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PROACTIVE REGULATION OF NEW TECHNOLOGY: MITOCHONDRIAL DONATION LEGISLATION IN AUSTRALIA

> 'At this moment it is incumbent on this government to give Australian parents the choice and opportunity to have children free from severe disease through the use of reproductive technology and to reduce the burden of disease for future generations. It is also essential that we remain at the forefront of advances in both medical science and reproductive technology. We cannot sit by complacently when the health and lives of Australian children are at stake and when the opportunity to provide hope and medical support is now with us.'[1]

I Introduction

In recent years, the use of in vitro fertilisation ('IVF') and other assisted reproductive technologies ('ART') in Australia has increased.[2] As with any new technology, this increased use necessitates adequate, responsive, and transparent legislation and regulation. This is in order to maintain public confidence in science and ensure that best practices are followed. A recent example of such legislation is the *Mitochondrial Donation Law Reform (Maeve's Law) Act 2022* (Cth) ('*MDLR Act*').[3] Part II of this article will examine the technical background of ART in general, and mitochondrial donation more specifically. Part III will explore both the contents and legislative history of the new *MDLR Act*. Part IV will canvass the wider discourse that surrounded the passing of the *MDLR Act*, within the context of the role of scientific regulation in general. Finally, some concluding thoughts will be offered in Part V. In summary, this new legislation is the product of many experts

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1 Commonwealth, *Parliamentary Debates*, House of Representatives, 24 March 2021, 3281 (Greg Hunt, Minister Assisting the Prime Minister for the Public Service and Cabinet and Minister for Health and Aged Care) ('Second Reading Speech').

2 Ashley M Eskew and Emily S Jungheim, 'A History of Developments To Improve in Vitro Fertilization' (2017) 114(3) *Missouri Medicine* 156; Jade E Newman, Repon C Paul and Georgina M Chambers, *Assisted Reproductive Technology in Australia and New Zealand 2019* (Report, National Perinatal Epidemiology and Statistics Unit, University of New South Wales, September 2021) vi, 4.

3 *Mitochondrial Donation Law Reform (Maeve's Law) Act 2022* (Cth) ('*MDLR Act*').

working together on a complex topic to produce a progressive piece of technical regulation.

II Technical Background

Mitochondrial donation is a technique used in conjunction with IVF. There are already existing legislative frameworks that govern IVF use in Australia.[4] However, newer techniques are still being examined by the legislature in an ongoing process. This article will comment on the legislative framework coming into force which regards mitochondrial donation, as recently enacted through the *MDLR Act* in April 2022.

Mitochondrial donation is a technique used to replace faulty mitochondria with healthy donor mitochondria.[5] The mitochondria are small organelles inside every cell that contain their own subset of circular mitochondrial DNA ('mtDNA').[6] Mitochondria are inherited maternally and as such, the paternal mitochondria are irrelevant to the risk of the offspring being affected as they are not passed on to the offspring.[7] The main function of the mitochondria is to create energy for the cell, which is in turn used to allow organs to function and everyday bodily functions to occur.[8] Therefore, the consequences can be dire when mitochondria are faulty.

Mitochondrial diseases 'vary in presentation and severity, but common symptoms include developmental delays, seizures, weakness and fatigue, muscle pain, vision and hearing loss, multiple organ failure and heart problems; leading to morbidity and in severe cases, premature death'.[9] As such, these diseases impact substantially on a person's quality of life. In addition, there is no known cure for mitochondrial diseases, with treatment options limited largely to management of symptoms.[10]

Mitochondrial disease can be treated through mitochondrial donation which, as mentioned above, involves replacing faulty mitochondria with working mitochondria. The procedure is done in conjunction with IVF.[11] The technique involves

4 *Prohibition of Human Cloning for Reproduction Act 2002* (Cth); *Research Involving Human Embryos Act 2002* (Cth).

5 Mitochondrial Donation Expert Working Committee, National Health and Medical Research Council, *Expert Statement* (Report, 11 March 2020) 4, 12 ('*Mitochondrial Donation Expert Statement*'); Marie A Dziadek and Carolyn M Sue, 'Mitochondrial Donation: Is Australia Ready?' (2022) 216(3) *Medical Journal of Australia* 118, 118.

6 *Mitochondrial Donation Expert Statement* (n 5) 12; Dziadek and Sue (n 5) 118.

7 Revised Explanatory Memorandum, Mitochondrial Donation Law Reform (Maeve's Law) Bill 2021 (Cth) 72 ('Revised Explanatory Memorandum').

8 Dziadek and Sue (n 5) 118; *Mitochondrial Donation Expert Statement* (n 5) 12.

9 Revised Explanatory Memorandum (n 7) 72.

10 Ibid; *Mitochondrial Donation Expert Statement* (n 5) 4, 12.

11 Revised Explanatory Memorandum (n 7) 2.

'combining the nuclear DNA from a male and female with healthy mitochondrial DNA from a donor egg'.[12] There are different methods, namely maternal spindle transfer ('MST') and pronuclear transfer ('PNT').[13] Regardless of the method, the outcome is such that every cell in the offspring contains the donated, healthy mitochondria, and the technique, in essence 'seeks to reduce the risk of a child inheriting mitochondrial disease from a woman carrying genes that cause the condition'.[14] That being said, there is a risk of the faulty mitochondria still 'carrying over' into the embryo[15] and therefore the carryover rates need to be monitored.[16] However, if successful, the procedure has a *lasting impact* on the offspring and all of their future children (if the offspring is female).[17] The procedure is sometimes referred to as creating 'three-parent' babies, as technically the resultant offspring contains nuclear DNA from the mother and father, as well as mtDNA from the donor.[18] However, it would be more accurate to refer to this as '2.002-parent IVF', due to the comparatively minimal amount of mtDNA compared to nuclear DNA.[19] This is crucial to the ethical issues concerning the technique and underpins some of the key legal challenges as well. In summary, the technique is irreversible, immutable, inheritable, and done before the resultant offspring can give any type of consent to the procedure.

III Legislative History

The *MDLR Act* passed both houses of federal Parliament on 30 March 2022. However, much work was done prior to this — this legislation was not rushed through Parliament, nor was it partisan in nature. Before discussing the *MDLR Act,* it is worth noting that mitochondrial donation was legalised in the United Kingdom in 2015,[20] with the first licences permitting mitochondrial donation issued in late

12 *Mitochondrial Donation Expert Statement* (n 5) 12; Revised Explanatory Memorandum (n 7) 72.

13 *Mitochondrial Donation Expert Statement* (n 5) 12; Dziadek and Sue (n 5) 118.

14 *Mitochondrial Donation Expert Statement* (n 5) 12.

15 Dziadek and Sue (n 5) 118.

16 John Christodoulou, Submission No 12 to Senate Community Affairs References Committee, Parliament of Australia, *Science of Mitochondrial Donation and Related Matters* (3 May 2018) 3; ibid 119.

17 Revised Explanatory Memorandum (n 7) 83.

18 Jessica Hamzelou, 'Exclusive: World's First Baby Born with New "3 Parent" Technique', *New Scientist* (online, 27 September 2016) <https://www.newscientist.com/article/2107219-exclusive-worlds-first-baby-born-with-new-3-parent-technique/>.

19 David Thorburn and John Christodoulou, '3-Parent IVF Could Prevent Illness in Many Children (But It's Really More Like 2.002-Parent IVF)', *The Conversation* (online, 11 November 2019) <https://theconversation.com/3-parent-ivf-could-prevent-illness-in-many-children-but-its-really-more-like-2-002-parent-ivf-126591>.

20 *The Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015* (UK) SI 2015/572.

2017.[21] This is relevant as the process followed in the United Kingdom has similarities to the process undertaken in Australia. This similarity in approach could be due to similar cultural views, social groups, and parliamentary systems. In the United Kingdom, the passage of the legislation followed lengthy consultation with the scientific community, as well as members of the wider population. There is currently only one facility in the United Kingdom, the Human Fertilisation and Embryo Authority ('HFEA'), that is licensed to treat patients with this technique.[22] The HFEA encourages follow-up appointments in order to continue to study the way the technique affects children born of it, but these follow-up appointments are not mandatory.[23]

Following the passage of legislation in the United Kingdom, Australia began considering the technology more seriously. In March 2018, the Senate referred the matter to the Senate Community Affairs References Committee ('Senate Committee'). The terms of reference included:

> (a) the science of mitochondrial donation and its ability to prevent transmission of mitochondrial disease;
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> (b) the safety and efficacy of these techniques, as well as ethical considerations;
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> (c) the status of these techniques elsewhere in the world and their relevance to Australian families;
>
> (d) the current impact of mitochondrial disease on Australian families and the healthcare sector;
>
> (e) consideration of changes to legal and ethical frameworks that would be required if mitochondrial donation was to be introduced in Australia;
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> (f) the value and impact of introducing mitochondrial donation in Australia; and
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> (g) other related matters.[24]

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21 Gráinne S Gorman et al, 'Mitochondrial Donation: From Test Tube to Clinic' (2018) 392(10154) *The Lancet* 1191, 1191.

22 Ibid; 'Mitochondrial Donation Treatment', *Human Fertilisation & Embryology Authority* (Web Page) <https://www.hfea.gov.uk/treatments/embryo-testing-and-treatments-for-disease/mitochondrial-donation-treatment/> ('Mitochondrial Donation Treatment').

23 'Mitochondrial Donation Treatment' (n 22).

24 Senate Standing Committees on Community Affairs, 'Terms of Reference', *Parliament of Australia* (Web Page, 2018) <https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/MitochondrialDonation/Terms_of_Reference>.

The Senate Committee then considered written submissions, held public hearings, and produced a final report.[25] This report had four substantive chapters, which considered disease burden, science, ethics, and regulation. The four overall recommendations from the Senate Committee were: (1) the necessity of public consultation; (2) tasking a National Health and Medical Research Council ('NHMRC') Expert Committee to answer key scientific questions; (3) the need to engage with the Council of Australian Governments ('COAG') Health Council; and (4) the need to explore facilitating access for Australian patients to existing United Kingdom services.[26]

To implement the second recommendation from the Senate Committee, the matter was referred to a NHMRC Expert Committee ('NHMRC Committee') which conducted an inquiry throughout 2019–20.[27] The NHMRC Committee provided advice on the legal, regulatory, scientific, and ethical issues that had been identified earlier, and was chaired by Associate Professor Bernadette Richards.[28] The NHMRC Committee produced two key reports: (1) a *Consultation Report* that highlighted social and ethical issues; and (2) an *Expert Statement* that commented on the scientific perspective. The *Expert Statement* discussed the need for further research, commenting:

> There were differing views within the Committee as to whether the current risks and scientific unknowns are such that it would be appropriate at this time to consider mitochondrial donation for introduction into Australian clinical practice.[29]

This uncertainty underpins the eventual legislative framework, with a proposed two-stage approach to be adopted to implement the legislation.[30] The two-stage approach was born out of another public consultation process, conducted during early 2021.[31] This consultation process consisted of a two-question survey, for which

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25 Senate Community Affairs References Committee, Parliament of Australia, *Science of Mitochondrial Donation and Related Matters* (Report, June 2018) ('*Science of Mitochondrial Donation Report*').

26 Ibid ix–x.

27 The NHMRC Committee was established under s 39 of the *National Health and Medical Research Council Act 1992* (Cth). See 'Mitochondrial Donation Expert Working Committee', *NHMRC: Building a Healthy Australia* (Web Page) <https://www.nhmrc.gov.au/about-us/leadership-and-governance/committees/mitochondrial-donation#:~:text=The%20Mitochondrial%20Donation%20Expert%20Working%20Committee%20('the%20Committee'),Mitochondrial%20Donation%20and%20Related%20Matters%20)>.

28 *Mitochondrial Donation Expert Statement* (n 5) 38–9.

29 Ibid 4.

30 Department of Health (Cth), *Public Consultation on the Approach To Introduce Mitochondrial Donation in Australia* (Consultation Summary Report, 23 March 2021) 3 ('*Public Consultation Summary Report*').

31 Ibid.

74 responses were received, and consideration of an additional set of 27 written submissions.[32] The survey was based on a public discussion paper released by the Department of Health.[33] The paper suggested a two-stage approach. The first stage comprises legalisation for research and training purposes and the selection and licencing of a pilot program for families impacted by mitochondrial disease. The second stage more broadly permits mitochondrial donation in clinical practice, depending on the outcome of the first stage.[34] The result of the 2021 consultation largely supported the two-stage approach suggested by the government in response to previous findings.[35]

After much debate in the lower house, where the Mitochondrial Donation Law Reform (Maeve's Law) Bill 2021 (Cth) was put to a conscience vote due to 'issues such as privacy of parents and children, creation and destruction of embryos, ensuring informed consent, donor rights and the newness of the science',[36] the final Bill was eventually sent to the Senate on 2 December 2021.[37]

A *Structure of the MDLR Act*

The *MDLR Act* passed the Senate on 30 March 2022[38] and received royal assent on 1 April 2022.[39] The final version of the *MDLR Act* primarily amends the pre-existing legislative framework, which consisted of the *Prohibition of Human Cloning for Reproduction Act 2002* (Cth), *Research Involving Human Embryos Act 2002* (Cth) and *Research Involving Human Embryos Regulations 2017* (Cth).[40]

The *MDLR Act* contains five types of licenses as outlined in ss 28A(a)–(e) of the *MDLR Act*:

(a) pre-clinical research and training licences;[41]

(b) clinical trial research and training licences;[42]

32 Ibid 4.

33 Ibid; Revised Explanatory Memorandum (n 7) 3, 85.

34 Revised Explanatory Memorandum (n 7) 3, 76–9.

35 *Public Consultation Summary Report* (n 30) 2–3.

36 Second Reading Speech (n 1) 3279.

37 Commonwealth, *Parliamentary Debates*, House of Representatives, 1 December 2021, 11293–304; Commonwealth, *Parliamentary Debates*, Senate, 2 December 2021, 7142–4.

38 Commonwealth, *Parliamentary Debates*, Senate, 30 March 2022, 577–88.

39 *MDLR Act* (n 3) s 2.

40 The *MDLR Act* also amends the *Therapeutic Goods (Excluded Goods) Determination 2018* (Cth) and *Freedom of Information Act 1982* (Cth).

41 *MDLR Act* (n 3) s 28A(a). See also at s 28C.

42 Ibid s 28A(b). See also at s 28D.

(c) clinical trial licences;[43]

(d) clinical practice research and training licences; and[44]

(e) clinical practice licences.[45]

These licenses allow for both research and clinical use of mitochondrial donation. The licenses will be offered with a two-staged approach, as outlined prior. This is a crucial part of the acceptance of the *MDLR Act*, and it is likely that the research phase could last as long as 10 years. Another important aspect of the *MDLR Act* is that mitochondrial donation recipients can apply to the Secretary of the Department of Health, once they are 18 years old, to receive information about their donor.[46] This has important implications for the individual patient, who has the right to 'know their genetic origins', which can have implications for their health and sense of identity.[47]

IV Arguments and Wider Discourse

The wider discourse relates mainly to three key issues: (1) creating human embryos that may then later be discarded; (2) creating heritable, germline changes in cells; and (3) the imperative upon doctors and scientists to continue to innovate and solve medical challenges for the good of patients. This discourse includes contributions not only from scientists and ethicists, but also religious groups, affected families, and members of the general public.[48]

43 Ibid s 28A(c). See also at s 28E.

44 Ibid s 28A(d). See also at s 28F.

45 Ibid s 28A(e). See also at s 28G.

46 Ibid s 29A(4).

47 Dziadek and Sue (n 5) 119.

48 Anna Salleh, '"Maeve's Law" Passes Senate Hurdle to Legalising Mitochondrial Donation through IVF', *ABC News* (online, 31 March 2022) <https://www.abc.net.au/news/science/2022-03-31/maeves-law-passes-senate-mitochondrial-donation/100954484>; Sarah Martin, 'Controversial Mitochondrial Donation Legislation Passed after Conscience Vote', *The Guardian* (online, 1 December 2021) <https://www.theguardian.com/australia-news/2021/dec/01/controversial-mitochondrial-donation-legalised-after-conscience-vote>; 'Mitochondrial Donation Now Legal in Australia', *Australian Genomics* (Web Page, 31 March 2022) <https://www.australiangenomics.org.au/mitochondrial-donation-now-legal-in-australia/?utm_source=rss&utm_medium=rss&utm_campaign=mitochondrial-donation-now-legal-in-australia>; Marilyn Rodrigues, 'Bishops Warn of Risks of Mitochondrial Donation Tech', *The Catholic Weekly* (online, 21 March 2021) <https://www.catholicweekly.com.au/bishops-warn-of-risks-of-mitochondrial-donation-tech/>.

A *The Use (and Destruction) of Human Embryos*

Throughout both the research phase and the clinical phase, human embryos would need to be made and then potentially discarded.[49] This is no different to 'regular' IVF, where embryos are destroyed on a routine basis,[50] however it is nonetheless controversial. Primarily, these concerns arise from religious groups, who are opposed to the needless creation and destruction of human life.[51] For example, the Australian Christian Lobby submitted that '[e]xperimentation on human embryos is problematic' and to do so represents instrumentalisation 'of the embryo for experimentation and destruction rather than implantation where it can fulfil its unique and dynamic destiny'.[52] However, certain methods can be chosen in order to reduce the waste of human embryos. For example, during the PNT method, two fertilised eggs are created and then one is destroyed. In contrast, the MST method involves the creation of only one fertilised egg which is then used.[53] Inherently however, regardless of the method adopted, the necessary research phase will consist of the destruction of many embryos due to the necessary clinical trials and further research.[54] This is a key sticking point for both conversative and religious groups. However, as is demonstrated by the passage of the *MDLR Act*, and the continued use of IVF, this concern is not held by a vocal majority in Australia.[55]

B *Creating Heritable Changes*

One of the primary concerns surrounding mitochondrial donation (of both a scientific and ethical nature) is that of heritability. For example, the NHMRC noted concerns regarding heritable changes inherited by future generations through mitochondrial donation:

> These concerns may relate to the future unknown impact of heritable changes, the inability for future generations to give consent to these changes, the

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49 *Science of Mitochondrial Donation Report* (n 25) 55–7 [4.4]–[4.12].

50 Ibid 57 [4.11]–[4.12].

51 Ibid 55–6 [4.4]–[4.9]; Australian Christian Lobby, Submission No 51 to Senate Community Affairs References Committee, Parliament of Australia, *Science of Mitochondrial Donation and Related Matters* (16 May 2018) 6–7.

52 Australian Christian Lobby, Submission No 51 to Senate Community Affairs References Committee, Parliament of Australia, *Science of Mitochondrial Donation and Related Matters* (16 May 2018) 6.

53 However, this does not necessarily ensure zero destruction of embryos. See Lyndsey Craven et al, 'Scientific and Ethical Issues in Mitochondrial Donation' (2018) 24(1) *The New Bioethics* 57, 65; Hamzelou (n 18).

54 *Science of Mitochondrial Donation Report* (n 25) 57 [4.11]; Craven (n 53) 65.

55 The courts in Australia have demonstrated reluctance to heed to religious groups on the topic of IVF. See, eg: *Re McBain; Ex parte Australian Catholic Bishops Conference* (2002) 209 CLR 372; *McBain v Victoria* (2000) 177 ALR 320; Kristen L Walker, 'Equal Access to Assisted Reproductive Services' (2000) 25(6) *Alternative Law Journal* 288.

> implications of changing a person's genetic makeup, and the potential use of the technology in ways that cause harm or are unacceptable to the community. … [A] girl born following mitochondrial donation will have a different mitochondrial genome to her mother, and one that may be inherited by her own children.[56]

There is a technical question as to whether this amounts to 'germline genetic modification', as this term is used in other key legal documents such as the United Nations Educational, Scientific and Cultural Organization ('UNESCO') *Universal Declaration on the Human Genome and Human Rights*.[57] However, scientists in Australia reached a consensus in the NHMRC *Expert Statement* that the technical definition of this is irrelevant, as it is clear that the technique can result in changes that are inherited by future generations.[58] The permanency of these changes to future generations raises serious questions. These are primarily concerns regarding the preservation of human health across generations, especially if unknown adverse effects begin to arise at some point in the future.[59] In addition, the rights of the unborn child ought to be considered, as a medical decision is being made for the child without their consent.[60]

There is a way to avoid the donor mtDNA being 'inherited' by the next generation, by restricting resultant offspring to males, given that the transmission of mtDNA occurs through the maternal line and only very rarely through the paternal germline.[61] But this, in turn, has serious ethical imperatives about access to healthcare between the sexes, and whether sex selection should and could be permitted under legislation.[62]

C *Imperative To Innovate*

Even amongst those in opposition to the legislation, most agreed that 'it's important to start the research and to have legislation that allows that to occur'.[63] There are still many key scientific questions left to answer. These include, but are not limited to: (1) 'whether compatibility between the nuclear and mtDNA [is] important'; (2) 'how the mutant mtDNA [is] distributed as cells replicate and divide after fertilisation'; and

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56 National Health and Medical Research Council, 'Mitochondrial Donation Issues Paper: Ethical and Social Issues for Community Consultation' (Issues Paper, 2019) 14 ('Mitochondrial Donation Issues Paper').

57 United Nations Educational, Scientific and Cultural Organization, *Universal Declaration on the Human Genome and Human Rights*, 29 C/Res. 16, 29th Comm, 29th sess, 26th plen mtg (1998, adopted 11 November 1997) vol 1.

58 *Mitochondrial Donation Expert Statement* (n 5) 15–21.

59 *Science of Mitochondrial Donation Report* (n 25) 71–3 [4.78]–[4.89].

60 Ibid 66–8 [4.56]–[4.61]; Plunkett Centre for Ethics, Submission No 30 to Senate Standing Committees on Community Affairs, Parliament of Australia, *Science of Mitochondrial Donation and Related Matters* (14 May 2018) 3–4.

61 *Mitochondrial Donation Expert Statement* (n 5) 5.

62 Revised Explanatory Memorandum (n 7) 84.

63 Commonwealth, *Parliamentary Debates*, Senate, 9 February 2022, 103 (Sam McMahon) ('Senate Second Reading Speech').

(3) 'does mitochondrial donation result in significant changes to the development of the embryo, compared with normal embryo development'.[64] These questions were reflected in a number of the submissions to the Senate Committee in 2018.[65]

The difficulty lies in the paradox that before more research is conducted, the answers to these questions will not be known. However, in order to do more research, new licenses need to be granted, and the research needs to be allowed. As such, the question becomes one of whether Australia wishes to be a leader in this field or not. Medical research has an important role to play in the Australian economy, and legalising new technology responsively can reduce the phenomenon of 'brain drain'. By the inclusion of a research-intensive phase (Stage One), Parliament has impliedly acknowledged this need for further research coupled with the imperative to innovate in Australia. Another important consideration is that if Australia fails to adequately innovate, and keep up with global practice, this is an invitation for 'IVF tourism', which in turn 'opens a number of legal and ethical issues that will not only affect the parents but also the offspring'.[66] In essence, a crucial takeaway was summarised by Senator Sam McMahon, who observed that, 'We can go ahead with phase 1, but it needs to come back to the parliament rather than just be delegated to a minister to make regulations on.'[67] When it comes time to grant clinical licenses, any research or clinical findings ought to be thoroughly re-evaluated.

V Concluding Thoughts

In conclusion, while the area is legally, scientifically, and ethically complex, it is clear that mitochondrial donation has the potential to bring a large benefit to families affected by mitochondrial disease. That being said, key scientific questions remain yet to be answered before the technique ought to be used in widespread clinical practice. The *MDLR Act* provides for just this; a sound framework to allow the beginning and continuation of the research phase for a number of years, followed by the potential for clinical use, when deemed appropriate. It is a great example of responsive science policy-making, where new developments are facilitated rather than restricted. Australia has developed a clear, nuanced and substantial legislative

64 'Mitochondrial Donation Issues Paper' (n 56) 15.

65 John Carroll and Mike Ryan, Submission No 19 to Senate Standing Committees on Community Affairs, Parliament of Australia, *Science of Mitochondrial Donation and Related Matters* (11 May 2018); Australian Academy of Science, Submission No 35 to Senate Standing Committees on Community Affairs, Parliament of Australia, *Science of Mitochondrial Donation and Related Matters* (May 2018); Wellcome Centre for Mitochondrial Research, Submission No 45 to Senate Standing Committees on Community Affairs, Parliament of Australia, *Science of Mitochondrial Donation and Related Matters*.

66 Jus St John, Submission No 31 to Senate Standing Committees on Community Affairs, Parliament of Australia, *Science of Mitochondrial Donation and Related Matters* (9 May 2019) 4.

67 Senate Second Reading Speech (n 63) 104.

framework, and this in and of itself is a positive development. In summary, this legislation is a display of well-considered, thought-out legislation on a technical health subject. Provided the stringent framework is followed, the *MDLR Act* could be a basis upon which to model the regulation of other similarly controversial health techniques.