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Senator the Honourable Fiona Nash  
Assistant Minister for Health  
Parliament House  
CANBERRA ACT 2600

Dear Senator Nash

The Biotherapeutics Association of Australasia (BAA) is the peak body representing the tissue banking sector in Australia. We are writing to you in response to your recent announcement of an independent review of the Organ and Tissue Authority (OTA). In the transplantation field, organ donation has always had a far greater public perception and awareness compared to tissue donation. This is despite there being internationally many more lifesaving or life enhancing tissue transplants with direct benefit to the community compared with organs.

Since the instigation of the OTA there has been progress in redressing this balance, not least by a focus on promoting organ *and tissue* donation, standardised collection and comparable reporting of tissue donation and implantation data, and government funding to cover the direct regulatory costs to not for profit tissue banks in meeting the requirements of the new TGA Biologicals Framework that could have had severe adverse impacts on the tissue banking sector.

The OTA has been progressing Measure 8 of the National Reform Agenda through the recently formed Eye and Tissue Advisory Committee (ETAC), which includes a work plan for;

- An Economic Analysis of the Eye and Tissue sector to assess the ability for banks to meet clinical demand for eye and tissue allografts and identify options for improved efficiency and effectiveness.
- An implementation plan for ISBT 128 in the eye and tissue sector as a WHO endorsed universal coding system for tracking allografts from donor to recipient. This will facilitate bio vigilance, collation of accurate data and impede trafficking.
- Completion and implementation of a national training and education program for both eye and tissue banks.
- A system for notification to all banks of emerging epidemiological situations.
- A review of the funding model applied to tissue banks which is currently a significant constraint.



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Although we welcome any review that improves tissue donation and positive patient outcomes in the transplant area, BAA would be concerned if this review causes any loss of positive momentum in the tissue donation space which will have a direct negative impact on meeting clinical demand. We hope we can work together to assure a sustainable self-sufficient tissue banking sector for Australia.

Yours respectfully

**President**  
**Biotherapeutics Association Australasia**