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Senate Standing Committees on Community Affairs
Department of the Senate
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Inquiry into the number of women in Australia who have had transvaginal mesh implants and related matters

The following submission is in response to the Committee's 2017 call for submissions into the number of women who have had transvaginal mesh implants and related matters.

In summary, the prevalence and severity of problems attributable to transvaginal implants over the past two decades – with a substantive cost to the public/private health systems and injury to patients – demonstrates that there is compelling need to strengthen Australia's regime for the regulation of medical devices. The problems are indicative of systemic weaknesses involving the key regulatory agencies and practitioners. Failure to address those problems will have a tangible impact on national productivity, health spending and the wellbeing of patients and families.

The following paragraphs are provided on an independent basis (author details are given at the conclusion of the submission) and reflect research over the past decade into pharmaceutical/device regulation.

They are consistent with overseas studies regarding harms, innovation and regulatory costs. They are also consistent with developments overseas, notably the strengthened European Union regulatory framework of March 2017 that addresses concerns regarding device implants.

Scope:

Specifically, the submission relates to Term of Reference 6:

The Therapeutic Goods Administration's:

a. role in investigating the suitability of the implants for use in Australia;
b. role in ongoing monitoring of the suitability of the implants; and
c. knowledge of women suffering with health problems after having transvaginal mesh implants.

Introduction:

This submission is informed by Australia's recent historical and current experience with medical device and pharmaceutical failure, which includes

- joint prostheses;
- breast implants;
- contraceptive implants;
- cardiac stents and pacemakers; and
- a range of pharmaceuticals;

in addition to the subject of the current enquiry, transvaginal mesh implants. That failure is indicative of systemic weaknesses in the prevention of and response to foreseeable harms.

Those device failures have resulted in multiple Senate inquiries, including the 2011 inquiry into the regulatory standards for the approval of medical devices in Australia, and the 2012 Senate inquiry into the role of the Government and the Therapeutic Goods Administration (TGA) regarding medical devices, particularly Poly Implant Prothese (PIP) breast implants, consistent with other studies of the regulatory framework such as that by the Australian National Audit Office in 2011, the 2014 Review of Medicines & Medical Devices Regulation, the Health Technology Assessment Review and the review to improve the transparency of the Therapeutic Goods Administration. They have also resulted in litigation that – similar to experience overseas – has either resulted in settlements by medical product providers and practitioners or in damages awards by courts.

In some instances, such as the PIP implants, consumer victims have been left without recourse against anyone over their failed device, notwithstanding that the device's failure is a product of multiple – in some cases egregious and criminal – failures on the part of manufacturers, distributors, and regulators to act in the interests of the consumer.

Common to each example of device or pharmaceutical failure is the significant burden, both economic and non-economic, inflicted on consumers as a consequence of the failure. Harms experienced by consumers as a consequence of device and pharmaceutical burden include death, permanent disability, and chronic pain, as well as direct economic costs such as additional medical care, and indirect costs associated with inability to work.

It is important to recognise that the burden extends beyond patients and their families. There is an adverse impact on the national economy through costs to the public and private health systems, and through lost productivity (eg patients and carers being off work because of injury attributable to the medical devices or drugs).

<u>The Therapeutic Goods Administration</u>

The Therapeutic Goods Administration (TGA), as the regulatory agency responsible for managing the Australian Register of Therapeutic Goods, has a critical role to play as gatekeeper to the Australian market. It must seek to balance the interests of the community in having speedy access to new pharmaceuticals and devices, against the requirement that those pharmaceuticals and devices be safe, while subject to market pressures from industry stakeholders, and global trends towards harmonisation and expedition of approval processes.

The TGA is generally performing its role well. However the consequences for consumers who are injured by inadequately regulated devices and pharmaceuticals are of sufficient magnitude and severity that the TGA's role in approving and monitoring the use of the device or pharmaceutical should always be examined, to identify opportunities for further improvement.

The current enquiry represents such an opportunity. Given our concern regarding systemic weaknesses in the regulatory regime we recommend that the enquiry should consider the role of the TGA not just in isolation, restricted to transvaginal mesh, but also in the broader context of recommendations arising from the recently completed Review of Medicines and Medical Devices Regulation, and the Government's response to those recommendations.

Recommendations of the Review of Medicines and Medical Devices Regulation

The Review of Medicines and Medical Devices Regulation was announced in 2014, and was established to examine Australia's medicines and medical devices regulatory framework and processes with a view to identifying:

> areas of unnecessary, duplicative, or ineffective regulation that could be removed or streamlined without undermining the safety or quality of therapeutic goods available in Australia; and opportunities to enhance the regulatory framework so that Australia continues to be well positioned to respond effectively to global trends in the development, manufacture, marketing and regulation of therapeutic goods.

Notwithstanding that the Review's objective was streamlining approval processes, thereby better enabling market access, it is significant that key recommendations arising from the Review relate directly to enhancing monitoring and reporting adverse events associated with medical devices and pharmaceuticals.

Of particular significance were Recommendation 22 and 27, which called for: the establishment of a register of high-risk implantable devices; better data collection; better data sharing between local and overseas regulators; and better communication with practitioners and consumers to promote reporting of adverse events, and alert practitioners and consumers to emerging risks.

In particular

> ***Recommendation Twenty-Two:*** *The Panel recommends that:*
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> *1. All high-risk implantable devices are included in a registry that is compliant with the requirements for registries established by the Australian Commission on Safety and Quality in Health Care (ACSQHC).*
>
> *2. Responsibility for ensuring that registries are operated consistent with the ACSQHC requirements should rest with the NRA.*
>
> *3. Data collected by device registries should be made available to the NRA in a timely manner to inform post-market monitoring.*

4. The NRA should implement an active programme of analysis and reporting on adverse events, and associated data, collected through registries or by other means.

5. The NRA should continue collaborative activities with overseas medical device regulators to actively share registry and other monitoring data, with a view to facilitating timely identification of emerging safety concerns and to inform better clinical practice.

Recommendation Twenty-Seven: *The Panel recommends that the Australian Government develop a more comprehensive post-market monitoring scheme for medicines and medical devices. Such a scheme to include:*

1. Better integration and timely analysis of available datasets, including analysis of matched de identified data from the Pharmaceutical Benefits Scheme, Medical Benefits Scheme, eHealth records, hospital records, private health insurance records and device and other relevant registries and datasets;

2. Establishment and maintenance of registries for all high-risk implantable devices;

3. Implementation of a scheme to alert practitioners and consumers that a drug is newly registered and to encourage reporting of any adverse events;

4. Provision for electronic reporting of adverse events; and

5. Enhanced collaboration with overseas NRAs to share information relating to safety or efficacy.

Government response

The Government's response to these recommendations has been disappointing. In essence, it has misread harms, risks and impacts on the national economy.

Citing concerns about the costs of establishing and maintaining a register of high risk implantable devices, the Government has deferred consideration of this recommendation, although it accepts the portion of the recommendations calling for improved data collection and sharing, and communication.

In evidence presented to the Review Panel, the National Joint Replacement Registry was identified as an example of a successful registry model, 'estimated to have reduced the number of unnecessary revision operations by 1,200 procedures per year and saved the health sector and consumers around $44.6 million' in its first decade of operation. Furthermore, the Registry was claimed to have

> enabled the identification of post-market signals, informed clinical practice, and identified better performing devices. It was involved in the identification and later worldwide recall of DePuy ASR hip replacements between 2007 and 2010.

Notwithstanding the creation of the NJRR, a recent class action before the Federal Court featured 1700 plaintiff victims claiming damages from DePuy International Ltd resulting from the ASR hip prostheses. The claim was settled in favour of the plaintiffs, for a sum of $250 Million. For many plaintiffs involved in that class action, compensation can never adequately represent the pain and suffering, loss of amenity, and ongoing disability they will experience for the remainder of their lives. The settlement further does not address the impact on the economy through patient incapacity, through the cost to public/private

health insurance and health facilities of any remedial action (eg surgery to replace defective implants), and lost productivity by carers. Research underway by Bonython and Arnold indicates that those costs dwarf the budget of the TGA.

Relevance to the current enquiry:

The Committee will undoubtedly hear similar testimony from victims of failed transvaginal mesh devices, who have similarly suffered debilitating severe pain and suffering, loss of amenity, and disability.

In the face of such harm, we would urge the Committee to reject the Commonwealth's deferral of the Review's recommendation to establish a register of high risk implantable devices based purely on narrow economic principles, and again call for the establishment of such a register.

At a minimum, we respectfully suggest the Committee recommend the Government commission a cost benefit analysis of the establishment of such a register, examining not only the direct costs associated with its establishment and maintenance, but also examining the potential for costs savings to the individual and the taxpayer through early identification of adverse events under a register.

As the basis of informed evaluation by all stakeholders the results of that analysis should be published. The analysis might be undertaken by the Productivity Commission, given that agency's expertise and wide recognition of its provision of empirically-based independent research.

Recommendation:

The submission recommends that the Committee seek authorisation for a broader enquiry into the activities of the TGA encompassing all of its regulatory activities, specifically considering the appropriateness of the existing industry funded model of regulation, and the effect of that model on the independence of the TGA, and the benefits of removing the legislated indemnity provisions currently protecting the TGA from being sued for negligent performance of its regulatory functions.

We consider that any analysis of the TGA's funding and its effectiveness in preventing/responding to substantive harms requires data collection not only on the TGA's running costs, but also on the costs associated with the long term financial hardship experienced by those affected by device failure, noting the high morbidity and mortality associated with some of these failures.

Background:

The authors of the submission are law academics at the University of Canberra, with a long-standing research interest in the effectiveness of the Therapeutic Goods Administration (TGA) in regulating access to market for pharmaceuticals, medical devices and appliances, and other related activities.

Bonython has a close relative who is a member of the one of the plaintiff groups involved in a class action against the manufacturer of one of these devices; however she is not involved in the matter as either a claimant or a legal advisor, and has no financial interest in its outcome. Furthermore, the class action post dates commencement of her research activities in this area. Otherwise, neither contributor to the submission has anything that could reasonably be construed as a conflict of interest.

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