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Committee Secretary
Senate Standing Committee on Community Affairs
PO Box 6100
CANBERRA ACT 2600

Dear Mr Humphrey,

**Proposal to Apply Cost Recovery Fees for National Joint Replacement Registry (NJRR)**

Medtronic Australasia, a supplier of spinal implants across Australasia, has been made aware of the Legislation Committee's review of the referenced proposed legislation aimed at recovering costs for the operation of the National Joint Replacement Registry (NJRR). We have a number of concerns that we wish to bring to the attention of the Committee.

We are concerned at the extremely limited time that has been allowed for consideration of such an important question. The Committee will be aware that this legislation is not informed by consultation with industry. We believe the broad question of cost recovery for the NJRR, effectively by levying an additional tax on industry, has probably been under consideration by the Department of Health and Ageing for some time. However, it is unreasonable to prepare such legislation without consultation and then to expect companies to bear the financial impact without notice to allow for budgeting.

Importantly, we believe that the advice which informed the Explanatory Memorandum is at the very least disingenuous. We refer to the reference to 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 fee 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.

In a general sense we support the thoughtful development of registries. Industry was a significant contributor to the establishment of the NJRR. A good post-market registry can assist device post-market surveillance and vigilance under conditions of actual use, rather than the often tighter controls that may be applied to clinical trials. Managing post-market surveillance and vigilance is a key role for the Therapeutic Goods Administration (TGA). The relationship between the TGA role and the "ownership" of registries warrants careful thought, as accurate data collection

extends beyond device performance and includes areas that are not the purview of the TGA.

We note and are concerned by the proposal in this legislation that while data will continue to be collected across the public and private sectors, costs are now to be moved wholly to the private health sector. There are numerous beneficiaries of a well-managed registry, not least the general public. Medtronic takes the view that the costs of maintaining a registry should be shared between all beneficiaries.

We hold to a view that registries are about more than device performance. Outcomes for surgical procedures involving implants are a complex mix of device selection and performance, patient selection and surgeon skill. Registries, such as NJRR, need to address each of these elements. The NJRR was identified in the Doyle Report of 2007 as needing to produce additional outcomes data, not just revision surgery rates.

Potentially, registries may extend for the life of the device, ie more than 20 years. This would make it extremely difficult for a sponsor to plan for the on-going resources required. At the very least cost recovery for a specific class of implant should have a mandated maximum period for which fees may be charged. Given the relatively short market lifespan of most implants (as opposed to the life of the specific implant), this would probably need to be in the order of not more than 2- 3 years.

Once data is collected who will be able to access that data? Are there safeguards against privacy trespass? 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.

It is easy to overlook patient/device-recipient views. Patients/recipients may often not be interested in participating in extended post-marketing studies/registries. Reasons for this include intrusions on personal privacy, intrusive nature of follow-up evaluation, burden of testing, and being reminded that they are "unwell" and/or dependent upon a device. While not an easy question, this issue needs to be considered before the rules/processes governing any registry are finalised.

Finally, long-term registries may often be difficult to interpret as they are typically less well-controlled than pre-market clinical evaluations, subjects may have diverse concomitant conditions (less restrictive selection/participation criteria), subjects may develop new conditions not present at the time of enrolment and concomitant therapies may change.

The proposal contained in the Bill appears to be hastily conceived and the rush to examine it may prevent thoughtful consideration by Parliament.

We believe that if this Bill is passed it would set an unacceptable precedent for the establishment and funding of other registries, yet to be considered.

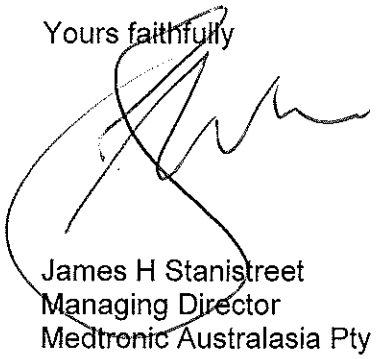
We ask that the Committee consider:

- whether the legislation should be withdrawn until it can draw upon and be improved by consultation with stakeholders;
- that it is unfair to expect industry to shoulder the costs for a registry with numerous beneficiaries;

- this additional tax cannot be borne by industry without these costs flowing on to product prices or where costs cannot reasonably be passed on, such products would no longer be supported; and
- what representation arrangements should be in place were industry required to meet costs.

Medtronic urges the Committee to consider a public hearing on this matter and indicates our preparedness to support such a hearing.

Yours faithfully



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