HEALTH INSURANCE (NATIONAL JOINT REPLACEMENT REGISTER LEVY) BILL 2009

THE INQUIRY

1.1 In accordance with a Senate Resolution of 14 May 2009 to refer certain budget-related bills to Senate Committees, the provisions of the Private Health Insurance (National Joint Replacement Register Levy) Bill 2009 (the Bill) have been referred to the Community Affairs Legislation Committee (the committee) for inquiry and report by 16 June 2009.

1.2 The committee received 19 submissions relating to the Bill and these are listed in Appendix 1. The committee considered the Bill at two public hearing in Canberra on 11 June and 15 June 2009. Details of the public hearings are referred to in Appendix 2. The submissions and Hansard transcript of evidence may be accessed through the committee's website at: http://www.aph.gov.au/senate/ca.

THE BILL

1.3 The Bill creates a new Act, the *Private Health Insurance (National Joint Replacement Register Levy) Act 2009,* for the purpose of establishing the National Joint Replacement Register Levy to fund the National Joint Replacement Registry (NJRR).

1.4 According to the Explanatory Memorandum, the Bill contains cost recovery arrangements to ensure continued funding for the NJRR whilst preserving its independence:

> As levies will be imposed under legislation, and collected by the Government on behalf of the Registry, there will be no possibility of funding being withdrawn from the Registry by medical devices sponsors.[1]

1.5 It is proposed that a levy will be imposed on each joint replacement prostheses sponsor on each day specified in the Private Health Insurance (National Joint Replacement Register Levy) Rules as a NJRR levy day and each day (if any) determined by the Minister of Health and Ageing by legislative instrument to supplement the NJRR levy day. The Bill specifies, however, that there can be no more than four levy days in a financial year.[2] It recognises a sponsor as:

> A person is a joint replacement prostheses sponsor if a joint replacement prostheses is currently listed in the Private Health Insurance (Prostheses)

---

1 *Explanatory Memorandum*, p. 1.

2 *Explanatory Memorandum*, p. 1.

> Rules (commonly referred to as the Commonwealth Prostheses List) either as a result of an application made by the person under subsection 72-10(2) of the *Private Health Insurance Act 2007*, or is listed in accordance with section 12 of the *Private Health Insurance (Transitional Provisions and Consequential Amendments) Act 2007* and the person was the sponsor of that prosthesis for the purpose of the *National Health Act 1953.*[3]

1.6 Sponsors will be levied in accordance with the number of joint replacement prostheses they sponsor with the levies utilised to fund the operating costs of the NJRR. The rate of levy for joint replacement prostheses will vary and may be set from zero to a maximum of $5,000.[4]

1.7 The Bill enables the Minister to make Private Health Insurance (National Joint Replacement Register Levy) Rules providing for matters required or permitted by the Bill to be provided, or necessary or convenient to be provided in order to carry out or give effect to the Bill. The Rules 'may provide that one or more kinds of prostheses are taken, or are taken not, to be joint replacement prostheses for the purposes of the definition of *joint replacement prosthesis*'.[5]

1.8 The Bill also provides that the Governor-General may make regulations prescribing matters required or permitted by the Bill to be prescribed, or necessary or convenient to be prescribed in order to carry out or give effect to the Bill.

1.9 The NJRR has been funded by the Commonwealth Government since 1998 and the introduction of the cost recovery arrangements under the Bill are estimated to amount to a budget saving of $5 million over four years.[6]

BACKGROUND

1.10 Approximately 70,000 hip and knee replacements are undertaken each year in Australia with the rapid increase in the rate of joint replacement surgery set to continue.[7] The Department of Health and Ageing (the department) stated:

> Expenditure on hip and knee prostheses represents around 30% of total expenditure by health insurers on prostheses. Insurers paid $1.039 billion in benefits for prostheses in 2007–08, out of a total of $7.4 billion spent on hospital benefits in that year. This means that prostheses expenditure represents around 15% of privately insured hospital benefit outlays.[8]

---

3 *Explanatory Memorandum*, pp 1–2.

4 *Explanatory Memorandum*, p. 2.

5 *Explanatory Memorandum*, p. 4.

6 *Explanatory Memorandum*, p. 2.

7 National Joint Replacement Registry, *About*, http://www.dmac.adelaide.edu.au/aoanjrr/about.jsp?section=about (accessed 9 June 2009).

8 Department of Health and Ageing, *Submission 18*, p. 6.

1.11 The NJRR was established in 1998 by the Australian Orthopaedic Association (AOA) with the operating costs of the registry funded the Commonwealth. The six aims of the NJRR are:

- to determine demographic and diagnostic characteristics of patients undergoing joint replacement surgery throughout Australia;
- to provide accurate information on the use of different types of prostheses in both primary and revision joint replacements;
- to evaluate the effectiveness of different types of joint replacement prostheses and surgical techniques at a national level;
- to compare the Australian joint replacement experience to that of other countries;
- to provide confidential data to individual surgeons and hospitals to audit their joint replacement surgery; and
- to educate Australian orthopaedic surgeons in the most effective prostheses and surgical techniques to achieve successful outcomes.[9]

1.12 The NJRR website states that its role is to monitor joint replacement in order to maintain safety and the quality of joint replacement prostheses:

> The purpose of the Registry is to define, improve and maintain the quality of care of individuals receiving joint replacement surgery. It achieves this by collecting a defined minimum data set that enables outcomes to be determined on the basis of patient characteristics, prosthesis type and features, method of prosthesis fixation and surgical technique used. The principal measure of outcome is revision surgery. It is an unambiguous measure of the need for further intervention. Combined with a careful analysis of the timing and reasons for revision this can be used as an accurate measure of the success or otherwise of a procedure. The Registry also monitors mortality rates. This information is then used to inform surgeons, other health care professionals, governments, orthopaedic companies and the community.[10]

1.13 In its submission, the AOA, which manages and administers the NJRR, noted the contribution it has played to date:

> Although the NJRR has only been in existence and fully operational for a relatively short time, the information provided by the NJRR is already influencing joint replacement and associated technologies in a beneficial manner.[11]

---

9 National Joint Replacement Registry, *Aims of the Registry*, http://www.dmac.adelaide.edu.au/aoanjrr/about.jsp?section=aims (accessed 9 June 2009).

10 National Joint Replacement Registry, *About.*

11 Australian Orthopaedic Association, *Submission* 1, p. 1.

1.14 Mr Ian Burgess, Chief Executive Officer, AOA, noted that the benefits of the registry will increase over time and that the registry enjoys worldwide recognition and respect as a high-quality registry.[12]

1.15 The NJRR's contribution was recognised by a number of submitters including the Medical Technology Association of Australia (MTAA) which noted that the NJRR:

> …is a class registry in that it collects information on close to 100 per cent of orthopaedic procedures in Australia. It is then able to track occurrences of revisions of the orthopaedic devices used in the original procedure. The information collected by the NJRR is able to identify a range of reasons for revision, including surgeon technique, hospital-related infection, patient compliance, and device performance.[13]

1.16 The MTAA further stated:

> NJRR is the first national comprehensive class register. The information collected by the NJRR is used for multiple purposes – to contribute to post market surveillance by the regulatory authority, Therapeutic Goods Administration (TGA), to monitor ongoing quality and safety of devices; to inform surgeons on clinical performance; to identify hospitals with a higher than expected infection rate; and to inform companies on product performance.[14]

1.17 The department commented that the NJRR assists in ensuring that expenditure on prostheses by the private and public sectors 'is directed to better performing products with lower revision rates'. The information provided by the NJRR has:

> …improved surgical practice and changed the use of particular devices, reducing the number of unnecessary revision surgeries by 1,200 Australians per year and saving the health sector and consumers around $44.6 million…These estimates are based on an analysis of the reductions in the proportion of hip and knee procedures that are visions during the period of operation of the NJRR.[15]

ISSUES

1.18 Submitters who supported the introduction of a NJRR levy included the Australian Health Insurance Association (AHIA) which stated that:

> The AHIA supports the proposed legislation. The Private Health Insurance Industry believes it should be incumbent upon those sponsors who wish to

12 Mr I Burgess, AOA, *Committee Hansard*, 11.6.09, p.1.

13 Medical Technology Association of Australia, *Submission 7*, p. 1.

14 Medical Technology Association of Australia, *Submission 7*, p. 1.

15 Department of Health and Ageing, *Submission 18*, p. 6.

> introduce prosthesis for use in the Australian health care system to demonstrate the device's efficacy, and quality and safety credentials.[16]

1.19 The Royal Australasian College of Surgeons noted that as the funding arrangements proposed in the Bill do not compromise the 'proven effectiveness' of the NJRR and existing arrangements whereby the AOA is contracted by the Commonwealth Government to administer the NJRR, it had no concerns with the passage of the Bill.[17]

1.20 However, concerns were raised by a number of submitters that there had been a lack of consultation with industry in relation to the levy, that the levy places an inequitable burden on industry, and that the levy mechanism had the potential to make some products unviable.

Lack of consultation with industry

1.21 A number of submitters raised concerns that the department had not consulted the industry and involved stakeholders before introducing the Bill.[18] Smith and Nephew Surgical held the view that consultation was important given the 'significant implications for companies' whilst St. Jude Medical noted that such consultation would have enabled delivery of 'good outcomes for all parties'.[19] Lifehealthcare Distribution also argued:

> Certainly this kind of proposal should follow appropriate consultation to achieve a result fairly across the spectrum of stakeholders, and there has been no consultation so far from the Department of Health and Ageing with the industry on this matter.[20]

1.22 Device Technologies questioned the logic of the timing of the Bill given that the Review of Health Technology Assessment (HTA) is currently underway and in light of a lack of consultation with industry stated:

> It is disappointing to note that despite the consultative progress being made through the current HTA Review and previous Productivity Commission reports, industry has not been consulted and appears not to be considered as an integral stake holder in the passage of this Bill, despite the proposed tax being directed specifically and exclusively towards sponsors of orthopaedic prostheses. Industry would have a conflict of interest in self funding a

---

16 Australian Health Insurance Association, *Submission 2*, p. 1.

17 Royal Australasian College of Surgeons, *Submission 11*, p. 1.

18 Stryker South Pacific, *Submission 5*; St. Jude Medical Australia Pty Ltd, *Submission 3*; Orthotech Holdings Pty Ltd, *Submission 6*; Smith and Nephew Surgical Pty Ltd, *Submission 4*. See also Advanced Surgical Technologies Pty Ltd, *Submission 8*; Austofix Group, *Submission 10*; Medtronic Australasia Pty Ltd, *Submission 13*.

19 Smith and Nephew Surgical Pty Ltd, *Submission 4*, p.1; St. Jude Medical Australia Pty Ltd, *Submission 3*, p. 1.

20 Lifehealthcare Distribution Pty Ltd, *Submission 9*, p. 1.

> registry of orthopaedic devices supplied by it to the Australian healthcare system.[21]

1.23 The department responded to these comments:

> For this particular budget measure, there was no consultation with industry prior to it being announced in the budget. Since budget night, we have provided a detailed briefing to the Medical Technology Association of Australia. That was on 21 May. They are currently holding information sessions which are open to members of the public including device manufacturers and importers. We held one in Canberra last week, one in Sydney and one in Melbourne, and we will have one in Brisbane on Thursday this week and in Perth on Friday.
>
> We have also had consultations with the industry about the proposal to cost-recover the cost of the National Joint Replacement Registry in the past. I think it was discussed in 2006.[22]

Joint Replacement Register Levy

1.24 A number of submitters from the industry, including the MTAA, supported the NJRR but held the view that the health system rather than industry alone should bear its costs:

> MTAA has long been a supporter of the value of well-designed and appropriate registries. Indeed, MTAA members committed funds to the pilot study for the establishment of the NJRR. However MTAA also believes that good public health policy which requires the active monitoring of the use and performance of products post-market should be a cost to the health system.[23]

1.25 St. Jude Medical Australia Pty Ltd also argued that the proposed funding arrangements placed the cost burden of the NJRR solely on the devices industry with limited benefits accruing to the industry:

> The Explanatory Memorandum to the Bill lists several moderate benefits that may accrue to industry but makes no mention of benefits that accrue to private health insurers, private hospitals, doctors, the public sector and consumers. It seems inequitable that industry only is to fund a registry that should be considered a public good.[24]

1.26 The MTAA noted that the NJRR was beneficial to multiple stakeholders including clinicians, the Therapeutic Goods Administration and hospitals.[25] It held

---

21 Device Technologies, *Submission 15*, p. 1.

22 Ms P Shakespeare, Department of Health and Ageing, *Committee Hansard*, 15.6.09, p.6.

23 Medical Technology Association of Australia, *Submission 7*, p. 2.

24 St. Jude Medical Australia Pty Ltd, *Submission 3*, p. 1.

25 Ms A Trimmer, MTAA, *Committee Hansard*, 11.6.09, p.6;

that the private health insurance industry also benefited as it was able to 'influence the level of reimbursement of comparator products listed on the Prostheses List'.[26] This view was supported by Advanced Surgical Technologies which stated:

> It could be argued that the NJRR serves us [the industry] least as certainly orthopaedic surgeons (through the AOA) and the Private Health funds utilize the data far more intensely than suppliers. Indeed the public sector is the primary beneficiary from the NJRR, hence Government's decision since its inception to fund the Registry.[27]

1.27 Emphasising the cost savings since the NJRR was established, Catholic Health Australia contended that the NJRR and any other registries be 'publicly funded on the basis that the savings realised will more than compensate for their running costs' and pointed to the 1,200 fewer revisions per year and saving (through reduced expenditure) of about $16–$32 million per year.[28]

1.28 Stryker South Pacific stated:

> Although industry is fully supportive of the NJRR and in fact assisted with its establishment costs, the beneficiaries are far broader than the stakeholders that have been targeted. This assistance has been provided in good faith to the benefit of the overall public. If orthopaedic sponsors are expected to take on the burden of these costs, the impact of this would be to the detriment of those it is intended to serve.[29]

1.29 Boston Scientific Australia New Zealand (BSC) suggested that the fiscal risk of the NJRR be shared between the government, AOA, health funds and sponsors:

> Each party contributes an equal share. BSC recommends that the levy on sponsors be based on a percentage of overall sales, not on a per listing basis. BSC also recommends that each orthopaedic surgeon be required to pay a flat fee to the College for the NJRR.[30]

1.30 Zimmer held the view that a model based on those of the United Kingdom and New Zealand where 'a levy is collected on each procedural invoice by the sponsor supplying the implants for that procedure' be introduced:

> The administrative cost of collecting this levy is borne by the sponsors, who then add their contribution and pass on the total levy to the registry at agreed intervals (quarterly, half-yearly or annually).[31]

---

26 Medical Technology Association of Australia, *Submission 7*, p. 2.

27 Advanced Surgical Technologies Pty Ltd, *Submission 8*, p. 1;

28 Catholic Health Australia, *Submission 19*, pp 1 & 2.

29 Stryker South Pacific, *Submission 5*, p. 1.

30 Boston Scientific Australia New Zealand, *Submission 14*, p. 4.

31 Zimmer Pty Ltd, *Submission 17*, pp 1–2.

1.31 Mr Andrew Wiltshire, Director of Corporate Affairs for Medtronic Australasia argued that there were two appropriate options: one based on the UK model where device companies collect a levy on behalf of the registry or alternatively, a user pays system for those who wish to access the data.[32]

1.32 In response to concerns regarding the levy, the department highlighted the appropriateness of manufacturers and importers of medical devices used in joint replacement surgery funding the NJRR's costs:

> …while there are other stakeholders who benefit from the data supplied by the NJRR, suppliers derive considerable direct financial benefit, as this forms part of their post-market surveillance of joint replacement prostheses. This monitoring of the safety and quality of devices provides benefit to the industry by improving consumer confidence in the safety and efficacy of joint replacement devices. Any devices showing high failure rates can be identified quickly and promptly removed from the market.
>
> The data produced by the NJRR also assists the industry by informing the development of new prosthesis, allowing manufacturers to draw on reliable performance information for existing products and designs.[33]

1.33 The department further commented that the arrangements proposed are consistent with the Commonwealth's cost recovery guidelines in that the costs would be met by those who have a direct financial benefit from the operation of the NJRR.[34] Examples of cost recovery arrangements through levies were provided by the department including the levy for the costs of the Private Health Insurance Ombudsman, who provides services to consumers, doctors, hospitals as well as private health insurers. As the most direct financial benefit of having those ombudsman services available in the industry accrues to the private health insurers, they are levied for the costs of running those arrangements.[35] The department concluded:

> Similarly, that is what is proposed in this case. Those that have the most direct financial benefit would contribute to the cost through the cost-recovery arrangements.[36]

---

32 Mr A Wiltshire, Medtronic Australasia, *Committee Hansard*, 11.6.09, p. 17; see also Johnson & Johnson Medical, *Submission 16*, p. 1; Mr S Dasgupta, JJM, *Committee Hansard*, 11.6.09, p. 12.

33 Department of Health and Ageing, *Submission 18*, pp 7–8; see also Ms P Shakespeare, Department of Health and Ageing, *Committee Hansard*, 15.6.09, pp 3–4.

34 The costs recovery guidelines are available at http://www.finance.gov.au/publications/finance-circulars/2005/09.html#FMG_4

35 Ms P Shakespeare, Department of Health and Ageing, *Committee Hansard*, 15.6.09, p.3; for further examples of cost recovery arrangements through levies see Department of Health and Ageing, Answer to Question on Notice, 15.6.09.

36 Ms P Shakespeare, Department of Health and Ageing, *Committee Hansard*, 15.6.09, p.3.

Implications on the viability of some products on the Prostheses List

1.34 St. Jude Medical held the view that as many products on the prostheses list attract relatively small benefits (and that benefits on the list have declined by eight per cent in real terms over the past years), an additional tax by way of the proposed levy could 'easily make some products commercially unviable, particularly if they are used infrequently or are specialised items'.[37] Medtronic Australasia held the same position and argued that the advice which informed the Explanatory Memorandum was 'at the very least disingenuous' and commented:

> We refer to the reference of some prosthetic devices receiving benefits as high as $67,000, as a justification for a potential maximum fee of $5,000. The Committee should be aware that only two items on the Prostheses List of more than 9,000 items are listed at this benefit level. Further examination would reveal these two items are very specialized and rarely used. The Committee's consideration of the suitability of free structures would have been better informed by advice that indicated more than 99% of the 9,000 items attract benefits of less than $8,000.[38]

1.35 This concern was also raised by Smith and Nephew Surgical and Stryker South Pacific who stated that there is no effective mechanism for passing on the costs by adjusting benefits.[39] Stryker South Pacific commented:

> The tax may well strike at the commercial viability of some listed products, eg revision items, such have had low utilisation however are absolutely necessary. It would be very unfortunate if such a scheme limited the access to many of the options that are available today, to those who need them to function and participate actively within the community. Such a scheme would well have this impact with the end user of the technology being the loser.[40]

1.36 Advanced Surgical Technologies shared the same concerns:

> Any tax imposed on suppliers would further erode our product margins and act as a barrier to introducing new technology, or even maintaining current products. Prostheses List benefits have reduced greatly over the last 3 years – minus 8% growth when adjusted for CPI. We have had to absorb business cost increases (eg wages, freight etc) well into double digits over the same period.[41]

---

37 St. Jude Medical Australia Pty Ltd, *Submission 3*, p. 2.

38 Medtronic Australasia Pty Ltd, *Submission 13*, p. 1.

39 Smith and Nephew Surgical Pty Ltd, *Submission 4*, p. 1; Stryker South Pacific, *Submission 5*, p. 1.

40 Stryker South Pacific, *Submission 1*, p. 1; see also Smith and Nephew Surgical Pty Ltd, *Submission 4*, p. 1.

41 Advanced Surgical Technologies Pty Ltd, *Submission 8*, p. 2.

1.37 The MTAA stated that as items listed on the Prostheses List are only those supplied to the private health system, supplies would be 'left with no alternative but to increase prices in the public health system as a result of the levy for the NJRR'.[42] Advanced Surgical Technologies maintained that removal of products from the Prostheses List, whilst remaining available in the public hospital system may lead to an increase in privately insured patients being treated in public hospitals with an on-cost to government.[43]

1.38 St. Jude Medical concluded that it was 'already disproportionately expensive and time consuming to market products in Australia which is only a tiny proportion of the international market'.[44]

1.39 Lifehealthcare Distribution maintained that the levy could jeopardise the commercial viability of both current and future innovations.[45] Global Orthopaedic Technology stated that Australian manufacturers will be 'effectively subsidising giant multinational manufacturers who dominate sales of joint replacement in Australia' if the Bill is passed in its current form which would discourage Australian manufacturers to develop new products and 'continue the trend towards loss of Australian manufacturing jobs'.[46] Global Orthopaedic Technology went on to state:

> The reality is that the large multinational orthopaedic device companies dominate the market. Each of these companies has significant numbers of Billing Codes to cover their product ranges. Smaller companies, such as ourselves, sell significantly lower numbers of joint replacements but are required by market pressure and the logistics of the industry to maintain similar numbers of Billing Codes in relation to hips and knee prosthesis.
>
> The end result of the Bill, as currently structured, is likely to be that our company will pay roughly the same amount under the levy as each of the large multinationals notwithstanding that each of the large multinationals sells approximately 10 times the amount of joint replacements that our company sells. This result is inherently unfair.[47]

1.40 In relation to concerns about viability, the department responded that:

> …the bill would allow levy rates to be set from nil, zero dollars, up to $5,000 as a maximum. If there are particular items that are going to be withdrawn from sale if there is a levy imposed, it is available to the government to set the levy for a particular product at zero. We need to discuss that with industry because our objective is to make sure that patient outcomes continue to be achieved and the levy is not designed to remove

42 Medical Technology Association of Australia, *Submission 7*, p. 3.

43 Advanced Surgical Technologies Pty Ltd, *Submission 8*, p. 2.

44 St. Jude Medical Australia Pty Ltd, *Submission 3*, p. 2.

45 Lifehealthcare Distribution Pty Ltd, *Submission 9*, p. 1.

46 Global Orthopaedic Technology, *Submission 12*, p. 1 and p. 3.

47 Global Orthopaedic Technology, *Submission 12*, p. 3.

> products from the prostheses list. We would need to assess, I suppose, if there were claims from a sponsor that they would withdraw a product, whether or not those claims were genuine by looking at utilisation data for those products.[48]

1.41 The department also noted that the additional costs could not be automatically passed on by device sponsors to private health insurers (resulting in increased premiums), because the benefits that private health insurers must pay for particular devices are set under Commonwealth legislation:

> Any increase in benefits for joint replacement products will need to be negotiated betweens sponsors and insurers and then approved by the Government through changes to the Prostheses List.[49]

Levy rate setting mechanism

1.42 Global Orthopaedic Technology raised concerns that the rate setting mechanism was based on the number of Billing Codes a sponsor has on the Prosthesis List rather than the number of joint replacements sold by a sponsor:

> The costs of operation of the NJRR relate directly to the numbers of prosthetic replacement operations actually performed and monitored.
>
> The Bill proposes to place a levy upon the sponsors of joint replacement prosthesis based upon the number of Billing Codes that a sponsor has listed on the Prosthesis List.
>
> We would point out that the number of Billing Codes that a sponsor has on the Prosthesis List is not the same thing, and is not related to, the number of joint replacements that a sponsor actually sells.[50]

1.43 The MTAA also commented that if the levy is based on listing rather than utilisation, then sponsors will need to reassess the benefit of retailing which might be used rarely.[51] BSC held the same concern, articulating potential ramifications:

> By basing the levy on the number of inclusions, there is an incentive to reduce the number of inclusions a company has on the Prostheses List. This is especially problematic for orthopaedics as companies have traditionally left products on the List in case of the need for revision. Some sponsors may consider it appropriate to remove earlier generations of products, therefore reducing the range of available products for patient revisions. This may lead to the need for surgeons to undertake a completely new replacement, rather than simply revising one component.[52]

---

48 Ms P Shakespeare, Department of Health and Ageing, *Committee Hansard*, 15.6.09, p.2.

49 Department of Health and Ageing, *Submission 18*, p. 8.

50 Global Orthopaedic Technology, *Submission 12*, p. 2; see also Mr S Dasgupta, JJM, *Committee Hansard*. 11.6.09, p. 12.

51 Ms A Trimmer, MTAA, *Committee Hansard*. 11.6.09, p.5.

52 Boston Scientific Australia New Zealand, *Submission 14*, pp 2–3.

1.44 The Austofix Group held the view that the Bill does not clearly identify the mechanism by which rates will be set and that any mechanism must take utilisation into account given that:

> In most categories, the majority of market share is held by a small percentage of items. For example, of the 200 or more femoral stems currently listed on the Prostheses List, the top 10 comprise 67% of sales, whilst the top 2 hold 33% of sales. These items attract a premium on the Prostheses List due to their utilisation, yet are out of patent and a number of 'generic' versions of these products are becoming available. To tax all femoral stems at a standard rate would create a further barrier to entry to cheaper alternatives and further entrench the market position of the market leaders. We believe such a system would be anti-competitive and would actually prove detrimental to both public and private health care systems.[53]

1.45 Smith and Nephew Surgical took the view that the levy, based on the Prosthesis List Billing Codes, would apply indiscriminately regardless of utilisation:

> The Explanatory Memo identifies the most expensive orthopaedic devise at $67K but omits the detail that these two specialised items are outliers with extremely limited utilisation and:
>
> - 47% of products have minimum benefits less than $1K
> - 89% of products have minimum benefits less than $4K
> - 99% of products have minimum benefits less than $8K.[54]

1.46 The MTAA held a similar view, noting that 'products will be attracting a significant, and disproportionate, individual levy to meet the projected Budget savings of $5 million over four years'.[55] This view was supported by the Austofix Group which argued that:

> Some items with large benefits are revision items that serve an important clinical purpose but which are not regularly utilised due to their specialisation. Their benefits reflect the considerable cost of maintaining inventories at such low utilisation and a poorly administered tax based upon benefit alone may affect the commercial viability of such items.[56]

1.47 Professor Stephen Graves, AOA, responded to industry comments concerning the cost of devices and stated:

> 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

53 Austofix Group, *Submission 10*, p. 1.

54 Smith and Nephew Surgical Pty Ltd, *Submission 4*, p. 1.

55 Medical Technology Association of Australia, *Submission 7*, p. 3.

56 Austofix Group, *Submission 10*, p. 1.

> would be used. That would be the minimum number of components… 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 prothesis for an individual.[57]

1.48 The department noted that the Bill allows for a single levy to be set for each levy day, or for different levy rates for different kinds of joint replacement prostheses. If all sponsors are levied an equal amount, the levy will be around $600.00–$650.00 per listing per year.[58] However, it is proposed that a range of levies be set in consultation with the industry as the Prostheses List benefit range for joint replacement devices is from around $50.00 to $67,000.00 per item.[59] The department stated:

> The government has proposed that there be a range of levies set in consultation with industry under the rules, because there is a broad range of approaches taken to listing products on the prostheses list. As I said, some sponsors have individual component pieces like bolts and screws listed separately on the prostheses list, whereas others have whole products with several components listed together, at a much higher benefit.
>
> We considered the best way to determine the levy and thought that, because there is such a wide range of benefits for different types of listings, it would be appropriate to set the levy based on benefit ranges rather than just having a flat fee that applies to anything listed on the prostheses list because there is a very broad range of benefits available.[60]

1.49 In relation to the maximum rates of levy, the department noted that the $5,000 maximum rate of levy has been set to cover increasing costs in the longer term.[61] The department also commented:

> Given the wide range of prosthetic devices used in joint replacement surgery and the corresponding variation in benefits for different kinds of joint replacement prostheses, a maximum rate of levy of $5,000.00 is considered reasonable.[62]

1.50 The department commented on the use of utilisation data to inform the levy setting mechanism. The department stated that the NJRR, while it collects information from all joint replacement surgeries and thus can identify how many of each particular device is used, it does not have access to costing data. The department stated:

> We have benefit data on the Commonwealth Prostheses List and we have all been in discussions with prostheses device sponsors over the last few

---

57 Prof S Graves, AOA, *Committee Hansard*, 11.6.09, p.3.

58 Department of Health and Ageing, *Submission 18*, p. 8.

59 Department of Health and Ageing, *Submission 18*, p. 8.

60 Ms P Shakespeare, Department of Health and Ageing, *Committee Hansard*, 15.6.09, p.2.

61 Department of Health and Ageing, *Submission 18*, p. 8.

62 Department of Health and Ageing, *Submission 18*, p. 8.

> years to try and match up those two data sets so that we can work out how many products sold at this benefit are being used, but that is not currently possible because the sponsors have declined to provide that information.[63]

1.51 However, the department indicated that the industry has recently reached agreement with the NJRR, after a number of years of negotiation, to provide billing code numbers to the registry and therefore 'in future we will be able to match up utilisation data with benefit data which will allow the levy to be set in a similar way to the UK levy'.[64]

1.52 In relation to the number of levy days, the department commented:

> Levies do not need to be imposed on all four or even six of those days. During our consultations with industry on the appropriate levy rates, we discussed that it would be better to levy only once year. That would reduce administration costs to the device sponsors who are being levied…So, if I have products on the prostheses list at this day, then I will be subject to a levy, which is imposed one month later. But again, the time between the census day and the imposition day will need to be discussed with industry before it is made under the rules.[65]

Industry representation on the National Joint Replacement Registry

1.53 A number of submitters from the industry questioned the logic that they were expected to pay for the NJRR but without greater representation in relation to the management of NJRR data. Ms Anne Trimmer, MTAA, noted that when the NJRR was first established there were two seats on the management committee for industry representatives. This is not longer the case.[66] Both Mr Sushobhan Dasgupta, General Manager of JJM and BSC articulated the industry's view that there should be 'no taxation without representation'.[67]

1.54 Orthotech Holdings stated that whilst the industry was expected to pay for the NJRR, it wouldn't have any say in the actual operation of the NJRR which it noted, 'could be run in a far more cost effective way'.[68] The Austofix Group also commented:

> We would also ask what oversight, if any, industry will have over the budget of the NJRR given that industry is the sole contributor to its operations?[69]

---

63 Ms P Shakespeare, Department of Health and Ageing, *Committee Hansard*, 15.6.09, p.3.

64 Ms P Shakespeare, Department of Health and Ageing, *Committee Hansard*, 15.6.09, pp 3 & 5.

65 Ms P Shakespeare, Department of Health and Ageing, *Committee Hansard*, 15.6.09, p.2.

66 Ms A Trimmer, MTAA, *Committee Hansard*, 11.6.09, p. 6.

67 Mr S Dasgupta, Johnson & Johnson Medical, *Committee Hansard*, 11.6.09, p. 12; Boston Scientific Australia New Zealand, *Submission 14*, p. 4.

68 Orthotech Holdings Pty Ltd, *Submission 6*, p. 1.

69 Austofix Group, *Submission 10*, p. 1.

1.55 Medtronic Australasia raised similar concerns:

> At present, with regard to the NJRR, industry does not hold any positions on the NJRR Management Committee. A position is held on the subordinate Advisory Committee. Should industry seek data from the NJRR, then it is only available on a payment basis. We are unclear as to what representation and access to data industry may have if the proposed legislation is enacted.[70]

1.56 In relation to such concerns, the department highlighted the importance of the independence of the NJRR, noting that the legislated cost recovery arrangements would ensure the continuation of such independence from industry as 'the levy will be mandatory and collected by the Government to fund the NJRR'.[71] The department went on to state:

> The proposed arrangements will preserve the independence of the NJRR. As levies will be imposed under legislation, and collected by the Government on behalf of the NJRR, there will be no possibility of funding being withdrawn from the NJRR by medical devices sponsors who are not happy with its findings.[72]

1.57 The department also noted that there is industry representation on the registry advisory committee as well as representatives of consumers, health insurers and the government.

A poor model for future registries?

1.58 Medtronic Australasia and the MTAA raised the concern that the imposition of a levy for the NJRR will create a precedent in relation to payment of registries in a context in which there are likely to be further registries established in the near future. MTAA argued that by:

> …aligning the cost of obtaining the information collected by a registry with the persons seeking it, there is an element of fiscal discipline. Failure to align incentives could result in a proliferation of registries and significant escalation of cost to the health sector. Ultimately, it is the funders (overwhelmingly the Federal Government) that will bear the costs of any increase in post market registries.[73]

1.59 BSC emphasised that if sponsors are required to 'foot the bill', it will 'discourage any sponsors from supporting the establishment of any future registries, for example the cardiac registry'. BSC also noted that sponsors are already supporting

---

70 Medtronic Australasia Pty Ltd, *Submission 13*, p. 2.

71 Department of Health and Ageing, *Submission 18*, p. 8.

72 Department of Health and Ageing, *Submission 18*, p. 10; see also Ms P Shakespeare, Department of Health and Ageing, *Committee Hansard*, 15.6.09, p.6.

73 Medical Technology Association of Australia, *Submission 7*, p. 3.

a range of local registries and trials and that they may review their current support to reduce the risk of 'unexpected new levies'.[74]

CONCLUSION AND RECOMMENDATION

1.60 As a means of ensuring the continuation of the NJRR, the committee welcomes the introduction of the Private Health Insurance (National Joint Replacement Register Levy) Bill 2009.

1.61 The industry raised a number of concerns during the inquiry, particularly in relation to equity of the levy arrangements and consultation with the industry. The committee recognises that as the primary beneficiaries, manufacturers and sponsors should cover the costs of the NJRR. The committee notes that the department is to undertake consultation with the industry before the finalisation of the regulations, including discussions with industry about the most appropriate ranges of levies. In addition, as the industry has now come to an agreement with the NJRR to provide data on billing codes, the department will be able to use this data to inform the levy setting process.

Recommendation

1.2 The committee recommends that the bill be passed.

Senator Claire Moore
Chair

June 2009

74 Boston Scientific Australia New Zealand, *Submission 14*, p. 3.