportunity to appear before the committee about a matter that is very important for health outcomes for an increasing number of Australians. The use of prostheses is expanding both because of an increased market for them—in other words, people tend to have them earlier—and because of the publicity that they are getting. People want to live a better lifestyle.

I want to address the terms of reference in my opening statement very briefly; first, the role of the TGA. Currently it focuses on safety and efficacy, but it is not the safety and efficacy of the device; it is the safety and efficacy of the manufacturing process. We think that that is not the focus and that either the role should be expanded or it should be given to someone else to focus on clinical effectiveness and cost-effectiveness.

In talking about the second term of reference, the cost-effectiveness of the devices, it is very strongly the view of the AHIA that there ought to be comparative cost-effectiveness, not only cost-effectiveness. In fact, we think there is a good cause for a comparative cost-effectiveness focus for the government, perhaps even the setting-up of a specific body. What do I mean by this? At the moment if someone brings in, for argument's sake, a stent to be put into a cardiac artery it is usually compared with another stent. It is, however, not compared on a comparative cost-effectiveness, or indeed comparative clinical effectiveness, basis with, for argument's sake, a coronary artery bypass graft. More importantly, it is not compared against, in this particular case, the use of optical medical treatment—in other words, standard drugs that are used every day, and there is a trial in America, called the COURAGE trial, which seems to indicate that optimal medical treatment is better than either of those other two things. So there is a need for comparative cost-effectiveness.

In relation to the third term of reference, 'the effectiveness and accuracy of the billing code and prostheses list', there is simply no billing code to catalogue number link, so the funders are in essence unsure of what they are paying for. We think that that is simply stupid and there ought to be action taken to make sure that there is a link between the billing code and the prostheses list.

With regard to your fourth term of reference, there are very few recalls by the TGA. We think that is not the right way. We think there is enough evidence that these devices need to be better policed. Certainly in other countries they are. As our submission details, there are many examples in other countries where recalls have occurred and have not in Australia.

On your fifth term of reference, term (e), we agree with remanufacturing provided the costing and the safety for the clinical outcomes of the patient into whom the remanufactured device will be inserted are taken into account.

In relation to term of reference (f), 'the processes in place to notify the relevant authorities and the general public of high revision rates', 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. Sadly, the best evidence that we have of devices being used after they have been identified comes from the National Joint Replacement Registry. In fact, it is a wonderful thing. I am in no way trying to denigrate the efforts of the AOA or indeed the National Joint Replacement Registry but I do point out that the most recent annual report that we have analysed shows that 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.

In relation to your term of reference (g), 'the effectiveness of the current regimes in place to ensure prostheses with high revision rates are identified', 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 decision as to whether they want to have the device or prosthesis inserted into them.

So, having given that overview as to your terms of reference, I will conclude with one final item—which we think is a key one—which affects all of the terms of reference. In Australia a device can be inserted into what in this instance would be an unsuspecting Australian patient and the only clinical evidence of that device's success which the TGA takes into account is information provided by the manufacturer of that device. They clearly have a financial conflict of interest and that ought to be stopped. With that, thank you very much for the opportunity to appear before this very important committee.

ACTING CHAIR: Thank you, Dr Armitage. We will proceed to questions.

Senator XENOPHON: Thank you, Dr Armitage, for your submission. Firstly, I will go to the last point you raised. Are you saying that we need to reform the system so that the information that the TGA receives is much broader than that from the manufacturer?

Dr Armitage: I do not think there is any question that that ought to happen. The TGA, in its other arm of looking at drugs that are to be used in Australia, is excellent. It does a wonderful job. It would no more not look at double-blind clinical trials of drugs than fly to the Moon. So I ask, when there can be dramatic effects from prostheses and devices which are inserted—quite as dramatic as the use of a poorly performing drug—why would we not expect the same quantum of evidence to be available for people to make a decision? If this means that some devices are not used in Australia, so be it, because the evidence ought to be there. In fact, with the National Joint Replacement Registry, a few years ago the chief executive or head of that organisation did a study of the latest 100 devices to be inserted into people in Australia and found not one of those devices led to an improved clinical outcome for the Australians into whom the devices were inserted. Seventy per cent led to a worse clinical outcome. So the point we would make is this: if a requirement to have completely appropriate clinical evidence means that devices are slower coming into the Australian market, so be it, because they do not perform as well.

Senator XENOPHON: So, in terms of the reforms and criteria that this committee will need to consider, you are saying on that question that improved outcomes need to be shown or proven before a device is allowed into the marketplace and that the mechanism for dealing with complaints or for monitoring the effectiveness of devices and adverse outcomes needs to be overhauled as well.

Dr Armitage: I certainly do but I actually believe, in the very first instance, that if a more rigorous analysis of independently determined clinical evidence were the criterion upon which the TGA made its original decision many of the other problems would not occur.

Senator XENOPHON: And you do not think we are getting that rigorous analysis now?

Dr Armitage: I do not. It would actually be a really good thing for Australia to do more of this. I believe that there would be university departments that would be thrilled to set themselves up as centres of excellence in doing clinical trials. You would not have to have many of them around Australia, but it would be quite an easy way. There would be a financial commitment. I accept that. But I think that is better than subjecting people to the failure of the device. But you would have to set up a system whereby if somebody wanted to bring a device into Australia they would actually have to you submit it to appropriate clinical testing. I think Australia could form a world-leading opportunity with this.

Senator XENOPHON: Currently, though, the TGA relies on third-party testing in that if a device has been approved overseas there seems to be a different process for approval. Is that your understanding?

Dr Armitage: My understanding is that there is a process called global harmonisation. If in fact one of the bodies with which the TGA is globally harmonised—in other words, similar bodies overseas—have authorised the use of a particular device the TGA is comfortable with accepting that recommendation and/or clinical evidence from the people who wish to sell the device. Unless there can be rigorous evidence that the overseas processes have had appropriate clinical testing there will always be an element of risk. I think it can be avoided.

Senator XENOPHON: So do you see global harmonisation, in some cases, as the lowest common dominator approach?

Dr Armitage: That is exactly right. My understanding—and I am not an expert in this arena—is that the TGA is regarded as the gold standard for the drugs side of the work that they do, so my understanding is that if the TGA was accepting similarly rigorous analysis of prostheses from another body with which it is globally harmonised we would have no problem because in fact it has had a rigorous assessment. The trouble is that, just as you say, if it is a race to the bottom there is obviously a risk for the person into whom the device is inserted.

Senator XENOPHON: I have just a couple more questions. In terms of best practice overseas, which jurisdictions do you think we could learn from and from which the TGA could adopt the approach of a more rigorous analysis of the device in the first place?

Dr Armitage: There are a number of examples. One of the most interesting about which I know is in France where they have a predetermined number of devices. If someone wishes to have a new device listed for reimbursement they must prove that their device performs better than the one that is already allowed for reimbursement. That seems, to me, completely reasonable. Why would anybody want to authorise the use of a device which potentially has dramatic consequences if it goes wrong unless it can be proven to give a better clinical outcome than the device that is already being used safely?

Senator XENOPHON: Further to that, do you think that there ought to be greater transparency in terms of any inducements or benefits between manufacturers, hospitals and medical practitioners? That is an issue that has been raised. Are there any concerns about that process and the interaction between medical practitioners and also in relationship to the DePuy device that has been the subject of much public comment? Should a medical practitioner who has had a role in designing the device disclose that to the patient if they have a commercial interest in it?

Dr Armitage: I believe that transparency of information is one of the most crucial ways of solving all of the problems. I do believe that the particular example that you have just provided of someone being aware that their doctor has a financial interest in the device should happen. I absolutely think that the whole question of transparency is one of the elephants in the room in relation to prostheses and devices. As far as inducements go, it is fair to say that the general medical industry is agog with stories but I have no direct evidence that I can provide the committee other than to say that I am sure I have heard all the stories you have heard—but I have no evidence. I think registries are crucially important. I referred previously to the National Joint Replacement Registry, which is a shining star of registries around the world. I reiterate that the Australian Orthopaedic Association deserves great commendation for it, as does Professor Stephen Graves, who runs it. If there were device registries along the same lines for many other devices and their results were transparent, again, many of the issues would be solved.

Senator XENOPHON: I note your comments about the National Joint Replacement Registry. Could it be improved? That is not a criticism of the registry and those who run it. But are there other ways in which it could be enhanced, in addition to what you have just said?

Dr Armitage: I believe that the Therapeutic Goods Administration should be required to take action on its results. The National Joint Replacement Registry has, voluntarily, undertaken an analysis of every single joint that is inserted into a patient in Australia through the orthopaedic surgeons who insert them. If that analysis shows, as I have said before, that a number of joints are in fact being re-identified as failing at more than twice the rate of others within that same class—according to an algorithm devised not by us but by the Joint Replacement Registry—and they are still being used, I think the TGA has a role in actually preventing the further use of that device. In other words, it is an answer to your question but not an action of the National Joint Replacement Registry. It is an improvement on the National Joint Replacement Registry's outcomes, but it requires the TGA to take action.

Senator XENOPHON: I understand. Finally, the reason why the AHIA has an interest in this—not to put too fine a point on it—is that your members are paying a lot more for revisions which you say could be avoided?

Dr Armitage: Ten per cent of the benefits that my fund members expend on behalf of their members are related to prostheses and that is increasing at about 10 per cent a year. Many years ago I was a practising doctor; now I am a non-practising doctor, so I do understand human error and that is a given. I am not trying to be an absolutist here. We are very keen to see appropriate devices used appropriately because, apart from anything else, if a device fails on a regular basis, in that instance everyone gets paid twice other than the patient and they in fact pay twice. What is worse is that, because it is a re-operation and often it is after fibrous tissue has formed around the wound and sometimes blood supply is not as good in the area, there is a greater risk of infection. Not only that but it is an inconvenience for that person's family. The person often has to take sick leave and holiday leave. They have to do rehabilitation again et cetera. The real patsy in all of this is in fact the patient. We represent 11 million Australians who are privately insured. We want them to get better outcomes and I am confident that the government does as well, whether constituents of theirs are operated on in the public or the private sector. One way we can do that collectively is to stop unnecessary revision operations.

Senator XENOPHON: Thank you.

Senator CAROL BROWN: I want to go back to the comments you made about global harmonisation, just to get it clear in my mind. You talked about France having best practice. Are they also part of this global harmonisation process?

Dr Armitage: I imagine they are; I am not certain about that. But the difference there is that global harmonisation, as I understand it, only means that the joint is safe for use. What they do in France—again, as I understand it, from information I have from France—is they say, 'Well, it may be safe, but we're not going to reimburse it; we'll only allow reimbursement if it performs better than one that's already on the list.'

Senator CAROL BROWN: Right. And that does not happen here?

Dr Armitage: No. In fact, there are thousands—I reiterate: thousands—of devices in Australia. The situation in Australia, we would contend, is that because the opportunity to have devices listed is too loose—it is being tightened, but we would say that is well overdue—there are in fact a plethora of devices. It is quite interesting to note that in the public sector, where they have greater control over the devices which they allow to be inserted into public patients, there is a much more constrained list of devices.

Senator CAROL BROWN: So in this global harmonisation regime, when a country decides that a device is safe to use, do you know what processes other countries undertake? This may not be a question you can answer. What processes do their bodies similar to the TGA undertake?

Dr Armitage: I am sorry; I am really not an expert on global harmonisation. All I know about it, I have told you, is from asking the TGA on various occasions why this plethora of devices is allowed onto the reimbursement list and the prosthesis list in Australia, and being informed it is because of global harmonisation.

Senator CAROL BROWN: So, essentially, we do not know what sort of testing is undertaken?

Dr Armitage: I am sorry, I do not.

Senator CAROL BROWN: Okay. You might be able to help me with this. Earlier we were talking about what happens when a product is withdrawn, and the difference between that and a recall. When a product is withdrawn, do you know what that actually means in terms of its use in Australia?

Dr Armitage: My understanding is that it is unable to be used once it is withdrawn. But where we would see a real dilemma in Australia is in the fact that, once evidence begins to show that there is cause for concern, what usually happens—again, on my advice from the TGA and other sources, such as the National Joint Replacement Registry—is that the National Joint Replacement Registry is obliged to inform the company which had successfully applied for the device to be listed in Australia that there is cause for concern in the results. My understanding is that the TGA and the company then have discussions about this.

What can then happen is that the company, for commercial reasons—rather than having their products withdrawn by a regulator—will in fact stop supplying the device. Now, my understanding is that some people say, 'That's good, because the device will not be used.' We would say that, because it is not a major sanction, the device manufacturers will keep trying to put devices on the registry in the hope that they will perform optimally, rather than being wary of having the good name of their company sullied by a withdrawal. We think recalls are actually important sanctions, if you like, in the whole area of devices. We do know that in overseas markets, which are very similar to the Australian market, there are much more. For argument's sake, in 2010 in the United Kingdom there were 99 device recalls and alerts; in the United States there were 43 device recalls; and, in Australia, my understanding is there was one recall and four alerts. We are using the same things, because the companies want to utilise them around Australia. So I would query why the bodies in the United Kingdom and the United States, which I personally believe would have exactly the same criteria for insertion and so on of devices, have this huge number of recalls and alerts when Australia does not. We think it is because the TGA is not active enough in this area.

Senator CAROL BROWN: I am really interested in the processes. When a company stops supplying, what do they have to do in terms of alerting surgeons, and others, that they are not supplying, as opposed to when there is a withdrawal? What processes take effect once that decision has been made?

Dr Armitage: Sorry, I am not an expert in that area. I can surmise, but I would suggest that you ask the TGA. I would love to be able to supply you with an answer but, because it does not directly affect what we do on a daily basis, I am unclear.

Senator CAROL BROWN: Okay. Thank you very much for your assistance.

ACTING CHAIR: Thank you, Dr Armitage. I know that your organisation has been taking a strong interest in this area for a long time. There is one paragraph in your submission that I would like to follow up on if you would not mind. I will read it to you. It is under 'Processes in place to ensure that approved products continue to

meet Australian standards'.' It starts: 'The AHIA would also highlight the area of cost implications where device failure occurs.' It goes on to say that, 'as any warranty with surgical prosthesis is usually negotiated at the hospital-sponsor interface, the liability that funds might choose to pursue with other stakeholders on behalf of their members is not always clear'.

Dr Armitage: If one of our member has a device inserted into them and it fails, the contract for the supply of the device is between the device manufacturer and the hospital. My understanding is that are a number of issues there, such as bulk purchasing and not passing on of discounts and so on, but that is a matter for the hospitals and the device manufacturers to identify. But, because that is the contractual level, at that level we find it difficult if we want to chase recompense on behalf of our members because we do not know whether the person liable is the manufacturer, the doctor who inserted it, the hospital or whatever. It is a grey area and, wherever there is a grey area, people will obviously be encouraged to game it.

ACTING CHAIR: So individual health funds can actually seek recompense on behalf of their members? If, as we have heard from some people who have supplied submissions, one of your members has to have a series of operations as a result of something wrong, the health fund itself can actually chase that up?

Dr Armitage: Some funds do, and some funds have.

ACTING CHAIR: I did not realise that.

Dr Armitage: It is more where there is something that would be deemed, dare I say it, 'completely outrageous'—and I cannot even think what those circumstances might be. It is not a routine action, but I am aware that some funds, on occasion, have said to a hospital that is neither the patient's fault nor theirs and they are not going to pay it—for argument's sake, where an infection has got in, and there is a belief that that infection should not have got in, and it has caused the need for lots of further hospitalisation and maybe a joint revision or replacement. That is an option but, as I understand it, it is not done frequently and it is only for the non-payment of any second bill. I think what a number of people would surmise—and certainly a number of people have said this to me as a representative of the funders—is that they want more than just not paying the bill; they actually think there should be some real financial recompense for the trouble, the time, the inconvenience, the anxiety, the family stress, the added risk of infection, the pain, the need to rehabilitate, the loss of holiday pay et cetera. Often when they have been worn down by long hospitalisations, infections and so on they look to the fund as a powerful ally to try to get some additional recompense, and that is what that paragraph addresses.

ACTING CHAIR: Thank you for that. Have you previously raised with the TGA and with the general players in this area the issues you raised in your submission?

Dr Armitage: As you said, we have been raising the general issues for I suggest my whole tenure of being the CEO, which is 5½ years. One of Senator Xenophon's questions quite properly addressed the issue of cost. This is one area of health expenditure which everyone says is going up inexorably—and we do not believe is going up inexorably; we think it is going up—but if action is taken to stop this sort of revision and so on it will not go up inexorably. This is obviously a prime concern, but our really major concern is the health outcomes of our members. Every one of my fund CEOs whom I represent has on their monthly board meeting an item that is designated something like 'patient complaints'. No CEO likes taking to their board letters in which people have said: 'I'm really angry that I got rotten treatment. Why have I got to go back? You should be taking more action. You are my representative.' We actually want the 11½ million Australians whom we represent to get the best possible health outcomes. Whilst we are their funder, we actually want to be an intelligent purchaser of their health care. We think that paying for devices which are proven to fail is not an intelligent purchase; it is a dumb purchase. We think there is a real health outcome that we should be active on. So, in that context, I have raised many of these arguments with every 'player', which I think was the word you used, Senator.

The disturbing thing—and I really hope that this committee is able to grasp the nettle—is that nobody disagrees with the basic tenets of what I am saying. I get lots of head nods. If I say that people should know whether the joints fail, everyone's head nods. If I say that they should only have clinical testing when they go in, there is a head nod. No-one says: 'That's stupid, Michael. We don't want to do that.' Yet, for reasons that sometimes elude me, no-one actually makes the decisions which would improve health care for all Australians.

ACTING CHAIR: Has your association done any research in this area? I know it has been an issue of concern. Has AHIA had a look at the revision rates and the kinds of things that are happening in individual hospitals?

Dr Armitage: The major source of our information is medical journals, which I read occasionally. As I indicated, I used to be a practising doctor and I am still a doctor so I still read some. We do not think one need go much past the National Joint Replacement Registry. This is an excellent registry. The annual report has it all

there. As I mentioned in my opening statement, we think equally that, if there were transparency of the information along the lines of the National Joint Replacement Registry and there was a requirement for comparative clinical and cost-effectiveness—in other words, comparing any new device with every form of treatment, not only similar devices, which is what tends to happen today—Australians would get better health outcomes and they would probably pay less. I do hasten to add that, whilst we have focused only a little on the cost implications, my fund members—the CEOs who make up my board, representing those 11½ million Australians—want the costs to be down but, if the costs need to go up to get a better health outcome, they will actually wear that too. What really angers them is that there seems to us to be some good clinical evidence, from what we read, that in fact clinical outcomes are being compromised, and that should not be the case.

Senator XENOPHON: You said the TGA is not active enough in recalls. Do you say that the system we have in Australia is a second-rate system when it comes to recalls?

ACTING CHAIR: I think that could be leading the witness, Senator.

Senator XENOPHON: Well, he laughed.

Dr Armitage: Rather than answering the direct question, I would reiterate the evidence that I gave before. In similar communities of the United Kingdom and the United States, the recalls and alerts are dramatically greater for basically the same devices. We do not have a unique device industry in Australia. The devices being inserted here are the same as those used elsewhere and I would question why there is a much greater focus on alerts and recalls in those very similar countries. But yes, I am prepared to say I do not think that the TGA is active enough in being, if you like, the umpire for these devices—particularly when, for argument's sake, hip prosthesis A is already listed and the TGA has hip prosthesis B, which it says is very similar, and so the TGA allows it onto the list. If the evidence later says no, hip prosthesis B is not like hip prosthesis A because it fails so often, I think the reason for its listing has evaporated immediately.

Senator XENOPHON: It is not just the umpire, though. It is the watchdog as well, isn't it?

Dr Armitage: That is a very astute way of describing it. They have the power to list, which is a crucial power. It ought to be exhibited more rigorously both as an umpire and as a watchdog.

ACTING CHAIR: I want to follow up on one point which you just made and which you made in your submission. The first part of your submission talks about clinical and comparative issues, as opposed to how you describe the key aspect of the TGA, which is to regulate for safety and efficacy. It would seem to me that the issues that have been raised by people about some of the things that are happening clearly fall within safety and efficacy.

Dr Armitage: But my understanding is that the safety and efficacy with which the TGA is concerned is in fact the safety and efficacy of the manufacturing processes.

ACTING CHAIR: We will follow up with the TGA on that particular issue, because their submission does not say that.

Dr Armitage: I am pretty sure that is the case. Certainly it was the case and I have evidence of that from a number of other people. It has always been my view that they have looked literally at the safety of the manufacturing process rather than the safety and efficacy of the device per se—

ACTING CHAIR: For use.

Dr Armitage: the evidence for which they take from someone who clearly has a financial interest in it being listed.

ACTING CHAIR: I just wanted to draw that out really clearly. Thank you very much.

Dr Armitage: Thank you all, Senators. As I said, I sincerely hope that you grasp the nettle. If I can be of any further assistance with anything at all, I am only too delighted to contribute.

ACTING CHAIR: Thank you.

Proceedings suspended from 10:48 to 11:06

ROSS, Mr David, Director, Healthcare Access, Medical Technology Association of Australia

TRIMMER, Ms Anne, Chief Executive Officer, Medical Technology Association of Australia

ACTING CHAIR: We will now hear evidence from the witnesses from the Medical Technology Association of Australia. I welcome you. Thank you for coming. Information on parliamentary privilege and the protection of witnesses and evidence has been provided to you, I know. We have your submission. Please make an opening statement, which I am sure you have, and then we will go to questions.

Ms Trimmer: Thank you for the opportunity to appear before the committee. MTAA, the Medical Technology Association of Australia, represents the manufacturers and suppliers of a wide variety of medical devices which together provide life-sustaining assistance to patients in need and deliver long-term improvements in the quality of life as well as aid the day-to-day comfort of patients. Without medical devices, patients would not be able to hear, to walk, to see and in some cases to survive. Tragically, from time to time there can be a catastrophic failure of the device. No doubt you have heard of this and read it in some of the submissions.

I think, however, that the challenge for us all, whether we be lawmakers, the regulator, the doctors or the industry, is to learn from these sorts of failures to ensure that the systems that we have are as robust as possible and consistent with global best practice so that Australian patients are assured of the safety and efficacy of the medical devices that do deliver life-enhancing benefits.

I would like to address some of the key issues that are raised in our written submission. The Australian regulatory system for medical devices is a risk-based system of assessment for approval and registration. In other words, the greater the risk of the device in terms of how invasive within the human body the product is, the duration of its use and the risk it poses to the patient, the user or another person, then the greater the evidence required to support the registration. The system that is used by the regulator, TGA, is similar in concept to that used in Europe. It requires a manufacturer to comply with a comprehensive set of essential principles of safety and efficacy which are based on international standards. The system combines an assessment of the manufacturer's documentation—the technical dossier—which includes a wide range of material, including clinical, prior to registration with ongoing obligations on the company to monitor and report on the performance of the approved device.

Dr Armitage, in his testimony earlier, was drawing on the need for types of evidence and comparing the differences between pharmaceuticals and medical devices, but I think there is more that needs to be understood in that difference. The regulation of safety and efficacy of medicines is based on pharmacology and chemistry where the properties and action of active ingredients can be determined in preclinical and clinical studies. The clinical evidence was obtained mostly premarket from large, double-blind, randomised controlled trials. In contrast, randomised, double-blind placebo controlled trial designs are very difficult and often unethical to implement as part of the evaluation of a device or a surgical procedure. That is for the obvious reason that it would not be ethical to put into a patient a device that is a placebo. Therefore, so much more of the assessment of a medical device happens after the device has been in use with the patient and the patient experience becomes a very critical part of assessment in an ongoing way.

Another key difference between drugs and devices lies in the development cycle. Medical devices are developed in a framework of continuous innovation and iterative improvements which can be based on advances in science, technology and materials. If you look at, for example, very early pacemakers, they were large, boxlike devices that were attached in some way to the outside of the patient. These days they are very small and implantable. In comparison, pharmaceuticals are developed following extensive research and development of a specific molecule or compound with the result that it can take many years for a new drug to enter the pipeline.

Turning to the reimbursement aspects, all high-risk implantable devices are assessed as part of the reimbursement process for listing on the prostheses list by the relevant specialist clinical group of doctors. The products are assessed on the basis of their clinical effectiveness. That is what is looked out for reimbursement. That clinical effectiveness for high-risk implantable devices is itself assessed on two years of clinical evidence of the device in use with patients.

Over the past couple of years there have been several reviews which have looked at the regulation and/or the reimbursement of higher risk medical devices and more recently the transparency of TGA and its processes. There are some key themes which emerge which are not dissimilar from the terms of reference of this inquiry. These include the need for: increased rigour of assessment of higher risk medical devices; improved alignment of assessment processes through the health technology assessment pathway, from regulatory through to reimbursement; improved transparency of information about medical devices available to consumers; and

improved post-market surveillance, recognising the key differences in preregistration assessment between drugs and medical devices.

Of these, the review of health technology assessment was the most wide-ranging. The HTA review was supported by both sides of parliament. The initial work was undertaken under the Howard government with Tony Abbott as health minister. The review itself was initiated by the Rudd government under Nicola Roxon as health minister and Lindsay Tanner as the finance minister. The review had been in gestation a while and followed several reports from the Productivity Commission and a review by Robert Doyle. The relevant recommendations for reform included that the TGA increased rigour of regulatory assessment of higher risk medical devices and that the processes for assessment and listing of implantable devices for reimbursement by private health insurers be improved with increased transparency and consistency in decision making.

There has been a very significant series of reform proposals which are currently at varying stages of implementation. Attached as an appendix to our submission is our assessment of where we are up to with all of those. I think it is fair to say that these are really transforming an area of the health system that has been much newer to come to the fore in policy terms and so a lot of the policies around it have been developed much more recently. On the positive side, this reform has been undertaken in a very consultative manner with regular engagement with all of the stakeholders—the clinicians, the hospitals, the consumers, the private health funds and industry. So where are we up to now? In terms of regulatory reform, phase 1 of TGA's response to that HTA review recommendation has been released; it was released late last week. It addresses three key areas. The first is the upclassification of orthopaedic joints following an earlier paper which was circulated in 2009. There are also better identification of individual products registered on ARTG and responses to the recent transparency review of TGA as they touch of medical devices, such as the provision of product registration material and the provision of consumer information. In terms of the reforms to reimbursement of implantable medical devices, we have much improved processes and more streamlined processes for the assessment of devices. We have the grouping of like products with allocation of a benchmark benefit rather than previously having to negotiate for the listing of every item. And we are starting to see the contribution of a cost-effectiveness assessment as one of the additional considerations.

We do believe that there are areas for further reform. Post-market surveillance is a key area for further reform and three of the recommendations from the HTA review that were deferred by government at the time really touch on this area. The reporting of adverse events and the improvements to the way in which reporting can be undertaken were highlighted by the transparency review. That is really to ensure greater awareness by both doctors and consumers of their capacity to also report adverse events. The mechanism has always been there but there is a need, I believe, for greater education, and that has been highlighted in the transparency review. We also believe that there is a contribution that can be made by clinical registries to monitor medical devices once used in a patient.

We do believe, however, that there need to be certain considerations applied to the types of registries, what their endpoints are and the way in which they are undertaken. One of the terms of reference touches on the use of single-use devices as a stand-alone term of reference. As with all regulated products, the overriding concern is for patient safety. We need to ensure that the standards to assess the remanufactured medical device are at least as rigorous as for any originally manufactured device and are able to identify and track remanufactured devices. The TGA's guidelines as published in the ARGMD, which is the guidance document on the regulation of medical devices, does set out significant additional requirements for remanufactured products. What we would like to see, however, and this sits across a lot of the transparency review, is a better understanding of what sits behind those assessments. We also have an agreement between the states and the Commonwealth under which the states have agreed that any remanufacturing by public hospitals will also meet these standards. We would likely reassurance that public hospitals do in fact comply with this requirement as set out in the agreement. We believe that it is an area where patient awareness and doctor awareness of remanufacturing devices is brought with informed consent.

So where are we with the key themes? We support an increase in the regulatory assessment of high-risk implantable devices, and that is evidenced in our response to the proposed upclassification of orthopaedic joints which, as I have outlined, has now been announced. We do need to keep in mind, though, that Australia is a very small market. We are about 2.5 per cent of the global market and any changes to requirements in Australia that put Australia out of step with comparable markets overseas will have the result that Australian patients do not have access to newer beneficial technologies. We do support the expansion of clinical registries for post-market surveillance but we believe these need to meet with the guidelines that have been approved by the Australian Health Ministers Council around shared funding, accountable governance and appropriate data management, and preferably that our decisions about which clinical registries we have meet Australia's health priorities, so based on

the cost of device or procedure, based on patient numbers or based on risk to patient. They are very expensive to set up and operate. The National Joint Replacement Registry, which is referred to as many submissions and by Dr Armitage, is funded by government via a levy on industry, so it is fully paid for by industry, which is but one stakeholder in the outcomes that are reported. We also support increased education in and awareness of processes for the reporting of adverse events by both doctors and patients, and we believe that the transparency review will help with providing better channels for this type of reporting. Thank you.

ACTING CHAIR: Mr Ross, do you have anything to add at this stage?

Mr Ross: No.

Senator XENOPHON: Chair, I wonder if Ms Trimmer could provide the committee with a copy of that statement. It might be useful to refer to.

ACTING CHAIR: Ms Trimmer, could we have a copy of the statement you just read out?

Ms Trimmer: I would be happy to provide it. It is in bullet points.

Senator XENOPHON: That is all right. Bullet points are fine. They might be useful to refer to.

Ms Trimmer: Sure.

ACTING CHAIR: I think Senator Xenophon would like to pick up on some of the points, and there was so much in your statement, as well is in your submission, that it would be very useful to have it in front of us. So we will get a number of copies. Senator Xenophon, can you start without it?

Senator XENOPHON: Yes, I can. Ms Trimmer, can I go to one of your last points first—that is, you said that Australia is a very small market, about 2½ per cent, for these devices, and that Australian patients ought to have access to newer, beneficial technologies. I am not saying that we should necessarily adopt the French approach, but you heard Dr Armitage's evidence about the safeguards they have in place in France, where there are a predetermined number of devices and, before a device is allowed into the marketplace, they must prove their device performs better—in other words, that is the threshold—than existing devices so there is a better outcome for patients. I guess the device's cost or efficacy would be part of that. What is wrong with that approach, which seems to be more rigorous than our current approach to the approval of such devices?

Ms Trimmer: My understanding is that that paring-out of products is for reimbursement purposes. France is part of the EU regulatory system, and its processes for the assessment of safety and efficacy are very much parallel to the processes used by the TGA in Australia. Australia and the EU are quite harmonised in their processes.

Senator XENOPHON: So if there is a threshold for reimbursement then, clearly, that would have an impact on whether a device is accepted into the marketplace. In other words, there are two aspects to the French scheme, aren't there?

Ms Trimmer: There are.

Senator XENOPHON: They are, firstly, the approval of the device and, secondly, whether there is reimbursement under the health scheme in France. Surely, getting that imprimatur, that stamp of approval, would be a big factor in a device being widely used in the marketplace, wouldn't it?

Ms Trimmer: I agree that there are the two factors. I would like to provide you with more information at a later stage, if I could, about the way in which—

Senator XENOPHON: If you could take it on notice, that would be useful.

Ms Trimmer: In terms of the regulatory processes, they would be quite aligned. The other point I would make—and I have used this example before—is that, if you talk to very long term, experienced orthopaedic surgeons, they will almost invariably say that they have their handful of favourite devices which they have used for a very long time, in which they have a high level of confidence and which perform very well. But they will always say that they would not like to limit the range of devices available in the Australian market because there will be occasions when there will be a patient for whom those long-term devices will not be suitable. It may be that the patient has a complex cancer or a complex revision requirement, or that the patient is very obese. So there will be individual circumstances around patients that make it necessary, quite often, to have a range of options available. So limiting devices to a small number will not necessarily meet all patient outcomes; that is my summary.

Senator XENOPHON: But, Ms Trimmer, aren't you taking a very narrow approach there? The information I have had from constituents who have had problems with the DePuy devices, the hip replacements, the metal on metal with cobalt toxicity and other horrible sequelae, in terms of adverse outcomes, is that they were not given

much of a choice by their medical practitioner. They were told, 'This is the device we're going to use.' If they said, 'My mate's had this other device, he's been very happy with it; what's wrong with that?' the response was, 'No, we're using this device.' Do you think—on behalf of your members—that there ought to be a greater level of information and informed consent on the part of the patients before these devices are used?

Ms Trimmer: I think that raises a quite difficult question. It is one of the reasons why consumers would like more information about the devices that are available. It is difficult for patients to make a fully informed decision comparing device on device. I am not sure any of us would have that—

Senator XENOPHON: After the High Court decision in Rogers and Whitaker many years ago there were some benchmarks and one was set by the High Court as to the level of information that should be given to patients. You accept that benchmark of the High Court, don't you?

Ms Trimmer: Yes, and that comes down to the way in which patients are informed by their doctors. We are very supportive of having more information available to patients through TGA processes and that, in fact, is one of the reform areas that are proposed.

Senator XENOPHON: In terms of potential conflicts of interest, and I understand you represent the manufacturers—so Johnson and Johnson would be one of your members, is that right?

Ms Trimmer: That is correct.

Senator XENOPHON: I think you also pointed out, quite rightly, the issue of devices that have been previously used. I have had discussions with other manufacturers and there are some legitimate concerns, and thank you for raising that issue. In relation to the hip replacement in question, the allegation is that one of the doctors who inserted these devices—the orthopaedic surgeons—actually had a commercial interest in a device as one of the designers of this device. What protocols are there amongst your members to ensure that patients are informed if a medical practitioner has a commercial arrangement with one of your members—so to advise patients— that 'I think this is the best device but, by the way, I am also one of the designers and I have a commercial arrangement or commercial link with a manufacturer'. Do you think that is a reasonable thing to ask of practitioners in those cases?

Ms Trimmer: What our industry association has in place is a quite detailed code of practice. The code of practice requires that all commercial arrangements with healthcare professionals are in writing and that any financial arrangements be at arm's length and for fair commercial value—in other words, they cannot be loaded payments and they need to be for the work actually done. As to the disclosure by a doctor to a patient, that is really something that should be put to the doctors. I believe that it should be addressed in their own codes of practice.

Senator XENOPHON: In terms of your own codes of practice, could you direct, as part of the commercial arrangements between the manufacturers of devices and the medical practitioner that may have a commercial interest, something to say, as part of that arrangement, 'we think you ought to be telling patients this as a matter of course'? You do have contractually that ability to do that—don't you?—or your members would have that ability to do that?

Ms Trimmer: Potentially but I do believe that it does come down to an ethical obligation on the doctor. We have, in fact, just in the past few months undertaken a review which I chaired for the government on the promotion of therapeutic products to healthcare professionals. That working group had on it healthcare professionals as well as industry.

Senator XENOPHON: Has that review been released?

Ms Trimmer: It has not unfortunately.

Senator XENOPHON: How close are we to that?

Ms Trimmer: It was lodged with government in March. We would like to see it released because it does address quite a lot of these issues.

Senator XENOPHON: So you are happy for it to be released from your point of view but—

Ms Trimmer: It is still with the government, yes.

ACTING CHAIR: We can follow that up.

Senator XENOPHON: Yes, no doubt during estimates shortly.

ACTING CHAIR: Even before estimates we will follow up that.

Ms Trimmer: If I can finish my sentence just to explain, one of the recommendations from that working group is that healthcare professional codes of practice should mirror the same kinds of constraints on doctors as are imposed on companies and that it is very much for the healthcare professionals to step up to the mark on that.

Senator XENOPHON: Dr Armitage, representing the health insurers who in turn insure 11 million Australians, was quite critical of the system. He said that there is a lack of interaction between the National Joint Replacement Registry, which he quite justifiably said does a lot of terrific work on this, and the information they get and the action or lack of action taken by the TGA. Do your members have a particular view on that, in that the nexus between the two should be strengthened so that the good work of the NJRR is taken into account by the TGA in terms of their determinations and their actions?

Ms Trimmer: My understanding is that it is taken into account. The outliers, if you like, that are picked up in the annual reporting by the joint registry are reported to the TGA and they are looked at by the Orthopaedic Expert Working Group. It has a role in examining a range of evidence that comes before it. One of the things that it is looking at in that evidence is to ensure that it is, in fact, evidence about the device that needs to be examined. As you would appreciate, with medical devices, there can be other influences on the successful outcome of the surgery. It could be doctor technique, infection in hospital or a range of other things. That committee will be looking specifically at device outcomes.

Senator XENOPHON: Dr Armitage asserts that the TGA is not active enough in recalls and alerts. He says that in the UK and in the US recalls and alerts are dramatically greater. Given that this is a global industry and your members operate in the United Kingdom and in the United States, they clearly do not have an issue with the regulatory regimes in the UK and the US. What is wrong with adopting that sort of approach, which seems to be more stringent, here in Australia? How would that prejudice your members, if they are subject to the same sort of regulatory regimes in other countries?

Ms Trimmer: They are, in fact subject to the same sorts of regulatory regime. Those systems are all connected. There is a global adverse event reporting system. Each of those countries, if it has an adverse event, will report it to the other participating countries, which would include Australia. I can only assume that the numbers that Dr Armitage is referring to refer either to products that are not on the market in Australia or instances where action has already taken, because the same recall notices will operate across all of those markets.

Senator CAROL BROWN: I am still trying to get straight in my head, first of all, whether there is a difference between the withdrawal of a product and the recall of a product. It has been mentioned that there is also a process of stopping the suppling of a device. What are the differences, if there are any; and what are the processes that then come into effect once a decision has been made to stop supplying, to withdraw or recall?

Ms Trimmer: I can answer part of that. Part of it the TGA might need to answer in terms of what action they take. A company could stop supplying a product for all sorts of reasons. It could be because it has been superseded by a newer product or it might be that the utilisation for it in this market has reduced to such a point that it is no longer commercially viable to supply it here. So you have voluntary withdrawal which has nothing to do with safety or efficacy. You might have a company which is provided with either evidence from its own user group—its doctors—or information from locations around the world that the product is not performing as optimally as it should, in which case the company might decide to withdraw the product from the market without any action having been taken. Or it may be that the regulator takes the action and issues a recall. Dr Armitage was suggesting that there was commercial advantage to a company in withdrawing a product from the market because there was some adverse finding underway. I do not think there is any commercial advantage in that, at all. I think that is a company being responsible when faced with evidence that shows that its product is not performing as optimally as it might wish. The company takes the action to withdraw the product as soon as it is aware of that.

Senator CAROL BROWN: What is the action? There is a difference between withdrawing and recalling, or does it just depend on who does it?

Ms Trimmer: Yes; a recall is when TGA takes the action; a withdrawal is when the company removes the product.

Senator CAROL BROWN: What does the company have to do to facilitate that withdrawal? Do they tell TGA? What do they do?

Ms Trimmer: Yes. They would first of all have had to tell TGA that something was occurring with the product that put it out of the norm. Anything that is adverse—even down to a labelling issue—has to be reported to TGA. It is quite an onerous, ongoing reporting requirement. That would need to happen and the company would also notify doctors and health authorities anywhere where the product may have been distributed, to ensure that it was withdrawn from the market.

Senator CAROL BROWN: So they can just stop supplying and that can be based on information that there are issues associated with the device?

Ms Trimmer: Yes.

Senator CAROL BROWN: And if they just stop supplying they have to advise the TGA—

Ms Trimmer: They have to take a whole series of actions.

Senator CAROL BROWN: If there is the withdrawal of a device here in Australia, given our commitment to a global harmonisation regime, do we then alert other countries that are using this device?

Ms Trimmer: I am not sure of the answer to that. If it is a company withdrawal then it is not an action that has been taken by the regulator. If the regulator took the action, it would notify the other regulators in the global adverse event reporting system. If it is a company initiated withdrawal then it would come down to the company's actions in other jurisdictions.

Senator CAROL BROWN: So it is not incumbent upon them to? If they withdraw, they do not have to withdraw in other countries?

Ms Trimmer: I do not believe so.

Senator CAROL BROWN: This goes a little to what Dr Armitage was saying about the TGA approval being based on manufacturing, efficacy and cost-effectiveness. You have talked about the difficulty in having clinical trials with devices. You also mentioned that companies continue to monitor and report on the device. Can you expand a bit further? Is that compulsory reporting?

Ms Trimmer: Yes. That is one of the conditions of registration. I mentioned that the way in which devices are regulated is through compliance with the essential principles. Part of the concept of essential principles is that ongoing monitoring of performance of the device and reporting, which does not have to be adverse in the sense of patient injury; it could be anything that puts the product outside the regulatory framework, including, as I said, down to the labelling.

Senator CAROL BROWN: They are only reports on whether there are any negative issues relating to the device; they are not just general reports stating that they are performing as expected?

Ms Trimmer: No. They are not in the positive; they are in the negative, but the negative is very wide ranging and companies tend to err on the side of caution and report anything that could be seen to reflect on the regulatory approval of that product. The approval is an approval to market, so that covers a wide range of factors.

Senator CAROL BROWN: And those reports are to the TGA?

Ms Trimmer: Yes, that is correct.

Senator CAROL BROWN: What would be the normal process if there were ongoing issues with a particular device? What is the normal process for the TGA to enter into?

Ms Trimmer: I think that might be a better question to put to the TGA in terms of the detail of the process.

Senator CAROL BROWN: Okay.

Senator McKENZIE: Thank you for your evidence. As the body that is representing distributors and manufacturers, could you outline the arrangements with hospitals from the manufacturing or distribution perspective, particularly with respect to hospitals using particular devices and whether there is any sort of commercial advantage such as buying in bulk and that kind of thing?

Ms Trimmer: Australia has two different parts to its healthcare system—the public and the private. I think what you are referring to is more likely to be in the public health system where purchasing is done more centrally through either state governments or regional health authorities. That can be done based on volume. It might have volume based incentives. With the product, of course, come a whole lot of additional services that the company provides, everything from training to transportation of the large kits that go with the implantable devices, particularly the orthopaedic devices. Those can all form part of what might be included in a tender to supply in the public health system.

Senator McKENZIE: Would you agree that that is a competitive tender process for medical devices?

Ms Trimmer: Yes, it is.

Senator McKENZIE: Okay. What is the difference between approval of pharmaceuticals and approval of medical devices? We cannot use randomised double-blind trials for medical devices, for obvious reasons. When people have a medical device implanted, they obviously become part of the trial and the body of evidence going towards understanding that device's behaviour within the human population. I am just wondering about the ethics

of that and whether patients are informed of their participation in what is essentially a medical trial, once they have a device implanted. Could you just comment on that. What is your opinion?

Ms Trimmer: If it is a trial, then it must be disclosed to the patient. All clinical trials of products in Australia are registered. That would need to be disclosed to the patient. The patient has to consent to be part of a trial. If it is a new device, then one of the things that we would very much like to see is for Australia to be part of a trial program for newer devices. We have excellent healthcare professionals in Australia and excellent teaching facilities. But, in all of those circumstances, the patient is made very well aware that they are part of a clinical trial and they do have to consent to that. It would be unethical to not do that.

Senator McKENZIE: At the moment, though, if a new device is put into a patient, what is the process for understanding how that device works in the human body? We watch over what happens in that scenario—for two years, was it?

Ms Trimmer: It is two years clinical evidence for reimbursement purposes.

Senator McKENZIE: So that is not technically a trial?

Ms Trimmer: Part of it could be during a trial period, I think—

Mr Ross: It could be.

Ms Trimmer: and part of it could be after it has received approval for market entry. So it is an accumulated period of two years.

Mr Ross: There is a higher onus to provide evidence for reimbursement than there is to get through the regulatory gateway. Certainly, one of the criteria for reimbursement is that the product has been compared to alternative products on the prosthesis list and has been assessed as being at least of similar clinical effectiveness. So there is that basic level, and that is in consideration of the evidence provided by the sponsor.

Senator McKENZIE: Okay. Thank you.

Senator CAROL BROWN: I want to go back to the process for withdrawing a product. When a product is withdrawn, are the users—the doctors—advised that the device is being or has been withdrawn?

Ms Trimmer: Yes, a company would do that as a matter of course.

Senator CAROL BROWN: Is it part of the process that they have to do that?

Ms Trimmer: I cannot answer that specifically, as to whether that is an obligation, but I think a responsible company would generally do that, yes, because the decision has been taken to withdraw the product for a variety of possible reasons. Whether it is done simply because it is no longer going to be made commercially available or whether it is for adverse reasons, the company would most likely still inform its doctor client group, or customer group.

Senator CAROL BROWN: What about devices that may already have been purchased by those users?

Ms Trimmer: The only circumstance in which there might have already been a purchase would be in the public health system, because in the private system that only happens at the time of the procedure. In the public system, I would assume that there would also be notification through the processes via which a company tracks where its products have gone. They would provide notification that they were withdrawing the product from the market.

Senator CAROL BROWN: Would doctors be able to send those products back to the manufacturer for reimbursement?

Ms Trimmer: I would have to take that on notice. I do not know the answer to that question.

Senator CAROL BROWN: Could you please do that for me? Thank you. You talked about the monitoring of devices and the reporting to the TGA being compulsory for manufacturers but I wondered about the reporting of issues from doctors or health professionals. That is a voluntary system?

Ms Trimmer: Yes, it is. As I mentioned in my opening comments, the facility for reporting by both patients and doctors to the TGA has always been available. One of the issues raised in the transparency review recently was the fact that, if doctors are aware of it, they are not very good at using, and patients are simply not aware of it. So part of the effort will be to make those pathways a lot more visible for both patients and doctors in the future.

Senator CAROL BROWN: Do you see any need to make that a compulsory reporting system?

Ms Trimmer: For doctors?

Senator CAROL BROWN: And other—

Ms Trimmer: I do not know that you could enforce it with patients. You could potentially do so with doctors, but there is a fine line as to whether an issue is actually with the device or with the doctor's use of that device. Sometimes that is a very grey area, and to make it compulsory might ending creating the wrong reporting lines.

Senator CAROL BROWN: Doctors report to the TGA. Do they also report to manufacturers?

Ms Trimmer: They do report to manufacturers as well, and that is quite often how a manufacturer will become aware—not because of something adverse—that a small modification to the product might improve either its ease of use for the doctor or improved patient outcomes. That is why so much product development in medical devices is very iterative, and it is based on feedback from doctors' use of devices on patients.

Senator McKENZIE: Just to clarify, are patients advised when a new device—not new to them but new to the Australian market—is being implanted?

Ms Trimmer: I do not know the answer to that question. I think that would come down to individual doctor practice. There is nothing in a regulatory regime to require that, unless it is in the clinical trial context. The Orthopaedic Association might be able to answer that for you.

Senator XENOPHON: If there is a new device—your constituent members are businesses—are rebates offered on occasions as they would be with many other new products to try and increase market share? Does that occur and are there rules, codes of practice, with respect to that?

Ms Trimmer: That is not an issue that is covered by our code of practice. The commercial arrangements for consultancies and the kind of advisory role that many healthcare professionals take with medical device companies is certainly addressed by the code of practice, but the issue of rebates is not.

Senator XENOPHON: Is that something you would have information from your members on, or would we need to ask your constituent members about that?

Ms Trimmer: Yes; I am afraid I do not have that information.

Senator XENOPHON: Does the association have a view as to whether there should be some transparency in the amount or nature of rebates and any other inducements that are offered?

Ms Trimmer: No, I do not have a particular view about that. I think it is very hard to have a blanket position because the commercial arrangements can be as various as the contracts that are on offer.

Senator XENOPHON: But if there is some transparency in the process, saying, 'This device gets a rebate of 10 per cent,' or 20 or 30 per cent or whatever, do you think your members would have any difficulty with that?

Ms Trimmer: Perhaps this is a question that you should put to the companies.

Senator XENOPHON: But you represent the companies.

Ms Trimmer: I think that the commercial arrangements generally are not disclosed publically. There is a degree of public information on pricing and so forth through things like the National Product Catalogue. But the individual pricing arrangements under contracts, as with most other contracts in the commercial world, are not made publically available.

Mr Ross: These commercial arrangements are generally between the company and the hospital, not the doctor. So, if there is any competitive pricing, it would not involve the doctor; it is the hospital being judicious in the way it purchases a product. But certainly in the reimbursement area the surgeon's preferences are paramount in the selection of devices that are best for the patient. The issue of conflict of interest is quite separate.

Senator XENOPHON: But couldn't the surgeon's choice be influenced in some cases—in some circumstances where there is a significant rebate and that surgeon may have an interest in that hospital, for instance?

Mr Ross: I think hospitals have generally had difficulty in forcing on surgeons what they will choose for their patients—in the private sector. In the public sector, it is a different issue.

Senator XENOPHON: But if a surgeon has an interest in a surgical facility then there is a close link between the surgeon and any rebate on a device, isn't there? You would agree with that?

Ms Trimmer: I must say that that particular example of doctors having an interest in the hospital has not been brought to my attention before. I think there is a lot of opportunity for conflicts of interest in a lot of these areas, which is why, both as an association and through the working group that the government put in place, there are attempts to address those issues about transparency and having any conflicts put at least onto arm's-length terms, if not transparent terms.

Senator XENOPHON: Thank you.

ACTING CHAIR: Thank you. We have a number of questions we have put to you on notice, and the secretariat will give you that in writing to remind you, because a few senators threw that at you. Because of the time frame, we would like those answers back by this time next week—the end of next Tuesday. So we will try to get them to you no later than tomorrow, because we are going to take them from the transcript to make sure we have picked up any issues that are being raised. Also, other senators might want to put questions there, so we will get them to you by the end of tomorrow. So thank you very much.

COSENZA, Mr Adrian Robert, Chief Executive Officer, Australian Orthopaedic Association

DAVIDSON, Dr David Charles, Deputy Director, National Joint Replacement Registry, Australian Orthopaedic Association

GRAVES, Professor Stephen Ellis, Director, National Joint Replacement Registry, Australian Orthopaedic Association

[11:52]

ACTING CHAIR: I welcome representatives of the Australian Orthopaedic Association. I know that you would have had information on parliamentary privilege and the protection of witnesses and evidence provided to you. We have your submission; thank you very much. Do you have anything to say about the capacity in which you have come to see us?

Dr Davidson: I am one of the two deputy directors of the National Joint Replacement Registry of the Australian Orthopaedic Association.

ACTING CHAIR: Thank you very much. If any of you or all of you would like to make an opening statement, that would be good, and then we will go to questions. You have seen how the system works. Are you going to start, Mr Cosenza?

Mr Cosenza: Thank you, Chair. The AOA members thank the committee for the opportunity to provide evidence to the committee in their deliberations in the matter of the inquiry into the regulatory standards for the approval of medical devices. AOA is a member-based organisation and it is the peak professional body for orthopaedic surgeons in Australia. It was established 75 years ago. AOA provides high-quality specialist education, training and continuing professional development. AOA is committed to ensuring the highest possible standard of orthopaedic care and is the leading authority in the provision of orthopaedic information to the community. AOA members provide advice on medical device regulatory matters to the Australian government by way of membership on many health technology related committees and working groups, both within the Department of Health and Ageing and the Therapeutic Goods Administration.

AOA members participate in the various government regulatory bodies governing the pre-market assessment, introduction and post-market surveillance of orthopaedic devices in Australia. Groups that AOA members are involved in include the Medical Device Evaluation Committee, the Prosthesis List Advisory Committee, the Orthopaedic Expert Working Group, various clinical advisory groups, a panel of clinical experts, the medical services advisory committees and the AOA National Joint Replacement Registry Consultative Committee. AOA members also participate in a number of ad hoc committees, working groups and working parties as established by the government from time to time. Professor Stephen Graves is the Director of the National Joint Replacement Registry, which is this year marking 10 years of existence and the reporting of its data, and Dr Davidson is the Deputy Director. We are here to answer questions for the committee regarding AOA's submission and other related matters.

ACTING CHAIR: Professor Graves or Dr Davidson, have you got any comments to make at this stage?

Dr Davidson: No.

Professor Graves: No.

ACTING CHAIR: We will go straight into questions, but I could I ask first: Mr Cosenza, in terms of the status of AOA, are all practising orthopaedic surgeons members of your organisation automatically? Do they need to be members of your organisation? I am just wanting to find out what percentage of practising orthopaedic surgeons are members of AOA.

Mr Cosenza: The overwhelming majority of practising orthopaedic surgeons are members. Once they retire or move on, they continue to be members but they have different subscription rates that apply. But yes, the overwhelming majority are members.

ACTING CHAIR: But you do not need to be a member to practise.

Mr Cosenza: You do not need to be a member to practise.

ACTING CHAIR: I just wanted to clarify that.

Senator XENOPHON: On Senator Moore's line of questioning: does that mean that if there are codes of practice, ethical guidelines for your members, and you have an orthopaedic surgeon who is not a member, are they subject to those rules or not?

Mr Cosenza: Anyone who is a member of the association is subject to the rules.

Senator XENOPHON: But sometimes there could be some professional standards or professional rules that, notwithstanding a lack of membership of an association, you are still bound by as a condition of practising. That does not apply in this case?

Mr Cosenza: As I said, you need to be a member of an organisation to be bound by the rules.

Senator XENOPHON: Is there any other alternative enforcement mechanism, if someone is not a member of your association, to be subject to the same sorts of rules and standards as your members are?

Mr Cosenza: Yes. As Professor Graves has just pointed out, we have members, or non-members, who could elect to continue to be members of the Royal Australasian College of Surgeons, for example, and that organisation has its own code of conduct and disciplinary measures.

ACTING CHAIR: I am just getting it in my mind because of the number of medical things that come before this committee. Is there a royal college of orthopaedic surgeons, or it there a royal college of surgeons? Who is the professional body that looks after orthopaedic surgeons?

Mr Cosenza: The professional body that has orthopaedic matters at its heart is the Australian Orthopaedic Association and that is its name. It is a member-based organisation. The AOA does have a relationship with the Royal Australasian College of Surgeons. It is one of about eight or nine sub-specialties that have a relationship with the surgeons. It covers a lot of surgical specialties.

ACTING CHAIR: I think I have it clear now, though I am not sure.

Senator XENOPHON: It is clear enough, I guess. What are the current rules for your members when advising patients before they operate that they have an interest, a commercial link, in a medical device? Do you say, 'I think this is the best advice but, by the way, I also have a commercial interest in this device'?

Mr Cosenza: The AOA has a professional code of conduct that requires all members to declare such interests to patients in patient surgery.

Senator XENOPHON: How long has that particular part of the code been in operation?

Mr Cosenza: The AOA has had a code of practice in place for quite a number of years. I would need to check the specifics on that particular component.

Senator XENOPHON: Perhaps you could take on notice the potential conflict of interest or commercial interest. If an orthopaedic surgeon does not advise the patient of a commercial link with a device, for instance, what sanctions are there for that breach?

Mr Cosenza: The process that the AOA has is that a complaint needs to be lodged by, let us say, a patient, directly to the AOA. Then there is a disciplinary procedure under the professional standards in conduct committee and there is a process to take the complaint into account and to list the basis of the complaint. For example, if this was not stated, and that is a breach of the conduct, then that is a legitimate basis upon which to have it considered by the professional standards committee.

Senator XENOPHON: In recent years, have there been any complaints in relation to that sort of conduct where a surgeon did not disclose their commercial interest in a device, for instance?

Mr Cosenza: Not to the best of my knowledge, though I have only been there a year.

Senator XENOPHON: If you could take on notice to advise about any previous complaints and in general terms what the outcomes of those were?

Mr Cosenza: Yes.

Senator XENOPHON: I am not sure whether you heard the evidence of Dr Michael Armitage from the Australian Health Insurance Association?

Dr Davidson: No, I did not.

Senator XENOPHON: Dr Armitage felt that the TGA was not active enough, but did say that the work that the NJRR does is terrific work and it is very useful. He was quite praiseworthy of the work that the register does. But he said that there ought to be a requirement for the TGA to take action on the results—in other words, there needs to be a nexus between the two; not a criticism of the NJRR. To what extent can the NJRR facilitate the approach that Dr Armitage is suggesting to ensure that there is action, or are you satisfied that you already provide information to the TGA—or it is there for the TGA to access? Do you think that the role of the NJRR should extend to making recommendations that say, 'We think action should be taken', or is it enough for there to be certain triggers in place, particularly, say, if there is double the rate of failure for a particular device?

Prof. Graves: I think it is important to understand that there are several ways that we provide information to the TGA. First of all, the TGA actually has direct access to our database. At any time, if they have an issue with a device—say, with the adverse events reporting system and a device is named—through a secure download they can look at the results of that device up to six weeks ago in the country. That will tell them where the device is performing in a way that seems to be similar to other devices or whether it is an outlier. If they have any concerns, they can come directly to the registry and we can do a more detailed report for them on a particular issue. Every year, however, as part of our annual report we also identify outlining prostheses and those outliers have gone through a very rigorous process of identification, which includes statistical analysis to say that they are an outlier. Also as part of the process, it is reviewed by an independent group of orthopaedic surgeons and it is that independent group of surgeons who make recommendations to the registry to identify those particular devices as being an outlier. Every year, however, as part of our annual report we also identify outlying 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. We are the only registry around the world that undertakes this process. But other registries are now looking at running a very similar process, including more recently the English and Welsh Registry, which is now the largest registry in the world. That is taking on the same process that we adopted a number of years ago.

When we go through that formal process, what happens is that we as part of our contract with the Commonwealth we are required to notify the Therapeutic Goods Administration of those outliers. What we do is, prior to the report being released, provide the Therapeutic Goods Administration with detailed reports on each of those devices. It has always been the AOA's view—and as director of the registry I think that this is a very important issue—that the registry does not have a direct role in regulation. The information that is provided to the registry is provided on a voluntary basis. 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.

The reason that I say that it is important to separate those functions is that there can be many reasons why a device is performing differently. It may be related to factors related to the patients that have been using them—for example, they have particularly difficult diagnoses that are known to have a higher risk of revision. It could be that there are surgeon issues or it could be that there is a device issue. 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.

Senator XENOPHON: Essentially, you gather the information. In a nutshell, it is for the TGA to decide what to do with that information.

Prof. Graves: The responsibility for regulation of devices rests solely with the TGA.

Senator XENOPHON: The primary role of the register is to gather that information. The regulator acts on that or not as they see fit.

Prof. Graves: Yes.

Senator XENOPHON: The information is provided on a voluntary basis. I know that Dr Armitage talked about the extensive information that you provide. Could it be strengthened by being provided on a mandatory basis so that there are not any gaps in the system? How robust is it now, given that it is on a voluntary basis?

Prof. Graves: In fact, one of the things that is quite impressive about the Australian registry is the cooperation of the surgeons and the hospitals throughout the country. We are able to check the robustness of the information that we receive. We have relationships with each of the state health departments and they provide us with a list of all of the procedures that have been undertaken, such as for hip, knee or other joint replacements.

Senator XENOPHON: Public or private hospitals or both?

Prof. Graves: Both. What we then do is run that against the list that we have received. If there are any discrepancies between those lists what we do is go to the hospital and say: 'We are missing data on these particular patients as identified by the UR number for the hospital. Could we please have a form.' We know that

we get well over 99 per cent of the procedures undertaken in the country, which is as high as any registry world wide.

Senator XENOPHON: Even a mandatory registry?

Prof. Graves: Even mandatory registries.

Senator XENOPHON: Thank you for clarifying that. It would be fair to say that, while a number of matters triggered this inquiry, it was in particular the metal-on-metal devices—the ASR, the DePuy, manufactured by Johnson and Johnson. One of the issues that have been put to me by people who have had terrible and shocking health problems that appear to be directly linked to these devices is that the NJRR said as far back as, I think, 2007, in your annual report, that there seems to be a higher rate of failure for these devices. For the record, can you provide details of when you first became aware of the higher rates of revision for these devices, both the resurfacing device and the hip replacement?

Prof. Graves: As you pointed out, there are two ASR devices. There is the ASR resurfacing and then there is the ASR, and for ease I will talk about that as the ASR for conventional hip replacement. The ASR prosthesis came on the market in about 2003 or 2004—both the conventional and the resurfacings. They were undertaken in relatively small numbers for the first few years but were increasing in use in 2005 and 2006. In 2006 we were just developing the process of identifying outlier prostheses. The ASR resurfacing did not quite fit, in that it did not come up in the statistical analysis as being an outlier. However, we had picked up that there was a sudden increase in the number of revisions with the ASR, and even though it was not officially in the outlier group—

Senator XENOPHON: Sorry—what is the difference? What is the outlier group?

Prof. Graves: The outlier group is the clear group that has at least twice the rate of revision of any other device.

Senator XENOPHON: So it was under that outlier threshold of twice the rate of revision.

Prof. Graves: It was under that, but we had seen quite a rapid increase in the number of revisions.

Senator XENOPHON: There was a spike.

Prof. Graves: So it looked like it was heading in that direction. In 2006—

Senator XENOPHON: Sorry—that was for the resurfacing or for the hip replacement?

Prof. Graves: The resurfacing. I will talk mainly about the resurfacing first because the identification of the conventional hip replacement came later. In 2006 we mentioned that we were concerned with that device.

Senator XENOPHON: In your report or to the TGA?

Prof. Graves: In the report.

Senator XENOPHON: Which was available to the TGA.

Prof. Graves: Yes. The Orthopaedic Association thinks it is very important that the information on joint replacement is transparent and accountable and available to everyone, so it is publicly available.

Senator XENOPHON: I just want to get the time line. Was that the 2006 annual report?

Prof. Graves: It was the 2006 annual report.

Senator XENOPHON: And what date was that released, approximately?

Prof. Graves: That report was released in 2006, and it would have been around 1 October of that year.

Senator XENOPHON: Prior to 1 October 2006, did you have any data that would have raised concerns in relation to that spike in the revision rates?

Prof. Graves: No.

Senator XENOPHON: But, obviously, prior to the preparation of the annual report there would have been a spike in the revision rates.

Prof. Graves: Yes, but it was not more than twice at that point in time. And that is just an arbitrary figure that we picked as being a reasonable number to say that this is behaving in a different way compared to other joints.

Senator CAROL BROWN: It was not twice, but what was the rate?

Prof. Graves: I am not sure. It would have been 1½ or 1¾. It was under twice.

Senator XENOPHON: Perhaps my line of questioning is a bit obtuse on this. Was it the case that the spike that you identified, which was reflected in your 2006 annual report delivered on or about 1 October, became apparent to the NJRR in the process of preparing that report?

Prof. Graves: Yes. We write the report, and the writing of the report is usually completed by the end of July. So it may have been in the few weeks during July that we became aware of that, because this area of the report is usually the last area that we write.

Senator XENOPHON: I appreciate that. It is in no way a criticism. I want to emphasise that.

Prof. Graves: No, I understand.

Senator XENOPHON: I understand that. You are doing your work, you go through the report you are preparing and this problem came up some time in July. Was that information passed on to the TGA, or is it protocol that you wait until the publication of the report?

Prof. Graves: No, we provide information to the TGA prior to the release of the report. There are a number of processes. The reason we complete our report by the end of July is that the whole report is reviewed by an independent panel of orthopaedic surgeons. The most important part of that review process is looking at the outlying prostheses that we have identified to be sure that there are issues related to those prostheses that this independent group of orthopaedic surgeons, who are specialists in arthroplasty, believe need to be notified to whoever requires that notification.

Senator XENOPHON: You first became aware probably sometime in July in the lead-up to the preparation of your 2006 annual report.

Prof. Graves: Yes.

Senator XENOPHON: The TGA would have been aware of that information shortly afterwards and prior to 1 October.

Prof. Graves: In 2006 the mechanism for notifying the TGA was not in place. That became in place in 2007.

Senator XENOPHON: Right, but certainly by 1 October 2006 the TGA would have been aware of this.

Prof. Graves: Absolutely. But it was not statistically significant; we had mentioned it just as a concern.

Senator XENOPHON: Yes, but that concern would have been noted by the TGA.

Prof. Graves: I would have hoped so. We did not have a formal notification process at that time.

Senator XENOPHON: Finally, by 2007 that statistical anomaly—

Prof. Graves: We clearly identified that it was an issue.

Senator XENOPHON: It was an outlier. In what month in 2007 would the TGA have been aware that it was an outlier?

Prof. Graves: They would have received the notification two weeks before the report was released, so they would have received that in mid-September.

Senator XENOPHON: The argument of one of the people who has been deeply, shockingly affected by this is: 'I had the hip replacement, but the NJRR identified a problem in 2007, about it being an outlier, with the resurfacing.'

Prof. Graves: Yes.

Senator XENOPHON: Is there a correlation, in your view, between a problem with the resurfacing and an associated device? The problem you identified was with the resurfacing device not with a hip replacement itself?

Prof. Graves: Not at that point in time.

Senator XENOPHON: If you are worried about the resurfacing device, would you also be concerned about the complete hip replacement device?

Prof. Graves: Yes. The devices are similar in one respect, in that the acetabular or the cup is the same, but the femoral component is quite different.

Senator XENOPHON: So there is a nexus—

Prof. Graves: Yes.

Senator XENOPHON: When was the NJRR aware of problems with the hip replacement itself, the ASR?

Prof. Graves: 2008.

Senator XENOPHON: By July 2008?

Prof. Graves: Yes, and we notified the Therapeutic Goods Administration in September 2008. We also re-emphasised at that point in time that the resurfacing was still an outlier as well. In 2009 we again emphasised that both the conventional hip and the resurfacing were outliers.

Senator XENOPHON: Thank you.

ACTING CHAIR: Professor Graves, can I just follow up on that whole sequence. You had told us that the process with the hip replacement register, as it became entrenched in 2006 onwards, was that when you identified an outlier it was also looked at by an independent group of orthopaedic surgeons within the registry arrangement.

Prof. Graves: Yes.

ACTING CHAIR: In 2007, once it had got to be a formal issue and the resurfacing was identified as an outlier, there was a review in that period, in 2007, of this particular joint.

Prof. Graves: By the independent surgeons. There was also a review by the TGA of the outcome.

ACTING CHAIR: In 2007?

Prof. Graves: Yes, there certainly was.

ACTING CHAIR: We will be going through the whole process with the TGA later but I just wanted to get that referenced.

Senator CAROL BROWN: I want to clear up a point on some questions I asked of a previous witness about when there is a withdrawal of the device. What happens when a device is withdrawn? What happens with public hospitals if they have a stock of these devices? Are they sent back and the hospitals are reimbursed?

Prof. Graves: Yes. When there is a withdrawal the company takes all those devices back.

Senator CAROL BROWN: Is there any circumstance where if the company chooses to stop supplying the device the hospital can still use that device?

Prof. Graves: Yes, they can use up remaining stock—that is certainly the case. One of the difficulties for companies if they are stopping the supply of a device is that it is very hard to just stop it dead from the point of view that, particularly if revision procedures are required, there may be parts of those devices that are required. So a company stopping the supply of a device is different from a company voluntarily withdrawing it from the market.

Senator CAROL BROWN: So a company would not stop supplying the device because there had been adverse events or comments?

Prof. Graves: No, they may not provide it if they thought that there were adverse events, but usually devices are stopped being supplied because they have moved on to another device.

Senator CAROL BROWN: I understand that, but is there able to be a circumstance where a manufacturer would just stop supplying it because they have had some adverse comments?

Prof. Graves: Yes, there have been situations like that.

Senator CAROL BROWN: And they would not have to take the devices back and reimburse the public hospital system if it is just a case of the stopping of supply, even though it is based on adverse comments or events?

Prof. Graves: The very first device that the registry identified was a thing called the UniSpacer, which was a product from Zimmer. There were only about 50 used in the country and, when we identified that, the company just stopped supplying it.

Senator CAROL BROWN: You obviously have a very good relationship with surgeons—

Prof. Graves: Yes.

Senator CAROL BROWN: and you have obtained some very impressive data that you base your comments on. Previously I asked the Medical Technology Association about whether reporting of adverse effects should be compulsory for surgeons. Do you have a view on that?

Prof. Graves: Where it becomes difficult is that it is not quite clear-cut what is an adverse event and what is a natural kind of progression. If you have a patient who has a revision because there is an infection, is that an adverse event? The answer from the patient's perspective is that it is a very adverse event. Is it an adverse event from the point of view of the device? Most people would say no, but it could be—for instance, if there was a problem with packaging and the device was not sterile. So, you see, it becomes quite difficult to know. Most surgeons would not regard that as an adverse event from the device, but it potentially could be. Say you have a revision because the device has dislocated, we know that a certain number of devices will dislocate but some devices dislocate more than others. If everyone was required to report revisions, there would be a clearer picture, I believe, as to those devices that were not performing well. I think that the adverse event reporting system is actually quite complementary to the post-market surveillance system that the registry establishes.

Senator CAROL BROWN: So you are happy with the reporting of events in terms of the work you do?

Prof. Graves: I am reasonably happy with it at the moment. One of the things anecdotally that we have been made aware of is that, when the registry identifies the device, the adverse reporting goes up for that device. For instance, the adverse reporting for the ASR went up after we identified that the device was an issue.

Senator CAROL BROWN: You talked about the close relationship you have with the TGA in that the TGA are able to access your data and you report to them.

Prof. Graves: Yes.

Senator CAROL BROWN: When you report data and you do not see some action taken from data that you think shows there is an issue, do you have conversations or do you have meetings together about the issues that you have identified as adverse events?

Prof. Graves: The registry is represented. I am actually one of the members of the Orthopaedic Expert Working Group, and so the registry does have an input into the Orthopaedic Expert Working Group. We have had discussions with the TGA about how best to identify prostheses and the processes that should be in place. But, in the end, the registry does not have a regulatory function and it is really up to the Therapeutic Goods Administration to assess the data and then make those decisions.

Senator CAROL BROWN: I understand that is the response you gave earlier but I just wondered whether there were other ins that the National Joint Replacement Registry and also the AOA had in terms of recommendations that would ultimately be put forward by the TGA itself.

Prof. Graves: Because of data from the registry, the Australian Orthopaedic Association has made recommendations to the Therapeutic Goods Administration about the regulation of new devices. The AOA has been concerned at the level of regulation of those devices and believes that the level of regulation needs to be increased for hip and knee replacements. A number of years ago the AOA made recommendations to the Therapeutic Goods Administration as to what it believed should happen. The AOA, through its members, has also had some influence within the reimbursement process, and I think that is why there is currently a difference between the reimbursement process requirements and also the therapeutic goods regulation in that the reimbursement requirements now require two years clinical data specific for that device. I think that has been an impact of the AOA members on those committees.

I am well aware of the functioning of those committees. I am chair of the hip clinical advisory group and I am also a member of the knee clinical advisory group. So I think I can comment with some degree of authority on the influence of the AOA on those requirements.

Senator CAROL BROWN: Would you say that, once issues about devices are flagged by the NJRR, you would be reasonably happy with the timeliness of the action taken by the TGA?

Prof. Graves: 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.

Senator CAROL BROWN: At those times, were you able to have further input by asking what action would be taken? You report to them and you have many meetings and you have an expert group. When something that you think should be happening does not appear to be happening, is there a report back process?

Prof. Graves: I can have informal discussions and certainly, more recently, I have been made aware that the head of the TGA is very open to direct contact if we felt that there were issues. The relationship is not a static thing. It is a developing thing. I think the relationship now is much better than it was a number of years ago.

Senator CAROL BROWN: I understand that, and that is good. Given the changes that have occurred that you have just outlined, is there anything else that you would like to see happen with the operation of the TGA, or are you happy with the changes that are now taking place?

Prof. Graves: There are now 20 or so registries around the world, and I think that there needs to be much more international collaboration. If we look at the ASR, in Australia we identified that it was an issue and it was withdrawn from the Australian market in 2009. It continued to be sold in other parts of the world until August 2010. I think that that was a mistake. The reason that the company gave for withdrawing it worldwide in 2010 was, they said, that the English and Wales registry had identified that there was a higher than anticipated rate of revision for these devices. Now, we had been identifying it for quite a few years at that point of time. But what that message really says is that two registries identifying an issue suddenly adds a lot more strength to the idea that there may be an issue with the device. Recently, Stryker withdrew a unicompartmental knee replacement called the EOS—this is only in the last few weeks—and the reason they gave was that it had been identified as

having a higher rate of revision in both the Australian and the England-Wales registries. So it was the two-registry effect. I think that that is something that can be strengthened.

Currently, the FDA are very interested in that process of linking registries and has formed an organisation called ICOR, which is the International Consortium of Orthopaedic Registries and is world wide. What they are doing is providing funding for registries to work together in a collaborative manner to identify issues with respect to joint replacement. We have talked about issues related to individual devices; however, there are classes of devices which are now being identified as an issue. The metal-on-metal group as a whole, particularly in conventional hip replacements and large-head metal on metal, is an issue of great concern worldwide. The Australian registry has been identifying another class where there have been devices that use what we refer to as exchangeable necks which appear to have over twice the risk of revision compared to devices that do not have those exchangeable necks. So there are a whole range of issues coming up that registries, if they work in collaboration, will identify very quickly and on which they will be able to provide very strong advice to regulatory bodies worldwide.

We are in a very fortunate position to assist with that process because I have been asked to chair that ICOR group, and I think that that reflects the standing that this country and the registry in this country have internationally. So I think there are a lot of things that we have achieved in this country that we should be very proud of, but I do not think we should rest on our laurels. There is a lot more that we can do.

Senator CAROL BROWN: Thank you, Professor.

Senator McKENZIE: Professor, I wanted you to expand on point (i)2 of the AOA submission, where you mention 'insufficient clinical evidence requirements before the devices are put on the market'. I am interested in that aspect. Could you provide some more comments on that for the committee.

Prof. Graves: I think that the issue with the ASR but also the large-head metal on metal and the exchangeable necks, as I have mentioned, indicate, from the point of view of the orthopaedic community, that the current regulatory processes prior to a device being approved are not sufficient. They are not identifying devices that are potentially, and do become subsequently, a problem. The Australian registry has reported previously, looking at new devices coming on the market. We have just had an article accepted for publication in the *Journal of Bone and Joint Surgery* in America, which is the premier orthopaedic journal, looking at new devices that came onto the market in the five-year period between 2003 and 2007. There were over 260 new devices, hips and knees, that came onto the market in that time, the vast majority of which were used only in a very small number of procedures, 75 per cent, less than 100 procedures, so it was very difficult to know whether or not they were going to work. Of the 25 per cent that were used in a large number of procedures the registry found that none performed better than the established prosthesis we already had on the market and that 30 per cent performed significantly worse. It is that 30 per cent that performed significantly worse that we do have concerns with.

So the AOA recommended to the TGA a number of years ago that there be the introduction of premarket clinical testing and recommended that that premarket clinical testing be at least two years and preferably using a technology called radiostereometric analysis, or RSA, which is a technique you can use with joint replacement which is strongly predictive of the long-term outcome. The reason we recommended that approach is because only a small number of patients need to undergo the procedure and you can very quickly determine whether the long-term outcome is likely to be satisfactory for that device. That would tend to prevent, hopefully, most of that 30 per cent reaching the market.

What has also been apparent with the problems that have occurred with joint replacement is that the premarket in vitro testing is currently not adequate because there are problems that have not been identified. The standards need to be reviewed for the premarket in vitro testing. With the pre-market clinical testing, international standards need to be developed as to what is the most appropriate. There is a third thing that needs to happen from the point of view of ensuring strong continued improvement in the outcome of joint replacement. It is very important to emphasise it is a very successful operation and what we are trying to do is make a good operation even better. The postmarket surveillance needs to be further strengthened. The way we would look at strengthening that postmarket surveillance is with the international collaboration.

Senator McKENZIE: What was the second dot point you mentioned?

Prof. Graves: In vitro testing, which is like when they put the hip or knee replacement on machines and run them for weeks on end to look at the wear that is occurring and so on—so it is not in a person; it is on a bench.

Senator McKENZIE: Thank you for that clarification. My second question is not specifically related to the regulatory environment. It goes to one of the negative experiences that one of my own constituents has had. It goes to the orthopaedic surgeon's ability to identify the symptoms of blood toxicity. Can you, as the representative

body of orthopaedic surgeons, see where maybe more training needs to be provided to surgeons around that or why at the first point of call when something is going wrong the patient goes back to the surgeon and every other avenue for why they are experiencing the symptoms they are seems to be investigated before it is identified that it might be the hip itself. Do you have any comments to make around the profession's understanding of the impact?

Prof. Graves: It is important to get the issue of cobalt toxicity into context. I have recently written an article, which will be published later in the year, with two other authors: Dr Joshua Jacobs from the Rush University Medical Centre in Chicago, who is regarded as one of the world's authorities on metal iron issues with hip replacement, and Keith Tucker from the UK, who is the orthopaedic surgeon who is principally involved in developing the guidelines of NICE around joint replacements and is also a representative on the regulatory body and the English and Wales registry. Cobalt toxicity is of great concern, but we would estimate that there are around a million patients with large metal-on-metal joint replacements in the world. 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. We have said that this is potentially a major concern, and what we have asked for and are recommending in this article is 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.

Currently the TGA has also approached us as to whether a study like that could be undertaken in Australia. So 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.

Senator McKENZIE: Thank you. Finally, on that period you mentioned earlier where you were not necessarily happy with the timing of the TGA with the response, I am just wondering if you have some broad dates around that period.

Prof. Graves: The specific issue—and I think that it will probably be a point of discussion that you can have with the TGA—is that, when we reported to the TGA in 2008 that there was a problem with the ASR conventional hip—

Senator XENOPHON: What month was that?

Prof. Graves: It would have been September 2008. The orthopaedic working group did not meet that year.

Senator CAROL BROWN: Sorry—the orthopaedic group?

Prof. Graves: The Orthopaedic Expert Working Group was not called by the TGA that year.

Senator XENOPHON: When were they called?

Prof. Graves: When we released the data in 2009, the group was recalled at that time.

Senator XENOPHON: What month was that?

Prof. Graves: I cannot remember. I suspect that that was November.

Senator XENOPHON: So over a year later.

Prof. Graves: We reported again in 2009, and it was on the repeated data of 2009.

Senator CAROL BROWN: Would you normally meet in two thousand and—

Prof. Graves: We had met in 2007, and on my recollection that was the first. Then we skipped a year, and then we met in 2009, and we met again in 2010, and there is a plan for this year to meet again.

Senator CAROL BROWN: So 2009 is sort of when relationships got a bit happier.

Prof. Graves: Yes, and also the ASR was withdrawn at the end of 2009.

Senator CAROL BROWN: Thank you.

ACTING CHAIR: So your follow-up questions have been asked?

Senator CAROL BROWN: They have been asked.

Senator XENOPHON: Just on that, which arose out of a line of questioning from Senator Brown and then Senator McKenzie, you made reference in answer to a question from Senator Brown about recommendations to the TGA.

Prof. Graves: Yes.

Senator XENOPHON: They were the recommendations you were referring to?

Prof. Graves: Yes, which was to introduce a two-year period of premarket clinical testing.

Senator XENOPHON: In relation to the ASRs or just generally?

Prof. Graves: No, I was talking about the general recommendations that the AOA had made, which were that this is for all new devices that we had recommended. It is, I would think, maybe three years ago now that we—

Senator XENOPHON: I just want to try to locate that report for when the TGA is here. What month and year was that?

Prof. Graves: Oh, I see—you want to go back to the 2008 issue? Is that—

Senator XENOPHON: No, the recommendation you made about the testing. You said earlier, in answer to questions from Senator Brown, that you made recommendations to the TGA—leaving aside the time line issue, which has been cleared up now. Did those recommendations relate to this or in more general terms to the ASR—

Prof. Graves: In more general terms.

Senator XENOPHON: What was that report? I ask so that I can pin it down.

Prof. Graves: It was a submission that we made directly to the TGA. It was a submission that the AOA made. It was not a requested submission. The Australian Orthopaedic Association Arthroplasty Society, which is the organisation within the AOA which represents all the joint replacement surgeons, has regular meetings, and at one of those meetings a number of years ago it was decided that the arthroplasty surgeons recommended to the AOA that they put a submission in to the TGA to consider the introduction of premarket clinical testing.

Senator XENOPHON: So it can be my lunchtime reading, what date was that?

Professor Graves: I am not sure, but we would be able to provide that report.

Senator XENOPHON: If you could, to the secretariat, or reference that. It is online, I presume?

Professor Graves: I am not sure whether it is online. That was a report that we submitted specifically and directly to the TGA a number of years ago. You could certainly have a copy.

Senator XENOPHON: If we could try, as a matter of some urgency, to get that, because I was not aware of that. Finally, on this issue of toxicity, I have a constituent who is gravely ill. There are some seriously ill people because of toxicity—cobalt toxicity in particular—and it appears that some constituents have said, 'When I have presented with these unusual symptoms—

Senator McKENZIE: 'They thought I had dementia.'

Senator XENOPHON: Yes. In some cases they were dismissed. In some of these cases their symptoms were dismissed as being unrelated. What protocols are there amongst surgeons? Mr Cosenza might want to consider this. Are there now flags so that these issues can be looked at? If a patient who has had this sort of surgery, with metal-on-metal devices, to actually have a set of protocols or a set of tests to ensure that it is not due to some cobalt or other metal toxicity?

Professor Graves: The Australian Orthopaedic Association has a metal-on-metal committee which has made recommendations to the membership about the follow-up and the testing related to metal-on-metal devices. In addition, the Australian Orthopaedic Association has an information sheet for patients—which is available on its website—related to metal-on-metal and what the association has recommended for follow-up.

In addition, the Australian Orthopaedic Association, through its membership of the Orthopaedic Expert Working Group, has had discussions with the TGA in assisting the TGA on what advice it should provide to surgeons and what advice it should release publicly related to metal-on-metal.

Senator XENOPHON: Because we are way over time, would you be able to provide to the committee details of those documents, or links to those documents? Also, as Senator McKenzie pointed out, when do they come into force?

Professor Graves: They have been there for some time, but we can provide you with copies and the dates that they were posted.

Senator XENOPHON: As long as you can understand the distress of some constituents who were completely dismissed.

Professor Graves: Absolutely, and it is of paramount concern to the Australian Orthopaedic Association.

Senator XENOPHON: Thank you very much.

ACTING CHAIR: Thank you, Professor, Dr Davidson and Mr Cosenza. There are questions we have put on notice, and the secretariat will go back and get them from the *Hansard* so that we can provide them to you

directly. There are a couple of documents that we have asked for more urgently, because we would really like to see them as quickly as possible. We need all answers by next Tuesday.

Proceedings suspended from 12:48 to 13:33

CAREY, Ms Karen, Board Director, Consumers Health Forum of Australia

BENNETT, Ms Carol, Chief Executive Officer, Consumers Health Forum of Australia

ACTING CHAIR: The committee will now reconvene. I welcome representatives of the Consumers Health Forum of Australia. Welcome back, Ms Bennett. Do you have any comments on the capacity in which you appear?

Ms Carey: I am also here as a patient who has had a failed medical device.

ACTING CHAIR: A genuine consumer, then, Ms Carey! Thank you. You have received information on parliamentary privilege and the protection of witnesses and evidence. We have your submission, thank you very much. If either or both of you would like to make an opening statement, that is fine, and then we will go to questions. I anticipate that we will go through till about 2.15 pm, to give you some sense of the time you have. Who would like to start—Ms Bennett?

Ms Bennett: I will start, and Karen will also make a statement. Good afternoon, senators. We really appreciate the opportunity to talk to you this afternoon about this important issue.

ACTING CHAIR: Ms Bennett, you will always get called by our committee!

Ms Bennett: It keeps us very busy, and we appreciate it. Australian health consumers have an interest in the effective regulation of medical devices in Australia. It is absolutely essential that we have strong systems in place to ensure the safety of medical devices and to address any issues quickly when they arise. Consumers will suffer the consequences if this does not occur. This is particularly the case for medical devices that are implanted in the body. In these circumstances it is not a straightforward matter to remove the device if something goes wrong. It is not like stopping taking a medication if there is an adverse reaction; it requires traumatic, invasive revision surgery that puts the consumer's health and life at risk.

Australia is currently experiencing a period of considerable review and reform of medical device regulation. The review of health technology assessment in Australia, the review of the transparency of the TGA and the proposed changes to the Medical Devices Regulatory Framework have all identified that there are improvements to be made and have put forward improvements and recommendations which are at various stages of consideration and implementation by government.

It has been pleasing to see some level of consumer involvement and consultation in all of these processes. Of particular concern for health consumers are the current processes for managing adverse events and failures of medical devices—and this is what I would like to address in the remainder of my opening remarks. Post-market surveillance is critical to ensuring the safety of medical devices as, in many cases, it is not until medical devices are on the market that failures become apparent. Consumers want to know that, when a device is failing at unacceptable levels, action will be taken promptly to contact and assist those who are already using the device and to prevent the use of the device where necessary. The recent Depuy ASR hip episode, in which hip prostheses continued to be used even after higher failure rates had been identified, provides a particularly compelling case study.

The review of health technology assessment, or the HTA review, recognised the need for improvements in the post-market surveillance system in Australia. Recommendations 13, 14 and 15 called for changes and improvements to existing post-market surveillance processes. Recommendation 13 was that, in order to improve the contribution of post-market surveillance to patient safety, the TGA should take steps to increase the rate of reporting of adverse events, including by health service providers and consumers. This is something that has been repeatedly identified by consumers as a necessity. Many health consumers would not know where to begin if they wanted to report an issue with a device, and health professionals have also identified similar concerns. Consumers have also identified the importance of providing formal feedback to all stakeholders involved in the reporting of adverse events to increase confidence that the action has been taken and encourage future reporting of adverse events.

The importance of this recommendation is reflected in recommendation 19 of the TGA transparency review, which calls for the TGA to more effectively facilitate the recognition and reporting of adverse events by health practitioners and consumers and promote the adverse event reporting system. It is quite clear that improvements in this area are urgently needed.

Recommendation 14 of the HTA review called for the Department of Health and Ageing to explore options for consideration by government to facilitate the expansion and use of post-market surveillance data to inform safety, effectiveness and reimbursement decisions for devices and procedures. Again, this is something that would be most welcome to consumers. It is essential that we use the available data to assess the safety and effectiveness of

devices to determine whether they should be on the market and to identify an appropriate level of reimbursement. Consumers have also called for stronger links between current processes for determining clinical safety effectiveness and the level of reimbursement. Recent moves in this area have been welcome but there is more work to be done.

Recommendation 15 called for registers of high-risk implantable medical devices and/or procedures to be established following the successful model of the National Joint Replacement Registry. Consumers have seen the benefits of the registry model and would welcome the establishment of additional registries in conjunction with other strategies to enhance adverse event reporting and action.

Regrettably, and to the disappointment of consumers, it is recommendations 13, 14 and 15 that remain subject to further consideration by government—19 months after the publication of the HTA review report. Consumers at a workshop held prior to the Joint Medicines Policy Conference in August argued vehemently for the implementation of these recommendations as a matter of urgency.

Improvements are also necessary in the communication of adverse events and potential issues to consumers and health practitioners. This is recognised in the recommendations of the TGA transparency review, particularly in recommendation 15, which calls for the feasibility study of an early postmarketing risk communication scheme for therapeutic goods; in recommendation 16, that the TGA actively promote the distribution of safety information and examine mechanisms for improving the timely communication of alerts and recalls; and in recommendation 21, that the TGA and state and territory governments work to improve the visible management of adverse event reporting in support of consumer safety. All the recommendations of the TGA transparency review remain under consideration by government several months after the release of the report.

CHF recognises that the government is operating in a tight fiscal environment and that the implementation of these recommendations is likely to require investment. But CHF argues strongly that postmarket surveillance and timely communication of adverse events and recalls are areas that will reduce health costs in the long term by ensuring that adverse events do not require increased health interventions. It will improve the health and safety of Australian consumers.

Significant and well considered reviews have been undertaken in this area of regulation. The question is why recommendations of these reviews remain on the shelf, with little government resourcing or commitment. I urge this committee in its reporting and recommendations to recognise that these are major gaps that are yet to be addressed and to call on the government to resource and implement recommendations of the HTA review and the TGA transparency review.

ACTING CHAIR: Thank you, Ms Bennett. We would like to get a copy of your statement so senators can refer to it in their questioning. I promise we will give it back. Ms Carey, could you now make your statement.

Ms Carey: Good afternoon, Senators. I have been a consumer advocate now for about 12 years. In 1996 I was implanted with a St Jude Medical mechanical heart valve which failed. Subsequent to that failure I had three strokes, an infarct kidney and spleen and three open-heart surgeries. I sat as the consumer representative on both those reviews. I think that there are some really good proposals that are very worthwhile but I have not seen anything that the government is actually supporting that would have changed my experience. The only thing that would have changed my experience was better information and better postmarketing surveillance, and neither of those two things are supported at the moment.

In health care, Australians really have three key roles—they are patients, they are consumers and they are also members of the community—and each role has different needs. Patients and their doctors need accurate information to make the right decisions about treatment options, the outcomes associated with each option and how likely it is that each outcome will occur. Consumers need an effective regulator for premarket assessment, postmarket surveillance and action when a breach is identified. We also need to know what the TGA does and does not do. I think it is really important to realise that the FDA have around 17,000 staff, the TGA have about 700 and they both manage about 60,000 products. So we have to be realistic about what it is the TGA can actually do, and I think that the public deserve to know that it is really 'buyer beware'. The public believe the TGA do a lot more than they could possibly do under their current budget constraints.

As a community we are the funders and we need accurate cost-effectiveness information about how devices work in real patients in the real world. Medical device funding and assessment have undergone significant change in the last decade, drawing heavily upon the pharmaceuticals model, but the premise is wrong. Whilst medicines can be chemically or bio equivalent, devices are not. With devices a small change can have a huge effect, and we have seen this in heart valves, hip joints and drug-eluting stents, all where small changes in the composition of surface materials have caused major problems.

These changes in the assessment process have been driven by wanting to save money instead of improving health outcomes. To this end, there has been a willingness to support the concept of substantial equivalence and allow 'me too' products to be listed without full assessment in order to get them to market early and drive price competition. For consumers, the trade-off for getting early to market before there is substantial clinical trial evidence to demonstrate safety and efficacy can only be justified when there is no comparable treatment available and where a new unproven device may be better than no device at all. To make this trade-off just to get price competition is not worth the increased risk that a 'me too' product may not be as safe as the existing product.

In cases where there is a decision to allow a product to come to market early, there needs to be a conditional listing with specific obligation for the sponsor to collect data over a predetermined time to demonstrate safety and efficacy. And there has to be rigorous post-market surveillance. Consumers understand the need to make the system cost effective and the best way to do this is to pay for only devices that work and to stop paying for the devices that do not work. To find this out we need effectiveness data in the real world with real patients. The glaring gap in the TGA proposals is the failure around post-market surveillance, which will give us this accurate, effectiveness data and which will, at the same time, create a much safer system.

The National Joint Replacement Registry has demonstrated that it is doable, that it delivers the results we need, that results do change clinical practice and that it is relatively cheap. The fact that we do not have a similar register for cardiac devices is a telling failure. We already have large amounts of data that can give us meaningful information. Consumers vote with their feet. We tend to buy things that meet our needs and not buy those things that perform poorly. Yet the government, acting as an agent for every Australian, continues to fund medical devices where there is a lot more than just money at stake, with no idea whether they do the job they claim to do, whether they cause unacceptable levels of harm and whether they represent value for money.

A post-market surveillance system is not an optional extra that we can do without; it is fundamental to the supply of high-quality, safe and cost-effective medical devices.

Senator XENOPHON: Thank you. Ms Carey, can I perhaps go to your matter—and I know it has been the subject of *Australian Story*. Two stories?

Ms Carey: One.

Senator XENOPHON: One is probably enough. Also, there was the judgment of that court case that I read some time ago. What do you think—and Ms Bennett has made reference to the HTA review and recommendations—would have made a difference in your case, which you alluded to, in you making an informed decision in terms of your surgery and avoiding the horrible sequelae?

Ms Carey: There are two things. That is, before the implant of the valve, had I had information about the options that were available to me I probably would have made a different choice.

Senator XENOPHON: A tissue valve?

Ms Carey: A tissue valve rather than a mechanical valve. Even if I had made the same choice I would have had information that put me on notice of symptoms to watch out for. So I could have acted more quickly. I could have encouraged doctors to have responded more quickly. The investigations would have been different. I think my health outcome could have changed. Even going back a step further, with proper post-marketing surveillance there would have already been records of a large number of cases before mine. When you look at the data produced by St Jude, you see that essentially the TGA should have been receiving about 600 reports a year. They had records for 10 years and yet, when my matter came up, mine was the only record they had. That shows that under the current system, although there is an obligation for sponsors to report problems, they do not get reported. That is usually because the sponsor does not find out about them because the clinician does not let them know. That whole part fell apart.

Senator XENOPHON: So really the pathway for information needs to be much clearer or mandated or there needs to be clearer guidelines for that information?

Ms Carey: There has to be an obligation on clinicians to report. Sponsors quite often do not hear about the problems because clinicians do not report. I think there needs to be clarity around what is an adverse event—whether an adverse event involves something that is an expected complication or whether it just involves something unusual. I believe it needs to include all complications. My experience is that the submissions from St Jude to the TGA said that a thrombus forms in two per cent of cases. When I went to a whole lot of published studies they were actually quoting six to eight per cent per year, which is a significantly different amount—

Senator XENOPHON: Which would have made a difference in terms of the decisions you made.

Ms Carey: Absolutely. It makes it a completely different decision, particularly where the results are life threatening. I think there is all of that around the rigour. We need to be hearing about all adverse events, not just the unusual ones, so that we can check that they are happening at the rate at which the manufacturer declares in the beginning but also the rate at which the patient is considering their decision.

Senator XENOPHON: We heard evidence earlier today from the National Joint Replacement Registry. It seems that, whilst it is a so-called voluntary system, there is a 99 per cent compliance rate, which is equal to mandatory systems anywhere in the world. I think Professor Graves and those who work with him do a terrific job. The Australian Health Insurance Association has acknowledged that. Is that the sort of model we need for other devices? Are you both satisfied that the NJRR provides a fairly robust model of information? Is that the sort of approach we need to gather that data in the first place for other devices?

Ms Bennett: Yes, we believe that that does need to be applied to other devices. Similarly to the NJRR, that would increase the rates of reporting and increase our capacity to undertake the postmarketing surveillance that is required.

Ms Carey: I agree. I think it is a good system that works. I think there are some issues around the governance and how that data is held and things that going into other registries we would want to fine tune. Certainly within months of its creation it was demonstrating that some devices were failing at much greater rates than others, and that is the proof of it really.

Senator XENOPHON: Dr Michael Armitage from the Australian Health Insurance Association gave evidence earlier today. I do not know if you heard his evidence, but he said that there should be more rigorous analysis of clinical evidence before a device comes into the marketplace, that in France there is a different approach—they must prove that their device performs better before it is allowed into the marketplace—that the TGA was not active enough in recalls and that in the UK and the US recalls and alerts are dramatically greater. Could either or both of you comment on that? What do you think the TGA is doing wrong? What do you say about Dr Armitage's criticism from the group representing all private health insurers and 11 million consumers in that regard? Where have they gone wrong? What sorts of questions would you put to the TGA when they are here in the next few minutes?

Ms Bennett: There is the issue for us of safety versus access. Of course, consumers want to have fast access to these products but at the same time we do not necessarily have the capacity with medical devices to undertake clinical trials, as you do with prescription medications, before the products are available in the market. We have not got that luxury here. We have to rely on a good, quality postmarket surveillance system that will enable us to capture that data. That is simply what we have not been able to do. That is why we are putting so much emphasis on that as being the key to ensuring that we can create faster access but with the appropriate quality and controls in place through the capture of that data.

Ms Carey: I think one thing the TGA is failing to do is follow through. Senator, I want to go back to your first question about my own experience. The third part of what happened was that I had to fight as an individual a very expensive litigation that in the end caused my bankruptcy.

Senator XENOPHON: Did they bankrupt you?

Ms Carey: Yes.

Senator XENOPHON: They did proceed, did they?

Ms Carey: They did proceed. That was really the job the TGA should have been doing. I was told by the TGA that they had no funds to prosecute. In the end, when the court case had been through and we had documents that 100 per cent proved that false disclosure had been given multiple times to the TGA, the TGA—in their own words—wrote a 'harshly worded letter' and took no action. I think that when you are going to allow devices in without the full amount of evidence you have to have post-market surveillance and you have to then have a big stick and be willing to use it. I do not believe the TGA has the capacity to be conducting those types of cases.

Senator XENOPHON: Some would argue, having read the judgment, that your case was almost a test case. But had the TGA had a more rigorous mechanism of compliance or a more rigorous assessment do you think that would have made a difference to the outcome of your litigation?

Ms Carey: It would not necessarily have made the difference because I could not demonstrate that the damage to the valve happened before it was implanted rather than during the surgery. However, the TGA should have prosecuted the fact that the manufacturer had given false disclosure about almost every material fact that they had been asked to give information about under section 30 notices. The TGA did nothing. Therefore, if you apply that across the system, they are the highest risk devices that are available and it was the world's largest manufacturer of heart devices. There is no question at all that the false information was given deliberately and not accidentally.

If the TGA cannot act in those circumstances, you would have to believe that it is a free-for-all and there is no strength behind the job that they are doing.

ACTING CHAIR: Ms Carey, when was your case? I am just following up the information.

Ms Carey: 2004.

ACTING CHAIR: Is the device that was the subject of your litigation still available?

Ms Carey: Yes, it is available.

ACTING CHAIR: Is it being used in Australia at the moment?

Ms Carey: It is being used. I would have to say, in fairness to the manufacturer, there was no adverse finding against them. What was found was that I suffered a known complication but I obviously had not been told about the fact that the complication was known and problems arose from that. It is a device in common usage and I would not want to alarm people that have it implanted.

ACTING CHAIR: But your point is that there was false disclosure to the TGA and no action was taken.

Ms Carey: There has been false disclosure and the known complication happens at a much higher rate than the rate at which it was disclosed. The device was approved 23 years ago. There have been over 1,000 studies published and the rates are much higher now, but that has never been changed.

ACTING CHAIR: Thank you. I just wanted to clarify that. I had not seen *Australian Story*, so I do apologise.

Senator CAROL BROWN: The committee has been given a document by the Department of Health and Ageing, headed *Reforms to the medical devices regulatory framework: proposals*. I am not sure of the status of this document, but I just want to read to you a section of it about proposed courses of action. It says:

The TGA considers that it is important to be more transparent and will explore the possibility of posting manufacturers' Instructions for Use (or an abstract thereof) and Australian Public Assessment Reports (AUSPAR) equivalents on the TGA website in the first instance.

Can I have your view on that and whether you think it is sufficient. I know you have outlined already some courses of action that you would like to see, but can you also comment on that for me.

Ms Carey: I think that that is a step in the right direction. To have that information available and to require that information to be available will help to bring some rigour to the information. The bottom line is that I doubt the average person on the street even knows that there is a Therapeutic Goods Administration. When I had my first problem, I did not know there was a TGA. I knew that there would be a government organisation. We all have a blind faith in a government organisation that protects us, but I would not have actually gone to a TGA website. But that does not mean that it would be the same now. Ten years down the track we are all much more internet savvy. I think it is a good step. It is a step in the right direction.

Senator CAROL BROWN: In the groups that you are here representing, how many people have come to you with issues about adverse events that have happened since they had a medical device procedure?

Ms Bennett: We have undertaken consultations with our members around the country on this issue. We do not necessarily invite individuals to talk with us. We are not a complaints body in terms of their individual cases. Certainly we have consulted consumers and used that as a basis for our recommendations to this inquiry and in other reviews that have been undertaken recently.

Senator CAROL BROWN: Can you outline to the committee how you consult. How does that work?

Ms Bennett: Sure. We have 250 members, which represent all of the disease-base groups—the small consumer self-help groups, state and territory consumer peak bodies and so forth. We call on all of those groups to provide input when we want to investigate an issue. We generally put together some kind of position or policy paper, ask some key questions and call for submissions. We run consultations. They may be face to face consultations, surveys or simply asking people to provide written comments to us in an email.

So in relation to this specific inquiry we called on our members to provide us with some comments and we made recommendations. Some of those recommendations, we note, have since been acted upon through the HTA review implementation. We know that this paper you just referred to from the TGA is now the subject of government consideration. So there have certainly been some moves in the right direction in addressing some of these issues, but we still feel that many of the concerns of our members have not been substantially addressed, largely because of the resourcing issue and because of the issue around post-marketing monitoring and surveillance. That issue was virtually unanimous in the feedback that we received from our members.

Ms Carey: I am also a former chair of Health Consumers' Council in Western Australia, which does direct advocacy for individuals. They represent between 400 and 500 serious complaints a year. They are members of the Consumers Health Forum and participate in the consultation phase. So they do get direct access to patients.

ACTING CHAIR: Of those 400 to 500 complaints, how many are to do with replacement issues? I know that it is a very hard question, but you put the figure on the table. I am really trying to ascertain the level of interest and concern.

Ms Carey: I would need to go back and check.

ACTING CHAIR: It would be wonderful if you could because Western Australia is one of the few places that do that direct advocacy. It would be useful to see what happens.

Senator McKENZIE: You mentioned in your verbal comments about improving pre-market testing. We did hear, from Professor Graves of the National Joint Replacement Registry, about his views on strengthening the rigour of pre-market testing. I just wondered if you wanted to expand on your views on that.

Ms Carey: Pre-market testing is absolutely crucial for medical devices, because once you put that device in it is really tough to get it out. It is not like a drug, which you can stop. So I do not think it is fair that patients should have devices put into them whilst they are being guineapigs. I think that you do need to have much evidence before hand.

I think that it is not unreasonable to put time limits on it. The only circumstance in which there is justification to go early to market—to give an early approval—is where there is no comparator device in that category, and therefore the patient is making a decision between a device that does not have a lot of evidence and no device at all. I think you can justify that. In terms of bringing things to market early, where there are already four, five, 10 or 20 similar devices, I just cannot see how you can justify the risk.

Senator McKENZIE: You made a comment about guineapigs. Can you clarify what you mean by that?

Ms Carey: 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 guineapigs, 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.

Senator McKENZIE: So the consumer of the device is not asked for their consent to participate in what effectively constitutes a trial.

Ms Carey: 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.

Senator McKENZIE: Right. You made a comment about putting things on the internet et cetera. I have got a constituent who has come to me quite independently of this inquiry with an issue with a medical device. They are an older Australian, into their 80s, and I am not confident that putting it on the internet would be enough of a disclosure for them. There is also, I guess, the power relationship that exists with certain cohorts within our community that are not necessarily as empowered as others in terms of that surgeon-patient relationship. As the consumer group, do you have any comments to make around that?

Ms Carey: When you are supplying information, you need to consider all of the target users and provide information in formats that suit all of those target users. There is no magic bullet and there is no one size fits all. One of the things I learned from my experience is that you get better safety information when you buy a hair-dryer than a heart valve. Other industries deal with the issue of safety warnings quite well and in health we do not. In health we rely on the doctor as the trusted intermediary. Maybe the doctor does not have all of the information, but what we know on the ground is that it is not always getting through to patients. Where you have a patient who is older, who obviously will not access the internet, that information has to be delivered in a consultation setting and it has to be written or the doctor has to give them notes to take home so they can review it, or they have to be accompanied. There has been quite a lot of work around targeting of different groups and the sort of information formats that they require.

Senator XENOPHON: I want to follow up the issue of potential conflicts of interest with medical practitioners, and in addition to that transparency in the process. What do you say should be done to address it? The matter that triggered this inquiry related to hip replacements and hip resurfacing where there were concerns expressed publicly about one of the medical practitioners who had a commercial interest in the device not disclosing, according to some patients, that he had a commercial interest. What do you think needs to be done

there? Does that include issues of rebates? Should they be disclosed of devices from manufacturers when they are giving a big rebate, for instance, to a hospital, or any other inducements? How do you deal with those potential conflicts or transparency issues?

Ms Carey: 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.

Senator XENOPHON: So if there is a commercial interest between the manufacturer of the device and the medical practitioner, that should be disclosed as a matter of course?

Ms Carey: Absolutely.

Ms Bennett: 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.

Ms Carey: There is a related issue also, and that is that some devices are complex to implant and therefore some surgeons will have trained with one device but not another. That also impacts the patient's choice. Whilst that is not a conflict of interest, it does need to be communicated, because if a patient wants a different type of device they may need to go and see a different surgeon.

Senator XENOPHON: So the surgeon should say, 'Look, that is an alternative. I don't do this surgery, but I can send you to somebody else if you want some advice on that'?

Ms Carey: Absolutely: 'These are the options, these are the ones I am trained in; if you want something else, you need to speak to somebody else.'

Senator XENOPHON: What do you think of the French approach? In France, before you can get a device on the list or get a subsidy from the state, you have to show that the device is more effective than the existing devices.

ACTING CHAIR: To be fair, Ms Carey, that is what we have been told the French approach is.

Senator XENOPHON: That is what we were told by Dr Armitage. Sorry, Chair; you are correct. Dr Armitage said that, in France, they have a more stringent approach: before a device comes onto the market, you need to show that it provides better outcomes for patients than the existing devices. There is that additional threshold.

Ms Carey: I think that it is a really difficult issue. It depends on whether or not the public is served by there being more choices available that have the same outcome. Certainly, at the very minimum, the bar should be that it is as good as the ones that are listed. I have sat on the Prostheses and Devices Committee for several years, and before that I sat on PHIMDEC, which was its predecessor, and my experience is that we make an assumption of equivalence without actually seeing the evidence—other than for joints, where we brought in the rule that you needed to have two years of evidence.

Senator XENOPHON: And that concerns you?

Ms Carey: Yes, it concerns me. It is like saying a Rolls Royce and a Mini Minor are the same because you drive both of them on the road. I am not sure that the basis for substantial equivalence is proven by the evidence.

Senator XENOPHON: Thank you.

ACTING CHAIR: Thank you, Ms Carey and Ms Bennett. I think we have asked you to follow up on some questions?

Ms Carey: Yes.

ACTING CHAIR: The secretariat will take those from the transcript, to see exactly what we asked for, and send them to you. We will try to get them to you tomorrow, along with the *Hansard*, but we will need the answers back by next Tuesday, if that is possible.

Ms Bennett: Okay. Thank you, senators.

BISHOP, Mr Anthony, Area Vice President, Australia and New Zealand, Johnson and Johnson Medical Pty Ltd

CAMPBELL, Mr Nicholas, Executive Director, Corporate Affairs, Johnson and Johnson Medical Pty Ltd

CHU, Ms Robyn, Director, Health Outcomes, Johnson and Johnson Medical Pty Ltd

ISAAC, Professor Graham, Distinguished Engineering Fellow, Hips, DePuy; Johnson and Johnson Medical Pty Ltd

Evidence from Professor Isaac was taken via teleconference—

[14:14]

ACTING CHAIR: I welcome representatives of Johnson and Johnson Medical. I note that Professor Graham Isaac is providing evidence from the UK via teleconference. While these proceedings are protected by Australian parliamentary privilege, this protection may extend only to evidence given within Australia. The committee and witnesses should be aware of the limitations of this protection. Information on parliamentary privilege and the protection of witnesses and evidence has been provided to you. Should there be an issue along those lines, Professor Isaac, I will advise you at the time. I just have to put that on the record before we start. It is not out of fear; it is just part of the guidance for what we do. The committee has your substantial submission. I think we have had a couple of letters from you as well as your major submission. We have them all on record and they are all public as you required. I invite all of you or any of you to make an opening statement and, at the conclusion of your remarks, I will invite members of the committee to put questions to you. Mr Bishop, who is going to kick off?

Mr Bishop: I will. Madam Chair and senators, thank you for the opportunity to be with you here today and to discuss some of our thoughts around the terms of reference of this inquiry. As I indicated earlier, my name is Anthony Bishop and I am the Area Vice President and responsible for Johnson and Johnson Medical, both in Australia and in New Zealand. I am joined by my colleagues who have already introduced themselves, so I will not do that again.

A bit about our company: globally Johnson and Johnson is in the arena of health care. We play in three healthcare sectors. We play in the consumer healthcare arena, we play in the medical device arena and we play in the pharmaceutical arena. Our company has been privileged to play a role in helping millions of people every day to get well and stay well.

Our company's mission is underpinned by the ethical foundation of our credo, and putting patients first is at the heart and core of everything we do. In fact, we believe we put patients first even when things do not go right. I will talk a bit about that later. The company for which I am responsible for in Australia, Johnson and Johnson Medical, is a major provider to the Australian healthcare sector, particularly to the hospital sector in both the private and the public sense. Locally, we market many different products in many areas, including keyhole surgery, minimally in invasive heart surgy, orthopaedic implants, diabetes care, stroke treatment and intervention as well as infarction prevention and many others. Our diversity of experience, we believe, positions us well to offer some thoughts on your terms of reference.

At this point, we believe it is appropriate for me to make some comments and talk about the recent experiences of some Australian patients with the DuPuy ASR hip recall. Clearly this recall has had an enormous impact upon patients, their loved ones and their healthcare professionals. Personally, I am very, very sorry for the impact that this recall has had on those patients. Senators, this is a very real issue for me and my company. We have staff members whose mothers, fathers and other family members have had the ASR hip implanted and are going through the same issues and stresses that all other ASR patients are facing at this time. Further, 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. So what actions are we taking?

Our first priority in response to this recall is the care and well-being of all ASR patients. 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 reimbursed over $21 million in approved claims, and at the date of this recall we have over 3½ thousand patients registered with Crawford.

ACTING CHAIR: Is that in Australia alone?

Mr Bishop: Yes, that is in Australia alone. We would like to see all ASR patients register with Crawford. This is just the beginning, and we will continue to work with patients during this difficult time.

Senators, as you may be aware, some patients are pursuing legal action with regard to ASR in the courts. In Australia there is presently a representative action in the federal courts that has been brought against Johnson and Johnson Medical. Naturally, we respect any patient's decision to take litigation against our organisation. As referenced in page 9 of our submission, to help ensure that the matters before the courts are heard before the courts appropriately and dealt with in the courts, we do not propose to address matters in our evidence today, ASR related or otherwise, that are contemplated and/or currently before the courts either here or overseas. My colleague Nick is rightly firm on this. That said, we remain willing to share what we can without transgressing on matters that are to be properly heard by the courts in accordance with their procedures.

As I noted earlier, the terms of reference for this inquiry are very broad, and you will note that we have provided our thoughts in our substantial submission. We have three things that we would like to highlight. Firstly, we believe that there should be alignment between the Australian regulations and the European Medical Device Directive, allowing for third-party conformity assessment to be implemented. Secondly, we believe that post-market surveillance for high-risk devices is important and that costs versus benefits need to be considered in contemplating any system. Lastly, we support the separate and clearly defined roles of the TGA as regulator, the HTA bodies and the payers in their assessment processes.

That concludes my opening remarks. As we have a team of representatives, some local and some on the phone, I am happy to facilitate our responses. Again, thank you for the opportunity to be here. We are happy to respond to your questions.

ACTING CHAIR: I just want to clarify, with reference to the rules of the Senate, whether the issues before the courts are before juries or judges—the federal courts.

Senator XENOPHON: They are civil cases.

Mr Campbell: We do not have all the information together here.

ACTING CHAIR: Certainly we will be very careful in terms of the line of questioning and the processes that we have, but I can provide you with the standing order which points out that under the rules of the Senate there is a balance in terms of legal responsibility, and, if the hearings that you are going through—and I understand that there is a case—is not before a jury and is before a judge, there is a limited protection in that the expectation of influence on a judge is less than it is on public jury. I will be watching the questions very closely, but just saying it is before the courts does not prevent questions being asked in this hearing. I will get copies of this to if you require.

Mr Campbell: We are fully aware of those standing orders and have been briefed on them. The challenge that we have and that I would like to point out at this point in time, is that the protections provided under the Senate here do not provide protections for us in relation to legal action in other jurisdictions. So that does create a challenge for us in being able to answer all of the committee's questions, where they touch upon these topics.

ACTING CHAIR: We understand that. As I have just been advised, quite rightly, by the secretariat if there are issues we would like to pursue we can go in camera, if senators would like that, in terms of information sharing, which means that there is full protection and it cannot be used outside the process.

Mr Campbell: With respect, our understanding is that an in-camera session, should it be offered and should we accept it, would give us those local protections in terms of the information but would not give us those protections in relation to litigation in other jurisdictions.

ACTING CHAIR: I am getting some clarification. We will continue and I will watch the questions very closely. It is just that possibly there could have been a meeting beforehand to have got this on record. I know that one letter came through but possibly so because of the sensitivities. Senators Xenophon, McKenzie and Brown, I will watch the questions and we will discuss each question as it comes if there is an issue. Professor Isaac, do you wish to make any comment at this stage? Mr Bishop has made a statement. Are you wishing to make an individual statement?

Prof. Isaac: No, I am not.

ACTING CHAIR: Mr Campbell and Ms Chu?

Mr Campbell: No, thank you, for us.

ACTING CHAIR: We will go to Senator Xenophon.

Senator XENOPHON: You should be well aware that a trial for damages, so any case for damages, will be before a judge alone and not before a jury. You are aware of that, aren't you? That is in Australia. In Australia there is no jury trial for damages out of the jurisdiction.

Mr Campbell: I am not aware of those details.

Senator XENOPHON: Maybe I am wrong. But take it from an old personal injuries lawyer that, unless something has changed recently, there is no jury trial and it would just be before a judge alone. Can I go to an issue similar to that which you have raised, Mr Bishop. I accept that Johnson and Johnson has many devices and many products that perform well and that are of benefit to people. But clearly something has gone seriously wrong with these ASR devices, both the resurfacing devices and hip replacements, and you acknowledge that.

Mr Campbell: Senator, if I can interrupt there. We really want to be helpful here today but because, as I mentioned just before, of legal action currently underway, not only in this jurisdiction but in others, we cannot really make any comment around anything to do with the potential aspects of ASR.

Senator XENOPHON: Well, can you comment on the work that the National Joint Replacement Registry has done in identifying higher than usual rates of revision for the devices that Johnson and Johnson manufactures?

Mr Bishop: We can comment that it has been published and we are aware of that.

Senator XENOPHON: You do not accept that it is in dispute from your point of view or you accept that—

Mr Bishop: It is not in dispute. We have seen that there is a higher rate of recurrence than we would have expected with this device.

Senator XENOPHON: And you are aware of some of the sequela and some of the awful consequences of the surgery that is required in terms of issues of metalline toxicity? You are aware that is one of the allegations made?

Mr Campbell: We would prefer not to speculate or comment on any of the allegations or suggestions that have been made in relation to the revision.

Senator XENOPHON: So you will not speculate but, Mr Bishop, you have said that you put your patients first even when things do not go right. You are not resiling from that comment of a few minutes ago?

Mr Bishop: That is right, absolutely.

Senator XENOPHON: And you don't want there to be any financial detriment to your patients if there are adverse outcomes? I acknowledge that you can do so and say there is a denial of liability but you do not want there to be financial detriment?

Mr Bishop: With regard to adverse outcomes, are you talking about the testing, the treatment and, if necessary, the revision surgery, because that is what my opening statement referred to?

Senator XENOPHON: Sure. Do we have a copy of your opening statement?

Mr Bishop: I am very happy to submit that to Hansard.

Senator XENOPHON: Yes, it might be more useful to refer to that. I am trying to understand this. Maybe I will stick to the pointy end of this and talk about how it came about that this product got onto the market. Say if I were to put to you that there was a patient that had one of these devices and the outcome has been so adverse that this person's lifespan is seriously compromised so that they would not make a court case and that they may not have long to live given where it seems on the balance of evidence. Again, I am not expecting an admission of liability. But if somebody presents to you in tragic circumstances that they have not got long to live and they will not make it to a court case because of the stage that they are at, is that something that your company would consider, with a denial of liability, to try and assist that family in terms of their loss and damage arising from what, on the face of it, appears to be linked to these devices?

Mr Bishop: We would not be able to talk about liability and such—

Senator XENOPHON: No, I am talking about general principles.

Mr Bishop: but what we are offering, if patients would like to contact Johnson and Johnson and talk to us about issues—

Senator XENOPHON: So if I knock on your door—

ACTING CHAIR: I think it would be better if you let the witness complete the answer.

Senator XENOPHON: Sorry.

Mr Bishop: If patients—or their families if they are unable to because of their condition—would like to contact the organisation, we would be willing to have conversations with individual patients, and we are doing that currently outside of the Crawford process. We would be very willing to do that and we are.

Senator XENOPHON: I make take you up on that offer on behalf of my constituent who is gravely ill. On the question of when you became alert to problems with these devices, you are aware of the NJRR findings back in 2006 where there seemed to be a spike in revision rates. I understand your constraints and the difficulties you have, but when did Johnson and Johnson become aware of a higher than usual rate of revision in these devices, both for the resurfacing and the hip replacement? Are you able to advise me as to what dates you became aware of that independently of any of the public documents from the NJRR?

Mr Campbell: We are not able to provide that information to you today. There are many different interactions that we have. We are continually monitoring and getting reports back on our devices. In relation to the one that you referred to, we do not have the exact date per se that you are referring to.

Senator XENOPHON: We know the date on which the National Joint Replacement Registry published its findings through its annual reports and information that it provided directly to the Therapeutic Goods Administration. Is there a date when Johnson and Johnson became aware, either here or elsewhere in Johnson and Johnson's worldwide operations, that firstly there was a higher rate of revision than was anticipated with these devices and also of the benchmark rate of twice the standard rate of revision, which seems to be the benchmark used by the NJRR? Is that information that would be within the possession of Johnson and Johnson either here or overseas?

Mr Campbell: We would need to take that question on notice because we do not have access to an exact date. As I said earlier, all of our devices are closely monitored by ourselves and trends are detected, but there is not necessarily a specific date that we can provide to you today.

Senator XENOPHON: But you monitor these devices closely as part of your quality assurance?

Mr Bishop: That is correct, absolutely.

Senator XENOPHON: The various jurisdictions talk to each other about a device—it is not as though Australia works in isolation from the US or Europe?

Mr Bishop: We believe so, yes. We assume so.

Senator XENOPHON: But there is an interchange of information? You are the same company.

Mr Bishop: Sorry, I thought you were talking about regulators talking to each other.

Senator XENOPHON: No, I am talking about the company itself. You exchange information on your devices on a regular basis?

Mr Bishop: We are an organisation.

Senator XENOPHON: Yes, and I would imagine, given the structure of Johnson and Johnson, you exchange information, so would there be a set of information saying 'at this point in time there was a higher rate of revision for these particular devices'?

Mr Campbell: There may be, but we cannot provide you with a specific date per se in relation—

Senator XENOPHON: At this stage or at all?

Mr Campbell: Certainly at this stage. We do not have that information available to us today.

Senator XENOPHON: Could you take that on notice?

Mr Campbell: We can take that question on notice and if we can identify that date we will get back to you.

Senator XENOPHON: On the issue of the Crawford assessment process, about 3½ thousand people have signed up to that and it involves some dialogue with those patients who potentially have been affected; is that right?

Mr Bishop: It does require the patient or someone on the patient's behalf to talk to Crawford—correct.

Senator XENOPHON: Does that affect their rights to pursue an action? If they pursue an action are they excluded from that process?

Mr Bishop: We are very clear on that. The Crawford process is about helping patients not suffer any financial detriment from the treatment, testing or, if necessary, revision. It is very separate from any other litigation that they may decide to take.

Senator XENOPHON: The financial detriment, from Johnson and Johnson's point of view, is confined to treatment, testing and revision; it does not include economic loss, pain and suffering or anything like that?

Mr Bishop: With regards to the Crawford process, the Crawford process is to do with the treatment and the testing and, if necessary, the revision. But if, under the Crawford process, if someone is unable to work we pay

lost wages. If they need to fly, say, from Kalgoorlie to Adelaide, we will pay for their taxi, flight, lunch and treatment.

Senator XENOPHON: On notice, could you provide some details about how the Crawford works. I think you have a fair bit about that in your submission.

Mr Bishop: We can do that. We can provide you with the Crawford process.

Senator XENOPHON: I would be interested in the mechanics of it. At this stage the litigation is not in your hands; it is in the hands of the plaintiffs, as normally occurs. At what stage do you think that this litigation process here in Australia and elsewhere may be resolved? Is it one, two, three or five years away?

Mr Bishop: I do not know.

Senator XENOPHON: To be fair, it is not a matter that is entirely in your hands.

Mr Bishop: That is correct.

Senator XENOPHON: It also depends on what points or take. Is Johnson and Johnson looking at an alternative dispute resolution mechanism? I will give you an example, although it is a completely different product. You may be familiar with an asbestos case in the Dust Diseases Tribunal in New South Wales—again, I am not comparing the products—where they have a fast-track system so that you do not have to reinvent the wheel for every case. The matters can be dealt with quite expeditiously. Given that there are potentially thousands of these cases worldwide has there been some consideration given to some fast-track alternative dispute resolution process for these people?

Mr Bishop: At this stage I do not have enough information to answer that. I will certainly pass that back to our team.

Mr Campbell: Can I just add something to that? Just so that the committee is very clear, the Crawford process is designed to help those patients, as Mr Bishop said, to receive adequate testing, treatment and care as they are going through all aspects associated with this recall. That is our first and foremost priority. The registration process gives them an opportunity, through the healthcare professional, to receive information.

As Mr Bishop pointed out, that includes a range of testing. It also includes things like, if they are a carer, reimbursement for those costs. It includes, for people who are self-employed, an opportunity to have another person take on their role whilst they are undergoing revision or treatment. It includes physiotherapists. It even includes gym membership. We are taking absolute care to ensure that patients who are going through this very difficult time, if they are registered under the Crawford process, receive everything that we can possibly provide to them. When it comes to matters relating to loss of income then those things are covered by the Crawford process and will be looked at. When it comes to other matters that are properly dealt with by the courts that is outside the Crawford remit. What happens—this is exactly relevant to your question—is that patients who are past that process are able to approach Johnson and Johnson direct and we will negotiate with those individuals, either directly or through their legal representatives.

Senator XENOPHON: If somebody wanted to go to Johnson and Johnson direct and say, 'I don't want to spend three years in court. I have issues in terms of losses, damages, pain and suffering,' are you saying that if they want to make a claim for pain and suffering they need to go through the court process?

Mr Campbell: No, we are not.

Senator XENOPHON: You are not precluding some negotiations direct.

Mr Campbell: Absolutely not. Any person can approach our company and we will negotiate directly with them.

Mr Bishop: We are doing that at the moment with some individuals who have decided to take that approach.

Senator XENOPHON: My final question might take more than a minute to answer. Perhaps I should direct this to Professor Isaac and also to the witnesses here. Firstly, what pre-market testing was done for these devices? Secondly, what action was taken by Johnson and Johnson in relation to the information that came out of the National Joint Replacement Register as early as October 2006?

Thirdly, Dr Tom Joyce, a bio-engineer at Newcastle University, has done work on these failures, and I think his work is well known, about the level of revisions and the failures of these devices. When did Johnson and Johnson become aware of Dr Joyce's work and his colleagues out of Newcastle University in the United Kingdom?

Mr Campbell: Your question has got three parts to it. What we might do, if it is okay with you, is answer them one after another and do the best we can in relation to that. The first question where you are talking about these devices, I think Professor Isaacs is the best person to answer that because he has the technical knowledge

and he is very able to present the right information in relation to the board testing in relation to all medical devices.

Mr Bishop: That was about what premarket testing was done, was it, in relation to the ASR product?

Senator XENOPHON: Yes, both products.

ACTING CHAIR: Professor Isaac, I think that has been effectively passed to you, so are you clear what the question is?

Prof. Isaac: Yes, I am. The design process was such that we looked at products that were already on the market and we engaged an expert team of experienced resurfacing surgeons and also surgeons who are experienced in total hip replacements. We then sought their views on how the products on the market at that time, which would be late 2001, may be improved. We then went through a design process and went through a period of testing. The sort of testing that was carried out was things such as wear testing on hip simulators. That was quite new for products of this type coming onto the market. We did a lot of cadaveric testing: how these components are implanted and whether there were any unforeseen issues. We also carried out the statutory tests that we have to do to make sure that the materials are appropriate and that they pass all the ISA standards. At that point we completed the development process and put it into a limited clinical evaluation with the designing surgeons—

Senator XENOPHON: Sorry to interrupt. Can you advise where the testing occurred? Did it occur just in one place and was it part of this global harmonisation model in terms of testing generally?

ACTING CHAIR: Also, the period of time. When was this done?

Prof. Isaac: The development process started in the second half of 2001 and the first clinical implementation was July 2003. So the testing took place during that period. I think you also have to remember that we were not starting from scratch. We had a lot of technologies that were successfully used on other products that we could utilise in resurfacing.

Mr Campbell: There was a supplementary question from the chair.

ACTING CHAIR: He began his answer with that. We did not get where.

Prof. Isaac: We had a number of centres we engaged. We worked with the University of Leeds, we did our own internal testing, we also worked with the University of Hamburg. It was a mixture of internal and external testing.

Senator XENOPHON: And the issue of Newcastle University and Dr Joyce: when were you aware of the issues in terms of the matters raised by the National Joint Replacement Register, any other registers overseas as well that may have highlighted the difficulties, and the work that Dr Joyce did out of Newcastle University?

Mr Campbell: Can you clarify for us what are you referring to in relation to the work out of Newcastle University?

Senator XENOPHON: Dr Joyce, a bio-engineer out of Newcastle University, did work on the failures of the devices, problems with the particular devices, as I understand it. He said this was happening back in 2008-09. They worked on a coordinate measurement machine which showed damage to the surface of the joint but measured it in 3-D as well in terms of the metal on metal rubbing.

Mr Campbell: Apologies, Senator; we cannot comment on that particular question because we are not actually familiar with that particular information, but it also comes into that realm of matters to do with potential courts, and we cannot answer those questions here today.

Senator XENOPHON: Can you answer about the work of, I think, Dr David Langton and his colleagues, who had been warning DePuy for years that their research was uncovering high failure rates of the ASR hip and high concentrations of metal ions in some patients? Is that something that you are able to comment on?

Mr Campbell: No, we are not. That question and the lead-up to it basically refer to matters that will be before the courts in this jurisdiction and in others. Whilst we would like to be able to help the committee and answer all of your questions here today, that particular one I am afraid we just cannot do.

Senator XENOPHON: Okay, I will not pursue that line of questioning for now, Chair.

Senator CAROL BROWN: Would you be able to just confirm with me whether you withdrew the ASR device or it was recalled, in 2009?

Mr Campbell: Could you repeat the question?

Senator CAROL BROWN: The ASR device—was that withdrawn or recalled?

Mr Campbell: Were you referring to here in Australia?

Senator CAROL BROWN: I am sorry; in Australia, yes.

Mr Campbell: Johnson and Johnson Medical through DePuy withdrew the ASR product from the Australian market in December 2009.

Senator CAROL BROWN: What action kicks in when you do that? When you withdraw a product, what do you do as a manufacturer? Do you write to somebody? You obviously tell the TGA. What happens?

Mr Bishop: Robyn, are you okay to talk through the process that we go through with the TGA?

ACTING CHAIR: Ms Chu, we have had a number of questions today about what happened after that, once you made the decision to withdraw. We would very much like to hear the process that happened from the time the decision—

Mr Bishop: We were going to talk generically about the process.

ACTING CHAIR: Generically, in terms of what happens when the withdrawal occurs.

Senator CAROL BROWN: Okay.

Ms Chu: Firstly, can I just say that my expertise relates to the terms of reference about the HTA review and reimbursement of products on the prosthesis list.

ACTING CHAIR: Ms Chu, Mr Bishop referred this question to you; we did not. I am happy to ask anyone, but Mr Bishop actually said that you would be answering this question.

Mr Bishop: Are you okay to answer this question?

Ms Chu: My knowledge is actually limited in this area, so I just wanted to say that upfront first. But 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.

Senator CAROL BROWN: So it was actually withdrawn and not recalled?

Mr Bishop: That is correct.

Senator CAROL BROWN: That was December 2009. And when was the ASR device subsequently withdrawn worldwide?

Mr Campbell: Sorry, I could not understand your question.

Senator CAROL BROWN: When was it withdrawn worldwide?

Mr Campbell: On 24 August 2010 a field safety notice was issued, and a worldwide voluntary recall of ASR products was undertaken after receiving information from some new sources around that time.

Senator CAROL BROWN: So the decision was made that you required more data to support a worldwide recall?

Mr Campbell: Sorry, Senator, we cannot speculate on the reasons for the decision.

Senator CAROL BROWN: As I understand it, part of the monitoring and reporting process that is in place with the TGA and manufacturers is mandatory monitoring of your devices and reporting to the TGA. Can you tell me how that process works within Australia and within your company, not just for the ASR but generally? Are adverse events reported to you by your users? How does it work?

Ms Chu: Part of our obligations when we receive approval to supply products is that we must have a quality management system in place, which means there is a post- market surveillance program to ensure that all product complaints, all adverse events, in the marketplace are reported back to our company. And then there is a review period, by which time the TGA is informed, and an investigation.

Senator CAROL BROWN: Can the TGA tell you to withdraw something, or can they only suggest?

Mr Bishop: My understanding is that they can tell us to withdraw. But I have a whole department that looks after this, so it would be unfair for me to be considered an expert in the TGA process.

Senator CAROL BROWN: If the TGA came back to you and suggested that a product be withdrawn, how long does it take you to respond? Have you ever withdrawn other devices from the Australian market if the TGA have asked for them to be withdrawn?

Mr Bishop: We have withdrawn other products from the Australian market. My understanding is that we have to let the TGA know within a certain period of time, and then our quality management system comes into play—

that is, that it meets the Australian regulatory guidelines and also our international Johnson and Johnson guidelines.

Senator CAROL BROWN: But you do not have the information on whether there is a—

Mr Bishop: I can take that on notice. I do not personally know. I think it is 24 hours for some devices and longer for others, but it would be difficult for me to comment.

Senator CAROL BROWN: That would be very good. And that is only when the TGA asks for it to be withdrawn, not just when they suggest it?

Mr Bishop: Correct.

Senator CAROL BROWN: If you have procedures in terms of a course of action suggested by the TGA, I would be happy if you could also provide that information.

Mr Bishop: Will do.

Senator McKENZIE: Thank you for attending our inquiry. As a provider of both pharmaceuticals and medical devices to the Australian market can Johnson and Johnson make broad general comments on the differences in meeting both the approvals and monitoring of both of those different types of products?

Mr Bishop: The individuals we have here today are all medical device people. Our organisation in Australia and globally is broken into three different areas. My expertise for 17 years has been devices.

Mr Campbell: Unfortunately, I am not able to answer that question but we will take it on notice and get back to you on it.

Senator McKENZIE: A lot of senators here today have asked around this question, but what internal monitoring process does Johnson and Johnson have with regard to the NJRR and other registries? We have heard comments that you monitor it closely. et cetera. I am interested in your internal processes that ensure that you can monitor it closely. What are they?

Mr Bishop: We look at all the different areas of post-market surveillance—the NJRR, the British registry and others. Our organisation looks at all of them. If we do require information, we can actually make a submission to the NJRR and they will provide us with data on our products over certain time periods. And we do do that from time to time.

Senator McKENZIE: Do you do that regularly? Do you every couple of months look at X, Y and Z?

Mr Bishop: I am not familiar with how often people look at the NJRR. We need to request information from them and we receive a yearly report. One of the recommendations that was made previously had the potential to have the industry and other stakeholders involved in the implementation and also the analysis of some of the data so that we could get more real-time data. We would see that as an improvement to the NJRR, which we believe is a good system today but could be improved in that area.

Senator McKENZIE: I guess that goes to my next question. I presume that hips are not the only device that Johnson and Johnson provides to the Australian market. Would you support similar registries across different devices?

Mr Bishop: Which ones?

Senator McKENZIE: I do not know the catalogue but I am assuming that you have other types of devices.

Mr Bishop: High risk devices?

Senator McKENZIE: Yes, in a similar category to the one that has caused this inquiry?

Mr Bishop: Yes, we do support that.

Senator McKENZIE: You would support a similar registry across all of those high risk devices?

Mr Bishop: We do support that. I think it is important that not every registry needs to be run in Australia. Certainly registries could be run in different countries and in different jurisdictions and they could provide good inputs for global understanding of products.

Mr Campbell: If I can add to Mr Bishop's answer, Senator. In terms of registries, you are correct: there are multiple registries. Because of our diversity in other medical devices area, our company is asked to be involved in a number of the registries. We believe that the registries have a very important role in post-marketing surveillance. It is important, though, that they all have guidelines from a body such as the TGA so that all these registries basically have some uniform guidelines to meet the governance aspects, the data sharing aspects and the reporting aspects, as well as the involvement of industry representatives where appropriate and patient

representatives where appropriate. We believe that they are some of the items that will improve registries here in Australia so that in this jurisdiction there will be some of the best registry processes in the world.

Senator McKENZIE: I have two more questions. You make a comment about resourcing for the TGA, and I wondered whether you could expand on that. This came up in other evidence today. I am not suggesting you do it.

Mr Campbell: Which page are you referring to?

Senator McKENZIE: Page 12 of your submission. This is in recognition of the resources available to the TGA. Could you expand on your comments there.

Mr Bishop: Certainly we believe that one of the areas for improvement in the TGA is the time it takes for a product to move from when we submit it for registration to when it is actually registered. Sometimes it takes longer than the time that we originally considered it should take under the legislation. That was really our comment.

Senator McKENZIE: Thank you. In what way do you think pre-market assessment can be strengthened?

Ms Chu: Our regulatory system in Australia is very similar, if not identical, to the European regulatory system in terms of technical standards and assessment processes. Our view is that a product which has already been assessed by a notified body in Europe should be accepted for approval in Australia. In terms of 'strengthening', I think if you are referring to the evidence requirements for product registration and approval, yes. A lot of products are being up-classified from class 2B to 3 and that is part of the harmonisation process that the Australian regulatory system is working with the European system.

Back to that point about resourcing: one of the issues we have is that the notified bodies in Europe are quite well resourced. If the product has already been assessed through these notified bodies and been given EC certification, we see that, in order for Australians to get access to innovative technologies, our regulatory system should adopt EC certification as approval.

Senator CAROL BROWN: We have heard evidence here today that favours pre-market clinical trials. That is not something that you would support, regardless of the international harmonisation regime?

Mr Bishop: Perhaps that is a question we could ask Professor Isaac, because he is an expert in this area. Professor Isaac, are you able to talk about more information about premarket testing?

Prof. Isaac: Could you clarify the question, please? What aspect of premarket testing? Laboratory testing or—

ACTING CHAIR: The committee's view was looking at issues around premarket testing. On page 19 of your submission—I do not know whether you have a copy of it—you put the kinds of evidence that Ms Chu has just given us. I will go back to Senator McKenzie, who asked the original question, to clarify what her question was.

Senator McKENZIE: It just goes to some evidence we have heard today about ways that we can strengthen premarket assessment, particularly around new devices. I am just wondering what Johnson and Johnson's view of that would be; if they had any ideas around how to strengthen that.

Prof. Isaac: I think we need to maintain a high level of laboratory testing to make sure that we have covered all the obvious issues that may arise. But I think in terms of premarket assessment there is quite a strong regulatory system in Europe. If the product is judged to be substantially equivalent to a product that is already on the market, then the product cannot be CE marked without a regulatory trial. However, there is a requirement for us to go into a post-market surveillance. That would give us detailed information on how the product is performing, and that is very important because registers can tell you a certain amount but cannot give you some of the detail. So post-market surveillance is obviously very critical in assessing how products are performing.

If, on the other hand, products are deemed to be significantly different, then they do go into a regulatory trial, and the terms and conditions of the trial will be agreed with the regulatory body in advance. Then we would go through a process of working through our trial and submitting to the notified body to apply for a CE mark.

Senator McKENZIE: Johnson and Johnson operates in a very competitive environment, I am assuming—I hope. What incentives does Johnson and Johnson employ within that competitive marketplace both to hospitals and to doctors in terms of getting their product on the shelves—like any other business in any other marketplace?

Mr Bishop: Sorry, Senator, can you repeat that question?

Senator XENOPHON: Rebates, for instance.

Senator McKENZIE: Yes, rebates et cetera; what mechanisms does Johnson and Johnson employ as a business, as any other business in any other market place positions their product if it is truly a competitive market place? Could you outline what they are in a general sense? Obviously commercial interests will not allow you to

get to the specifics, but in a general sense both with hospitals and with practitioners themselves how do you position your products most effectively?

Mr Campbell: Before Mr Bishop answers that question, I want to say that we do have to be very careful, Senator—and you have pointed to this in your question—because matters in relation to dealings with hospitals and the like very much come under competition, and we have to be very careful in providing information like that in an open forum. That might overstretch our remit here today.

Mr Bishop: Thank you, Nick, for that start. We do follow the MTAA code of practice, so any interactions we have with doctors and with hospitals need to go through the Medical Technology Association of Australia's code of conduct. We also have our own internal Johnson and Johnson code of conduct so that everything we do is audited independently and is all above board. We have commercial arrangements with hospitals; we do not have commercial arrangements with regard to the use of our products with surgeons.

Senator McKENZIE: Can you comment more broadly on rebates?

Mr Bishop: Rebates to hospitals? Rebates to doctors? Rebates to—

Senator McKENZIE: To hospitals.

Mr Bishop: We have commercial arrangements with hospitals.

Senator XENOPHON: May I just follow that up, Chair? I know we are going over time, but there are just a couple of things. If a medical practitioner has a commercial arrangement with Johnson and Johnson as the manufacturer of a device, what requirement do you place on that medical practitioner to advise his or her patients that they have a commercial interest in that device?

Mr Bishop: Can you repeat the question, Senator?

Senator XENOPHON: Yes, sure. If a surgeon has a commercial relationship with Johnson and Johnson, the manufacturer of a device, and is also practising surgery, do you tell that surgeon, 'You ought to notify your patients that you have a commercial arrangement as part of the process of advising the patient of the risks of surgery and getting consent from the patient'?

Mr Bishop: Certainly, we believe that the surgeon should let the patient know of that relationship.

Senator XENOPHON: But from your company's point of view as the manufacturer, if there is such a commercial relationship, do you require the doctor to advise patients of that?

Mr Bishop: I am not sure if that is a requirement, but we would and as the head of this company I would—

Senator XENOPHON: If you could take that on notice. You have referred to internal codes of practice; could you provide those internal codes of practice to us?

Mr Bishop: Yes, we can.

Senator XENOPHON: The other issue is that, presumably, the Australian division talks to other parts of Johnson and Johnson worldwide. So what protocols are in place and what thresholds are there—you can provide this on notice—for Johnson and Johnson to advise regulators, both regulators in the jurisdiction where the problem is highlighted and regulators generally, about what appear to be early signs of difficulties with a particular product or device? In terms of sheer risk management, presumably there would be some thresholds and criteria in place to say, 'Once we get to this stage, we ought to notify the regulators that we see this emerging as a potential issue.'

Mr Campbell: Senator, we will take that question on notice and come back to you on that.

Senator XENOPHON: But you do have risk assessment procedures for notifying regulators, don't you?

Mr Campbell: Yes, we do, and they follow the requirements of the regulators in each of those jurisdictions.

Senator XENOPHON: You do not have anything independent of the regulators? Do you have any internal criteria for the company worldwide?

Mr Campbell: Yes, we have internal criteria that we follow in terms of collecting the information and then notifying the regulators.

Senator XENOPHON: If you could take that on notice, that would be very useful. Thank you.

ACTING CHAIR: I have one question to put on notice. Could you explain further the statement on page 30 of your submission that 'Australian standards are out of date'. That would be very useful.

Mr Campbell: Yes.

ACTING CHAIR: Also, we note that the bulk of your submission was on the re-use of single-use devices. I can assure you, the committee has heard that, even though there are no questions on it. You spent so much time

telling us your position on it that I thought you should know that we did note it. Thank you very much. In terms of the process, we will check the *Hansard* to make sure we get all the questions on notice to you tomorrow, and we need the answers back by Tuesday.

Mr Bishop: On behalf of Johnson and Johnson, senators, thank you very much for the opportunity to be here.

ACTING CHAIR: Thank you very much. The committee will take a short break.

Proceedings suspended from 15:08 to 15:21

BARTLETT, Mr Richard, First Assistant Secretary, Medical Benefits Division, Department of Health and Ageing

CHESWORTH, Mr Peter, General Manager, Pharmaceuticals, Health Industries and Enabling Technologies, Department of Innovation, Industry, Science and Research

HAMMETT, Dr Rohan, National Manager, Therapeutic Goods Administration

KEANEY, Dr Megan, Principal Medical Adviser, Therapeutic Goods Administration

LEARMONTH, Mr David, Deputy Secretary, Department of Health and Ageing

RICHARDS, Dr Brian, Executive Manager, Health Technology and Medical Services Group, Medical Benefits Division, Department of Health and Ageing

WOODLEY, Mr Peter, Assistant Secretary, Private Health Insurance Branch, Medical Benefits Division, Department of Health and Ageing

ACTING CHAIR: We welcome officers from the departments. My understanding is that we have the Therapeutic Goods Administration; the Department of Innovation, Industry, Science and Research; and the Department of Health and Ageing. I think it is just easier for you all to be here together and for the questions to be answered by whomever we ask. Thank you very much. You all have information on parliamentary privilege and the protection of witnesses and evidence. I remind witnesses that the Senate has resolved that an officer of a department of the Commonwealth or a state shall not be asked to give opinions on matters of policy and shall be given reasonable opportunity to refer questions asked of the officer to superior officers or to a minister. This resolution prohibits only questions asking for opinions on matters of policy and does not preclude questions asking for explanations of policy or factual questions about when and how policies were adopted.

The committee has your submissions. Mr Chesworth, we do not often have you in front of this particular committee, so you are welcome. We are old friends with the other officers! If any or all of you have opening statements, we can go with them and then we will go to questions. Does any of you have an opening statement?

Dr Hammett: No.

Mr Learmonth: No.

ACTING CHAIR: I take it that the officers have been listening to the evidence and are aware of the submissions we have, because there have been a number of questions, I am sure, that have come specifically out of today's evidence and the submissions, as well as personal questions.

Senator XENOPHON: Thank you for being here today. You may have heard the evidence—and you may be familiar with the submission—of Dr Michael Armitage from the Australian Health Insurance Association.

Dr Hammett: I have seen the submission and am aware of some of the evidence; I was not able to see it all.

Senator XENOPHON: Dr Armitage essentially said that the Therapeutic Goods Administration is 'not active enough in recalls'. He said that, in contrast, in the United Kingdom and the United States recalls and alerts are dramatically greater. How do you respond to that criticism?

Dr Hammett: I would be very interested in what led Dr Armitage to form that opinion. Certainly the data we have would suggest that that is not the case. As a background to that, it is important to understand that there is in place an international system of recalls of medical devices, and there is a process of notification amongst regulators of those recalls. That network is known as the NCAR system, the National Competent Authority Reporting system. Australia and the TGA actually host that system and provide the secretariat for the rest of the world for that system. In fairness to Dr Armitage, one of the challenges TGA has had is in adequately communicating how it undertakes its regulatory functions. Perhaps the reason Dr Armitage is not aware of the fact that we undertake extensive numbers of recalls every year is the fact that we have not been—

Senator XENOPHON: But the number of recalls is in the public arena—is it not?

Dr Hammett: It has not been in the past. In fact, we are just moving to publish that and make that fully available. To give you a sense of it, in 2010-11 we have undertaken 422 recalls of medical devices. Indeed, any of the recalls that would apply in the US or the UK for products that are on the Australian market would be undertaken here.

Senator XENOPHON: Is the system of transparency now in place for the number of recalls, the type of recalls and the basis for those recalls?

Dr Hammett: The transparency review of the TGA has made a number of recommendations about that which are currently under consideration by government.

Senator XENOPHON: Was that review concluded in March of this year?

Dr Hammett: No, 30 June this year.

Senator XENOPHON: Can the department advise when that review and the government's response is likely to be made public?

Dr Hammett: The review has been made public but the response is a matter for the government.

Senator XENOPHON: I understand another review was undertaken in March this year regarding a number of recommendations that were made. Is that a separate review?

Dr Hammett: A separate review was referred to in evidence earlier today. The health technology assessment review was a joint ministerial partnership that reported, I believe, in March 2010. There was one particular recommendation of direct relevance to the TGA which was around recommendation 8—improving the oversight of a high-risk, implantable devices—and that recommendation was accepted. There were a number of other recommendations that related to post-market surveillance.

Senator XENOPHON: Dr Armitage's submission said:

> The recent HTA has seen significant changes to the PL process, in particular the accelerated grouping and benchmarking exercise. The inherent problems of the PL and listing processes, which were not addressed prior to exercising the HTA Review recommendations, still exist.

Do you have a view on that? Do you agree that there are still outstanding matters in terms of the recommendations that were made and that there is still a gap in the information and the way action is undertaken by the TGA?

Dr Hammett: That recommendation does not refer to the TGA at all. It relates to the reimbursement processes in the department, so I will handover to my colleagues to respond to you on that.

Mr Bartlett: The HTA review on the changes made to the Prostheses and Devices Committee and now the Prostheses List Advisory Committee was about rebalancing the arrangements to make it work more effectively. We are in the process of going through a grouping and benefits setting process, which is designed to minimise the level of co-payments consumers pay and ensure a consistent price is paid for similar devices. That work is going well.

Senator XENOPHON: Dr Armitage said that, in contrast, in France there is a predetermined number of devices that are approved for co-payments; that they must prove their device performs better before they are listed. Is that the criteria that apply in Australia?

Mr Bartlett: No. The criteria that are applied in Australia are essentially about maximising choice for both doctors and consumers. The difficulty of the approach that you are using is that there may be a number of devices—

Senator XENOPHON: No, do not verbal me. I was just referring to what Dr Armitage referred to. He said, 'It is not my approach; it is the approach that appears to be used in France.'

Mr Bartlett: Yes, and in Australia we have taken an approach which is one about maximising choice. The difficulty of generalising is that what is true in general may not be true when you deal with a specific case of a patient. A device that may not perform in a superior way across the board may well perform in a superior way with an individual patient. We have a system that in effect allows doctors to make those choices with patients.

Senator XENOPHON: But how do you assess that?

Mr Bartlett: If you are talking about hips and knees, for example, we have the National Joint Replacement Register that looks at the relevant performance of some of these devices, but at the end of it it is down to doctor choice with patients. If there are ongoing problems in terms of particular devices, TGA deals with them.

Senator XENOPHON: Let us look at the relationship between the National Joint Replacement Register and the TGA. Dr Hammett, did you hear the evidence by Professor Graves earlier today?

Dr Hammett: I heard some of it.

Senator XENOPHON: Okay. Professor Graves says that the TGA has direct access to the NJRR's database. Is that correct?

Dr Hammett: That is correct.

Senator XENOPHON: That whilst the information is provided on a voluntary basis there is 99 per cent compliance, so it is very comprehensive in terms of world's best practice. He said in relation to the ASR devices that triggered this inquiry in relation to the hip resurfacing device that the NJRR was first alerted to issues about that device back in 2006, that there were some concerns back in 2006 that there seemed to be a spike in revision rates. When did the TGA become aware of the spike in revision rates for the ASR hip resurfacing device?

Dr Hammett: There is probably a bit of background that you need to understand in understanding an adequate answer to that question. In 2006 when Professor Graves reports that the joint registry noted potentially an upswing in the number of revisions for the ASR resurfacing hip there was not at that time a well-established process for provision of data from the NJRR to the TGA. Indeed, having heard him make that comment in his evidence today I had a look at the 2006 report and with the committee's indulgence I am quite happy to read the relevant section from that report. Even in hindsight, I think it reflects the fact that there is very limited information about the ASR at that time. The report actually says on page 57:

The ASR has a higher revision rate when compared to the BHR—

which is another sort of hip—

but it is not significant.

That is what the report said. So there was no transmission of information directly from the NJRR to the TGA in 2006. We did become aware of the ASR issue in 2007 as a result of the NJRR. It is important that the committee understands that the TGA regards the NJRR data as critical to us undertaking our regulatory functions and we work very closely with them and we highly value their work. But many of these things look easier in retrospect than they do prospectively, and prospectively in 2006 the joint replacement registry said that the ASR issue was not significant.

Senator XENOPHON: Let us not try and look at things through the benefit of hindsight, let us look at things at the time you were given the information. By September 2007 did the TGA have further information from the NJRR about the rates of revision that were in the realm of outlier rates of revision for that device?

Dr Hammett: We certainly did. As a result of the 2007 report, which showed there was a higher rate of revision of the ASR resurfacing type prosthesis, in 2007 the TGA established a new committee of the TGA, the Orthopaedic Expert Working Group. Mindful of the excellent data coming out of the joint replacement registry, we saw a need to actually capture that data—

Senator XENOPHON: Sorry, when was the Orthopaedic Expert Working Group established?

Dr Hammett: In 2007 it met for the first time.

Senator XENOPHON: What month?

Dr Hammett: I may have to take that on notice. It was established as a subcommittee of our Medical Device Evaluation Committee. Its establishment was endorsed in June 2007, according to the notes I have here. We specifically set up a process so we could 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.

Senator XENOPHON: So the outlier rates of revision became apparent by September 2007. Is that right?

Dr Hammett: Indeed, they were apparent to the NJRR probably prior to that. As part of the finalisation of the annual report, they go through a number of steps.

Senator XENOPHON: Probably July or so.

Dr Hammett: Somewhere around there. Sure.

Senator XENOPHON: In September 2008, there was a further report, wasn't there, that again emphasised the rates of revision of the ASR hip resurfacing?

Dr Hammett: There were a number of things that happened between 2007 and 2008. The Orthopaedic Expert Working Group had a look at the data around the ASR. We asked them: 'What do you think is the significance of this and what do you think it might be related to?'

Senator XENOPHON: When was that? You may be aware of the criticism of Professor Graves. He said that he was not happy with the timeliness of action by the Therapeutic Goods Administration. You may have heard that evidence.

Dr Hammett: I did.

Senator XENOPHON: In terms of timeliness, I think in answer to a question from Senator Brown, he said that in September 2008—when I think there was a further report—the Orthopaedic Expert Working Group was not called at that time and they did not meet until November 2009 and that it was in the province of the TGA to

call the expert working group to meet about the concerns with this data of high rates of revision. I think that is a fair summary of what Professor Graves has said. Does that accord with your understanding?

Dr Hammett: It does. I would not want you to verbal Professor Graves. It accords with my understanding of his comments.

Senator XENOPHON: Yes, but you agree that my notes reflect accurately what Professor Graves said.

Dr Hammett: On the evidence he gave; that is correct. Perhaps just to clarify that time line, because I think it is important to have clarity on that: between 2007, when we first became aware of the issue and sought the advice of the expert working group, their advice was that this may be due to the technical complexity of implanting this particular joint prosthesis. Their recommendation to the TGA—and you need to be aware that Professor Graves was part of this group and was part of the group that made this 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 that in fact reduced—

Senator XENOPHON: What time frame is this?

Dr Hammett: This is in 2007. I will look to my colleagues to check that that is correct. Perhaps we will take on notice the exact time that that occurred. Between 2007 and 2008 that training program was instituted. Ultimately, what it did was in fact reduce the rate of implants for the ASR hip at that time. So, while it had been increasing in its rate—

Senator XENOPHON: Sorry. Reduce the rate of implants or revisions?

Dr Hammett: Implants. 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.

Senator XENOPHON: Can we just go back a second. You said that was a risk mitigation measure in terms of retraining surgeons because those hips were not being inserted appropriately. But, in hindsight, can you say that that was not the problem at all; there was a fundamental problem with the device in terms of the metal rubbing on metal and the very design of it, which, I think, Newcastle University in the UK did a lot of modelling on. In other words, it was risk mitigation but was it the appropriate risk mitigation? Wasn't the problem something quite different from the nature of the insertion?

ACTING CHAIR: Senator, I will just caution on the fact that we begun this whole series of questions by saying that we were not going into hindsight; we were looking at the times. That was the way the officer was answering.

Senator XENOPHON: Sure. I can rephrase that. I am happy to rephrase that. Can you say on what basis risk mitigation was the factor in terms of retraining surgeons, and did it eventually change the outcomes in terms of the number of revisions for these devices? Retrospectively, can you say that that risk mitigation did not lead to a better outcome?

Dr Hammett: My answer to that would be that the decision around that risk mitigation was made on the best available scientific and clinical evidence at the time. We pulled in the best experts from around the country, including Professor Graves, who said, 'Here's what's happening.' You need to understand that, for any new technology, any new device or any new surgical therapy—and we have talked about this at previous estimates hearings—there is a learning curve for surgeons as they undertake a new procedure and get better at it. So the best advice was: let us train them more and let us watch it. And that is what we continue to do.

Senator XENOPHON: I understand, but is the best advice now that that retraining would not lead to different outcomes, given the nature of the device?

Dr Hammett: The outcome that occurred was that fewer people used it. So in fact it did lead to a direct reduction in what has subsequently been shown to be a high revision rate, because fewer patients got the procedure. So it was effective in that sense, and certainly Australia has fewer ASR hips implanted than many other countries. As you are aware, Australia removed the product from the market before anywhere else in the world. There is a very good story about the way Australia has put in place effective mechanisms for monitoring these products. It is no accident that Professor Graves is chairing the international joint replacement registry. It is no accident that the TGA is chairing the international regulatory group, because Australia is in fact leading the world in how to monitor these devices.

Senator XENOPHON: But I think both the criticism from the Australian Health Insurance Association and the concerns expressed by Professor Graves have been about the timeliness and appropriateness of actions on the

part of the TGA given the information provided by the NJRR. There is no question about the utility of the information that the NJRR provides, but what do you say about the timeliness of that action? The Orthopaedic Expert Working Group was not called until November 2009 to assess matters that some say you would have been alerted to as far back as 2007.

Dr Hammett: There are a couple of separate issues, as you would appreciate. There are two separate Johnson and Johnson and ASR hips. The 2007 data related to the ASR resurfacing component, and the training program was put in place. It is unlikely that the effect of the training program is going to be realised in a week, a month or even potentially a year. To upskill surgeons, to improve their techniques for inserting a particular device, will take some time. As we said, in 2006 there was no significant issue identified—it was identified as not significant. In 2007 it did reach statistical significance. In 2008 that was confirmed, but again in 2008 the Orthopaedic Expert Working Group were consulted and they agreed that the monitoring and training program that had been put in place was appropriate for the ASR hip. That was in 2008.

Senator XENOPHON: Can you provide the committee the flow of information between the TGA and the Orthopaedic Expert Working Group back in 2007 and 2008? I think your evidence is that the Orthopaedic Expert Working Group said, 'We don't need to do any more on this,' back in September 2008.

Dr Hammett: I am sure we can provide you with correspondence that is relevant to that.

Senator XENOPHON: But is it your evidence that you did not push the issue further in September 2008 because the Orthopaedic Expert Working Group advised the TGA that no further action was needed at that time, other than the retraining or upskilling of surgeons?

Dr Hammett: No, that would not be my evidence. My evidence would be that there were some recommendations made to us in 2007 or 2008. They were followed, and we continued to use the Joint Replacement Registry data to monitor the effect of that. In fact, in the 2008 and 2009 reports a new problem with the ASR hip became apparent. With the XL head conventional hip, as opposed to the resurfaced—

Senator XENOPHON: Which year—2008 or 2009?

Dr Hammett: It became apparent in 2008. It was repeated in 2009's registry data and, very shortly after the release of that, with the TGA having communicated with the company, they withdrew it from the Australian market. Again, that happened 10 months before anywhere else in the world because of the information arising from the Joint Replacement Registry being communicated by the TGA to the company to effect removal from the market.

Senator XENOPHON: So in September 2008 a different sort of problem became apparent with the device. At that stage you were alerted to a different sort of problem in terms of why the device was failing. Is that right?

Dr Hammett: No, there are two different devices.

Senator XENOPHON: Yes, I know that, but there is a link between the two. There is an argument that, if there is a problem with the resurfacing device, that could well alert you to a potential problem with that part of the hip replacement device where there is commonality.

Dr Hammett: I am not sure that that is actually true, and I am aware of your question to Professor Graves. There are multiple components and combinations of prostheses that are monitored by the Joint Replacement Registry, and, where there is a fundamental problem with a device and it has multiple different components, problems with other components may appear. But it is not a necessary thing that, just because the ASR resurfacing component had a higher revision rate, the XL would—that is not a necessary sequela. It happened to be the case in this situation, but I do not think that anyone could have predicted that, and certainly the advice we had from the Orthopaedic Expert Working Group did not say, 'Immediately take off all the ASR hip replacements from the market.' That was not the advice.

Senator XENOPHON: So when Professor Graves appears to criticise the TGA for there not being a meeting until November 2009 of the Orthopaedic Expert Working Group, you say that that criticism is not warranted despite the September 2008 report which again highlighted concerns about these devices?

Dr Hammett: No, what I would say is that 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 now have access to the database and can make specific inquiries. I think, as Professor Graves alluded to, the relationship and the communication between the NJRR and the TGA currently is better than it ever has been, and he expressed his happiness with the current state of interaction.

Senator XENOPHON: Sure; but do you think there was a problem in the timeliness of the TGA's response at least from September 2008 until November 2009 when the Orthopaedic Expert Working Group was finally convened on the particular issue of these devices?

Dr Hammett: There was a meeting of the Orthopaedic Expert Working Group in June 2008, and there was another meeting, I am advised, in August 2009. There was a 12 month window, and during that period the TGA was reviewing the processes of gathering information and responding to it from the NJRR data. 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.

Senator XENOPHON: Can you provide the committee the minutes of those meetings of the Orthopaedic Expert Working Group and the communications between both the TGA and the working group—

Dr Hammett: I am sure we can.

Senator XENOPHON: and also the NJRR in this period that we are talking about—from 2006, when there were some apparent problems, and subsequently since that time up until the recall.

Dr Hammett: Just so I am taking that on notice correctly—you would like the minutes of the Orthopaedic Expert Working Group in the period from when it was convened, which was in 2007, to December 2009, when the ASR hip was removed from the Australian market.

Senator XENOPHON: Yes.

Dr Hammett: Absolutely.

Senator XENOPHON: Thank you. Also, the communications during this period between the TGA and the NJRR.

Dr Hammett: Which communications specifically? There are multiple offices of the TGA—

Senator XENOPHON: In relation to these particular devices.

Dr Hammett: In relation to the ASR..

Senator XENOPHON: Yes.

Dr Hammett: Certainly.

Senator XENOPHON: One of the issues that has been raised is whether it is appropriate for there to be third party conformity assessments. Is it the case that third party conformity assessments do not apply to Australian made devices?

Dr Hammett: The TGA undertakes conformity assessments for Australian manufacturers.

Senator XENOPHON: Right. But, if a device is manufactured overseas, do you rely on a third-party conformity assessment from overseas or do you undertake a further assessment here?

Dr Hammett: It depends on where that device arises from. If it is manufactured in Europe, it may be supplied under a mutual recognition agreement in Australia, provided that there is certification by a European conformity assessment body and a mutual recognition certificate is provided. If it is reviewed in the European Union and provided with an EC certification by a European conformity assessment body then generally, upon review of the necessary documentation by the TGA, it is included in the Australian Register of Therapeutic Goods.

Senator XENOPHON: How many staff do you have in the TGA—700?

Dr Hammett: No, 647, I think, at last count.

Senator XENOPHON: Okay, but who is counting?

Dr Hammett: Yes, who is counting?

Senator XENOPHON: The FDA in the US has something in the order of 17,000 staff.

Dr Hammett: Something in the order of that.

Senator XENOPHON: We have a similar number of devices that would be here and we are at one-fifteenth of the population.

Dr Hammett: Correct.

Senator XENOPHON: So how do you deal with that? I do not think Senator Wong, as Minister for Finance and Deregulation, would want to approve a 20-fold increase in your staff. How do you deal with that dilemma

that you cannot be across everything? How do you pick the assessments that you do, and to what extent do you rely on other regulatory bodies such as the FDA?

Dr Hammett: It is a constant matter of balancing the challenges of regulating the large number of products we regulate. One of the important foundations of how we approach this is that we have an understanding that it does not matter what amount of resources we have; it is not possible to create a completely safe medical device, medicine or medical procedure. That just does not exist. So in fact, despite the FDA's 17,000 staff, the ASR hip was approved and inserted in the US. We would, I think, expect that, regardless of how many resources we had, there would be some products that at some point in their life would result in adverse events to consumers. That is the nature of health care, unfortunately: it is a risky business. What we have to do is try to manage those risks. We do that with a stratified framework of assessment, so we apply more assessment resources pre market to high-risk devices than we do to low-risk devices. Then we balance that with postmarket monitoring. Again, Australia has been very smart in allocating its resources to things like the Joint Replacement Registry which give us very good data in the postmarket space. We have to balance that premarket-postmarket mix of regulatory activity. I think we would be kidding ourselves if we thought that just throwing resources at premarket evaluation would solve safety issues for all medicines and all medical devices. That is not likely to be the case.

Senator XENOPHON: What do I say to a constituent of mine in South Australia who is gravely ill, who was implanted with this device in late November 2008 and who is in a serious medical condition? She is severely ill, and there are issues there of the terminal nature of her condition. There was information by the end of 2008 about problems with these devices, wasn't there? That was clearly apparent.

Dr Hammett: It depends on which device you are talking about.

Senator XENOPHON: We are talking about the ASR device—I am sorry.

Dr Hammett: The XL or the—

Senator XENOPHON: The hip replacement.

Dr Hammett: The XL.

Senator XENOPHON: Yes.

Dr Hammett: Yes, the first piece of information that was provided around that was at the end of 2008.

Senator XENOPHON: Sorry—it was a hip-resurfacing device. I apologise. So the information was out there earlier.

Dr Hammett: I do my job—and I am sure you do as well—not to see people suffer the sort of harm that results from complications from medical devices. My heart goes out to people who have suffered adverse events related to this device or any therapeutic product. The challenge of course becomes: when do you push the button on here is a major safety problem. If, for instance, a car developed a flat tyre, does that mean that you take that car off the production line? Probably not. But if the—

Senator XENOPHON: I would not use a flat tyre analogy here.

ACTING CHAIR: Senator, let the officer finish and then make your comment.

Senator XENOPHON: Sorry.

Dr Hammett: If there were a series of flat tyre blowouts that resulted in fatal crashes, as happened in the US due to a manufacturing problem with a tyre, that would be a major problem. Obviously you do not react when one flat tyre occurs. What you do is put in processes to make sure you can react when there is a real problem. I guess what I am saying is that the best advice that was available at the time with the processes that have been put in place to monitor these types of devices said we should train the surgeons better in how to use them and we should watch it. We did watch it and subsequently it was found that there was a real problem with this device and it was taken off the market in Australia before anywhere else in the world. Yes, there are people who have suffered as a result of having this implant. There is a risk that people will suffer as a result of many types of implants. What we have to do is have systems that can react in a timely and appropriate manner.

Senator XENOPHON: I guess the question the husband of this woman is asking is: if she had her implant at the end of November 2008, was there not sufficient information from the NJRR to the TGA by, at the very latest, September 2008 that there was a real issue here?

Dr Hammett: I do not believe there was sufficient information to say that device should have been taken off the market at that time. We had in fact asked the best clinical experts in the country and that was not their advice to us. Their advice to us was: it can still remain on the market. We need to improve the training and we need to continue to monitor the data.

Senator XENOPHON: You are aware of the issue raised on *Four Corners* about potential conflicts of interest if a medical practitioner who is implanting these devices has a commercial association with the manufacturer and has been part of the design of that device. Could the TGA have a role in saying that ought to be disclosed or that there is a higher duty on that medical practitioner? Is that something that could be within the purview of the TGA?

Dr Hammett: It is not under the objects of our act unfortunately. Our role is to regulate the products, the devices, not to regulate the professionals, the surgeons, or to regulate their behaviour in interacting with the companies. Our role is around the devices themselves.

ACTING CHAIR: Mr Bartlett, would that be something that comes under PSR?

Mr Bartlett: It does not come under PSR directly, but we have had discussions with orthopaedic and other groups and have suggested that informed consent needs to include disclosure of those sorts of connections should they exist.

ACTING CHAIR: Is seems to me—and I am just following up on the point Senator Xenophon has made—that this has come up consistently across all the evidence. It does seem to be a statement that is so obvious. What can you do in terms of such a threshold issue, not just in terms of medical devices but in terms of a whole range of treatments? What, from the department's point of view, is the process within our health system for ensuring that this does not occur? We need to get some guidance.

Mr Bartlett: I think there are a couple of areas that can be covered. One is informed consent. 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 also a professional and ethical element to this that one would expect the relevant college to have a level of interest in.

Dr Hammett: Can I just add to that. I am a physician by training and part of what I do as a gastroenterologist is insert medical devices. We put stents into people's bile ducts or bowels or whatever. Clinicians have a very real and responsible role in aiding in the development of medical devices. Part of the work I did in London or in Boston was around trying to design better ways to insert these devices or better devices themselves. Clinicians are the people who know how they can be adapted to better meet the needs of patients—instead of having huge out-of-the-body pacemakers, turning them into tiny little things that get inserted. As was mentioned earlier, the clinicians actually have a real role there. That does not abrogate any responsibility for appropriate informed consent and appropriate financial disclosure. Indeed the professional colleges have statements, requirements and responsibilities in that field.

Senator XENOPHON: Thank you.

Senator CAROL BROWN: When you decided to talk to the manufacturers of the ASR XL hip and the resurfacing systems, on what were you basing that approach? What data brought you to the decision that there was an issue with these systems?

Dr Hammett: The usual process with the NJRR report is that the devices for which there are higher rates of revision than others—

Senator CAROL BROWN: I do not mean to interrupt, but I do understand that. I do not wish to go over what the Senator Xenophon was asking about again—forgive me if it seems like I am. You have said that in 2007 the data that was presented about resurfacing contained figures indicating, as I understand it, that there was twice the natural revision rate you would expect. Then, in July 2008 you received data about the XL hip replacement system.

Dr Hammett: No, in October 2008.

Senator CAROL BROWN: And it was in June 2008 that the expert working group met. When in 2009 was the next set of data?

Dr Hammett: What I was going to try to explain, because it is pertinent to that, is that generally, as part of the NJRR process, companies and devices that have a high rate of revision are notified, often before we, the regulator, are as part of that process of the NJRR checking the veracity of their data. I cannot be sure about 2007, but the company would have been aware in 2008, when the Joint Replacement Registry—and you might like to follow up with them—would have had discussions with J&J. Certainly in 2007 we had communication with the company based on the NJRR data, and we did again in 2008 and subsequently in 2009. It was very much based on the NJRR data. There was at that time no other particular data available around the world pointing to a problem here.

Senator CAROL BROWN: The expert working group met in June 2008 and only then and not after the subsequent data was produced in 2008. Is that right?

Dr Hammett: Not until August 2009.

Senator CAROL BROWN: I am trying to find out what data brought you to inform DePuy or Johnson and Johnson that there was an issue with these devices.

Dr Hammett: We would have talked to them at different points over that 2½-year period using the NJRR data. That was the data we were using at all points in that conversation.

Senator CAROL BROWN: What recommendation was there from this expert working group? You have told us that the expert working group recommended there be more training.

Dr Hammett: Yes.

Senator CAROL BROWN: Did they at any time recommend any other actions to be undertaken for these systems? Or did you, using the data presented to you through the normal processes of the NJRR, proceed to talk to the manufacturer yourself?

Dr Hammett: We proceeded to talk to the manufacturer. I think, in fact, in the 2008 annual report of the Joint Replacement Registry they highlighted for surgeons—and again, this report has use for surgeons themselves as well as for the regulator and companies—some of the aspects of these resurfacing hips related to the size of the components that were used and the individual patients who were being selected. So advice went out to the surgical community saying, 'You need to be careful which patients you are using these in, for a variety of reasons based on information in the NJRR.' But the information we went to the company with was very much the NJRR data, and we said, 'There seems to be an unacceptably high revision rate.'

Senator CAROL BROWN: As published in 2008 or 2009?

Dr Hammett: Correct.

Senator CAROL BROWN: Both?

Dr Hammett: Both.

Senator CAROL BROWN: I know data is available to the public by 1 October if it is in the annual report.

Dr Hammett: We get it about a week or maybe two weeks before it is released to the public.

Senator CAROL BROWN: I used to be a public servant. So sometime in September?

Dr Hammett: Correct.

Senator CAROL BROWN: When did you go to see the manufacturers?

Dr Hammett: I did not go to see anyone. There would have been communication between officers of the TGA and the company regarding the data. I cannot tell you whether that was a face-to-face meeting at that time. But in communicating the 2009 data to them, the company made the decision to—

Senator CAROL BROWN: But it was based on the data in the annual reports not on any recommendation from the expert working group?

Dr Hammett: I am advised we had written to them about the data, but in fact there had not been a recommendation from the expert working group to remove the product from the market.

Senator CAROL BROWN: Had the expert working group met on the September-October 2008 data that was presented in their annual report and their following 2009 report?

Dr Hammett: They met in August 2009. One of the challenges in this is understanding how the orthopaedic expert working group works. 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. It would be simplistic to simply say, 'As soon as something is identified as having a high revision rate remove it from the market.' That actually would not help patients. There are many useful devices contained within the Joint Replacement Registry data that do have a real role for you, me and my family.

Senator CAROL BROWN: Certainly, I am not suggesting that at all. I am trying to ascertain whether the expert working group did not recommend that the ASR hip system and resurfacing system be withdrawn or recalled.

Dr Hammett: I would have to check the minutes. My recollection—and I stand to be corrected by any of my staff here—is that in December 2009 they had actually identified that they thought the revision rate was

unacceptable and that it should be removed from the market. The notes I have here of the meeting of December 2009 note a resolution—and we will provide this to you and the minutes—that states, 'Members agreed that the ASR should no longer be on the market but that some components such as the femoral head should be available for revision surgery.' That was in December 2009 and it was removed from the market in Australia in December 2009.

Senator CAROL BROWN: That was what I was after.

Dr Hammett: Sorry I took so long to get you there.

ACTING CHAIR: Is there any way we can get a time line?

Dr Hammett: Yes, I am sure we can provide you with a time line.

ACTING CHAIR: It would be really useful. I know you are already providing Senator Xenophon with the interaction between the various bits. It seems to me we have concentrated for almost half an hour now going through a date and what happened. It would be a useful exercise if we could get the time line around this particular issue.

Dr Hammett: Certainly, in fact, I have one on a single page that will give you the key dates for the process. We will table that.

ACTING CHAIR: That would be very useful. There has been a number of questions at senate estimates about this issue and so on. I know the research has been done. If there are any further questions from the committee having read that, we will get back in contact with you.

Senator CAROL BROWN: From the point in the beginning when issues were raised about the resurfacing system, my understanding is that the manufacturer would have been advised from other various sources that issues were arising. I am certain they would have read the NJRR's report. Having read through some of the submissions, I understand that there is a mandatory obligation for manufacturers to report to the TGA about any adverse effects from devices. Are you able to tell us exactly what you received from the manufacturer on the issue of the ASR XL hip system and the ASR hip resurfacing system? You can take that on notice.

Dr Hammett: I may have to take it on notice to give you exact numbers. You are correct: there are mandatory requirements in our legislation for manufacturers to report. Actually, I can tell you that, as at 25 August 2011, we had received 208 reports of revision of the ASR hip. Two-thirds of those were reported to the TGA after removal of the device from the Australian market.

Senator CAROL BROWN: So those reports were from the manufacturer?

Dr Hammett: I do not have that data in front of me. Some of them may have been directly from patients or from surgeons. It is possible for consumers, health professionals and industry to report adverse reactions or adverse events to the TGA. Again, in the spirit of trying to make this knowledge widely disseminated within the community, we have mechanisms in place for people to report on the web, via email, via phone, via fax or in writing, and we would be delighted to receive reports from consumers, healthcare professionals and industry. Indeed, we have written to all the relevant professional bodies, consumer associations and others to try and promulgate the information about our reporting systems.

Senator CAROL BROWN: To a layperson, that seems quite a large amount of reports, but, in your view, over that time line do you think that is an unusually large amount of adverse effects reported or not?

Dr Hammett: In fact, the NJRR data is probably more useful in determining the significance of the problem with the revision rate. Because it looks broadly across all of the prostheses that are available and compares the rates of revision between them, it actually provides us with a better signal of when there is a problem emerging with a device. Yes, that is a high number of revisions, but you have to take into account the number of people who have had that implant inserted, so there is a denominator that has to be accounted for. Also, in the context of removal of a product from the market, and a whole lot of media publicity, we see a phenomenon called stimulated reporting, where we get an increase, a spike, in the number of reports related to a particular prosthesis or medicine.

Senator CAROL BROWN: I will move on to a different subject. Is the global harmonisation regime evaluated in any way? Do you have international meetings to talk about how it is going? Are there any mooted changes to the way it currently operates?

Dr Hammett: That is a very good question. There are. Just to provide some clarity: it is actually a thing called the Global Harmonisation Task Force for medical devices. It is made up of five founding members, which are Australia, the US, Canada, Japan and the European Community. Essentially it was a body of regulators and industry that devised guidelines for regulatory frameworks about the appropriate ways to regulate medical

devices. That framework has become the basis of regulation of medical devices in most of the world. It has now been picked up by a mirror body called the Asian Harmonisation Working Party, which has adopted similar regulation throughout the Asia-Pacific region.

In recent times, I think the regulators that are part of that group—us, the US FDA, the European Commission, Health Canada and the Japanese medical device regulator—have formed a view that we need to have a look at those frameworks and bring in a broader set of views as to the appropriate application of those frameworks. Australia is chairing a process whereby stakeholders, including consumers, health professionals and academics, will be brought into a process of reviewing the current guidance arrangements for how medical devices should be regulated. So we are in fact trying to move the international community to have a look at the current arrangements for the regulation of medical devices. As the committee will be aware, the TGA with the Australian government have recently announced reforms to the way medical devices are regulated and we are trying to work with our international regulatory partners to effect that change globally. We are mindful that we are only two per cent of the world's market and, if we want to see improvements in the safety of products on the market, as we all do, we need to impact on the global regulatory system for medical devices. That is what Australia is actively engaged in doing currently.

Senator CAROL BROWN: Is that task force that you have just talked about chaired by Australia?

Dr Hammett: Yes.

Senator CAROL BROWN: Has it met yet, or when will it be meeting?

Dr Hammett: The GHTF has met regularly over the last almost 20 years. There are working groups that work on particular aspects of the device framework. The recent developments to broaden the church of stakeholders that have input into that are still underway. There is a meeting of the regulators from those regions taking place in Canada early next month to work through what might be suitable arrangements for ensuring that the consumer and health professional voices are adequately heard within the design of these regulatory frameworks.

Senator McKENZIE: A number of submitters have proposed the establishment of additional clinical registries similar to the NJRR. Do you have a view on this and what the appropriate funding mechanism might be?

Mr Bartlett: The establishment of registries is one of the recommendations out of the HTA review. It is a matter that is under consideration by government.

Senator McKENZIE: Do you have any idea when we might get a response from government?

Mr Bartlett: No.

Senator McKENZIE: And you would not have a recommendation around funding because it is a matter of policy. The Brandwood Biomedical submission has raised concerns that the TGA's proposal to carry out direct assessments of all class III medical devices will strain the TGA's existing resources. We have heard evidence on this and Senator Xenophon earlier raised the difference in resourcing between equivalent international organisations and the TGA. As a result, the TGA is considering outsourcing this review process. Can you comment on that?

Dr Hammett: We constantly have to balance the demand for efficient, rapid access to market for new products going through regulatory processes, being mindful of the broader deregulatory agenda within the Australian government, along with our statutory obligations to ensure the safety and efficacy of the devices that we regulate. It is a constant challenge balancing those often conflicting demands. What we proposed in the reforms that have been agreed to by government, to up-classify joint prostheses from class IIb to class III, is that we will have an implementation time frame of approximately two years to enable existing devices that are classed as IIb to transition to the new arrangements. We have also released on our website arrangements that will minimise the impact of that transition in terms of the impost on our evaluation resources. So, while Arthur Brandwood's sentiments are well intentioned and much appreciated, we think we can manage this process adequately and have developed an implementation plan to do that.

Senator McKENZIE: Finally, I have a question about metal concentrations in blood. This takes me back to millimoles from chemistry lessons in year 12. I am just wondering who makes the recommendations about what constitutes normal levels of metal in blood in the Australian context.

Dr Hammett: Dr Keaney is saying 'a pathologist' but in fact I am not sure that there are well-described normal levels of the different metal ions in blood. As Professor Graves alluded to earlier, there is an enormous paucity of information about the whole issue metal iron levels and toxicity.

Senator McKENZIE: Would you agree that there must be some sort of range? The GP either says, 'Whoa!' or 'We don't need to call this patient back.' Internationally the range for cobalt, for instance, is two to seven millimoles per litre, and in Australia we have gone to 20. I am just wondering: when did that change and why?

Dr Hammett: I am not sure I could answer that question for you, other than to comment that these heavy metals are not usually found at significant levels in blood. So in terms of having a range that we would expect in someone who does not have an implant in them, we would not expect to see significantly high levels.

Senator McKENZIE: But we have heard evidence that there has been a change in the Australian definition, or trigger, of what is considered that normal range.

Dr Hammett: I have not heard that and I have no knowledge about that at all.

Senator McKENZIE: My final question is: what research are we doing into metals in blood, how much money are we spending on it, and where is it being spent?

Dr Hammett: 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.

Senator XENOPHON: Could I just follow on from Senator McKenzie's line of questioning. You say it is nascent in terms of metalline toxicity. You may have seen, for instance, the *Four Corners* story in May this year where a number of patients had presented with very high levels of toxicity. Aren't there some international benchmarks, as Senator McKenzie has referred to, about what is an acceptable level of toxicity—in the case of my constituent in Adelaide, extraordinarily high levels of cobalt toxicity, and this person is gravely ill How nascent is it if you have got some foreign substance like cobalt in you at levels that are hundreds of times higher than what seems to be accepted? Would that trigger some course of inquiry or action on the part of the TGA?

Dr Hammett: As Professor Graves alluded to, there are over a million metal-on-metal implants in people around the world, and yet there are literally, in the scientific literature, four patients who have been reported as having symptoms that might be attributed to that.

Senator XENOPHON: It worries me that I know at least four patients—

Dr Hammett: They may not have been reported in the scientific literature. What we need to do here—and I am not in any way wishing to underplay the potential significance of this—is to get the scientific answers on this and there need to be studies. Unfortunately, the TGA is not a research organisation. That is not what we are convened to do, but there are clinical groups with a great interest in this out there working out ways to do this.

Senator XENOPHON: Is it not relevant, though, in terms of your role, that if you are alerted to a potential problem because of metal-on-metal devices, of metalline toxicity, that at the very least there ought to be some protocols in place for follow-up, for monitoring of those patients so that patients do not get the sort of response that one Senator McKenzie's constituents had—what did they say?

Senator McKENZIE: Dementia. She is being treated for dementia—

Senator XENOPHON: For instance, Senator McKenzie pointed out that one of her constituents had a metalline toxicity issue and was initially told, 'You've got dementia,' and other patients were told it was all in the head, so it was quite dismissive. To what extent, given the potential nature of this problem and the potential revision rates as to metal-on-metal devices, does the TGA have the authority to have some protocols in place and to have some requirement for follow-up so that at the very least there can be some earlier intervention if there is a problem?

Dr Hammett: Senator—

Senator XENOPHON: Maybe Dr Keaney wants to answer this and wants an invitation.

Dr Hammett: Dr Keaney might want to answer this.

Senator XENOPHON: Sorry, Dr Keaney, as I had just glanced at you.

Dr Hammett: What Dr Keaney and I have been discussing is the fact that we have actually sought advice from the orthopaedic expert working group in the Australian Orthopaedic Association about the best way of doing the sort of thing that you are talking about and how that can be progressed. We share concerns about the need to understand whether metal ion toxicity is a real thing and whether it is going to occur in—

Senator XENOPHON: What do you mean by if it 'is a real thing'? If you have got cobalt levels 200 times more than what is accepted—

Dr Hammett: And it may do nothing to you. 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 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—

Senator XENOPHON: It sounds like it.

ACTING CHAIR: Senator, it happens too often that when the officer is speaking you interrupt.

Senator XENOPHON: I am sorry. It is those meetings chaired by Senator Heffernan!

ACTING CHAIR: It is a wonder anyone gets a chance!

Dr Hammett: What we need to understand is the local consequences at the site of the implant with the irritation of the metal-on-metal fragments and whether there are any impacts when the metal gets into the bloodstream. There is a whole lot of scientific work that does need to be done and regulators around the world will have to take that into consideration as to how they deal with these implants.

Senator McKENZIE: My question goes to asking the leaders in our health system if it has been identified as an issue, if the work is being focused and if we are getting somebody to look at this. I guess that is basically the premise of where I was coming from with the question.

Dr Hammett: Certainly we are exploring mechanisms for doing that currently with the relevant clinical experts who have all the patients in Australia. We are looking at ways of this being progressed.

Senator XENOPHON: Two more questions, Acting Chair, if I may and I promise not to interrupt this time.

ACTING CHAIR: Absolutely, and I will stop you if you do.

Senator XENOPHON: I am sure you will. And that before was not being offensive to Senator Heffernan, whom you know I am very fond of.

ACTING CHAIR: I understand that. It is now on *Hansard*.

Senator XENOPHON: Well, he needs some friends! I am referring to the *Four Corners* report and what is on the public record. If a person has a cobalt level of over 1,000 nanomoles per litre and levels greater than 85 per litre indicate toxicity and normal levels are somewhere between zero and 20—so if those levels are 50 times higher than that upper range of normal levels—wouldn't that concern you as something that ought to be monitored from the TGA's point of view? There might be some people who could tolerate that but many others who could not.

Dr Hammett: As I was trying to explain, I think the science on this is unknown. It may be that a thousand nanomoles per litre is tolerated by human beings without any side-effects. We just do not know that yet. There is not sufficient scientific information anywhere in animal models or in human models to suggest a clear answer to that question. While intuitively it might seem it would be nice to have lower levels, we just do not know the answer scientifically.

Senator XENOPHON: Could you take notice, given the potential significance of metal-on-metal devices and the potential issues of toxicity—and I am putting it in as neutral terms as possible—what research the TGA has done—

Dr Hammett: I can tell you we have done none. As I referred to, we are simply exploring at the moment whether such research is feasible in the Australian context and how it could be conducted and who should conduct it.

Senator XENOPHON: Not even any cursory research on this?

Dr Hammett: We have certainly reviewed the scientific literature but, as I have said, there is very limited scientific literature relating to this.

Senator XENOPHON: Could you take on notice what reviews you have undertaken of the literature in the context of your assertion that something over 1,000 nanomoles per litre may be tolerated by humans.

Dr Hammett: Sorry, I am not asserting that that is tolerated asymptomatically. I am just saying that we do not know. I am not trying to assert that 1,000 is an acceptable level. I am simply saying that there is not scientific literature that would guide us as to what is the appropriate level of cobalt in the blood stream. We just do not have that information in the global body of scientific knowledge at present.

Senator XENOPHON: Finally, on a different topic, the Australian Orthopaedic Association have argued in their submission, at page 2:

... the way HTA processes are currently structured and more importantly currently work, many prostheses that are rejected from listing for clinical reasons on the PHI Prostheses List remain available for use in the public sector thus creating a two tier health system.

What is your view on that assertion?

Dr Hammett: I am not entirely sure I understand. My colleagues might be able to help me. This is presumably referring to products that are approved for marketing in Australia—

Senator XENOPHON: Yes.

Dr Hammett: and then go through a reimbursement review—

Senator XENOPHON: Yes.

Dr Hammett: through the prosthesis listing and are knocked back for reimbursement. It is important to understand that they are two separate processes with two separate standards that need to apply. So for regulatory purposes there is an act that sets out what the requirements are, and those products get onto the market. There is a separate process for listing. Those two things are not the same process, necessarily; nor do they look at the same information.

Senator XENOPHON: But the concern of the Australian Orthopaedic Association is, I think, that there could be a two-tiered health system as a result of that process. What is your view of that, Mr Bartlett?

Mr Bartlett: One example of that is that in terms of hip devices there is a requirement of the Prostheses List Advisory Committee that all devices must have two years of evidence of safe use. There are some devices out there at the moment—they got some media coverage on the weekend—that people are seeking to get onto the market, badged as generic devices. They argue that they should use the same evidence as the device that they are effectively a copy of. The Prostheses List Advisory Committee does not accept that, because the evidence about equivalence is not categorical. There are cases where state systems are choosing to use those devices. That is a decision that is made within the state system, and that is under the control of the state government. Again, it is basically a question of the rules they choose to apply in determining whether or not these things can be used.

Senator XENOPHON: Do you think there should be some uniformity in those rules between the various state health bodies?

ACTING CHAIR: You are touching on an opinion.

Mr Bartlett: I cannot answer that question; it is policy.

Senator CAROL BROWN: We received a document today from the TGA, off your website, *Reforms to the Medical Devices Regulatory Framework: Proposals* 23 September 2011. I just want to know the status of that document. That is obviously the TGA's view but are you awaiting a government response?

Dr Hammett: No, those reforms have now been approved. We released a consultation back in October 2010 and we received 77 submissions. Based on those we provided advice to government, and those reforms have been accepted by government. We are now moving to implement those reforms.

Senator CAROL BROWN: Can I just quickly go to the publication of device product information. This was raised by a consumer health group that was here earlier today. It is about information that is available to the public so that the public is fully informed. Your proposed course of action is:

The TGA considers that it is important to be more transparent and will explore the possibility of posting manufacturers' Instructions for Use (or an abstract thereof) and Australian Public Assessment Reports (AUSPAR) equivalents on the TGA website in the first instance.

What sort of people do you think go to your website—apart from senators and members of parliament?

Dr Hammett: We have 47 million hits on the TGA website every year.

Senator CAROL BROWN: There was some concern raised that this was a good first step but that perhaps more needs to be done. So will this be an ongoing issue that you will continue to look at as to what else can be done? Do manufacturers post that sort of information that you are proposing to post on your website on their own websites?

Dr Hammett: I think some probably do for some devices. Generally, high-risk devices are implanted by surgeons and the instructions for use are usually provided to the surgeon rather than to the consumer. But our colleagues in the US FDA have implemented a process whereby they make information about these high-risk devices available on their website so that anyone can go and look at that. If you want to know about what sort of

hip you have had put in or something else, there is some information on a trusted government website. The TGA has implemented a similar process for consumer medicines information and product information over the last two years, and we have been of the view that similar information may well be of use to consumers who do want to find out about the medical devices. So, yes, it is a first step. It is what has been approved at this point based on our learnings of what we have done with medicines.

Senator CAROL BROWN: But still the question is there: will you still be looking at other ways if the aim is to get it out for the public to be aware of the instructions for use and other information to do with products? I know you know how many hits your sites had. Do you have an understanding of where they are coming from? Manufacturers—

Dr Hammett: I do not have that information here, and I have to say I do not know if our monitoring system is as sophisticated as that. I can say in broad terms that the TGA is very interested in making sure that the Australian community has the level of information that it requires and wants to understand our regulatory processes.

Senator CAROL BROWN: Is it a watching brief for you then, at least?

Dr Hammett: It is more than a watching brief. We have a heck of a lot of work to do just to implement that. That is a major change in the Australian situation, so we are going to do that. The second part of that is that we are proposing to publish detailed information about what assessments we have undertaken for high-risk devices, just as we are now doing under the AUSPARs for prescription medicines.

Senator CAROL BROWN: So how will you evaluate—it might be too early—whether putting this information on your website is actually getting out to the people that you are proposing to reach.

Dr Hammett: One of the recommendations that has been publicly released around the transparency review is that there should be methods for the TGA to ensure that we are meeting our information provision requirements with the community. Should government accept those recommendations, we will have to continue to think about how we do that. We do, in fact, already undertake stakeholder surveys of the stakeholders who we do interact with to assess whether the level of information we are providing currently is adequate. But, yes, you are right: it is important in implementing any new initiative that we measure the success of that initiative.

Senator McKENZIE: Can I add cadmium and chromium to cobalt.

Dr Hammett: You are adding to something I was taking on notice—is that correct?

ACTING CHAIR: We will provide it in writing to you.

Dr Hammett: Okay, thank you.

ACTING CHAIR: I think there will be a number of questions on notice. We will try to get them to you tomorrow in terms of taking them from the *Hansard* record. There are two or three documents in particular that we wanted to follow up on. I think I know the answer but I am going to ask what their status is anyway, and whether we can have them. One is the report by the Working Group on the Promotion of Therapeutic Products chaired by the manufacturing organisation—

Dr Hammett: MTAA.

ACTING CHAIR: Yes. It is a working group that was put in place to look at the promotion of products, and its report was delivered to government in March this year. The other is the transparency review of the TGA. We know that there were a number of recommendations made about the transparency of the TGA; where are they at now?

Also, in terms of the report of the Health Technology Assessment review, what is happening with the three recommendations, I think, that the government did not pick up on—recommendations 13, 14 and 15? We understand that they were not dismissed but were taken on for further consideration. Those recommendations covered issues around registers for medical devices, the involvement of key stakeholders such as health consumers and, in particular, how the registers interact across the world. I think that links in with your answer about the universal process that is going on. We will put these on notice.

One other particular thing I would like the TGA to respond to was in evidence from the AHIA, from Dr Armitage. In his submission, at point (a), his first point about the role of the TGA and how it links in with clinical activity, he says:

Quality tends to be a subjective term unless clearly qualified.

He goes on to make a number of statements about the way the TGA operates, how it works. I would really like to get your response to that. We will make a full note of all the issues that we are putting on notice so we can get them to you.

Thank you very much to all the officers. I know that was a long session. I do apologise to Innovation that we gave you no questions. We will try and think of one on notice for you! This hearing is concluded.

Committee adjourned at 16:41