



COMMONWEALTH OF AUSTRALIA

# Official Committee Hansard

## SENATE

COMMUNITY AFFAIRS LEGISLATION COMMITTEE

**Reference: Private Health Insurance (National Joint Replacement Register Levy)  
Bill 2009**

THURSDAY, 11 JUNE 2009

CANBERRA

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**SENATE COMMUNITY AFFAIRS**

**LEGISLATION COMMITTEE**

**Thursday, 11 June 2009**

**Members:** Senator Moore (*Chair*), Senator Siewert (*Deputy Chair*), Senators Adams, Boyce, Carol Brown and Furner

**Participating members:** Senators Abetz, Back, Barnett, Bernardi, Bilyk, Birmingham, Boswell, Brandis, Bob Brown, Bushby, Cameron, Cash, Colbeck, Jacinta Collins, Coonan, Cormann, Crossin, Eggleston, Farrell, Feeney, Ferguson, Fielding, Fierravanti-Wells, Fifield, Fisher, Forshaw, Hanson-Young, Heffernan, Humphries, Hurley, Hutchins, Johnston, Joyce, Kroger, Ludlam, Ian Macdonald, McEwen, McGauran, McLucas, Marshall, Mason, Milne, Minchin, Nash, O'Brien, Parry, Payne, Polley, Pratt, Ronaldson, Ryan, Scullion, Sterle, Troeth, Trood, Williams, Wortley and Xenophon

**Senators in attendance:** Senators Adams, Boyce, Carol Brown, Furner and Moore.

**Terms of reference for the inquiry:**

To inquire into and report on: Private Health Insurance (National Joint Replacement Register Levy) Bill 2009

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**Committee met at 2.33 pm****BURGESS, Mr Ian, Chief Executive Officer, Australian Orthopaedic Association****GRAVES, Professor Stephen, Director, National Joint Replacement Registry, Australian Orthopaedic Association***Evidence was taken via teleconference—*

**CHAIR (Senator Moore)**—We are commencing our inquiry into the Private Health Insurance (National Joint Replacement Register Levy) Bill 2009. You have information on parliamentary privilege and the protection of witnesses. We have your submission, thank you very much. I would now ask either or both of you to make some opening comments and then we will go to questions.

**Mr Burgess**—The Australian Orthopaedic Association wishes to thank the committee for the invitation to provide evidence. The Australian Orthopaedic Association, AOA, is the peak professional body for orthopaedic surgeons in Australia. As I have mentioned, I am the chief executive and Professor Graves is the director of the registry and, as such, is responsible for its operation and management. I would also mention that Professor Graves has extensive experience not only through his involvement with the registry since its inception but also through his liaison and involvement in international registries. Professor Graves is appointed Director of the National Joint Replacement Registry by the board of AOA. I will also mention that, unfortunately, Professor Graves and I are in different locations for this teleconference.

I will just give you some background very briefly, if I may. The purpose of the registry is to define, improve and maintain the quality of care for individuals receiving joint replacement surgery. AOA recognised the need to establish a registry back in 1993. At that time, the outcomes of this surgery in Australia were unknown. It was not clear who was receiving joint replacements or the types of prostheses and techniques being used to implant them. The need to establish a registry was in part based on the documented success of a number of arthroplasty registries in other countries, in particular the Swedish arthroplasty registries. The ability to identify factors important in achieving successful outcomes had resulted in both improved standards and significant cost savings. The key driver behind AOA's desire to establish a registry was to improve patient outcomes. That is, AOA's primary concern is patient welfare, and, as such, I think it is fair to say that we do enjoy a somewhat unique perspective with regard to the various stakeholders in the National Joint Replacement Registry.

It is also important to recognise the significant pro bono contribution that members of AOA provide to the National Joint Replacement Registry. Many members are involved in reviewing data and developing the annual report of the registry, for which they receive no remuneration. Our members also actively participate in the governance of the registry through the board of AOA and various committees, again for no remuneration. The director of the registry, Stephen Graves, and also two deputy directors are partly remunerated. However, this does not fully compensate their involvement. In addition, the infrastructure that AOA provides to support the National Joint Replacement Registry is not fully cost recovered. I highlight the pro bono commitments of AOA and its members to the National Joint Replacement Registry simply to underscore the dedication of our members to improving patient outcomes.

The registry is a valuable resource for the Australian community. Although it has only been in existence and fully operational for a relatively short time, the information provided by the registry is already influencing joint replacement and associated technologies in a beneficial manner. The data provided by the registry has directly resulted in a reduction in the number of revisions in Australia, which has provided substantial financial benefits to the Australian community, medical device companies, insurers and governments. Major benefits from the registry will be achieved when longer term outcomes can be established—that is, the benefits of the registry will only further increase over time. The registry also enjoys worldwide recognition and respect as a high-quality registry.

With regard to the private health insurance bill, AOA does not have specific comments. AOA has a contractual arrangement with the government to manage and administer the registry. How the government chooses to fund the registry is solely the decision of the government, and AOA plays no role in determining or influencing the funding arrangements. However, AOA do wish to advise the committee that we do not consider that the bill will have any impact on the continued independence, integrity and world renowned quality of the registry. AOA also appreciate the government's support of the registry over the last 10 years and we recognise and support the government's efforts to provide assurance with regard to the long-term funding of the National Joint Replacement Registry. In this respect, AOA considers that the bill will provide longer

term security for the funding of the registry as opposed to the current annual funding arrangements. That concludes my statement.

**CHAIR**—Are you wanting to make any comment at this stage, Professor Graves?

**Prof. Graves**—No. I am happy to answer any questions that there may be but I do not think I have anything more to add to what Mr Burgess has already said.

**Senator ADAMS**—Could you comment on the consultation with stakeholders prior to this legislation? Was there a lot of consultation with your organisation?

**Mr Burgess**—There was no consultation with AOA. We were first aware of it with the budget announcements but we are not concerned or surprised by that. As I mentioned, we are not involved in the cost recovery processes of the registry and do not play any part in that process.

**Senator FURNER**—I have seen other information in respect to the Prosthesis List benefits being minus eight per cent adjusted for CPI and the view that there is no way of passing those costs on. Firstly, is CPI the right vehicle in respect to providing what the actual benefits should be in this area and secondly, is it reasonable, in your particular experience, to suggest that there is no way of passing those costs on to patients or other providers?

**Mr Burgess**—I will offer a comment in relation to the second question first, and I might ask Professor Graves to address question 1 and also expand possibly on question 2. In terms of the pricing, we cannot comment on the pricing practices or the commercial decisions of prostheses companies although, on a cursory basis, with around 70,000 joint replacement procedures a year and a funding requirement of \$1.6 million that would equate to in the order of \$22 per procedure. With an average cost of prostheses of around \$6,000-\$7,000, \$22 would not appear to be a significant impost. But we offer those comments, as I said, on a cursory basis. I might hand over to Professor Graves to expand on that and also question 1.

**Prof. Graves**—I was just wondering if the senator could clarify. It was my understanding that you were talking about the price for prostheses that is determined by the PDC and I am not quite sure of the relevance to the registry of that question.

**Senator FURNER**—It was in another submission that I have seen. It is not your organisation, of course, but they expressed the concerns about that being able to be absorbed with no mechanism of passing on those costs.

**Prof. Graves**—I think that it is an important discussion to have from the point of view of whether or not the registry fee is an impost on companies and whether they should be able to pass that on to either the health insurers or state governments and then, from the point of view of the health insurers, to patients through their health levy. But I am not sure that the Australian Orthopaedic Association, and certainly the registry, would have any particular view about that as we would regard this as a cost recovery exercise by the government and that our funding, from the point of view of the registry, is related to the government's. I think the points you raise are important ones but I am not sure the Orthopaedic Association is in a particular position to comment about that.

**Senator FURNER**—Okay. Thank you for that.

**Senator BOYCE**—Good afternoon. Could you please describe for me the contractual arrangement that you have with the Commonwealth government?

**Prof. Graves**—Each year the Australian Orthopaedic Association signs a contract which is negotiated with the Commonwealth and that contract details what work is required to be done by the registry in the 12-month period of the contract and the payment schedule. One of the things that the Australian Orthopaedic Association does is subcontract the Data Management & Analysis Centre at the University of Adelaide to undertake a lot of the data management and analysis work. It is also detailed within the Commonwealth contract that the Australian Orthopaedic Association will subcontract that part of the work to the Data Management & Analysis Centre at the University of Adelaide.

**Senator BOYCE**—I presume de-identified information from the registry is then available for all manner of researchers in Australia?

**Prof. Graves**—The de-identified data from the registry is publicly available. It is available on the website. We produce an annual report detailing our findings each year and there are multiple reports which look at demographics. We also look at outcomes of specific prostheses and look at the outcomes in different clinical situations for particular prostheses and approaches to joint replacement surgery. We also provide a lay

summary which details in clear, simple English the main findings of the report each year. In addition to that, we also provide reports to academic institutions, individual surgeons or companies that request those reports during the year, so specific analysis can be done on very specific issues. We provide around a hundred of those separate reports each year.

Most of those reports are provided free of charge; however, a number of years ago the Commonwealth asked us to bill companies for doing the reports and so we bill them at the Australian Bureau of Statistics rate, which I think is a relatively cheap rate. It is about \$250 an hour. Most reports can be done within two hours or so of registry work and they are provided to the companies. One of the things that the AOA has emphasised with the registry is the accessibility of the information, and I think we have worked very hard to ensure that. That is one of the reasons why the registry is regarded quite highly internationally—because that information is publicly available. It is also used by international regulatory bodies and other interested parties involved in joint replacement around the world.

**Senator BOYCE**—Your current contract is for the calendar year 2009?

**Prof. Graves**—Yes, it is, and we are currently negotiating the contract for 2009-10.

**Senator BOYCE**—When you talk about the details of the payment schedules, is that the reimbursement?

**Prof. Graves**—That is right. Those are the payment schedules to the Australian Orthopaedic Association. In the contract those payment schedules are linked to certain milestones, and certain reports are to be made available to the Commonwealth before those payments are received.

**Senator BOYCE**—What is the contract for 2009 worth?

**Prof. Graves**—It is worth \$1.468 million, and that is pre-GST.

**Senator BOYCE**—We have had evidence from other organisations, particularly suppliers of prostheses, suggesting comments that the benefits can be as high as \$67,000 per product are at the extremely high end and, in fact, the average benefit from a listed orthopaedic product is around \$1,700. Does that agree with the Orthopaedic Association's view?

**Prof. Graves**—Shall I answer that, Ian?

**Mr Burgess**—Yes thanks, Stephen.

**Prof. Graves**—No, I do not think that is true. I think you have been given a misleading picture there in that, while many of the components used within a joint replacement may be of that value, what is not mentioned is that multiple components are used. For instance, in a knee replacement a femoral component, a tibial component and an insert would be used. That would be the minimum number of components.

**Prof. Graves**—A femoral component on average in Australia would be worth around \$3,000, a tibial component on average would be of a similar value and the insert would be worth \$1,000.

**Senator BOYCE**—So that is \$7,000.

**Prof. Graves**—A similar situation occurs with the hip, where the acetabular component usually comprises a shell and an insert, and the femoral component consists of a stem plus a head. The heads are usually worth around \$1,000. Depending on the nature of the stem, the stem could vary in value from \$2,000 to \$10,000. The value of the acetabular component probably varies. The insert would be worth about \$1,500, unless you are looking at a ceramic insert or a metal insert, which are more modern technology and considerably more expensive. The shell would be worth around several thousand dollars. I think there is an element of truth in what you have been told, but what has not been explained to you is that multiple pieces are used to make up one prosthesis for an individual.

**Senator BOYCE**—Are those figures you gave me the costs or the benefits for those items?

**Prof. Graves**—They are the benefits that are paid by the government—the fee that is charged by the orthopaedic manufacturing distributing companies to the health insurer. Those fees are not necessarily relevant to state governments, the public health system, because the amount is negotiated separately from the private system.

**Senator BOYCE**—I realise this is probably available in your annual report, but I am just trying to check the timing on these. I would like to see a table of the most common joint replacement operations performed and the aggregated cost figures. Would that be available for the first half of this year?

**Prof. Graves**—It depends on the exact details you want, because, as I have mentioned, there are multiple components used. The registry does not hold any costings data, because the PBC determines the benefit for a prosthesis. I would think that the PBC would be able to give you that information. We would have some difficulty in giving you that information. We could give you details of the most used components, but the costings would then have to be linked to that. To do that we would need to link catalogue number and billing code number. We have had discussions with the Commonwealth, who have an interest in that linkage occurring, but that has not occurred to date. It would be possible but not easy to give you exactly what you are after.

**Senator BOYCE**—On that basis, could you just provide us with the data on the quantum of joint replacement operations? That would be useful.

**Prof. Graves**—We could do that. We can give you all sorts of breakdowns on that. We can relate it to manufacturers and suppliers, if you wish, or in any way that you would like.

**Senator BOYCE**—Yes, to have it broken down into the manufacturers would be of use.

**Prof. Graves**—Would you like that this afternoon?

**Senator BOYCE**—We are due to report on this bill on Tuesday, so as soon as possible—but not in such a way as to cause anyone injury!

**Prof. Graves**—No, it would not—that is readily do-able for us. We could supply that to you this afternoon without any problems.

**Senator CAROL BROWN**—I want to follow up on a question about the reports that you make available. Under the proposed new system of cost recovery, will those that are not sponsors that currently receive reports from you still be able to access those reports?

**Prof. Graves**—The answer is yes, of course they will be able to access any reports that they wish. In fact, in recent months the Australian Orthopaedic Association has been discussing with sponsors ways of assisting them from the point of view of being able to provide them with more detailed information which is relevant to their needs. It is the Australian Orthopaedic Association's view that it would be quite happy to provide additional information to companies. In particular, we were looking at establishing secure web access for a company so that it could look at its own products and the real-time outcome of those products; so very accurate postmarket surveillance up to about six to eight weeks prior to the date that is being looked at for checking the data. They would be able to do that and look at their own products and see how they are performing. That would be a secure weblink that they could access at any time.

We are trying to support the companies because it is very important for the companies that their products have very good outcomes. They are very keen to access detailed information that the registry would be able to provide. The Australian Orthopaedic Association can see no particular problem in doing that.

**Senator CAROL BROWN**—Are you aware of any other jurisdiction that has similar cost recovery arrangements for their joint replacement registries?

**Prof. Graves**—Yes. Probably the most classic example of that would be the UK. They have also established a registry and they cost recover by levying a fee on prostheses. That fee is around £25 for one prosthesis within an array of prostheses that are used for a procedure. So it is about £25 per procedure. You can see that our registry is less than half that price.

**CHAIR**—There are no other questions, so I think you have worn them out. Thank you very much for your time this afternoon and your submission, Mr Burgess and Professor Graves.

[3.00 pm]

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

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

**CHAIR**—Our next witnesses are from the Medical Technology Association of Australia. Good afternoon, Ms Trimmer and Mr Ross. You have information on parliamentary privilege and the protection of witnesses. We have your submission. Thank you very much for it. I now invite either or both of you to make an opening statement and then we will go to questions.

**Ms Trimmer**—We thank the committee for making the time available for us to follow up on our submission. I think in the overall context of the budget this might seem quite insignificant but it has quite important implications for our industry.

First of all, we, as the Medical Technology Association, are the peak national body for the companies that manufacture, export, import and distribute a whole range of medical technologies, amongst which are the orthopaedic devices that we are looking at under the coverage of this bill. At the moment there are just under 9½ thousand products listed on the Prostheses List, which is the list that the government is using as the mechanism for the levy. MTAA represents about 87 per cent of the products that are listed. So we have a good coverage of the products. Approximately 30 per cent of that 9½ thousand are orthopaedic devices and about another 20 per cent are classified as orthopaedic related products. So it is quite a large segment of the Prostheses List.

Registries themselves deliver many benefits. Certainly, MTAA and our member companies support the benefits that are delivered by well-designed registries. In fact some of our member companies provided the seed funding for the original pilot project to be undertaken and registries are very familiar items for the way in which our particular part of the healthcare industry works. We use them for a range of reasons. In this case, though, with the National Joint Replacement Registry there are many beneficiaries of the data which is generated by the Joint Replacement Registry. In fact, that is echoed in many of the other submissions which you have received, including those of the department and the Australian Orthopaedic Association.

In summary, I think you could say that MTAA has two primary concerns. The first is issues of unintended consequence arising from this bill and the second is issues of equity. Turning to unintended consequences first, we believe that the application of the levy to a product simply because it is listed on the Prostheses List is not an equitable basis. That can be demonstrated when you look at the diversity of the products that are in fact listed. The most expensive item, which has already been referred to, is \$67,000. It is in fact an implant that is used primarily for children with bone cancer. It might be used once or twice a year and—happily, I think—our supplier member would be very happy if it were never used. But, of course, it is on the list because it needs to be available for the occasion when it has to be used. The sponsor also points out in their submission, and you may have noticed this, that if that particular device were not available then the treatment options would be multiple layers of surgical procedures which could cost up to \$250,000. And that is without taking into account the pain that would be suffered by the patient and, of course, the anxiety and rehabilitation costs that their family would carry.

What our sponsor member has indicated is that if a levy were to be imposed—and the government has indicated in its explanatory memorandum that because of the expense of the item it would be at the higher end of the levy range—then it would really have to weigh up whether or not it retained registration of that product on the off-chance that it might be used once or twice. Our analysis of the products that are used is that 99 per cent of the listed products have minimum benefits back to the sponsor of less than \$8,000, with 47 per cent having benefits of less than \$1,000. So we are talking about quite a large number of items with very small benefits returned to the sponsor.

This means to us either that the government is proposing to spread the imposition of the levy very widely across a very diverse range of value products, which could go right down to screws and items such as those which are used in the surgery, or that there is a possibility that a small number of the items will be unreasonably taxed at a much higher rate. If the levy is applied based on listing and not on utilisation, then sponsors will need to reassess the benefit of retaining a product which might be used rarely, as in the paediatric example I have given, or in those circumstances where earlier use of a product has to be revised. There are many products kept on the Prostheses List at the moment which are not routinely used. They are kept there in case their prior use has for some reason to be revised in the future.

A further flaw in basing the levy on products listed on the Prostheses List is that the Prostheses List only looks at products that are used in the private health system and of course the National Joint Replacement Registry data covers pretty well all orthopaedic procedures in both public and private hospitals. One of the unintended consequences we see is that underutilised products may then be withdrawn from the private health sector and only become available in the public health sector because there would be no impost.

There are also implications, we believe, in the extrapolation of this precedent to other registries which might evolve in the future. I must say as an aside that, for the reasons I mentioned before, we are not averse to the development of well-designed registries, but other registries are less likely to be class-specific, as the National Joint Replacement Registry is. One example that the Australian Health Insurance Association has included in its submission is the concept of a cardiac registry. A cardiac registry, in order to be really effective, has to look not only at the range of devices which might be used, such as drug eluting or bare metal stents, but also at pharmaceutical solutions, which are often used, and cardiac surgical procedures such as coronary artery bypass graft or CABG procedures.

In such a scenario, there is an even greater spread of parties who will benefit from the information available—in particular the funders, both public and private, who will make informed decisions about comparative treatments. We believe that capacity to make an informed decision is of benefit to the healthcare system but, as you can see, there is not just one beneficiary of that. In the UK—and our colleagues at AOA have referred to the UK system—the levy is based on the procedure rather than the individual item.

Another unintended consequence of levying an individual item, as is proposed in Australia, may be that sponsors will combine products into what is called a ‘system’, so that you have the various bits that Professor Graves was referring to being listed as a ‘system’. That of course has the benefit of reducing the amount of the levy applicable; it also has the big disadvantage that not only is the item going to be more expensive because it integrates several products but also that any revision is going to be a lot more expensive because it will be revising the lot rather than revising a component, right down to the screws that are needed.

If I could turn to the issues of equity, I have mentioned already that there are multiple users and beneficiaries of the National Joint Replacement Registry data, and that is as it should be. Clinicians, hospitals, funders and the TGA all make use of the data in different ways. The Department of Health and Ageing in its submission recognised that the data from the registry serves to inform the safety and quality of both surgery and devices for the benefit of patients, and ultimately it is the patients who are the beneficiaries of registries like this. The Australian Orthopaedic Association also states that the registry is used to monitor mortality rates and the incidence of surgical complication which, again, enhances patient safety.

A look at all of the applications of the data that comes out of the registry serves to demonstrate that the registry is used to improve clinical technique. The surgeons use it to identify where there is an underperforming surgical procedure and the mechanisms by which that might be improved, so it is used as part of clinical education. The data is also able to identify where there is hospital infection control in cases where the data indicates a higher than usual infection rate post-procedure. It assists suppliers to look at the design of their product and how they might be able to improve that and it assists the TGA in its regulatory role in identifying possible safety issues.

Unlike in the UK, which has been cited by the department as the model, there is no suggestion by government that industry have any say in determining the amount or the methodology for the levy. In the UK, if you look at how that levy operates, the minister for health sets the amount of the levy but this is supported by a memorandum of understanding between the Department of Health; the National Assembly for Wales, which also participates in that registry; the Independent Healthcare Forum; and the industry body, the Association of British Healthcare Industries.

Again unlike the UK, industry has no involvement with the administration of the Australian registry. In the UK there is provision for three industry representatives on the steering committee. When the NJRR was first established in Australia there were two seats on the management committee for industry, but that no longer prevails. Apart from the UK, MTAA has not been able to find any other orthopaedic registry that is not funded as a public health cost, although there are some registries where there will be a diversity of contributions to the cost, usually from multiple bodies including funders and clinical bodies.

As we have pointed out in our submission, there are limited opportunities for suppliers to recover the cost. This is an issue that was also identified in the department’s submission and it is in part because of the aggressive price setting which has been undertaken in the current negotiations for reimbursement through the PDC process. Senator Furner has already made mention of the negative increase with CPI adjustment over two

years. Industry has effectively been at a standstill over that time, regardless of the increase in cost. Government has also stated its position to not allow any automatic indexation, so there is no mechanism by which industry is able to recover this additional burden. The fact that there was no consultation with industry has meant that there has been no opportunity for us to work with government to frame an equitable model for the ongoing sustainable funding of the NJRR.

If I could conclude, this is a not a significant amount of money but it raises important issues of concern for public health policy because of the unintended consequences and because of issues of equity. MTAA and its members are not averse to an equitable arrangement for ongoing funding, but suppliers should not be the one interested party in the scheme that carries the whole cost, particularly where suppliers have no say in the structure of the levy nor in the application of funds raised by the levy.

**CHAIR**—Thank you, Ms Trimmer. Mr Ross, would you like to make any comments at this stage?

**Mr Ross**—No, thank you, Chair.

**Senator ADAMS**—I am interested in the management board. You said that originally there were two seats for industry representatives. When were they removed?

**Mr Ross**—I believe it was around 2005-06.

**Senator ADAMS**—Do you have any idea what the reason for that was?

**Mr Ross**—You should probably direct that question towards the Australian Orthopaedic Association. We received no correspondence relating to the exact reason at that time.

**Senator ADAMS**—And you had a seat on the board at that time?

**Mr Ross**—We had two industry representatives who were on the National Joint Replacement Registry management committee. The government since that time has formed an NJRR advisory committee, which is an outlier, if you like, and it involves membership from the TGA, the Health Insurance Association, the MTAA and a consumer representative. They teleconference quarterly to the AOA in Adelaide, but it has a different role completely from the management committee, as you would understand.

**CHAIR**—You are the industry group involved in that?

**Ms Trimmer**—Yes, we are, through one of our member companies.

**CHAIR**—I sometimes get drowned in the acronyms. MTAA was used.

**Mr Ross**—Yes, that is us.

**Senator ADAMS**—I am just trying to get my head around how things could be organised in a better way so that you do have not just the one area paying for the levy.

**Ms Trimmer**—I think it would be through some kind of equitably shared arrangement. We would certainly be happy to participate as an industry on an equitable basis. I guess the concern for us in putting forward some kind of shared arrangement, without thinking through how it might be apportioned, is the reference I made to the development of other registries in the future which will have a much higher degree of complexity than this registry. If we use this as a model and get this right then it will be a lot easier to set up other registries in the future.

**Senator ADAMS**—You feel that this could create a precedent in an environment where it is likely that there will be further registries in the future and, therefore, they would follow this model?

**Ms Trimmer**—I think that would be the tendency. This would be one of the rare registries where it is very class specific. In this case, the class is simply orthopaedic joints. Most other registries would require some kind of comparative analysis. If they were well designed registries they would involve comparative analyses across in some cases pharmaceuticals, in some cases procedures and in some cases all three components.

**CHAIR**—You gave us the example of cardiac, which was across a whole range of treatments. But this particular one does not have the same supplementary issues. For a joint, you do not have to look at pharmaceuticals or other things.

**Ms Trimmer**—No. That is correct.

**CHAIR**—The only other thing I was thinking of was whether the physiotherapy aspect could be taken into account with orthopaedic stuff—but that is just off the planet.

**Senator FURNER**—On the subject of equity, you draw your examination of the explanatory memorandum and cite the paediatric surgery, the \$67,000 product. Of the 30 per cent of the 9½ thousand products that are listed, are any in a similar cost range?

**Mr Ross**—There are other similarly priced items on the prosthesis list but they are in other categories. Defibrillators and pacemakers would be up around that amount. I have not got those particular amounts today because our focus is on orthopaedics.

**CHAIR**—There is no registry for those things?

**Mr Ross**—No.

**Ms Trimmer**—Not at the moment. They would fall into that cardiac registry.

**CHAIR**—The justification for the registry in your submission is that it is looking at the future, efficacy and all those things, yet there is no other. It is a fascinating study in itself.

**Ms Trimmer**—There are individual registries that are often set up by companies. You will have the opportunity to speak with a couple of companies and perhaps explore that further. They are often done as part of the clinical testing of products to enable the close monitoring that is undertaken.

**CHAIR**—So it is in with the TGA

**Ms Trimmer**—Yes. But it is a slightly different context; we are talking about post-market surveillance. I guess the other reason in support of our concern about precedence with this registry is that, even in the regulatory environment, the TGA is moving away from pre-market surveillance and putting much more emphasis on post-market surveillance, which works for these sorts of products. These are not like drugs, where you need to do a vast amount of clinical research before you can release them onto the market. A lot of the benefits of medical technologies can really only be observed when they are used with patients. So registries perform a very important function, but it is partly to inform the whole benefit of the healthcare system rather than simply the suppliers.

**Senator FURNER**—Other than the UK model that you relied upon, are there any other countries that have the same types of matters that we are discussing here today?

**Ms Trimmer**—There are quite a few other countries that have registries. In fact, I think orthopaedic registries' origins were in the Scandinavian countries. But there are no others that require supplier subsidy; they are generally seen as public health issues and generally supported by government. In Canada, for example, it is a shared cost of the federal and state health agencies. In some of the Scandinavian countries it is a shared cost between government—I think in some it might even be clinicians—and funders.

**Senator FURNER**—Are they more equitable in those countries in your experience?

**Ms Trimmer**—It is a bit hard for us to comment on that because industry does not pay at all in those countries. The UK is the only one where industry does pay and, as I said at the beginning, we are not averse to making a contribution and there may well be a model that could be designed that would enable a spread of contribution. It is just when it is sourced to the easiest collection point, I guess, that there is lack of equity.

**Senator CAROL BROWN**—How much expenditure is there on hip and knee prostheses in the total expenditure by health insurers?

**Ms Trimmer**—I think that figure is actually in the department's submission. We might be able to turn it up quite quickly.

**Senator CAROL BROWN**—You don't keep that sort of information yourself?

**Ms Trimmer**—No, we do not.

**Senator ADAMS**—There are currently about 70,000 hip and knee replacements undertaken each year in Australia.

**Senator CAROL BROWN**—I don't think I have that data, Senator Adams.

**Ms Trimmer**—Some of that data is included in the Department of Health's submission.

**Senator CAROL BROWN**—Do you have any information about amounts paid by insurers for prostheses in, say, 2007-08? I am trying to get an idea of how much is actually spent on benefits.

**Mr Ross**—I could give you figures that we have collected from the Private Health Insurance Administration Council. They are for the year up to March 2009, which is as recent as they have figures. The annual expenditure is approximately \$1.155 billion.

**Ms Trimmer**—That, of course, covers all prostheses and not just orthopaedic—

**Mr Ross**—Cardiac, ophthalmic, and there are other significant categories of expenditure.

**Senator CAROL BROWN**—So that figure is from July 2008 to—

**Mr Ross**—No, it is from the year to the March 2009 quarter. So it is the 12 months up till March this year.

**Ms Trimmer**—If you took 30 per cent of that, based on that number that we heard earlier, that would give you the percentage.

**Senator CAROL BROWN**—Is there a maximum number of times under the proposal that the levy can actually be imposed?

**Mr Ross**—It is, as I read the proposal, up to a maximum of \$5,000 a year, which can be apportioned several times across the year.

**Senator CAROL BROWN**—So it cannot be any more than \$5,000 per year?

**Mr Ross**—As I understand it.

**Ms Trimmer**—That is per item, but of course in one procedure you might have numerous items being used ranging from a screw, which might be worth a few dollars, to a significant component part which could be worth several thousand dollars.

**Mr Ross**—And I think the point came up before that it is rare that only one orthopaedic device would be used in a particular procedure. There would normally be several.

**Senator BOYCE**—Ms Trimmer, could you give me some background information on the Medical Technology Association of Australia? How many members do you have and how many of those would be manufacturers or suppliers of prostheses?

**Ms Trimmer**—The most relevant figure is the one that I provided in my comments. Of the products listed on the Prostheses List, our members account for about 87 per cent. Our total membership, in numbers of companies, is around 130. They range from large, global companies to Australian manufacturers and across a whole range of technologies from devices, such as orthopaedic implants, to diagnostic, both equipment and in-vitro diagnostics. We have companies that supply cardiac devices, cochlear implants and lenses right through into hospital equipment. So it is a very diverse range. It is easier to think of it as everything that is used in the healthcare space that is not a pharmaceutical.

**Senator BOYCE**—I am sorry; I missed that. You are saying 80 per cent of those 130 are—

**Ms Trimmer**—I said that 87 per cent of the 9½ thousand products on the Prostheses List are listed by member companies.

**Senator BOYCE**—How many companies, then, would produce or distribute products in Australia that are used for prosthesis?

**Ms Trimmer**—Of our members?

**Senator BOYCE**—Yes, of your members.

**Ms Trimmer**—I would say that it would probably be a good—

**Mr Ross**—Probably about 50 or 60, I would think.

**Ms Trimmer**—Per cent.

**Mr Ross**—Whilst my figures might be a bit dated, I believe there are probably about 110 or so companies that actually have listings on the Prostheses List—perhaps a few more. So, from that, you can identify that there are many companies that have only a small number of listings, as well as a number of companies that have large listings.

**Senator BOYCE**—Could you characterise those companies? I think you have started to do so, Mr Ross. Do they range from quite tiny to multinational?

**Mr Ross**—Our members range across that. I notice that we have Johnson & Johnson speaking after us. They are one of our largest member companies, particularly in the orthopaedic space through DePuy. But you will have noticed, through some of the submissions that you have, that there are also some smaller companies that have written in and put in submissions. Global Orthopaedic Technology and Austofix are Australian manufacturers and they are relatively small.

This is a difficult area for the small manufacturers. When costs are increased—as they have recently—for application and listing fees, and if this is added to their burden as well, it is very difficult to pass on those costs at the moment, as Ms Trimmer mentioned before. In fact, the pricing mechanisms in the prosthesis committee, as I am well aware, are very tight. Over the last three years, it has gone backwards by eight per cent with regard to those benefits that have been on the list.

**Senator BOYCE**—I was reminded earlier, when you were talking about the possibility that people would choose not to list, of the situation that was brought to our attention by the palliative care association about drugs that have a very small potential market in Australia. Could you talk a little about what you mentioned as the unintended consequence of what you see happening there?

**Ms Trimmer**—I think it is likely to arise with those large, expensive items which might be rarely used, such as the paediatric device. It is also likely to arise where companies might keep on the list, for many years, products which are no longer the ones that are currently in the market but which would be used for revision surgery to replace an earlier device.

**Senator BOYCE**—Sort of like the spare parts bag, so to speak?

**Ms Trimmer**—Exactly.

**Mr Ross**—In fact, some of the costs of keeping those spare parts, if you like, available are rather more significant than would otherwise be the case. In fact, some companies actually have to manufacture obsolete items to meet potential needs.

On the unintended consequences, one of the advantages of the prosthesis listing process is its predictability. Where you have patients who need particular devices, if their surgeon identifies that they need a device, it can be readily provided and the benefits of private health insurance are realised. If an item is not listed and it has to be brought into Australia, then it would have to go through the Special Access Scheme. The supplier would also have to ensure that the purchaser—or the reimbursing in this case, the private health insurance funds—would be prepared to meet the cost of that item. All this takes time and effort and would certainly detract from the benefit of private health insurance, particularly for a family who might be under stress in such circumstances, as was mentioned previously. It is not impossible to get the items, but it does make it more difficult.

**Senator BOYCE**—You partly answered what was to be my next question—whether there was a mechanism for prostheses to be used that were not on the list. That is called a special access—

**Mr Ross**—A special access scheme. If a supplier found it uneconomical or commercially not viable to list on the Prostheses List, potentially it may not be viable to bring the item into Australia. In that case, they would not be registered on the ARTG and they would need to apply to the TGA through the Special Access Scheme.

**Ms Trimmer**—The ARTG is the Australian Register of Therapeutic Goods. It is the place where all approved products are listed by the TGA for use in the Australian market.

**Mr Ross**—Once an item is listed on the ARTG, it can be used in the public sector but it has to go through the next step, the Prostheses and Devices Committee, to be reimbursed through the health fund process.

**Senator BOYCE**—Would I be right in assuming that the profession are less likely to be aware of items which are not on the list?

**Mr Ross**—I would not be sure on that. Perhaps the J&J people would be in a better position to answer that. Certainly the items on the Prostheses List achieve a higher visibility and are more readily identified for use because of that. It streamlines access for those who are privately insured.

**CHAIR**—Mr Ross, remind me why something would be considered to not be economically viable. I understand with drugs but I am trying to get my head around the prosthesis area.

**Mr Ross**—At the moment, the Prostheses and Devices Committee has a very strong process which conducts a clinical assessment and then a negotiation of benefits.

**CHAIR**—And the person putting it on the market has to pay to have that done. It is an exact mirror of the pharmaceutical process, is it not? You have to put a proposal up to see whether it will be approved by the TGA. If it is a device which may not be used very often, it may not be considered economically viable to do that.

**Mr Ross**—We might be a bit confused here. To get a drug through to the Pharmaceutical Benefits Scheme, it has to first be approved by the TGA.

**CHAIR**—That is right.

**Mr Ross**—We have to have our devices approved by the TGA before they can then go to the Prostheses and Devices Committee.

**CHAIR**—Yes—we are on the same wavelength.

**Mr Ross**—If the costs in getting that entry are significantly higher than the return available for the device, a sponsor might deem it commercially not viable. There are also other ways that it could become commercially unviable. Increasingly I am getting reports from some of our sponsors that the offered benefit is below their landed costs and is below the cost they are getting in the public sector. That is not directly related to this hearing, but it is certainly an issue which is of concern to us at the moment. It does reflect the difficult nature of getting your increased costs recognised through this process.

**Senator BOYCE**—The other increased cost might be holding stock, as you said, for some considerable time for people who have had operations in the past and need a replacement.

**Mr Ross**—That is right.

**CHAIR**—There are no further questions. Thank you very much for your submission and for your evidence.

[3.35 pm]

**CHU, Ms Robyn, Director of Health Outcomes, Johnson & Johnson Medical**

**DASGUPTA, Mr Sushobhan, General Manager, Johnson & Johnson Medical**

**VICARY, Mr Peter, Director of Government Affairs and Policy, Johnson & Johnson Medical**

**CHAIR**—Welcome. Information on parliamentary privilege and the protection of witnesses and evidence has been provided to you. We have your submission, thank you very much. Would any or all of you like to make an opening statement and then we will go to questions.

**Mr Dasgupta**—Thank you for providing us with the opportunity to present evidence for this very important National Joint Replacement Registry bill. At the outset, let us comment on behalf of Johnson & Johnson that we do support and we recognise the importance of the registry work that is being done—which is benefiting the entire community as a whole, along with the surgeons and patients, as well as the medical devices industry. Having said that, we in Johnson & Johnson Medical feel that the legislation has a number of fundamental flaws which could have been avoided if the industry had been given a prior opportunity for consultation.

The primary flaw is in regard to the imposition of the entire cost of the operation of the registry onto the medical devices industry. Johnson & Johnson Medical does not object to some of the costs of the registry being carried by the medical devices industry but we do object to the entire cost being carried by the industry. There are a number of beneficiaries of the registry—something that is acknowledged by the registry itself and in the minister's own second reading speech.

In 2008, 296 hospitals provided data to the registry—142 public and 154 private. Benefits are being provided across the hospital sector. What this clearly demonstrates is that the registry provides benefits to the surgeons, to the public and private sector hospitals and, more broadly, to the community. On this basis that we are to move to a user-pays system, then it would be appropriate that all users contribute to the cost of the registry and not just the medical devices sector.

The second issue is the proposed method of determining the levy to fund the registry. Johnson & Johnson Medical believes that the proposed levy approach, on the basis of listing of devices on the Prostheses List, is inappropriate. The proposed levy does not reflect usage. For example, devices may remain on the Prostheses List but may have limited usage and remain available on the list in case of an emergency or urgent patient need. To place a levy of up to \$5,000 on such an item may make it uneconomic to continue to make that item available. Importantly, the bill sets out no clear principles upon which the levy will be determined, placing this power in the hands of the minister. This is a situation that is inappropriate.

The third weakness in the bill comes down to the well-accepted concept of no taxation without representation. It is proposed that the medical devices industry be taxed to fund the operation of the registry on which it does not have appropriate levels of representation. We have heard about the UK registry and the Swedish registry and we know that the industry representation is there in the steering committee of the UK registry for sure. The operation of the registry is not transparent to the industry and the industry has no effective input or oversight of its operations. If the medical devices industry is being asked to pay for it, then there needs to be at least a basic level of transparency and operational accountability. According to us, it is inappropriate to hand over the millions of dollars in taxation to a group with only limited accountability to those paying the tax.

In summary, we feel that the bill has a series of fundamental flaws. Only one beneficiary of the registry is being asked to pay for its operation. The method of imposing the levy is unclear and has the potential to negatively impact the availability of some of the products. There should be no taxation without representation and there is a need for greater accountability and transparency in the operation of the National Joint Replacement Registry. We feel that, if passed, the bill would enshrine these fundamental flaws into policy and set an inappropriate precedent for future legislation. Johnson & Johnson Medical would therefore request that senators consider rejecting the bill in its current form and recommend that the government undertake an appropriate round of consultations prior to the bill being further considered.

**Senator ADAMS**—As your industry is fully supporting the levy, is there any recompense that you get back? Because you are the group that is actually paying the levy, is there anything that comes back to you?

**Mr Vicary**—We do access data from the registry. For example, I think we recently made a request for data on how specific prostheses were performing. Yes, we do receive benefit from the registry. We openly recognise

that it does make a contribution to our operations and to delivering better patient outcomes at the end of the day.

**Senator ADAMS**—Do others have access to the registry as well?

**Mr Vicary**—Yes, I think any company can make a request fairly well across the board.

**Ms Chu**—As long as it is coming from the medical officer and they are making a request to review their own data for their own devices.

**Senator BOYCE**—Do you have to pay \$250 an hour for those reports? Is that correct?

**Ms Chu**—I think the costing is dependent on the type of data that is required and how much work would be required to retrieve the data.

**Senator ADAMS**—When did you first know about this levy, seeing there was no consultation? You had no consultation whatsoever?

**Mr Vicary**—We did become aware of it as part of the announcement in the budget. It was announced in the budget, but there was not any indication given at that point in time or subsequent to that as to when there would be any legislation coming forth. We did not receive any informal or formal notification of the legislation. In fact I think the first time we actually became aware of it was not that long ago, when the notice was published in the paper from this committee requesting input into this inquiry.

**Senator ADAMS**—Oh dear! Well, at least you are observant and you read the notice—that is the main thing there!

**Mr Vicary**—Your ads actually are effective in notifying the public about what is going on.

**CHAIR**—It is good to know that.

**Senator FURNER**—You expressed some concerns about privacy trespass as a result of the data being available with the registry. I imagine that has been an issue in the past, or something you are unfamiliar with concerning privacy?

**Ms Chu**—The concern we have is more about identifying the reasons a procedure is not ideal in terms of outcomes. There are multiple factors which impact on tracking how a procedure is performed and patient privacy should certainly be considered.

**Mr Vicary**—One of the ongoing concerns we have with the registry is around the fact that if there are failures in certain procedures they are sometimes attributed solely to the device failure rather than another wide range of factors which go into the success or otherwise of a procedure, such as surgical technique and patient health et cetera. So we are concerned that it can lead to a very narrow definition of what is a contributing factor to failure. In the statement we refer to transparency as well; transparency in the operation of the registry and also transparency in terms of the operation of the data insofar as not all factors are identified in the data.

**Senator FURNER**—So you are not opposed to having data identified, or to show reasons for, say, operational failure; you are concerned about how that data is used. Is that the issue here?

**Mr Vicary**—Yes, and also in some cases where, for example, if there were problems or issues with a particular surgeon and their surgical technique, that is not necessarily fully transparent in the data which is produced and available, I think, to most users of the registry, and that also includes patients.

**CHAIR**—Maybe we should have a look at this register. We have not seen the register. I am just thinking it might be useful to see what is listed there. The point you make about the surgeon is really important, because the way the register has been explained to us is that it gives information about effectiveness and safety and all those things, but we are all aware in this committee of issues around different techniques and surgeries and hospitals and things like that, so it cannot just be the device.

**Mr Dasgupta**—Yes. If I could expand a bit on this, if you look at some products, over the history of the registry it is the endpoint which talks about revisions or it goes into the implant. As Peter rightly pointed out, there are several factors—

**CHAIR**—In every surgery.

**Mr Dasgupta**—you include, which are surgical technique and the patient themselves—the selection of the patient—as well as the hospital environment. If we go into the registry in a bit more detail, there are instances where we find that the data gets very skewed when it comes out. Because we know the internal facts as well,

where it is coming from, there are a certain proportion that come out of one single hospital. So you realise there are 37 cases of revisions, and that could be an instance where, out of those 37, nine or 10 have come from one single hospital, but that does not get commented on in that interpolation of the results. It comes up as there being 37 revisions. So there are multiple factors at play in terms of the registry. So the question is: how do we interpret the registry results? That is the question to consider.

**CHAIR**—That is right—to gradually interrogate the system.

**Mr Dasgupta**—That is right.

**Senator ADAMS**—Rather than saying it is product failure every time.

**Senator FURNER**—If you had the delivery of the information specific to those types of issues, therefore would you have an issue with—

**Mr Dasgupta**—One of the things that we feel as an industry is that we are not able to get real-time data; I think Anne and David commented on this as well. We would love to have real-time data so that if there are issues coming up we would be able to take a call in terms of post-market surveillance and also to be appropriate and sure of where to take the right measures on. What we are getting is much-delayed data which does not help either the community or the patients at large. That is one of the issues that are coming up as well. So it is interpretation as well as the timeliness of the data, which is not there. This would be resolved, we guess—which I think is what our submission talks about—if the industry is allowed to be part of a steering committee, like it is in the UK. It has a lot of say in the governance of the NJRR, without an element of bias creeping in.

**Mr Vicary**—I think, if I could draw senators' attention, if they have time, to have a brief review of the 2008 annual report of the registry. Even just a short read of its introduction, I think, is very illuminating. If I could just quote a number of sections in terms of the stated aims of the registry. One is:

- Provide confidential data to individual surgeons and hospitals to audit their joint replacement surgery.

Once again, data on individual hospitals and surgeons is kept confidential; it is not available to broader groups. Certainly, I think there is an issue there about patient right to know and patient awareness. Another aim, to quote again from the report, is:

- Educate Australian orthopaedic surgeons in the most effective prostheses and surgical techniques to achieve successful outcomes.

Once again, I think that adds to the point in regard to who the beneficiaries of the registry are. The registry report itself states that both hospitals and surgeons are major beneficiaries, through confidential means, of the results of the registry, across both the public and private sectors.

**Senator FURNER**—Lastly, in the third dot point of your considerations, you draw the conclusion about not being able to pass on these costs to industry, therefore making the products no longer supported. Why do you draw that conclusion?

**Ms Chu**—It is to reiterate the points Anne and David made. We need to remember that, unlike pharmaceutical products, when we bring these products to market they require a lot of support and training from companies, to make sure that surgeons are appropriately trained. Maybe Sushobhan can explain more about that. Basically there is a cost to bring the products into the market, to have products go through the regulatory process, through the PDC process, and there are fees for applying for products to be listed. To have an additional fee where the total cost is borne by the industry—we think the beneficiaries are across the other stakeholders, as Peter mentioned—it would get to the point where products would perhaps be made available only to the public sector and not to the private sector.

**Mr Vicary**—The amount which we are reimbursed for a prosthesis is fixed through the reimbursement and regularity process. So if it is \$1,000, it is \$1,000. For example, if a \$150 or \$200 fee were added to a prosthesis cost, there would be an inability for us to pass it on and that cost would have to be absorbed out of current margins. We could not then charge \$1,150.

**Mr Dasgupta**—One of the elements of the orthopaedic devices industry is the efficiency with which the entire system works. This involves a lot of instrumentation, a lot of inventory, and obviously if this is used maybe once in six months, we cannot keep inventory at our warehouse. There are a lot of factors involved outside training aspects, in terms of costs. Having said that—and this is something on which there is absolutely no compromise—we have to keep it to the highest quality so that the clinical outcomes delivered by the surgeon are at the best level. So there is a possibility that, with coming into this, we would be having an operation under the system.

**Senator BOYCE**—In the comments you made regarding the way that registry results may be skewed, are you suggesting there is a potential conflict of interest in the Orthopaedic Association running the register?

**Mr Vicary**—I refer senators to the registry's annual report when it talks about confidential data on individual surgeons and individual hospitals. That data is not made available publicly and I think there is an element of patients' right to know and having informed patients, to enable them to make appropriate decisions about their care. If data is available on individual devices, the patient may wish to know data or information on individual hospitals or individual surgeons. This comes up not just in regard to this particular issue but right across the healthcare sector at the moment there is an ongoing drive and public discussion around patients' right to know. The government has already made moves in regard to publishing data on public hospitals in Australia and also on private hospitals.

**Senator BOYCE**—Let us hope. However, if I go to this register today I can find out whether product A for hip replacements is better than product B. Is that the case? I can accept the analysis from the figures that they have given me?

**Mr Vicary**—Yes.

**Senator BOYCE**—There is information on this topic—whether it is true or not.

**Mr Vicary**—That is right but you could not, for example, if you lived in Sydney do a search on the orthopaedic surgeon who has the best outcomes on the registry, because that remains confidential data.

**Senator BOYCE**—I want to go back to your comments suggesting that whilst you have no objection to there being a levy to underpin the register you do not feel that only manufacturers and suppliers should be the ones paying it. Who else do you think should be contributing towards the cost of the register?

**Mr Vicary**—Once again, if we refer to the stated aims of the registry to provide data to hospitals, individual hospitals, both public and private, which are beneficiaries of that data could be in a position to make a contribution. Individual orthopaedic surgeons are also provided with data not only on their performance but also, as the annual report states, to educate orthopaedic surgeons on the most effective surgical techniques, so there are beneficiaries individually both on a data level and on a performance level just as there are beneficiaries in ongoing professional education and professional information.

**Senator BOYCE**—How would you see that being done?

**Mr Vicary**—It is open to a number of ways. There is the UK example of the levy and how that is rolled out and charged, because in some cases a hospital would pay that levy. You could have a charge for data. We pay for data at present. I am unclear at present about whether or not individual hospitals or individual doctors are charged a fee for that performance report, so that may be another.

**Senator BOYCE**—The evidence they gave us earlier suggested that all requests for reports are charged at the same rate that the Bureau of Statistics charges for individual reports.

**Mr Vicary**—So both through a levy and some form of data charge or some form of participation charge, for example. If you took our quoted numbers of about 350 public and private hospitals contributing at present a fee of, for argument's sake, \$500 to \$1,000 for participation—

**Senator BOYCE**—Per annum?

**Mr Vicary**—per annum—that could raise \$150, 000 to \$350,000 and the annual cost that we are talking about is approximately \$1.5 million.

**Senator BOYCE**—What would it cost Johnson & Johnson if this legislation were to be implemented in this format?

**Mr Vicary**—That is what we have been trying to nut out. Based on our percentage of the Prosthesis List and assuming that was levied at a flat rate, I think we calculated it in the range of about \$300,000 to \$400,000, which is a sizeable chunk of change in regulatory costs for us. That would, of course, come on top of our current regulatory costs in regard to TGA PDC processes.

**Senator BOYCE**—Your industry association gave evidence earlier that if this legislation were to be put through in its current format it could potentially lead to the unintended consequence of some manufacturers not putting prostheses forward to be listed because of the cost involved. Would that be the case for Johnson & Johnson, and, if so, can you give me some examples of that?

**Mr Vicary**—We have a number of products that are currently listed of which the usage is very low—that may be anywhere between zero and one or two per annum—which remain on the list but that are available for

revision in accordance with patient need. If we had to pay, at the extreme end, \$5,000 and made no sales of that product for the year, and if you add that up across a range of products, that may add up to a considerable sum of money which may force us to withdraw a number of products.

**Senator BOYCE**—I am interested in how you manage those stocks of products that are presumably superseded but that might be needed for a revision. What is the method you use currently of knowing how long to stock those products and at what levels?

**Mr Dasgupta**—I will give you an example, just to return to your point, and that is special revision surgery, where they use a particular stem for a hip. Revision surgery comes up very rarely, and you have to use a particular stem solution which has been there in the Prostheses List for a long time but has not been used the last three years. We still have to maintain the inventory because at any point in time you never know when these things will come up. There are several series of components listed in those revision surgery components, and that makes up a sizeable proportion of our inventory. So, just coming back to your point, I think we would keep it until such time as the product which is the primary implant is being used in the market, because you never know. I will give you another example: a knee that was discontinued way back in 1998—

**Senator BOYCE**—I love the idea of a discontinued knee! Do go on, Mr Dasgupta.

**Mr Dasgupta**—So the knee was discontinued in 1998, but we still have to maintain the revision component because after 10 or 15 years, when the revision comes, you need not revise the entire knee; you need to revise a certain component. So we keep that component in our system and in the inventory.

**Senator BOYCE**—Thank you.

**CHAIR**—I thank these witnesses for their evidence.

[4.03 pm]

**STANISTREET, Mr James, Managing Director, Medtronic Australasia Pty Ltd**

**VALE, Mr Brian, Technologies Advocate, Medtronic Australasia Pty Ltd**

**WILTSHIRE, Mr Andrew, Director, Corporate Affairs, Medtronic Australasia Pty Ltd**

*Evidence was taken via teleconference—*

**CHAIR**—The technical problems have been fixed and we can now hear from Medtronic Australasia. I welcome the witnesses. Information on parliamentary privilege and the protection of witnesses in evidence has been provided to you. We have your submission, thank you very much. I would now ask either or all of you to make some comments if you choose to and then we will go to questions.

**Mr Stanistreet**—To the chair and the committee members, we do appreciate the opportunity to speak to our submission. We regret that we are unable to be there in person but due to the meeting we have with all our staff on the next three days it has been impossible to do that.

I would like to state that we do support the development of registries in selected areas such as the NJRR. There is little doubt that they fill a useful purpose in adding to our collective knowledge around therapies and technologies. We believe that this in turn leads to improvements in healthcare delivery. This particular registry has minimal impact on our business as we only have four spinal implants products in our range. So the impact for Medtronic is pretty minimal.

You may wonder why we wanted to contribute. We would really like to be involved in this submission because we are looking at the impact of these registries going on in the future and we believe that this legislation appears to have been drafted hastily and without the benefit of broad consultation with stakeholders. We believe this process could be improved and we think that in its current form the legislation appears to be flawed. The committee will be aware that the development of further registries is contemplated in the future. So that is our real concern. We think it is unfortunate that this legislation addressing the NJRR has been developed without stakeholder input. We hope this can be addressed before it is enacted and becomes a guide for the development of future registries. We ask that in reviewing this legislation the committee acknowledge the many beneficiaries of this registry—in particular: the general public, doctors, device companies and private health insurers—and question why it is proposed to ship all the cost to suppliers by a private health insurance arrangement.

If the committee sees fit to reject the legislation in its current form then we ask that you: first, consider directing wide stakeholder consultation to ensure the complex issues around registries are understood; secondly, consider ensuring that costs are shared between all beneficiaries and thirdly, that you make it clear that the significance of registries capturing wider therapy and device data is understood and addressed before we go into putting these registries together, and that all players should have representation in the management of registries.

That is our opening statement in terms of how we are approaching this submission at this stage.

**Senator ADAMS**—Thank you. I would like to ask you a question about those other beneficiaries as you see them. Can you somehow work out how all those people could be involved in partaking in the levy? What sort of process would one use to actually capture all the people that have benefited from it?

**Mr Stanistreet**—That is a challenging one. There is one suggestion: that the TGA manage this. We see the TGA's role really as post-market surveillance and they could manage this process.

**Mr Wiltshire**—I am not sure if anyone else has brought up the example of the NJR registry in the UK where device companies do collect a levy from purchasers on behalf of the registry and pass that funding on to the registry?

**CHAIR**—Could you clarify a little more how people who use the registry would pay?

**Mr Wiltshire**—I guess there are two potential options. The UK example is that the purchasers of the product pay a levy which the device manufacturers collect and pass on. The other option would be potentially that those who wish to use the data would pay a fee to access the data.

**Senator ADAMS**—If this legislation was held up and you had the opportunity to consult with the department on these ideas, how would you go about it? Who would you bring in with you to do this consultation?

**Mr Stanistreet**—The three of us would certainly like to be involved. We see it as broader than just Medtronic and that all stakeholders should be involved in this process going forward. That is the way we would like to see it approached. The device company, the doctors, private health insurance would need to be involved in consultation. We think this process is being rushed through and therefore needs more consultation to make sure we get it right before we go forward. We believe there will obviously be further registries in the future and we need to get the process correct before we put this through for approval.

**Senator ADAMS**—Since you found out about the legislation, have you been in touch with the department?

**Mr Stanistreet**—Just through the industry association. The industry association, the MTAA, has been in contact with the department of health.

**Senator ADAMS**—Have you been in touch with the other stakeholders that you mentioned before?

**Mr Stanistreet**—No.

**Senator BOYCE**—I note that you are a private company. Could you give us some sort of indication, either by staff size or something else, what size company Medtronic Australasia is please?

**Mr Stanistreet**—We are part of a multinational organisation, which has its head office in America. In Australia we are around about 400 employees.

**Senator BOYCE**—Thank you. I certainly was not aware, until the evidence from your industry association and one other supplier in the area, of the potential biases that might come up in using results from registry data. Do you perceive that there is a conflict of interest in the Orthopaedic Association being the only managers of the registry?

**Mr Wiltshire**—When any single group that is involved runs the entire process there is the potential for a conflict of interest. We do not suggest that the Orthopaedic Association has a particular conflict of interest. However, if data being collected that involves multiple stakeholders and only one stakeholder group owns the data and directs the design of the registry, there is always the potential for a conflict of interest.

**Senator BOYCE**—You mentioned earlier the management of the registries should be broadened. Is that what you were suggesting? That other groups should be involved in managing the registry?

**Mr Wiltshire**—I think that would be appropriate. I am sure you have heard some of this from MTAA and Johnson & Johnson, but if the registry is to be truly useful for all of the stakeholders then the design of the registry needs to be broader as well to include a wider variety of end points.

**Senator BOYCE**—It is more the design that you think should be changed. You are not suggesting that in fact there should be some sort of an independent body managing it?

**Mr Wiltshire**—I think we would also suggest that an independent body, or at least a body that involves a broader representation, should manage the registry.

**Senator BOYCE**—I note that in your submission you say:

Industry was a significant contributor to the establishment of the NJRR.

Can I ask when that was?

**Mr Stanistreet**—I do not have an answer of a specific date.

**Senator BOYCE**—A year would be sufficient.

**Mr Vale**—I understand it was in the middle to late 1990s. The answer may be with the industry association, if they are still with you.

**Senator BOYCE**—When you say ‘a significant contributor’, was Medtronic involved in that?

**Mr Stanistreet**—No.

**Senator BOYCE**—I was just thinking that, if there had been a significant amount of consultation et cetera at that time, it would be doubly disappointing that this had occurred now with no consultation whatsoever. Would that be your view?

**Mr Wiltshire**—Yes, it would be our view.

**Senator BOYCE**—You also make the point in your submission that this cannot have been something that the Department of Health and Ageing just came up with the day before the budget. What made you make that suggestion?

**Mr Vale**—I do not think we actually used those words in our submission.

**Senator BOYCE**—No, but I think there is a suggestion here that you believe that the Department of Health and Ageing must have been considering the move for some time. Perhaps that would be a more temperate way to phrase it. Is that correct or not? I may have confused submissions by this time of the day.

**Mr Vale**—Yes, that is correct. We had understood from our industry association that this was a move that had been contemplated for some time. Again, just to confirm, our position is really one around the way in which this seems to have been developed hastily, and our concern is particularly that it may serve as a poor model for registries in the future. The committee will be aware that further registries have been developed and it would be a pity if we ended up with a model which did not optimise all the great benefits that can come from registries. We think this is an opportunity to take a second look at this and perhaps be sure this is a very good one that sets a benchmark for other registries going forward.

**Senator BOYCE**—I think you will find within the next couple of years that every hollow log in Australia will have been picked up and shaken very hard. I would like to ask you now a couple of questions that I asked Johnson and Johnson. One was: what would you expect the cost to your company to be if this legislation were implemented as it currently stands?

**Mr Stanistreet**—We are not quite sure, but we have four key items that would fall under this legislation. If it were the maximum of \$5,000, we are talking about \$20,000 potentially at this stage with this particular registry.

**Senator BOYCE**—The other point that has been made to us by a number of witnesses is that there would be less incentive for suppliers and manufacturers to list products that are not used very often or products that are kept in stock for revisions if this legislation were passed. Would that be your view and, if so, what types of products that you currently supply might that effect?

**Mr Wiltshire**—It is our view that that is a potential. For our current products there is probably not an example of that, but if you look at the potential extension of this registry into the cardiac area we could give you quite a number of examples of revision kits and revision equipment that is used for pacemaker implants, heart valve implants and stent placements that would fall into that category.

**Senator BOYCE**—Your company does not make cardiac implants, but you are just aware of that information, are you?

**Mr Vale**—Our company does make them. Medtronic covers a number of different areas, including cardiac, diabetes, ear, nose and throat, spinal, cardiac rhythm management.

**Senator BOYCE**—Sorry, I always thought spinal implant was your area of specialty. Could you summarise how many products in the cardiac area you think might be affected?

**Mr Wiltshire**—We could not give you that number off the tops of our heads, but it is quite a number of products. We do keep quite a number of kits that are purely for revision purposes.

**Senator BOYCE**—How long would you currently hold revision stock? How many years?

**Mr Wiltshire**—I will give you a similar example to Johnson & Johnson. The lifetime of a pacemaker, for example, is up to 10 years or even longer. We would have to keep products in stock for at least that amount of time.

**Senator BOYCE**—Thank you, that answers my questions.

**CHAIR**—Thank you so much for making yourselves available and for having the interest. As you said at the beginning of your evidence, this particular bill does not impact on you greatly, but in terms of the wider issue, you felt it was important to be involved, so we do appreciate that. If you think of anything else that you think we should know, you have the secretariat's email. What happens to me is I walk away and immediately think of exactly what I should have said. If that does happen to you, just email us.

**Mr Stanistreet**—Thank you very much.

**CHAIR**—The committee stands adjourned until Monday morning at nine o'clock when we will be hearing from the department. That will also be a public hearing and it will be webcast. If people are interested in that, they will be able to see the department give evidence.

**Committee adjourned at 4.21 pm**