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4 July 2025

President Hon Justice Mordecai Bromberg,
Commissioner Maeghan Toews

Australian Law Reform
Commission
PO Box 209
Flinders Lane
Victoria 8009

Submission for the Review of Human Tissue Laws

Dear Justice Bromberg and Commissioner Toews,

Norton Rose Fulbright is a global law firm, providing legal services to a range of corporate and institutional clients. We welcome the Government's intent to harmonise and modernise human tissue laws and are supportive of the Australian Law Reform Commission's (**ALRC**) inquiry into this area of the law.

We have had reason over a very considerable number of years to advise clients on multiple aspects of the tissue laws across all the States and Territories of Australia. We have provided such advice both from the perspective of those supplying tissue based or derived products, and those who may be contemplating the receipt or purchase of such products.

We have in the course of providing such advice, engaged with multiple of the Departments or agencies charged with the administration of the various acts, and in some cases been involved in the amendment of the relevant legislation.

In broad terms, our submission divides into two themes:

- First, the desire for uniform laws across Australia.
- Second, the content of those laws.

As to the first, we will deal with it now. As to the second, we will endeavour to provide our views in a manner that aligns with the questions posed in the issues paper.

Desire for Uniformity

Whilst different laws across the State and Territories are good for the legal profession, they are not good for business, and in this case, the broader health sector.

This is doubly so where concepts such as sale, supply or purchase are terms which invariably have a territorial nexus. It also vexes issues such as advertising which is apt to have the opposite problem.

On the basis that a well considered "model law" might arise from this process, we can nonetheless understand that a given State or Territory may have a basis for wishing to depart from that model, but it would be hoped this would be on the basis of some clearly articulated framework, determined having regard to the implications it may have.

Further the desire for uniformity will not be effectively achieved if issues are left to discretionary processes, where some approval process is required to be engaged in. Apart from the uncertainty of outcome of such processes, there is also the delay. That said, we can understand that novel circumstances which have not had the benefit of consideration in the course of this review, might be appropriate matters for such processes.

Content of the laws

Norton Rose Fulbright makes this submission against the backdrop of the two fundamental questions we get asked to address:

- Does the legislation apply?
- If it does apply, how do we comply with it?

Given that the ALRC has been recommended to consider 'contemporary research, emerging technologies and clinical practices for cell, tissue and organ donation, retrieval and transplantation' and 'any other relevant matter, including international experience and approaches', we hope that this submission proves useful in the inquiry.

- ***Do you agree that the issues set out in the section 'Priority reform areas' should be a focus for our Inquiry? Please tell us about why you think these issues should or should not be a focus.***

  The ALRC's current 'priority reform areas' capture several of the issues we have considered in the context of human tissue laws, and we agree that they ought to be given focus when considering legislative reform.

  <u>Definition of tissue</u>

  A number of issues we have encountered have arisen in a context of sub-components of tissue (particularly blood). These may through varying degrees of processing or treatment, and possible modification, be incorporated in various products. In some cases, the processes may involve a degree of replication, so that none, or only an untraceably small sub-component of the original material is present in the end product. The question is, when does the product cease to be tissue?

  We understand that to some extent these issues are ameliorated by exemptions for registered therapeutic goods, but that exemption does not cover tissue derived products that are supplied as sub-components.

  We consider that stem cells are perhaps worthy of specific consideration. The tissue from which they are collected, and their pluripotency characteristics raise interesting issues.

  The application of the tissue acts to otherwise regulated activities is an area of concern, and was a particular concern when the early tissue derived products on the Australian Register of Therapeutic Goods (**ARTG**) started to emerge. Apart from anything else, they were clearly commercial products. They were clearly sold, potentially through multiple distribution layers. They had prices reflective of the cost of development and risk, and commercial returns, far removed from a cost recovery exception, which has functioned as a sort of safety valve to allow for some limited charging by those who collect and supply tissue.

Anatomical and post-mortem examinations

We agree that anatomical and post-mortem examinations must be considered a point of focus in human tissue law reform. There is no disagreement that human remains must be treated with authenticity and dignity. However, with the aim of promoting scientific discovery and public welfare, we recommend that the law in this area be reformed to increase transparency and facilitate access for those with the appropriate intentions.

As a first point, the ability of a person to allow their whole body to be donated ought to be clarified. It is also recommended that the provisions related to consent in this context be reviewed with the aim of promoting greater consistency across jurisdictions. For instance, some jurisdictions may primarily consider *written* consent for post-mortem anatomical examination,[1] whereas other jurisdictions may also allow authorisation of such examination even if the deceased person has expressed *oral* consent during their last illness.[2]

The scope of what the body or its components can be used for needs to be considered. For example, is the training of already qualified surgeons fairly described as for scientific purposes or research? One can readily appreciate the virtue of training of surgical technique on a cadaver as opposed to a live individual.

Some focus on schools of anatomy has merit. When we have considered this issue, there was great disparity between various jurisdictions. Almost invariably, the statutory framework was limited and much depended on processes and guidelines applied by relevant departments. One issue of concern was provisions which might restrict the maximisation of the benefit that might be obtained from a donated body. This might manifest around transfer restrictions, destruction obligations and so forth.

Advertising and trade in human tissue

We also welcome the focus on advertising and trade in human tissue by the ALRC given that the prohibitions in these areas are somewhat inconsistent and perhaps overly stringent in some respects.

First, it must be observed that the acuteness of the concerns about this issue are quite closely tied to the definition of human tissue, and when the restrictions “run out” in the sense that the product then being considered is no longer properly considered subject to these tissue advertising restrictions. Is a wholesaler listing bone putty with a relevant price on their widely circulated price list offensive?

Clearly, at the other extreme, payments to persons from whom tissue is taken might be regarded as close to the essence of the prohibitions in the tissue acts in the first place. Anything that taints the consent and donation concept needs special scrutiny.

However, the Issues Paper does highlight the highly problematical issue of blood donations, in a society where there is a critical, and as we understand it, increasing need for blood.

We note that there may be ethical and scientific purposes which do not recognisably fall into any of the exceptions for tissue trading or advertising. Often, these ‘special circumstances’ require Ministerial permission to legally deal with human tissue in the intended way. Historical grants of permits by the Ministers reflects the necessity and benefits of such use of human tissue. It may be useful to consider incorporating additional exemptions to the prohibitions on trading in tissue to allow for circumstances which have repeatedly been recognised by Ministers as non-offensive to the objectives and principles of human tissue laws.

[1] *Anatomy Act 1977* (NSW) ss 8-8A.
[2] *Human Tissue Act 1982* (Vic) s 28.

We support the ALRC's intention to review the language of the statutory prohibitions on trading in human tissue. Almost all prohibitions on trading in human tissue carve out an exception for 'therapeutic', 'medical', and/or 'scientific' purposes, yet these terms are not expressly defined. They beg a variety of questions as to just what they mean. For instance, do they cover obtaining material to be used in a diagnostic test, to test the safety of blood donations?

A commonly used exception is on the costs front which allows the ability to recover costs associated with the removal of tissue. This is an exceedingly narrow concept in our view and ignores the reality that commonly there are other costs associated with the use of tissue, such as testing it, storing it or treating it. It is undesirable if what is happening in day-to-day practice is not in accordance with laws as written.

There are material differences in advertising prohibitions which exist across the different jurisdictions. Some jurisdictions do not contain an explicit prohibition (beyond the restrictions contained in other legislation), whereas others, such as Victoria, have a relatively broad approach to the issue.[3]

For multiple products, there are existing advertising overlays (and quite profound prohibitions) on advertising. But typically, they have no geographical dimension. Most advertising is difficult to geographically limit. Even the passive provision of information through a website, that can be viewed Australia wide, would give rise to concerns in some jurisdictions.

In an area where criminal penalties exist, we understand and emphasise that greater clarity in these provisions is of significant importance. This need for precision is even more apparent when observing the regulatory landscape as a whole and considering the impacts of privacy legislation and regulators' approaches.

- ***When we think about the laws governing how human tissue is obtained and used, what are good aims or objectives for these laws?***

  We appreciate the ALRC's focus on increasing access to human tissue, prioritising respect, supporting equitable participation in and access to the system, and promoting and upholding public trust.

  In consideration of the past regulatory issues we have considered, we also recommend that human tissue laws aim to capture modern uses of tissue which may not be currently captured expressly by the legislation. One would like to see legislation where there is a coherent rationale behind the limitation in the scope of the fundamental prohibitions.

- ***When we think about reforming human tissue laws, what principles should guide reform?***

  Our understanding of the principles underpinning the human tissue laws aligns with those identified by the ALRC, that is, the need for informed consent, restrictions on the commodification of tissue, and requirements to respect persons and the human body. In addition to these principles, we believe that adaptability and efficiency are two other principles which should guide legislative reform. This is especially relevant in the present where emerging biotechnologies and development in modern practices calls for a flexible and adaptive approach to legislative reform. It is recommended that the law accommodate for modern examples of tissue use and maintain the 'special circumstances' exceptions to prohibitions in order to support any unknown or emerging scenarios. Greater legislative consistency across the jurisdictions will also likely enhance efficiency as organisations are more easily able to navigate the regulatory and legal landscape.

- ***What, if any, other issues should we be focusing on in this Inquiry?***

[3] *Human Tissue Act 1982* (Vic) s 40.

In those circumstances where there is an exemption or permission pathway for trading in and advertising human tissue, the scope of those exemptions or the permissions are typically not publicly available, nor are they readily subject to FOI. Perhaps some consideration should be given to whether this is appropriate, noting that often these pathways are used when no settled parliamentary or community view exists. Visibility would allow broader consideration of such matters and assist organisations with their confidence in progressing with their development, research, or other operations. We do not consider these processes should be subject to external review through formal processes. This issue is of additional importance if the laws make the acquisition of products an offence if the supplier does not have a permit.

Beyond this however, these pathways, are typically put in place to deal with new circumstances, or where the balance of supply or not supply was nuanced. Accordingly, we can understand it may be essential that they remain in place to accommodate for any emerging developments in the context of human tissue.

We are grateful for the opportunity to provide a submission and hope that this submission is of assistance to the ALRC. We also appreciate that the Issues Paper is a first step towards modernising and aligning human tissue legislation in Australia and look forward to the further opportunities to engage in the coming year.

If we can be of any further assistance, please do not hesitate to contact us.

Sincerely,

Bernard O'Shea

Partner [redacted]tralia

[redacted]thank all the contributors to this submission including in particular Chitra Malik (Law

