



**Private Healthcare Australia**  
Better Cover. Better Access. Better Care.



## Review of Human Tissue Laws

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## About Private Healthcare Australia

Private Healthcare Australia (PHA) is the Australian private health insurance industry's peak representative body. We have 22 registered health funds throughout Australia as members and collectively represent 98% of people covered by private health insurance. PHA member funds provide healthcare benefits for more than 15 million Australians.

## Response

PHA welcomes the opportunity to provide feedback to the Australian Law Reform Commission Review of Human Tissue Laws.

The trade in human tissue products in Australia has changed, with very large and increasing sums of money now involved. These funds are ultimately coming from people with private health insurance through legislated benefits under the Prescribed List of Medical Devices and Human Tissue Products (PL) managed by the Commonwealth. Income for one entity has increased by a staggering \$45 million in seven years, with no oversight of the commercialisation of the supply chain, where the human tissue product is coming from, and where the money is going.

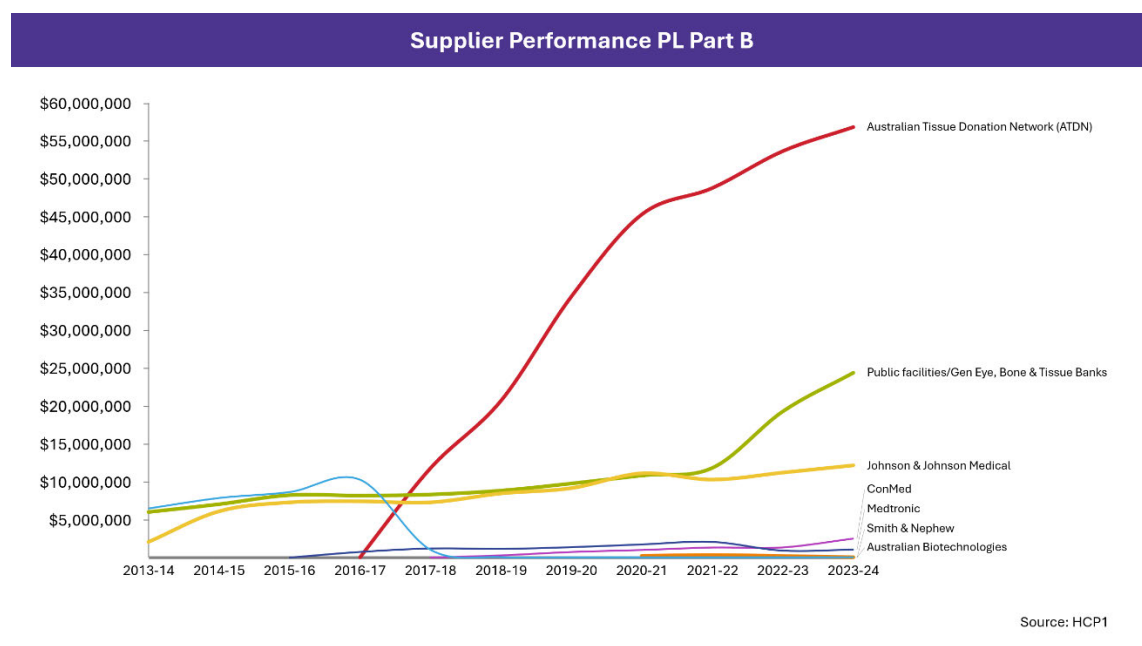
The rise of a new commercial model has been associated with large changes in clinical practice, which have the potential to increase low value care, to endanger patients and corrupt the traditional market of not-for-profit tissue banks. There have been no evidence-based changes in clinical practice that account for these changes in clinician behaviour.

There has been a considerable shift in the use of human tissue products in Australia over the past decade with more patients receiving higher volumes of human tissue in surgery now than ever before. This is despite clinical guidelines around the use of human tissue products remaining the same. Evidence for this change in clinical practice is lacking as there are no quality assurance mechanisms in place to determine if what is occurring is in the best interests of patients.

The large sums of money being made through the trade in human tissue products in Australia is a significant contributing factor for this increase, despite this coming from consumers with private health insurance (PHI) through legislated benefits under Part B of the PL.

Graph 1 outlines data for commercial operators of human tissue products on the PL over the past five years. It shows income from one entity alone has increased from less than \$10 million per annum in 2016-17 to \$55 million in 2023-24.

**Graph 1: PHI billing data from human tissue suppliers**



The growth in volume and cost of human tissue products in Australia is also outlined in Table 1.

**Table 1: Part B Prescribed List data<sup>1</sup>**

	<b>2023-24 cost (est.)</b>	<b>Five-year growth in volume (est.)</b>	<b>Five-year growth in cost (est.)</b>
01 - Cardio-thoracic (Part B Human Tissue)	\$870,000	39.2%	59.0%
02 - Ophthalmic (Part B Human Tissue)	\$4,800,000	17.8%	38.8%
03 - Orthopaedic (Part B Human Tissue)	\$91,490,000	132.9%	183.6%
04 - Dermatologic (Part B Human Tissue)	\$12,460,000	32.0%	65.2%

The increased utilisation in orthopaedic surgery is largely due to the extraordinary growth in use and amount of bone allograft – crushed bone transplanted into another individual in surgery – being used in Australia. PHI data shows there has been a 350% in the use of allograft over the past decade, despite surgery rates and the amount of hardware being used in surgeries remaining stable during the same period.

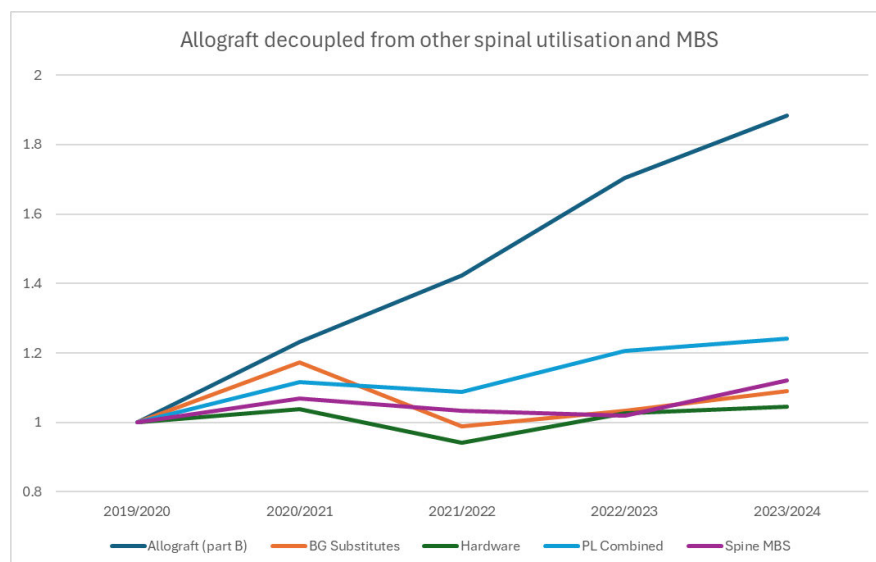
<sup>1</sup> From HCP1 data. Figures are extrapolated from 89.4% complete data set in 2023-24, with dollar figures rounded down to the nearest ten thousand.

Allograft is commonly used in spinal surgeries and some knee and hip procedures to replace damaged bone. While 5-7cc of bone graft is recommended per level for a spinal fusion, health funds have been invoiced for quantities as high as 70-75cc of allograft in a single level spinal fusion.

Graph 2 highlights the increase in allograft compared to other products on the PL. Allograft is in such high demand that a considerable amount put into Australian patients has to be sourced from overseas, raising concerns about its safety, origin and the circumstances surrounding its donation.

There is also anecdotal evidence that the shortage in allograft is resulting in Australian patients being encouraged to donate any autograft – crushed bone from their own body – leftover from elective surgery so it can be used in other patients. Questions have been raised about whether patients are being properly informed that their donated tissue may be sold, therefore, whether they have consented to Australian surgeons and/or companies profiting from their donation of human tissue.

**Graph 2: Increase in allograft used according to PHI billing data**



A national review of human tissue laws is needed to ensure there is consistency across all state and territories regulating the retrieval and use of human tissue.

PHA has made the following submissions to the Australian Government in recent years in relation to human tissue products:

- [Reforms to the Prescribed List Part B](#)
- [Modernisation of Part B of the Prostheses List - Consultation Paper 2\(a\)](#).

Given the increasing use and volume of human tissue products being used in Australia from overseas, especially allograft, the review should examine whether law reform is needed in relation to:

- the origins of donated human tissue products from overseas being used in Australia
- the circumstances of overseas donations (i.e. to rule out organ harvesting, organ trafficking or other potential human rights violations), and
- the adequacy of testing of foreign tissue products in Australia to ensure it is safe to be put into Australian patients.

PHA also encourages the review to examine whether commercial operators and individual surgeons should be allowed to continue to profit from human tissue donations or whether law reform is needed. Current disclosure requirements are inadequate in ensuring Australian patients are being properly informed and are consenting to their donated tissue being sold for use in other patients.