National Joint Replacement Registry Levy
Senate Community Affairs Committee

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Submission from Boston Scientific Australia New Zealand

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Introduction

Please accept this submission on the proposed Levy to fund the National Joint Replacement Registry. While Boston Scientific is supportive of increasing the use of post-market surveillance as part of a comprehensive medical device management strategy, the proposed Levy is ill conceived and will lead to a number of perverse incentives that will negatively impact on the future of post market surveillance systems in Australia.

Who are we?

Boston Scientific is the world's leading supplier of drug eluting stents, and a significant supplier of cardiac rhythm management devices such as defibrillators and pacemakers.

Boston Scientific is also a major sponsor of a number of international registries, including the SYNTAX Trial and Registry comparing complex cardiac patients being treated with drug eluting stents vs CABG. Boston Scientific also has 100,000 patients in its ALTITUDE Registry examining the real world impact of remote patient monitoring of implantable cardiac devices.

Boston Scientific Australia New Zealand employs 140 people, with an annual turnover of $150 million. Our head office is in Sydney, and we also have offices in Melbourne, Brisbane and Perth.

While Boston Scientific does not supply orthopaedic products, the use and funding of registries is of vital importance to all working in the health sector.

Background

Boston Scientific is very supportive of strengthening the role of post market surveillance mechanisms and the use of 'real world data' from registries. However, BSC cautions that poorly thought out public policy such as the proposed NJRR Levy might make it more difficult for Australia to strengthen its post-market surveillance capability.

The NJRR is a unique type of registry in Australia. It was established by the AOA with the initial backing of industry. The NJRR has buy-in from all AOA implanters and therefore provides an universal data collection on orthopaedic prostheses. The NJRR limitations include its only endpoint of revision, and concomitant interpretation of that revision purely as prosthetic failure.

The Senate Committee, in considering the bill needs to take into consideration the following potentially perverse incentives, and implications.

1. The proposed billing mechanism based on Prostheses List inclusions may lead to a reduction in available products, especially the removal of grandfathered products for revision.

   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.

Consolidation of inclusions is also a risk. A company would be encouraged to list as many models under the same inclusions as possible. The PDCs relatively immature system, with no clear definitions of 'product change' or 'product difference' means that there is already inconsistencies in what is listed on the PDC – single products, or entire product families under the same listing.

Equally, it could also encourage companies to simply list the entire system, and not the individual components. This would have huge impact on the health funds. Hospital would no longer be able to bill a fund for a single component, instead they would bill for an entire system, even if only a single items was used.

Utilisation is a vital component, as some products have no sales in a year, while others have a huge volume. The proposed blanket charge approach would disproportionally impact small volume (often specialised) products.

2. This type of Levy will impact on sponsor's willingness to support Australian registries in the future. As noted, the NJRR was established with the support of sponsors, for the benefit of the AOA. Sponsors rightly believed that in supporting its establishment they were assisting Australian clinical practice but that their obligation to provide on-going support would be limited. By requiring sponsors to foot the bill, it will discourage any sponsors from supporting the establishment of any future registries, for example the cardiac registry.

   Equally, sponsors are already supporting a range of local registries and trials. To reduce the risk of unexpected new levies, companies would review their current support in case the Government moves to charge them for these as well.

3. Australia has been pushing to increase its role in international research, and linkages with global studies and advances in medicine. Sponsors are less likely to risk funding registries and trials in Australia if they think that any initial support could lead to the Government forcing them to pay for research sought by the professional colleges and/or health funds. Put simply, why would a company support research in Australia if they are likely to end up funding it forever, especially if the research itself is only useful to Australia, which is 2% of the world market.

4. One of the significant criticisms of the NJRR is that its usefulness is limited. It simply looks at revisions, and until recently argued that revision means device failure. The NJRR could do more for both Australia and in international markets. However, its usefulness is limited by it governance structure. Industry should be represented on the Governance, and work with the AOA to 'power' up the registry to examine clinical effectiveness, clinical skill and patient satisfaction factors. This type of information would make the NJRR internationally relevant. It would also make funding it more palatable because the results could be used elsewhere.

5. Sponsors of low volume specialised products are likely to simply withdraw them from the Prostheses List. These products would be funded via the health funds ex-gratis mechanisms. At its most extreme it would increase "Today Tonight" access to care. Namely the use of media campaigns to lobby for access for identifiable patients. I note that two of the most expensive orthopaedic items on the Prostheses List are for children.

6. BSC also believes that if sponsors are going to be required to fund a registry, the sponsors should be represented. Its an old rule of democracy, no taxation without representation.

7. The proposed NJRR Levy is not a useful model for the future. While the NJRR is restricted to just orthopaedic devices, a cardiac registry will look at devices (drug eluting and bare metal stents), pharmaceutical treatments, and also critically at surgical procedures such as Coronary Artery Bypass Graft (CABG). The proposed levy structure would not work, as there are no sponsor's products listed on the prostheses list for CABG. Using the same principle, a levy would be placed on cardiac surgeons. It would be unfair for device sponsors, or even pharmaceutical companies to fund the surgical registry arm.

Alternative Approach

Boston Scientific does believe that there is a role for industry in supporting the development and on-going costs of registries. Industry already funds registries around the world, and supports local Australian registries for a range of procedures. To limit the risk of registry proliferation and unsustainable cost shifting to industry, the fiscal risk should be share between:

- government;
- professional colleges;
- health funds; and
- sponsors.

In this way, there would be a direct financial incentive to ensure any use of resources on a registry is maximised by all four stakeholders.

Boston Scientific recommends that the Senate Committee change the proposal Bill to share the fiscal risk of the NJRR 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.