

## DEVICE TECHNOLOGIES

DEVICE TECHNOLOGIES AUSTRALIA PTY LTD  
ABN 40 058 091 973

June 4<sup>th</sup>, 2009

Senate Community Affairs Legislation Committee  
By email to [community.affairs.sen@aph.gov.au](mailto:community.affairs.sen@aph.gov.au)

Dear Sir or Madam

### PRIVATE HEALTH INSURANCE (NATIONAL JOINT REPLACEMENT REGISTER LEVY) BILL 2009

Device Technologies is an independent Australian company representing a vast diversity of independent global manufacturers that develop and launch leading edge medical technology. Device Technologies has recently participated in submissions to the Productivity Commission and to the Review of Health Technology Assessment (HTA). The HTA Review was announced jointly by the Ministers for Health and Ageing and Finance and Deregulation in December 2008 and submissions have only just closed on May 22<sup>nd</sup>, 2009. Device Technologies finds it surprising that Government is attempting to implement a new Bill effectively placing the financial burden of joint registries upon the medical industry and suppliers before reviewing the outcomes of the HTA Review. 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 registry of orthopaedic devices supplied by it to the Australian healthcare system.

Device Technologies is opposed to the motives of the new Prosthesis tax being suggested in the Senate Bill for the following reasons.

- An indiscriminate tax to orthopaedic sponsors, regardless of prostheses utilisation, is an unacceptable burden to this industry. An industry which of recent times has endured escalating costs to business with reduced access to prosthesis rebates (-8% growth in real dollar terms on average). In these difficult global economic times, affordability must further decrease the Australian healthcare system's availability and access to innovative new technologies due to the prohibitive financial and bureaucratic burdens placed on this industry.
- Gapped prostheses as a percentage of the Prostheses & Devices Committee's (PDC) Prostheses List have grown from 1.2% in 2005 to 18.5% in 2009. These gap numbers are certain to increase in the face of additional costs and charges imposed by the proposed Bill. Medical Technologies Association of Australia (MTAA) data suggests that Australia has the fastest growing percentage of patient out of pocket payments in the developed world and further financial burdens on industry would only serve to exacerbate this unenviable trend.
- The National Joint Replacement Registry (NJRR) has previously attempted to secure industry funding and so it should be no surprise that Government may seek to shift the financial burden again.
- Industry is supportive of registries and indeed assisted with the establishment costs for the NJRR in the late 1990's, however registries need to have a comprehensive scope to review not just product "failure" or some other end point parameter but also other material influences such as technique, operator competency, and hospital care outcomes which are all as important to the success of the clinical intervention than the implant in isolation. It is worth noting that one of the limitations of the NJRR is its measurement parameter of "revision" as the endpoint and the concomitant assumption by many as revision equating to "prosthesis failure" and its implications in the market and with funding agents.

Locked Bag 521  
Frenchs Forest,  
NSW 2086, Australia

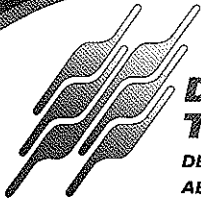
Unit 8/25  
Frenchs Forest Rd,  
Frenchs Forest  
NSW 2086, Australia

P: (61 2) 9975 5755 Toll Free: 1800 429 551  
F: (61 2) 9975 5711 Toll Free Fax: 1800 999 323  
[www.device.com.au](http://www.device.com.au) [customers@device.com.au](mailto:customers@device.com.au)

Sydney • Melbourne • Brisbane • Adelaide • Perth • Auckland



*First Choice*



## DEVICE TECHNOLOGIES

DEVICE TECHNOLOGIES AUSTRALIA PTY LTD  
ABN 40 058 091 973

- Many agents and bodies would seek to access information from the joint registry and would stand to gain significantly from the data collected. These may include the Therapeutic Goods Administration (TGA), Health Insurance groups, Government and Government agencies (PDC), clinician and professional groups, manufacturer and others. With such a wide audience, it seems patently unfair that one stake holder be responsible for the financial support of such an important public reporting body. It is worth also noting that as the greater public benefits from the data from any registry, it is interesting that only the Private Insured sector and industry would be funding the registries.
- Significant fees are currently paid annually to the TGA by device sponsors. The TGA clearly has a mandated role in ensuring products are safe. If the role of the registry is to track safe performance, then it would not be unreasonable to expect that this is handled by the appropriate body. Device Technologies' view is that the post market surveillance of medical devices may be best left where it currently resides, with the TGA.
- If the purpose of the registry is to track comparative performance and clinical outcomes against "like products" then this data is of far more importance to funders (Government and Private) and as they would be the main beneficiaries of this information should be the financiers of such registries for HTA.
- The collection of data and compliance by clinicians, hospitals and allied health professionals needs to be considered also. Any registry is only as good as the information fed into it and Device Technologies would have ongoing concerns that a mechanism needs to be in place to ensure that data collected is accurate and cannot be misrepresented.
- Device Technologies has concerns that a tax to fund the NJRR would be an unacceptable precedent for future registries and as such is extremely anxious of future increases in this tax to fund potential new registries.
- Device Technologies is also aware that there is no transparency of the current running costs of the NJRR nor is there evidence of the cost effectiveness and benefit delivered to the Australian public. As with all current fees and charges imposed on industry, there is no way of determining their efficient use in the management and collection of data by the agency (TGA or NJRR).

Device Technologies will further address its concerns and objections to this Bill directly with the Minister of Health, the Opposition and the Medical Technologies Association of Australia.

Yours sincerely

  
Brent van den Berg  
Australasian Marketing Manager

Locked Bag 521  
Frenchs Forest,  
NSW 2086, Australia

Unit 8/25  
Frenchs Forest Rd,  
Frenchs Forest  
NSW 2086, Australia

P: (61 2) 9975 5755 Toll Free: 1800 429 551  
F: (61 2) 9975 5711 Toll Free Fax: 1800 999 323  
www.device.com.au customers@device.com.au

Sydney • Melbourne • Brisbane • Adelaide • Perth • Auckland



ISO 9001



*First Choice*