Australian Law Reform Commission
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To whom it may concern

Review of Human Tissue Laws Issue Paper 51 (May 2025) - Submission regarding Issues 3 and 4

Thank you for the opportunity to make submissions concerning the Issue Paper published in respect of the Australian Law Reform Commission's ongoing inquiry into Australia's human tissue laws (the ***Commission***).

By way of introduction, I am a doctoral student at Sydney Law School. I am admitted to practice law as a solicitor in New South Wales and also hold general nursing registration. The current title of my in-progress thesis is 'Mixing Money and Medicine: Improving Australia's Organ and Blood Donation Rates Through Economic Incentives'.

I refer to Issues 3 and 4 of the Issue Paper which seek to identify 'good aims or objectives' for tissue laws and 'principles to guide reform'. These are commendable focusses and, in summary, I wish to raise a few points for the Commission's consideration of these Issues:

1. (**Future Proof Not Reactionary**) The regulatory framework should not be reactionary or overly driven by historical ideals but instead seek to provide a stable and 'future-proof' structure within which dealings with human tissue can efficiently and effectively occur. To achieve this, reform should be driven by a consultative process that seeks to uncover the views of a broad range of stakeholders not merely a certain type of stakeholder.

2. (**Four Principles Behind a Good Reform**) Any reforms should be grounded in a quadripartite of principles: they must be effective, ethical, legitimate and acceptable.

3. (**Primacy of Human Dignity**) The use of human tissue is closely intertwined with the dignity of the human person. The regulatory framework should have human dignity at the centre. This requires balancing and respecting the communitarian objective of making human tissue available for medical use, transplantation and research, individual autonomy and the importance of choice, and the position of vulnerable populations.

I elaborate on these points below.

Future-Proof not Reactionary

The genesis of the human tissue laws and the Commission's initial inquiry in 1977 occurred in the context of:

- a difficult legal and social history around the use of cadavers in science and medicine and complex cultural views on human remains;[1]

- a fairly rapid journey from the initial successful organ transplants to shortage and accessibility issues as these techniques became safer and more widely available; and[2]

- little existing judicial review or legislative frameworks.[3]

The result was that a legislative framework, highly influenced by contemporaneous community ideals, was created and implemented to fill a lacuna rather than to codify existing accepted legal norms as was the case, for example, in respect of medical negligence law.

While such a reactionary approach to regulation was necessary in the context of the initial enactment, any present reform and evaluation of the human tissue laws should seek to take a more measured and long-term approach. At least in the case of tissue, organ and blood for treatment, shortages are likely to worsen as Australia's population ages and grows and as the rates of chronic disease increase.[4]

An objective of the review should be: how can we make these tissue laws sufficiently adaptable to the technological advances and social changes of the next fifty years? The human tissue laws should engage with the potential directions of science, medicine and technology (including artificial intelligence and the prospect of synthetic tissue). It should

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[1] Unethical conduct in the procurement and use of cadavers was common in the UK and US, and to some extent Australia, over the course of the 18th to 20th centuries and the implementation of laws regulating the acquisition and use of human remains were the subject of intense ethical debate. See Helen McDonald, 'Humanity's Discards: The New South Wales Anatomy Act 1881' (2007) 12(4) *Mortality* 365; Piers D. Mitchell, Ceridwen Boston, Andrew T Chamberlain, Simon Chaplain, Vin Chauhan, Jonathan Evans, Louise Fowler, Natasha Powers, Don Walker, Helen Webb and Annsofie Witkin, 'The Study of Anatomy in England in 1700 to the Early 20th Century' (2011) 219 *Journal of Anatomy* 91; Sally Wilde, *The Body Divided: Human Beings and Human Material in Modern Medical History* (Routledge, 1st edition, 2012); Bretton A. Varga, Mark E. Helmsing, Cathryn van Kessel, Rebecca C Christ, 'Snatching Bodies, Snatching History/ies: Exhuming the Insidious Plundering of Black Cemetries as a Curriculum of Postmortem Racism' (2022) 55(3) *Equity and Excellence in Education* 283.

[2] Success in organ transplanting really only occurred in the 1950s (for example, the successful kidney transplant between living identical twins in 1954 in Boston) and during the 1950s, 1960s and early 1970s transplantation was predominantly pursuant to directed living donation (such as between family members) and rates of rejection remained high until developments of immunosuppression culminating in the discovery of cyclosporine in 1977. Transplantation became more readily available in the decade that followed.

[3] The Commission's 1977 report, which ultimately led to the recommendation and adoption of the existing human tissue laws, noted that there was no judicial authority directly on the subject of removing human tissue from a deceased person for transplant or therapeutic purpose and a need for regulation. See Australian Law Reform Commission, *Human Tissue Transplants,* Report No. 7 (1977) at [58].

[4] See Australian Institute of Health and Welfare, 'The Ongoing Challenge of Chronic Conditions in Australia', *Australia's Health 2024: Data Insights* (Web Article), https://www.aihw.gov.au/reports/australias-health/chronic-conditions-challenge.

also engage with if and how community perceptions around mortality and our bodies have changed over the past 50 years and how they might change in the future.

In that respect, the human tissue laws exist in and contribute to a broader public discourse on death, healthcare, property and research. In evaluating the operation of these laws and potential reform, I would urge the Commission to undertake or advocate for engagement and consultation with a wide range of stakeholders.

Views should be sought not just from those on the front line of human tissue usage but also from the fields of:

- palliative care;
- chronic diseases specialists;
- population health specialists;
- organ donation and transplant teams;
- law;
- research and education in the areas of anatomy, medicine and science;
- bioethics;
- different cultural communities and indigenous groups; and
- corporate and commercial operators in related contexts such as those involved nationally or internationally in the supply of blood, tissue, organs and cadavers.

Wide consultation will enable three things. First, as you know, it is a way of testing public attitudes to laws that touch a broad range of people and engage with multiple fields. Second, it will allow potential adverse consequences, inadvertent operational effects or ethical issues to be identified earlier in the law reform process. Third, it will increase the process legitimacy of any reforms and so be more likely to engender support from the broader population. I discuss legitimacy a little further below.

Ultimately, any discussion around reform and how to ensure the tissue laws have longevity would be made richer and more nuanced by engagement with diverse stakeholders.

Four Principles Behind a Good Reform

The second point I wish to raise relates to principles that ground a "good" law reform. In my view, four principles should guide law reform: efficacy, ethical alignment, legitimacy and acceptability.

Efficacy

The first, seemingly trite, principle is that the reform should be effective. Efficacy is three-pronged. The reform must achieves its objectives to an adequate level of success, the cost of that success (whether monetary or otherwise) must be minimal or proportionate to the level of success, and there must be no inadvertent adverse effects or, if there are, they need to be minimised.

For example, presumed consent or "opt-out" systems are frequently proposed as a means of increasing the availability of organs for transplantation from deceased donors. The UK,

Brazil and a number of European countries have transitioned to an "opt-out" model for organ donation whereby an individual's consent to be an organ donor is presumed unless they specifically registered their objection or, in some jurisdictions, where their next of kin vetoes or provides evidence of the deceased individual's objection.[5] Aside from potential issues with the quality of the consent in such a system, the efficacy of "opt-out" organ donation models is unclear. Some studies have reported a steady positive effect on the rate of donation[6] whereas others suggest that it decreases living donation, has only a modest effect on boosting deceased donation and, in countries where family veto rights are preserved, increases the likelihood of veto.[7] In countries that have reported success following their transition to an 'opt-out model', such as Spain and Wales, it can be hard to distinguish the success of the legislative reform from the success of the marketing campaigns and improved hospital protocols that accompanied the transition.[8]

An alternative example that relates to cost efficacy is the controversial proposal of blood or organ donation in exchange for cash compensation. Iran famously has a paid paired kidney exchange program and paid plasma donations are a common phenomenon in the United States. While such measures may be effective in terms of meeting their objectives (ie, they would likely raise the rates of donation and therefore increase availability of the tissue types in question), the "costs" would be significant and undesirable. If a government body were responsible for funding the payment, it could represent a significant financial burden thus diminishing any cost savings made as a result of less patients on, for example, long-term dialysis. In a non-monetary sense, the risk of exploitation if the compensation were provided by recipients and the potential ethical cost to society of facilitating a regulated organ market would no doubt outweigh any potential success.

When proposing any reforms to the human tissue laws we should be considering potential adverse effects of change, undertaking a thorough and "eyes-wide-open" cost-benefit analysis and assessing whether a legislative reform is even the best mechanism through which to enact change.

Ethics

The second principle is that the reform needs to be ethical. It should withstand genuine ethical scrutiny and emerge from a principled analysis in the "ethical" bucket. We should, of course, not be aspiring to or accepting of a reform that is unethical, not only from a moral

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[5] J. Miller, S. Currie & R.E. O'Carroll (2019) "If I donate my organs it's a gift, if you take them it's theft: a qualitative study of planned donor decisions under opt-out legislation" 19(1463) *BMC Public Health* 1, 2.
[6] See, for example, M. Usman Ahmad, A Hanna, Ahmed-Zayn Mohamed, Alex Schlindwein, Caitlin Pley, Ingrid Bahner, Rahul Mhaskar, Gavin J. Pettigrew, Tambi Jarmi, 'A Systematic Review of Opt-Out Versus Opt-in Consent on Deceased Organ Donation and Transplantation (2006-2016)' (2019) 43 *World Journal of Surgery* 3161; S. Madden, D. Collett, P. Walton, K. Empson, J. Forsythe, A. Ingham, K. Morgan, P. Murphy, J. Neuberger, D. Gardiner, 'The Effect on Consent Rates for Deceased Organ Donation in Wales after the Introduction of an Opt-Out System' (2020) 75 *Anaesthesia* 1146.
[7] See, for example, Adam Arshad, Benjamin Anderson, Adnan Sharif, 'Comparison of Organ Donation and Transplantation Rates Between Opt-out and Opt-in Systems' (2019) 95 *Kidney International* 1453.
[8] S. Madden, D. Collett, P. Walton, K. Empson, J. Forsythe, A. Ingham, K. Morgan, P. Murphy, J. Neuberger, D. Gardiner, 'The Effect on Consent Rates for Deceased Organ Donation in Wales after the Introduction of an Opt-Out System' (2020) 75 *Anaesthesia* 1146, 1150.

perspective but also because an unethical reform is likely to have negative social ramifications and lack longevity.

I overview one aspect of this in the next section in respect of human dignity. A topic such as human tissue laws inevitably results in tension points between different world views and ethical principles. Any reform in this area ought to align with our more general approach to health and bioethics in this country and seek to identify safeguards that can be implemented to strengthen the ethical integrity of the tissue laws as a whole.

Legitimacy

The third principle is legitimacy. Although difficult to ascribe a set meaning, legitimacy broadly relates to support for why an individual might obey a law or abide by a policy even though it may be against their interest or at least contrary to their personal opinion of what is "best".[9] The reform should engender trust and support from the population, even where it may not be the subject of consensus. Consensus is likely to be impossible in an area such as human tissue laws and so it is important that any reform is viewed as 'legitimate'.

In my view, consideration of whether a reform is legitimate involves assessment of:

1. whether the reform is justifiable in the particular legislative, social and cultural context? That is, do we need this reform, are its objectives appropriate and will they be adequately met?
2. who is responsible for administering this reform? That is, is there appropriate oversight, accountability and impartiality in how the reform is going to be administered and by whom?
3. how is the reform going to be implemented and conducted? That is, was there sufficient consultation and procedural fairness to make the adoption of the reform inclusive and transparent?

Legitimacy also goes hand in hand with trust. Trust is essential for long-lasting perceptions of legitimacy and conversely a lack of legitimacy can result in a crisis of trust. For example, if people perceive that a specific reform or its mechanics are illegitimate, it may engender distrust in the broader tissue donation, transplantation, research and health systems.

We should approach the design and consideration of reforms to the human tissue laws from the perspective of promoting transparency and trust in both the process for identifying and adopting reform and in the reform itself when implemented.

Acceptability

Fourthly, the reform needs to be acceptable. This relates to community perceptions and its alignment with socio-cultural norms. This is not to say that a reform should be trapped by the

[9] There is significant variety in the academic literature around how to define and assess legitimacy. This can include defining legitimacy as something that is inherent and founded on normative moral content, defining legitimacy by reference to another institution or ideal through which legitimacy is inherited, defining legitimacy by reference to process and conduct, or some mix of the above.

social norms of the day but that subversion or complete divergence from those social norms is likely to result in criticism and rejection.

An action or policy can be rejected by a community due to an emotive response of distaste or 'recoil' that has little to do with the effectiveness, ethics or legitimacy of the action and everything to do with the socio-cultural context and the values of a society. For example, in 2016, the Space World theme park in Japan froze some five thousand fish purchased from a market into an ice rink as an attraction to boost attendance. The overwhelming public reaction was one of outrage and disgust more due to sociocultural norms than to any genuine ethical objection.[10]

I raise this because there are influential socio-cultural perspectives that persist in the way in which we view the human body, research and healthcare as well as our viscerally negative reaction to economic or commoditizing language when used in the context of healthcare. The application of the human tissue laws also exists in an emotionally-charged context where availability of tissue is strained and the supply of tissue usually occurs pursuant to the death or illness of an individual. This means that human tissue laws are also caught up in the broader narrative of how we as a society see and deal with concepts such as death, family and community bonds, dignity and desire for legacy. Any reforms must be guided by and informed by these broader values and narratives to prevent rejection and criticism.

Primacy of Human Dignity

Dignity relates to a status or characteristic belonging to each human being that speaks to intrinsic worth and worthiness and therefore should engender and require respect.[11] Dignity is related to autonomy and, in surveys by the World Health Organisation conducted in 41 countries, was identified as being the second most important non-clinical component of healthcare (after prompt attention).[12]

Use of tissue that comes from a human body is therefore inextricably linked with the dignity and integrity of that body. The existing human tissue law is informed by notions of dignity even if these notions are more easily observed in the hospital protocols that shape the interactions resulting in acquisition of human tissue than in the words of the legislation itself.

There are many ways in which a person's dignity can be diminished. One way highly relevant to the use of human tissue is objectification. In a study undertaken by Jacobson, many participants discussed loss of dignity when they felt they were being treated like a 'thing'

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[10] See Healy & Krawiec's article on moral repugnance and the Space World rink: Kieran Healy and Kimberly D. Krawiec, "Understanding Moral Repugnance in Markets: Repugnance Management and Transactions in the Body" (2017) 107(5) *American Economic Review: Papers & Proceedings* 86.

[11] Kant's definition of dignity is in terms of unconditional and incomparable worth that accords with a human being's ability to reason and exercise autonomy: see Immanuel Kant, *Groundwork of Metaphysic of Morals* (Harper and Row Publishers, 1948). Beauchamp clarifies this definition by noting that an inability to exercise autonomy for whatever reason does deprive a person of their dignity: see Tom L Beauchamp, *Philosophical Ethics: An Introduction to Moral Philosophy* (McGraw-Hill, 2001).

[12] Martin Tattersall, 'Dignity and Health' in Jeff Malpas, Norelle Lickiss (eds), *Perspectives on Human Dignity: A Conversation* (Springer, 2007), 187; Nicole Valentine, Charles Darby, Gouke J Bonsel, 'Which Aspects of Non-Clinical Quality of Care are Most Important? Results from WHO's General Population Surveys of "Health Systems Responsiveness" in 41 Countries' (2008) 66 *Social Science & Medicine* 1939.

rather than a 'person'.[13] Any reforms aimed at increasing the supply of organs need to avoid perceptions that they inappropriately reduce people to a number of organs or source of tissue without respect for the person they are or were before that tissue became available.

A more significant aspect of protecting dignity is in the prevention of organ tourism and trafficking. The human tissue laws address a portion of this through the prohibitions on commercial transactions involving organs and tissue. Justification for such a prohibition is linked with exploitation risk and therefore dignity.[14] Despite this, the nature of shortage and the high stakes of those waiting for organs or tissue for treatment means that some Australians will travel overseas to seek access. A study undertaken by Coates et al found that most survey responders had discussed overseas travel for transplantation with at least one patient and just over half had cared for at least one patient after an overseas transplant.[15] In this context, the human tissues law should aim to pair prohibition of exploitative conduct with measures to decrease the shortage of tissue.

However, it is erroneous to view autonomy as the sole contributor and backbone of human dignity. Enhancement of communitarian and reciprocal relationships in society are also linked to human dignity and making tissue available for research and transplantation is necessary for the improved wellbeing and dignity of those struggling with illness. It is evident that these two components though both important to the promotion of human dignity can be in tension with one another as the desire to increase supply, based on communitarian utility, may tempt us to limit individual autonomy in order to achieve this aim.

A 'principlism' approach is often taken to ethical dilemmas in healthcare.[16] That is, principles and ideals are used to inform the decision-making process, for example by reference to autonomy, beneficence or utility. While some scholars criticise the use of a principle-based approach, it is widely employed in healthcare and is helpful in identifying tension points in certain situations because sometimes application of one principle diminishes another.[17] While as a general rule property or ownership in a body is only recognised in specific circumstances[18], respect for the autonomy and choice of an individual is a fundamental pillar of the existing human tissue laws and of health law in general. However, our desire for accessibility and the broad positive consequences that accessibility can have on population health and scientific progress in healthcare can sometimes result in an approach of 'the ends justify the means' or 'it's in the common good' at the risk of diminishing autonomy.

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[13] Nora Jacobson, 'Dignity Violation in Health Care' (2009) 19(11) *Qualitative Health Research* 1536.
[14] See discussion of exploitation and justice in Zumrut Alpinar-Sencan, 'Selling Organs Dignity as a Further Concern' in Solveig Lena Hansen and Silke Schicktanz (eds), *Ethical Challenges of Organ Transplantation: Current Debates and International Perspectives* (JSTOR, 2021), 209.
[15] Georgia Smith, Diba Gujari, Oscar Russell, Lyle Palmer, Maeghan Toews, Germaine Wong, Wai Lim, Stephen McDonald, Phillip Clayton, Dominique Martin, Patrick T Coates, 'International Travel by Australians for Overseas Transplantation' (2019) 211(10) *Medical Journal of Australia* 460.
[16] Often referenced is Beauchamp and Childress' approach in their 2001 book: Tom L. Beauchamp, James F. Childress, *Principles of Biomedical Ethics* (Oxford University Press, 5th edition, 2001).
[17] See for example, Samuel Dale, 'A Critique of Principlism: Virtue and the Adjudication Problem in Bioethics' (2023) 9 *Voices in Bioethics* 1.
[18] *Doodeward v Spence* [1908] HCA 45.

This is not to advocate for complete libertarian individualism which is clearly at odds with our approach to public health and welfare in Australia and should not be the goal. It is more a case of emphasising that any attempts to increase the supply of human tissue (however laudable) must not diminish an individual's ability to *choose*. This choice should not just relate to the decision to, for example, donate organs for transplantation or a body to research, but also to broader related choices such as how, when and where to die. A more complex reform or solution to tissue supply shortages, even if it involves slightly greater cost or administrative burden, should be preferred if it preserves and respects the role of patient choice. In the case, for example, of an 'opt-out' model of organ donation, arguably the desire for positive and immediate consent for donation is traded for the simplicity and low cost of reform. Alongside the questionable efficacy of an 'opt-out' system, this is, in my view, an undesirable trade off.

In essence, prioritisation of human dignity (of all persons involved in the giving, acquisition and use of human tissue) is a worthwhile objective for the human tissue laws. While community benefit and increased availability of human tissue should be the primary aim of any reform, preservation of autonomy and the implementation of safeguards against exploitation must be indispensable components of this.

Conclusion

Thank you for accepting my submission on these issues.

In essence, my view is that evaluation and reform of the human tissue laws is a worthwhile and necessary endeavour but that any reform must occur as a result of a complete, transparent and consultative process that adequately reflects the importance of tissue laws in Australian society, their use on a day-to-day basis and the high ethical stakes that are in play.

I hope that this submission will be useful to the Commission in embarking on that process. Please feel free to contact me if I can assist in any way.

Yours faithfully

Madeline R Fisher

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