The Senate

Community Affairs Legislation Committee

Mitochondrial Donation Law Reform (Maeve's Law) Bill 2021 [Provisions]

August 2021

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Abbreviations

AHEC	Australian Health Ethics Committee
ANZICA	Australian and New Zealand Infertility Counsellors Association
ART	Assisted Reproductive Technology
bill	Mitochondrial Donation Law Reform (Maeve's Law) Bill 2021
committee	Community Affairs Legislation Committee
ERLC	Embryo Research Licencing Committee
FOI Act	*Freedom of Information Act 1982*
GVT	Germinal Vesicle Transfer
HFEA	United Kingdom's Human Fertilisation and Embryology Authority
ISSCR	International Society for Stem Cell Research
IVF	In vitro fertilisation
MCRI	Murdoch Children's Research Institute
MST	Maternal Spindle Transfer
mtDNA	Mitochondrial DNA
NHMRC	National Health and Medical Research Council
first PBT	First Polar Body Transfer
second PBT	Second Polar Body Transfer
PHCR Act	*Prohibition of Human Cloning for Reproduction Act 2002*
PNT	Pronuclear Transfer
RIHE Act	*Research Involving Human Embryos Act 2002*
RIHE Regulations	*Research Involving Human Embryos Regulations 2017*
scrutiny of bills committee	Senate Standing Committee for the Scrutiny of Bills
UK	United Kingdom

List of Recommendations

3.77 The committee makes no recommendations as this is a conscience matter. The report is simply a summary of the submissions and views available at the time of reporting.

Chapter 1
Introduction

Purpose of the Bill

1.1 The Mitochondrial Donation Law Reform (Maeve's Law) Bill 2021 (bill) seeks to allow for the staged introduction of mitochondrial donation techniques in Australia under a national regulatory framework.

1.2 The bill amends the following legislation:

- the *Prohibition of Human Cloning for Reproduction Act 2002* (PHCR Act);
- the *Research Involving Human Embryos Act 2002* (RIHE Act);
- the *Research Involving Human Embryos Regulations 2017* (RIHE Regulations);
- the *Therapeutic Goods (Excluded Goods) Determination 2018*; and
- the *Freedom of Information Act 1982* (FOI Act).

1.3 The bill presents a two staged approach to allow for research and training, as well as further evidence to be collected, in relation to the safety and efficacy of mitochondrial donation techniques before it is considered for introduction in a broader clinical setting.

Background

1.4 The PHCR Act and the RIHE Act are the principal frameworks that regulate practices in the use of assisted reproductive technology (ART), and for research involving human embryos.

1.5 Mitochondrial donation is currently prohibited in Australia as the PHCR Act prohibits the creation of human embryos by fertilisation with genetic material from more than two people.[1]

1.6 Mitochondrial DNA are inherited only from the biological mother to child. Mitochondrial donation is an ART that seeks to reduce the risk of transmitting mutations in mitochondrial DNA (mtDNA) from a mother to child.

1.7 Several mitochondrial donation techniques involve the creation of an embryo containing nuclear DNA from a woman (the mother), a man (the father), and mitochondrial DNA from a donor egg (the donor).[2]

Mitochondrial disease

1.8 Mitochondrial disease refers to a group of inherited conditions that significantly lowers an individual's health and life expectancy. Abnormalities may be inherited either through the mitochondrial DNA (inherited from the

[1] Explanatory Memorandum, pp. 1–5.

[2] Department of Health, Public Consultation Paper, 2021, pp. 3–4.

mother) or through the nuclear DNA (inherited from both parents). Mutations or inherited abnormalities in an individual's mitochondrial DNA impacts the ability of the mitochondria to function normally.[3]

1.9 Mitochondrial donation can only assist women with mtDNA mutations, and the technology aims to reduce the risk of children inheriting some forms of mitochondrial disease. This form of mitochondrial disease is the cause of approximately half of mitochondrial disease and assists in reducing the risk of mothers passing it on to their children.[4]

1.10 Mitochondrial disease varies in presentation but can cause multiple organ dysfunction or failure, and in severe cases, premature death. Other common symptoms include seizures, fatigue, muscle pain, vision and hearing loss, and heart problems.[5]

1.11 The explanatory memorandum to the bill notes, the risk of developing serious illness due to mitochondrial disease is considered to be between one in 5,000 and one in 10,000. Approximately 56 children are born each year with a severe form of the disease and the prognosis for these children is that most will die within their first five years.[6]

1.12 There is no one age group affected by mitochondrial disease and people can develop it in infancy, early childhood, teenage years or as adults. While some symptoms can be managed, there are no effective treatments available for serious mitochondrial disease and there is no cure.[7]

United Kingdom's experience

1.13 The United Kingdom (UK) is the first country to regulate mitochondrial donation. The UK legalised mitochondrial donation techniques for clinical implementation in 2015.

1.14 The UK's Human Fertilisation and Embryology Authority (HFEA) conducted public consultation and ongoing scientific reviews on the safety and efficacy of mitochondrial donation prior to legalisation. Currently, only the Newcastle Fertility Centre at Life has a licence to conduct research and treat patients using mitochondrial donation techniques.[8]

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3 Department of Health, Public Consultation Paper, 2021, p. 3.

4 Senate Community Affairs References Committee, *Science of mitochondrial donation and related matters*, 27 June 2018, p. 3.

5 Explanatory Memorandum, pp. 1–2.

6 Explanatory Memorandum, p. 1.

7 Explanatory Memorandum, p. 66.

8 Human Fertilisation and Embryology Authority (HEFA), *Mitochondrial donation treatment*, 13 February 2021, www.hfea.gov.uk/treatments/embryo-testing-and-treatments-for-disease/mitochondrial-donation-treatment/ (accessed 2 August 2021).

1.15 At the time of writing this report, the HFEA has not published a report on the safety and efficacy of mitochondrial donation since its 2016 scientific review.[9] The explanatory memorandum also notes, 'in order to protect the privacy of patients, no data has been released to date regarding the outcomes of treatment'.[10]

Previous Senate inquiry into mitochondrial donation

1.16 In 2018, the Senate Community Affairs References Committee conducted an inquiry into the science of mitochondrial donation and related matters. The final report made four recommendations for further community consultation and scientific review to be undertaken and for those findings to inform options for legislative change.[11]

1.17 In response to the recommendations, the National Health and Medical Research Council (NHMRC) convened a Mitochondrial Donation Expert Committee to answer the three scientific questions raised in the final report.[12]

1.18 In 2019, the NHMRC conducted a series of community consultation activities to explore the ethical, legal and social issues associated with introducing mitochondrial donation in Australia. The NHMRC's consultation report identified several themes from this process, including the rights and wellbeing of the child and the donor, genetics of embryos and implementation considerations for granting access to the technology.[13]

Department of Health consultation

1.19 In February and March 2021, the Department of Health conducted community consultation on the government's proposed approach to introducing mitochondrial techniques in Australia. The Department of Health acknowledged the proposed regulatory and licensing approach is broadly aligned with the UK model.[14]

1.20 The summary of this consultation process noted the ethical issues associated with mitochondrial donation being, the creation and destruction of embryos and the belief that it creates children with three parents or is a form of genetic modification. Individuals and groups supporting the introduction of

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9 HEFA, Scientific review of the safety and efficacy of methods to avoid mitochondrial disease through assisted conception, 2016, pp. 3–4.

10 Explanatory Memorandum, p. 2.

11 Senate Community Affairs References Committee, *Science of mitochondrial donation and related matters*, 27 June 2018, pp. 96–97.

12 See, National Health and Medical Research Council (NHMRC), *submission 17*, pp. 2–3.

13 NHMRC, Mitochondrial Donation Community Consultation Report, 2020, p. 21.

14 Department of Health, Public Consultation Paper, 2021, pp. 6–7.

mitochondrial donation supported the proposal of a two staged regulatory approach.[15]

Proposed implementation

1.21 Under stage 1, mitochondrial donation would be legalised for certain research and training purposes, and to support the selection and licensing of a clinical trial to deliver mitochondrial donation to impacted families.

1.22 A single clinical trial will be allowed and is expected to run for approximately 10 years. The Commonwealth Department of Health will run a competitive grant process to identify a suitable organisation to run this trial.[16]

1.23 The NHMRC's Embryo Research Licensing Committee (ERLC)[17] would be given an expanded licensing and regulatory role to oversee mitochondrial donation licences, including administering applications and monitoring compliance with the licence conditions.[18]

1.24 Transition to stage 2 will be based on an evaluation of stage 1 and the outcomes of the clinical trial. Under stage 2 there would be a national regulatory framework which will allow for mitochondrial donation to be available in a broader clinical practice setting in participating states and territories.[19]

Key provisions

1.25 The bill includes one Schedule with three parts.

1.26 Part 1, Items 4 and 5 deal with the main amendments to the PHCR Act to allow, under a mitochondrial donation licence, the creation of an embryo with the genetic material of more than two people, and changes to its genome that would be heritable by the child's descendants.[20]

1.27 Part 1, Item 17 contains the bulk of amendments to the RIHE Act to establish mitochondrial donation licences.

1.28 Parts 2 and 3 contain other consequential amendments and transitional provisions.

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15 Department of Health, Consultation Summary Report, 2021, pp. 2–3.

16 Department of Health, Public Consultation Paper, 2021, p. 5.

17 Embryo Research Licensing Committee (ERLC) was established in May 2003 and currently regulates research involving human embryos. See, NHMRC, *Submission 17*, p.4.

18 Explanatory Memorandum, p. 28.

19 Explanatory Memorandum, p. 25.

20 Mitochondrial Donation Law Reform (Maeve's Law) Bill 2021, Schedule 1, Items 4-5; Explanatory Memorandum, [pp. 17–18].

Licences

1.29 Part 1, Item 17 defines the five types of mitochondrial donation licences and authorised activities. The five licenses are:

- a pre-clinical research and training licence;
- a clinical trial research and training licence;
- a clinical trial licence;
- a clinical practice research and training licence (only available under stage 2); and
- a clinical practice licence (only available under stage 2).[21]

1.30 Part 1, Item 17, establishes the following provisions to regulate mitochondrial donation licences:

- Subdivision A, specifies the kinds of mitochondrial donation licences and what they authorise;
- Subdivision B, specifies rules and requirements to applying for a mitochondrial donation licence;
- Subdivision C, determines applications for mitochondrial donation licences; and
- Subdivision D, outlines the conditions of mitochondrial donation licences.[22]

1.31 Part 1, Item 17, Paragraph 28P(4)(a) refers to women's eligibility to access mitochondrial donation techniques. For a woman to be eligible the woman must provide clinical diagnostic evidence that her mitochondria carries specific mutations that would give rise to the woman's offspring inheriting mitochondrial disease.[23]

Mitochondrial donation techniques

1.32 Part 1, Items 19 and 20, inserts the below definitions of mitochondrial donation techniques.[24]

Maternal spindle transfer (MST):

- removing the maternal spindle from a human egg (egg A) of a woman;
- removing the maternal spindle from a human egg (egg B) of a different woman;
- implanting into egg B the maternal spindle removed from egg A, while seeking to minimise carryover of mitochondria from egg A to egg B;
- fertilising egg B with a human sperm to create a zygote.

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21 Bill, Schedule 1, Item 17; Explanatory Memorandum, [pp. 24–30].

22 Bill, Schedule 1, Item 17; Explanatory Memorandum, [pp. 24–30].

23 Bill, Schedule 1, Item 17; Explanatory Memorandum, [pp. 32–33].

24 Bill, Schedule 1, Items 19-20; Explanatory Memorandum, [pp. 40–43].

Pronuclear transfer (PNT):

- fertilising, with a human sperm, a human egg of a woman to create a zygote (zygote A);
- removing the pronuclei from zygote A;
- fertilising, with a human sperm, a human egg of a different woman to create another zygote (zygote B);
- removing the pronuclei from zygote B;
- implanting the pronuclei from zygote A into zygote B, while seeking to minimise carryover of mitochondria from zygote A to zygote B.

Germinal vesical transfer (GVT):

- removing the germinal vesicle from a maturing human egg (egg A) of a woman;
- removing the germinal vesicle from a maturing human egg (egg B) of a different woman;
- implanting the germinal vesicle removed from egg A into egg B, while seeking to minimise carryover of mitochondria from egg A to egg B;
- maturing egg B in vitro to the stage ready for fertilisation;
- fertilising egg B with a human sperm to create a zygote.

First polar body transfer (first PBT):

- removing the first polar body from a human egg (egg A) of a woman;
- removing the maternal spindle from a human egg (egg B) of a different woman;
- fusing the first polar body to, or implanting the first polar body into, egg B;
- fertilising egg B with a human sperm to create a zygote.

Second polar body transfer (second PBT):

- fertilising, with a human sperm, a human egg of a woman to create a zygote (zygote A);
- fertilising, with a human sperm, a human egg of a different woman to produce another zygote (zygote B);
- removing the second polar body from zygote A;
- removing the female pronucleus from zygote B;
- transferring the second polar body from zygote A to zygote B.[25]

1.33 Under a mitochondrial donation clinical trial research and training licence or a clinical trial licence only the techniques known as maternal spindle transfer (MST) and pronuclear transfer (PNT) would be permitted.

1.34 Under a pre-clinical research and training licence, emerging techniques known as germinal vesicle transfer (GVT), first polar body transfer (first PBT) and second polar body transfer (second PBT) would be permitted.

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[25] Bill, Schedule 1, Items 19-20; Explanatory Memorandum, [pp. 40–43].

1.35 Permitted techniques will only be prescribed for clinical practice research and training licence or a clinical practice licence once they have been shown to be safe and effective for use in clinical practice.[26]

Egg donor

1.36 Part 1, Item 17, section 28R, requires a holder of a clinical trial licence or a clinical practice licence to collect information about donors, and children born as a result of mitochondrial donation techniques. It also requires them to share this information with the Secretary of the Department of Health.[27]

1.37 Part 1, Item 18, requires the establishment and retention of a Mitochondrial Donation Donor Register (Donor Register) by the Secretary of the Department of Health. Any child born using a mitochondrial donation technique can apply for identifying information about their donor when they turn 18.[28]

1.38 The Donor Register will not be made public and would not be available under the FOI Act.

1.39 In line with current ART sperm and egg donors' rights and responsibilities established under the *Family Law Act 1975*, mitochondrial egg donors would not be considered legal parents.[29]

Counselling

1.40 Under item 17, section 28P, a condition of a clinical trial licence and clinical practice licence requires an individual and their spouse to attend pre-treatment counselling. This would include being provided information in relation to the risks associated with using mitochondrial donation and alternatives to these techniques.[30]

Embryo sex selection

1.41 Under item 17, section 28Q, if after attending the pre-treatment counselling mentioned above, a patient and her spouse can request to have only male embryos selected for implantation, where it is deemed safe and practical to do so.[31]

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[26] Bill, Schedule 1, Items 19-20; Explanatory Memorandum, [pp. 40–41].

[27] Bill, Schedule 1, Item 17; Explanatory Memorandum, [pp. 34–35].

[28] Bill, Schedule 1, Items 18; Explanatory Memorandum, [pp. 38–39].

[29] Explanatory Memorandum, p. 78.

[30] Bill, Schedule 1, Items 17; Explanatory Memorandum, [p. 32].

[31] Bill, Schedule 1, Items 17; Explanatory Memorandum, [p. 34].

Financial implications

1.42 The explanatory memorandum states that activities proposed in the bill will be undertaken as an extension of existing Government processes, and ongoing costs are anticipated to be minimal and will be offset within the Department of Health portfolio.[32]

Legislative scrutiny

Senate Standing Committee for the Scrutiny of Bills

1.43 The Senate Standing Committee for the Scrutiny of Bills (scrutiny of bills committee) reported its concerns regarding the significant matters proposed to be dealt with in delegated legislation.

1.44 The scrutiny of bills committee questioned why matters, such as provisions defining key terms and requirements relating to the withdrawal of consent, are not included in the primary legislation.

1.45 The scrutiny of bills committee also highlighted the bill's proposed 'application for a mitochondrial donation licence must be accompanied by the fee, if any, prescribed by the regulations'. It noted the bill contains no cap on the maximum fee amount or any guidance on how the fee will be calculated.[33]

1.46 The Hon Greg Hunt MP, Minister for Health and Aged Care provided a response to the concerns raised in the scrutiny of bills committee report. Minister Hunt proposed not amending the bill but updating the explanatory memorandum to reflect his response and noted the following:

> These regulation-making powers are primarily included to ensure that appropriate guidelines are referenced, and to ensure that the legislative scheme can respond appropriately to unforeseen technological advances, and to new mitochondrial donation techniques that might be developed and prescribed in regulations made under the RIHE Act in the future. It is necessary for there to be a reasonable degree of flexibility in order to ensure that this can properly be done.[34]

Parliamentary Joint Committee on Human Rights

1.47 The Joint Committee on Human Rights made no comment on the bill's engagement with human rights, 'based on an assessment of the bill and

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[32] Explanatory Memorandum, Finical impact statement, p. 6.

[33] Senate Standing Committee for the Scrutiny of Bills, Scrutiny Digest 6 of 2021, 21 April 2021, pp. 25–29.

[34] Hon Greg Hunt MP, Minister for Health and Aged Care, Ministerial response to Scrutiny Digest 6 of 2021, 16 June 2021, p. 4.

relevant information provided in the statement of compatibility accompanying the bill'.[35]

1.48 The bill's statement of compatibility with human rights noted that the bill engages with a number of human rights and freedoms.

1.49 However, the statement of compatibility with human rights notes that the bill is compatible with human rights as it:

> … promotes the right to health and the best interests of the child, does not affect the right to life, and to the extent that it may limit the right to privacy and the right to freedom of opinion and expression, those limitations are for a legitimate purpose and are reasonable, necessary and proportionate.[36]

Conduct of inquiry

1.50 The bill was introduced into the House of Representatives on 24 March 2021.[37] Pursuant to the adoption of the Senate Standing Committee for the Selection of Bills report, the provisions of the bill were referred to the Community Affairs Legislation Committee (committee) for inquiry and report by 18 August 2021.[38]

1.51 The committee wrote to relevant organisations inviting them to make a submission to the inquiry by 16 July 2021.

1.52 The committee received 56 public submissions, which were published on the committee's website. A list of submissions received is included at Appendix 1.

1.53 A public hearing for the inquiry was held on 6 August 2021. The committee heard evidence from a range of organisations, peak bodies and academics. A list of witnesses is included at Appendix 2.

1.54 The committee would like to thank those individuals and organisations that made submissions and gave evidence at the public hearing.

1.55 The committee notes this bill will be subject to a conscience vote for Members and Senators.

Note on references

1.56 References to the *Committee Hansard* are to the proof Hansard. Page numbers may vary between the proof and official Hansard transcripts

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[35] Parliamentary Joint Committee on Human Rights, Human Rights Scrutiny Report 5 of 2021, 29 April 2021, p. 44.

[36] Explanatory Memorandum, p. 12.

[37] House of Representatives, *Votes and proceedings*, No. 111, 24 March 2021, p. 1777.

[38] *Journals of the Senate*, No. 106, 24 June 2021, p. 3757.

Chapter 2
The proposed approach

2.1 The inquiry heard a range of views regarding the bill from people who strongly support the introduction of mitochondrial donation, and those who strongly oppose it.

2.2 This chapter focuses on how the bill intends to introduce mitochondrial donation and the key issues identified with the proposed approach. They include removing the existing prohibitions in embryo research and cloning legislation, the design and implementation of the staged approach, and aspects of the governance arrangements and safeguards proposed in the bill.

2.3 The next chapter outlines some of the broader ethical considerations that apply to the introduction of mitochondrial donation, and the moral, scientific and social issues raised by witnesses and submitters during the inquiry. It also provides concluding comments from the committee and lists areas for possible clarification or amendment in the bill.

Exemption for mitochondrial donation

2.4 As discussed in Chapter 1, the use of mitochondrial donation techniques is currently prohibited under the *Prohibition of Human Cloning for Reproduction Act 2002* (PHCR Act) and the *Research Involving Human Embryos Act 2002* (RIHE Act).[1]

2.5 Currently, under the PHCR, it is an offence to create or develop embryos through fertilisation with genetic material from more than two people.[2] It is also an offence to make heritable changes to the genome of a human embryo for reproductive purposes.[3]

2.6 The Department of Health (department) told the committee that the bill creates a narrow exemption in the existing laws to enable mitochondrial donation to be introduced in Australia.[4]

2.7 In addition, the department said that in order to legalise any other techniques outside of mitochondrial donation, a further legislative process would be required.[5] According to Ms Bronwyn Field, First Assistant Secretary:

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1 Explanatory memorandum, p. 2. See also, Chapter 1, paragraph 1.4.

2 *Prohibition of Human Cloning for Reproduction Act 2002* (PHCR Act), section 15.

3 PHCR Act, section 15.

4 Ms Bronwyn Field, First Assistant Secretary, Portfolio Strategies Division, Department of Health, *Committee Hansard*, 6 August 2021, p. 48.

5 Ms Bronwyn Field, Department of Health, *Committee Hansard*, 6 August 2021, p. 48.

> … we have not lifted the prohibitions in any of the current laws that are in place. What we've done is actually to provide an exemption so that mitochondrial donation can occur. So this really does narrow and limit the extent of what we're legalising, and there is no other legal change to allow for any other techniques to occur, outside of mitochondrial donation.[6]

2.8 Several inquiry participants told the committee they considered the bill would appropriately narrow the legislative changes to introduce mitochondrial donation solely for the purpose of avoiding transmission of mitochondrial disease.[7]

2.9 Others, as discussed further in Chapter 3, felt strongly that the amendments to embryo research and cloning legislation are risky and not justifiable, and could leave the door open for mitochondrial donation techniques to be misused in the future.[8]

Staged approach

2.10 Of the inquiry participants that were in favour of the introduction of mitochondrial donation, the committee heard broad support for the staged approach outlined in the bill.[9]

2.11 Inquiry participants were also supportive of the bill's cautious and strict regulatory framework for introducing mitochondrial donation, with a robust licencing and oversight regime.[10]

2.12 Many expressed their hope that through the proposed staged approach, families could soon gain access to mitochondrial donation, within a safe and highly regulated framework.[11]

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6 Ms Bronwyn Field, Department of Health, *Committee Hansard*, 6 August 2021, p. 48.

7 See, for example, Progress Educational Trust, *Submission 27,* p. 2; Mito Foundation, *Submission 16,* p. 16; Professor David Thorburn, Murdoch Children's Research Institute, *Committee Hansard,* 6 August 2021, p. 35.

8 See discussion in Chapter 3 on 'Scientific evidence', 'Human Germline Manipulation', 'Cloning' and 'Other uses for mitochondrial donation' paragraphs 3.44, 3.53, 3.53, 3.64 and 3.68.

9 See, for example, Murdoch Children's Research Institute, *Submission 1*, p. 2; Human Genetics Society of Australasia, *Submission 2*, p. 1; Rare Voices Australia, *Submission 4*, p. 2; Childhood Dementia Initiative, *Submission 8*, p. 1; International Society for Stem Cell Research, *Submission 9*, p. 2; Professor John Christodoulou, *Submission 13,* p. 1; Mito Foundation, *Submission 16*, p. 8; Genetic Alliance Australia, *Submission 19,* p. 1; Professor Ainsley Newson and Dr Christopher Rudge, *Submission 49,* p. 1; Monash IVF Group, *Submission 5*, p. 1.

10 See, for example, Monash IVF Group, *Submission 5*, p. 1; Mito Foundation, *Submission 16*, p. 12; The Lily Foundation, *Submission 25*, p. 1; Australian Society for Medical Research, *Submission 35*, p. 1; Name withheld, *Submission 42*, p. 1.

11 See, for example, Research Australia, *Submission 3*, p. 2; Mito Foundation, *Submission 16,* p. 13; Name withheld, *Submission 38*, p. 1.

2.13 One witness, who works with people suffering from mitochondrial disease, told the committee:

> … it's vitally important for, say, the caring physicians that the patients are allowed to access safe procedures to help them have family when they're planning their families. This legislation and the proposed tiered introduction to it does allow for the safe introduction of mitochondrial donation as a procedure in the way that it has formal licensing at the various stages of the introduction.[12]

2.14 However, as discussed in further detail in Chapter 3, for those who are opposed to the introduction of mitochondrial donation, the staged approach proposed by the bill does not address some key ethical, moral or scientific concerns.[13]

Stage 1 clinical trial phase

2.15 As discussed in the previous chapter, during stage 1, the Department of Health proposes to undertake a competitive grants process to identify a suitable organisation to undertake the clinical trial. The clinical trial is anticipated to take approximately 10 years.[14] The explanatory memorandum notes:

> … [w]hile there is a relatively small number of women that may be assisted through the trial, it will not be a fast process due to the potential for participants to require multiple IVF procedures before a successful pregnancy is achieved.[15]

2.16 Those in favour of introducing mitochondrial donation expressed overwhelming support for a clinical trial in stage 1.[16] For example, Research Australia commented:

> The approach of initially allowing mitochondrial donation as part of a clinical trial is an appropriate recognition of the stage of development of this technology. It ensures that mitochondrial donation will only occur with the informed consent of participants and in a highly regulated environment.[17]

2.17 The Mito Foundation told the committee that the two-stage implementation process would provide multiple opportunities for mitochondrial donation to

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[12] Professor Carolyn Sue, Fellow, Australian Academy of Health and Medical Sciences, *Committee Hansard*, 6 August 2021, p. 3.

[13] See, for example, Chapter 3 discussion under 'Creation and destruction of embryos', 'Three parent child', 'Human Germline Manipulation' and 'Cloning'. See also discussion in Australian Christian Lobby, *Submission 23,* p. 15.

[14] Explanatory Memorandum, p. 72.

[15] Explanatory Memorandum, p. 72.

[16] See, for example, Murdoch Children's Research Institute, *Submission 1*, p. 2; Dr Suzanne Sallvelt, *Submission 20*, pp 1–2; Professor John Christodoulou, *Submission 13*, p. 1.

[17] Research Australia, *Submission 3*, p. 1.

be considered and any changes to be made before it is introduced into clinical practice.[18]

2.18 The International Society for Stem Cell Research (ISSCR) noted that the bill would enable a cautious introduction of mitochondrial replacement therapy that will provide access for eligible Australian families while monitoring safety and efficacy through the National Health and Medical Research Council's (NHMRC) licencing committee.[19]

2.19 However, the committee also heard a range of concerns about the proposed clinical trials in stage 1. Some concerns were around the limited number of licences for clinics available during the clinical trial stage.[20] Others noted the need for training to develop the appropriate expertise in Australia in mitochondrial donation.[21]

2.20 More broadly, however, many inquiry participants expressed concerns about proceeding to a clinical trial phase *at all* on the basis of current scientific evidence on the safety and efficacy of mitochondrial donation. These concerns are discussed in further detail in Chapter 3.[22]

Stage 2 clinical practice

2.21 The bill contemplates that under stage 2 there will be a national regulatory framework which will allow for licenced clinical practice of mitochondrial donation in participating states and territories. This would be overseen by the NHMRC.[23]

2.22 However, before mitochondrial donation can be introduced into clinical practice, several preconditions would need to be met:

- that the safety and efficacy of any mitochondrial donation techniques would need to be demonstrated; and
- further legislative changes would need to be introduced at the Commonwealth, State and Territory levels.[24]

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18 Mito Foundation, *Submission 16*, p. 12.

19 Professor Megan Munsie, Member and immediate past Chair, Ethics Committee, and Member, Guidelines on Stem Cell Research and Clinical Translation Taskforce, International Society for Stem Cell Research (ISSCR), *Committee* Hansard, 6 August 2021, p. 20.

20 Rare Voices Australia, *Submission 4*, pp. 2 –3.

21 See, for example, Name withheld, *Submission 50*, p. 1; Robinson Research Institute, *Submission 32*, p. 2; Australian Academy of Science and the Australian Academy of Health and Medical Sciences, *Submission 33*, p. 2.

22 See Chapter 3 discussion on 'Scientific considerations' from paragraph 3.44.

23 Explanatory memorandum, p. 25.

24 Explanatory memorandum, p. 25.

2.23 The Department of Health outlined what is required to introduce mitochondrial donation into clinical practice in stage 2:

> … stage 1 involves clinical trials, and so evaluation of those trials would be required before we went to stage 2. There's also a seven-year review point for the legislation, so that would be likely to happen as well, prior to movement to stage 2. And then, when we get to stage 2 … there has to be agreement by the parliament to do that … In addition, states and territories will also have to opt in.[25]

Reviewing the clinical trial

2.24 The Department of Health told the committee that the focus of reviewing the outcome of the clinical trials is to determine the safety and efficacy of mitochondrial donation.[26]

2.25 Inquiry participants argued for longitudinal data on a minimum number of participants to demonstrate the safety and efficacy of mitochondrial donation techniques before it becomes clinically available.[27]

2.26 Commenting on the lack of publicly available data on the UK mitochondrial donation regime, Associate Professor Megan Best of Ethicentre, said:

> A requirement needs to be written into the legislation of how many people have to be followed up, a minimum number of participants needs to be stipulated as having data collected over time, and also intergenerational safety needs to be looked at before it is approved by parliament as a clinically safe technique.[28]

2.27 The committee also heard that more detail is needed regarding the process for the five listed mitochondrial donation techniques in the bill to be considered and potentially approved through stage 1 for introduction into clinical practice.[29]

2.28 The Department of Health told the committee that an evaluation program for the clinical trial will be developed with the NHMRC, in conjunction with the licencing scheme. According to Ms Angela Wallbank, Assistant Secretary from the Department of Health, a cautious approach will be taken:

> We're very, very conscious of how sensitive this issue is and we want to do it as well as we can, with a view to things like privacy, whilst also being

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[25] Ms Angela Wallbank, Assistant Secretary, Strategic Policy Branch, Department of Health, *Committee Hansard*, 6 August 2021, p. 46.

[26] Ms Angela Wallbank, Department of Health, *Committee Hansard*, 6 August 2021, p. 46.

[27] Ethicentre, *Submission 7*, p. 8. See also discussion in Women's Bioethics Alliance, *Submission 37*, p. 4;

[28] Associate Professor Megan Best, Director, Ethicentre, *Committee Hansard*, 6 August 2021, p. 16.

[29] Professor John Carroll, *Submission 22*, pp. 2–3.

> sure that we can say whether the techniques are safe and they have efficacy.[30]

National regulatory framework

2.29 The bill contemplates that there will need to be legislation introduced by states and territories in order to implement mitochondrial donation into clinical practice.[31]

2.30 This is because, in clinical practice, mitochondrial donation techniques are expected to be classified as an assisted reproductive technology (ART), which is the responsibility of states and territories.[32]

2.31 At the Commonwealth level, there will also need to be further regulations to specify the permitted mitochondrial donation techniques for clinical practice. This will be a disallowable instrument to be put before the Parliament following the outcomes of the clinical trial and having regard to expert advice.[33]

2.32 One submitter noted the risk that states and territories might choose to opt out of a national regulatory framework, raising issues with equity of access:

> … it will be important for State and Commonwealth governments to prepare for the possibility that, if not coordinated well with each of the States and Territories, this approach may lead to a disuniform regime across the country, with different access rights to mitochondrial donation.[34]

Licencing framework

2.33 As discussed in Chapter 1, the bill allows for five types of mitochondrial donation licences to be administered by the NHMRC's Embryo Research Licencing Committee (ERLC).

2.34 The bill sets out what is authorised under each kind of licence, what conditions can be attached, and other administrative requirements.[35] It also applies offence provisions to certain conduct outside the authorisation of a licence.[36]

2.35 Inquiry participants noted that the ISSCR has recently recommended that research and clinical use involving mitochondrial donation is permissible, but

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30 Ms Angela Wallbank, Department of Health, *Committee Hansard*, 6 August 2021, p. 47.

31 Explanatory Memorandum, p. 25.

32 Explanatory Memorandum, p. 25.

33 Explanatory Memorandum, p. 25. See also Mr Paul McBride, Acting Deputy Secretary, Strategy, Evidence and Research Group, Department of Health, *Committee Hansard*, 6 August 2021, p. 46.

34 Professor Ainsley Newson and Dr Christopher Rudge, *Submission 49,* p. 5.

35 See Bill, Item 17, and proposed sections 28A to H.

36 See Bill, Items 11 to 15, and the new offence provision in proposed section 11A. See also Explanatory Memorandum, p. 24.

only when subject to strict regulatory oversight and limited to patients at high risk of transmitting serious mitochondrial DNA based diseases to their offspring.[37] Witnesses commented that the licencing measures in the bill would provide the required limitations and oversight outlined by the ISSCR.[38]

Licencing decisions

2.36 The committee heard broad support for the ERLC's role in the licencing and approval processes.[39] However there were concerns the ERLC lacks the specific expertise in clinical and genetic aspects of mitochondrial disease.[40]

2.37 There was support amongst submitters for the use of clinical experts in mitochondrial disease to support licencing decisions.[41] For example, the Murdoch Children's Research Institute suggested that the ERLC be supported in its licencing decisions by a small expert group to provide advice on an ongoing basis.[42] Australian Genomics suggested that an expert clinical panel could be used to review referrals.[43]

2.38 The NHMRC submitted that the bill will allow the ERLC to call on external expertise, including people with expertise in mitochondrial disease, people with expertise in clinical trials, and other experts as required.[44]

2.39 According to the Department of Health there is no need to establish specific membership requirements or have a standing advisory committee. It explained that the bill will enable the ERLC to access to the advice they need to administer the licencing regime:

> … it may not be appropriate just to have someone who has expertise in mitochondrial disease, for example; they might need more information

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[37] Professor Carolyn Sue, Fellow, Australian Academy of Health and Medical Sciences, *Committee Hansard*, 6 August 2021, p. 32

[38] Professor Carolyn Sue, Fellow, Australian Academy of Health and Medical Sciences, *Committee Hansard*, 6 August 2021, p. 32; Professor David Thorburn, *Submission 21*, p. 2.

[39] See, for example, Mito Foundation, *Submission 16*, p. 9; Joint Submission of Associate Professor Karinne Ludlow, Ms Esther Lestrell and Professor Catherine Mills, *Submission* 48, [p. 2]; Professor Ainsley Newson & Dr Christopher Rudge, *Submission 49*, p. 2.

[40] Murdoch Children's Research Institute, *Submission 1*, p. 2. See also, for example, Human Genetics Society of Australasia, *Submission 2*, p. 1; Research Australia, *Submission 3*, p. 2; Mito Foundation, *Submission 16*, p. 10; Dr Suzanne Sallvelt, *Submission 20*, p 1.

[41] Murdoch Children's Research Institute, *Submission 1*, p. 2; Professor John Christodoulou, *Submission 13* p. 2; Professor Mike Ryan, *Submission 15*, p. 2.

[42] Murdoch Children's Research Institute, *Submission 1*, p. 2.

[43] Australian Genomics, *Submission 6*, p. 2. In their submission, Australian Genomics noted that 'careful thought will need to be given as to the governance of the licencing body to minimise any perceptions or actual conflicts of interest'.

[44] NHMRC, *Submission 17*, p. 6.

> than that. It was also to assist with ensuring that there's no conflict of interest, given the small pool of experts in this area.[45]

Licence requirements and ongoing monitoring

2.40 Inquiry participants commented on the important ongoing monitoring requirements for licence holders.[46]

2.41 The NHMRC submitted that the ERLC are already contemplating the need to ensure authorised embryologists are competent, and remain so, for the duration of their authorisation under a licence.[47]

2.42 According to the NHMRC the bill places significant requirements on licence holders to collect a body of data relating to the clinical trial and its outcomes:

> The bill is quite explicit that the holder of the clinical trial licence—so at the clinical trial stage—must monitor the outcomes, including pregnancies, any childbirth resulting and the ongoing health and development of the child born as a result of such pregnancies… So there will be quite a lot of outcomes monitoring that takes place.[48]

2.43 Several submitters and witnesses commented on the need for long term monitoring of persons born from mitochondrial donation.[49] These submitters reiterated concerns about the lack of published data on the efficacy and safety of the clinical trials in the UK, and information on the health outcomes of children (and future generations) born from mitochondrial donation.[50]

Accessing mitochondrial donation

2.44 In order for a family to access mitochondrial donation during the clinical trial, the clinic must apply to the ERLC for approval. The bill sets out a range of factors the ERLC must be satisfied of before granting approval, including:

- that there is a particular risk that mitochondrial disease will occur in the child;
- that there is significant risk of serious illness or other serious medical condition occurring in that child as a result;

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[45] Ms Angela Wallbank, Assistant Secretary, Strategic Policy Branch, Department of Health, *Committee Hansard*, 6 August 2021, p. 47.

[46] See, for example, Ms Prue Torrance, NHMRC, *Committee Hansard*, 6 August 2021, p. 44; Science and Technology Australia, *Submission 18*, p. 3.

[47] NHMRC, *Submission 17*, p. 6.

[48] Ms Prue Torrance, Executive Director, Research Quality and Priorities Branch, NHMRC, *Committee Hansard*, 6 August 2021, p. 44.

[49] Ethicentre, *Submission* 7, p. 7; Associate Professor Megan Best, Director, Ethicentre, *Committee Hansard*, 6 August 2021, p. 16; Ms Rebecca Kerner, Chair, Australian and New Zealand Infertility Counsellors Association, *Committee Hansard*, 6 August 2021, p. 27;

[50] See discussion in Chapter 3 'Scientific evidence' at paragraph 3.44.

- that other available techniques to minimise risk would be inappropriate; and
- that the woman and her spouse have attended counselling and are fully informed of the risks and alternatives.[51]

2.45 One witness noted that the bill recognises that mitochondrial donation will not be appropriate in every case:

> This type of intervention will not be suitable for all people with mitochondrial disease who wish to have their own child. In fact, there are other techniques that could be used for some people, so it will be done on a case-by-case basis.[52]

2.46 Some inquiry participants were concerned about ambiguity in the bill regarding what the ERLC must consider before it gives approval for a woman to have mitochondrial donation. For example, one witness commented on the requirement that there be a significant risk of serious illness or other serious medical condition occurring in the child. They argued that it is not clear what is meant by 'other serious medical condition' or how this is different from a 'serious illness'.[53]

2.47 It was suggested that further evidence could be required from women that they carry a homoplasmic mitochondrial DNA mutation before they become eligible for mitochondrial donation.[54] One witness explained:

> One way [the bill] could be tightened is to specify that the women involved, to be eligible for admission into the clinical trial, must provide evidence of carrying homoplasmic mitochondrial DNA mutations. That is the severe form of the disease.[55]

2.48 Several submitters suggested that the bill could have the unintended consequence of excluding surrogacy arrangements, which could be necessary for women who suffer from mitochondrial disease who are too sick to carry a child, or for male couples using a surrogate.[56]

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51 See Bill, Item 17, proposed section 28P(4); Explanatory Memorandum, pp. 32–34.

52 Professor Megan Munsie, ISSCR, *Committee Hansard*, 6 August 2021, p. 26.

53 Wellcome Centre for Mitochondrial Research, *Submission 26*, p. 1; Australian Christian Lobby, *Submission 23*, pp. 3–4.

54 Australian Christian Lobby, *Submission 23*, p. 15.

55 Associate Professor Megan Best, Director, Ethicentre, *Committee Hansard*, 6 August 2021, p. 15.

56 Joint Submission of Associate Professor Karinne Ludlow, Ms Esther Lestrell and Professor Catherine Mills, *Submission* 48, p. 1; Victorian Assisted Reproductive Treatment Authority, *Submission 30*, p. 1.

Avoiding delays

2.49 The committee heard of the need for timeliness in the delivery of the clinical trials, and to avoid delays for families attempting to access the treatment.[57]

2.50 Under the bill, where the ERLC provides approval for a woman to undergo a mitochondrial donation procedure, that approval lasts five years or until the birth of a live child from the procedure, whichever is earliest.[58]

2.51 Several submitters noted that the bill's approach to giving 'approval', over the issuing of an individual licence, is preferable, and could help avoid the kinds of delays experienced in the UK.[59]

2.52 The Progress Education Trust told the committee that 'time is of the essence' for those wanting to start a family:

> … particularly for prospective mothers who will need to undergo treatment and carry a pregnancy. Each delay can be a bitter blow to those who wish to have a child free from life-limiting mitochondrial disease.[60]

2.53 Time limits and reporting requirements were suggested to improve transparency and accountability around the timeliness of ELRC decisions.[61]

The need for equitable access

2.54 Amongst those supportive of the bill, there was a call for equitable access to mitochondrial donation, noting the demand around Australia.[62] One witness described the situation for her patients:

> There are many patients around Australia who have mitochondrial disease, and at my clinic we see patients from all different states and territories within Australia. So I can tell you from that experience that there are patients across the country who would be seeking this type of technique as part of their family planning.[63]

2.55 It was suggested that clinical trials should be required to offer mitochondrial donation in all states and territories, or, that support be provided to families to

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[57] Mito Foundation, *Submission 16,* p. 9; Genetic Alliance Australia, *Submission 18*, p. 2. For discussion about the delays experienced in the UK's mitochondrial donation regime see, for example, Progress Educational Trust, *Submission 27,* p. 1; Name withheld, *Submission 50,* p. 1.

[58] See Bill, Item 17, proposed section 28P(8); Explanatory Memorandum, p. 33.

[59] See MitoCanada, *Submission 10*, p. 1; Australian Genomics, *Submission 6*, p. 2; Dr Suzanne Sallvelt, *Submission 20*, pp 1–2.

[60] Progress Educational Trust, *Submission 27,* p. 2.

[61] Joint Submission of Associate Professor Karinne Ludlow, Ms Esther Lestrell and Professor Catherine Mills, *Submission* 48, p. 1; Victorian Assisted Reproductive Treatment Authority, *Submission 30*, p. 1; Professor Ainsley Newson & Dr Christopher Rudge, *Submission 49,* p. 1.

[62] Professor Carolyn Sue, *Submission 29*, p. 2.

[63] Professor Carolyn Sue, Fellow, Australian Academy of Health and Medical Sciences, *Committee Hansard*, 6 August 2021, p. 32

access a clinical trial even if they live in another state or territory.[64] The committee also heard the suggestion that priority populations should be identified to access mitochondrial donation.[65]

Permitted techniques

2.56 As discussed in Chapter 1, the bill prescribes five mitochondrial donation techniques:

- maternal spindle transfer (MST);
- pronuclear transfer (PNT);
- germinal vesicle transfer (GVT);
- first polar body transfer (first PBT); and
- second polar body transfer (second PBT).[66]

2.57 All five are permitted techniques for a pre-clinical research and training licence.[67] However, only two mitochondrial donation techniques would be permitted under a clinical trial licence. These are the MST and PNT techniques.[68]

2.58 Inquiry participants expressed support for the bill limiting the permitted techniques to MST and PNT during clinical trials, having regard to the current state of the research into mitochondrial donation.[69] The explanatory memorandum also notes these techniques are considered safe for clinical use in humans the UK.[70]

2.59 There was also support for the bill recognising GVT and PBT techniques, and acknowledgement of the possibility of techniques being developed into the future.[71]

2.60 Several submitters from the scientific community argued the bill should not limit the potential for future techniques to be developed.[72] It was suggested

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64 Rare Voices Australia, *Submission 4*, p. 4.

65 Rare Voices Australia, *Submission 4*, p. 4.

66 See Bill, Item 19, proposed section 7A of the RIHE Regulations; Explanatory Memorandum, pp. 39–41.

67 See Bill, Item 19, proposed section 7B of the RIHE Regulations; Explanatory Memorandum, pp. 39–41.

68 See Bill, Item 19, proposed section 7B of the RIHE Regulations.

69 Mito Foundation, *Submission 16,* p. 9; Progress Educational Trust, *Submission 27,* p. 1

70 Explanatory Memorandum, p. 41. Progress Educational Trust also noted that, in the UK, only MST and PNT are provided for in their equivalent mitochondrial donation regime. See *Submission 27,* p. 2.

71 See, for example, Progress Educational Trust, *Submission 27*, p. 2. See also Professor Mary Herbert, *Submission 40*, p. 2, in discussion on 'future proofing'.

72 Professor John Carroll, *Submission 22*, pp. 1–2; Professor Mary Herbert, *Submission 40*, p. 2.

that the bill may have the unintended consequence of limiting future pre-clinical research and clinical use of techniques currently under development.[73]

2.61 The committee heard that the licencing regime and training requirements outlined in the bill will provide important safeguards for the use of the techniques during the clinical trials:

> … the techniques themselves have been used but do require a skilled hand. I would like to draw your attention to the licensing that recognises and requires, before a clinical trial licence is granted, that the embryologist who would be performing the technique must first apply for a training and research licence and be able to justify their skill before applying for a clinical trial licence.[74]

2.62 However, the committee also heard concerns about some of the permitted techniques outlined in the bill, specifically, PNT and Second Polar Body Transfer.[75] It was argued that these techniques are problematic for two reasons:

- that the techniques used in PNT and Second Polar Body Transfer are similar to that used for human cloning; and
- these techniques necessitates the creation of a human embryo 'for its parts' which once harvested destroy the embryo.[76]

2.63 According to a number of submitters, the bill should be amended to only allow the use of MST.[77] Ethicentre told the committee that:

> … [a]s other techniques are available and show promise, for example, Maternal Spindle Transfer, this project can proceed without including Pronuclear Transfer and Second Polar Body Transfer.[78]

2.64 The Australian Christian Lobby noted their concerns with the PNT technique and destruction of embryos:

> Pronuclear transfer and similar techniques lead to higher rates of embryo wastage and should not be pursued at the outset when alternatives exist. Maternal spindle transfer should be the focus of research.[79]

2.65 Overarching concerns regarding the use of mitochondrial donation techniques, including the creation and destruction of embryos and concerns about human germline manipulation, are discussed in further detail in Chapter 3.[80]

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73 Professor John Carroll, *Submission 22*, pp. 1–2.

74 Professor Megan Munsie, ISSCR, *Committee Hansard*, 6 August 2021, p. 21.

75 Ethicentre, *Submission 7*, p. 6; Australian Christian Lobby, *Submission 23,* p. 16; Right to Life Australia, *Submission 47*, p. 13.

76 Ethicentre, *Submission 7*, p. 6.

77 Ethicentre, *Submission 7*, p. 6; Australian Christian Lobby, *Submission 24*, p. 5.

78 Ethicentre, *Submission 7*, p. 6.

79 Australian Christian Lobby, *Submission 24*, p. 5.

Donor register

2.66 The donor register proposed by the bill was widely supported by inquiry participants, including those with concerns about the potential confusion and distress for children born of 'three biological parents'.[81]

2.67 Under the bill, the donor register would not be publicly available, and would allow any person over 18 born as a result of mitochondrial donation to access identifiable information regarding their mitochondrial donor. The donor would also have access to information on the register about themselves, and whether a child has been born of their donation.[82]

2.68 Submitters suggested that the bill be amended to give children under the age of 18 the right to information from the donor register in some circumstances to be consistent with the approach in states and territories.[83]

2.69 It was also suggested that the donor register be able to facilitate a donor notifying a donor-conceived children of any potential heritable medical issues as they become known.[84]

Other safeguards

Consent

2.70 Under the bill, proper consent is required from the prospective mother, father and donor before proceeding with mitochondrial donation.[85]

2.71 The NHMRC in its submission highlighted the importance of appropriate processes for obtaining proper consent.[86]

2.72 However, the committee heard some concerns about families consenting to the risks of mitochondrial donation. It was suggested that informed consent will be difficult due to the 'complexity of the procedures' involved.[87] It was also suggested that the future generations of children born of this technique are not

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[80] See Chapter 3 discussion in 'Creation and Destruction of Embryos' and 'Human Germline Manipulation' at paragraphs 3.21 and 3.53.

[81] See, for example, Dr Bernadette Tobin, Director, Plunkett Centre for Ethics, *Committee Hansard*, 6 August 2021, p. 9; Australian Christian Lobby, *Submission 24*, p. 7. See further discussion in Chapter 3 under 'Three parent child' at paragraph 3.26.

[82] See Bill, Item 18, proposed section 29A; Explanatory Memorandum, pp. 38–39.

[83] Joint Submission of Associate Professor Karinne Ludlow, Ms Esther Lestrell and Professor Catherine Mills, *Submission* 48, p. 1; Victorian Assisted Reproductive Treatment Authority, *Submission 30*, p. 5; Victorian Assisted Reproductive Treatment Authority, *Submission 30*, p. 1.

[84] Victorian Assisted Reproductive Treatment Authority, *Submission 30*, p. 2.

[85] See Bill, Item 17, proposed section 28N. Explanatory Memorandum, pp. 30–32.

[86] NHMRC, *Submission 17*, p. 6.

[87] Australian Christian Lobby, *Submission 23*, p. 15.

able to consent to the intervention.[88] The Australian Christian Lobby explained:

> Included in the 'consent' is a high level of risk-taking for a procedure that is still largely experimental. Couples are dependent on experts to make an informed decision and concepts of mitochondrial inheritance are particularly difficult.[89]

2.73 In response, the Australian and New Zealand Infertility Counsellors Association (ANZICA) stressed the importance of counselling for all parties:

> Given the clinical and psychosocial complexities associated with mitochondrial donation, ANZICA strongly recommends that rigorous counselling and regulatory conditions (currently in place for third party reproduction) be applied.[90]

2.74 The explanatory memorandum also notes the importance of counselling to help parents make informed decisions. It further stated that using a medical procedure which could prevent that child from having a debilitating illness meant that consent could be anticipated.[91]

Counselling

2.75 Under the bill, a condition of a clinical trial licence and clinical practice licences requires an individual and their spouse to attend pre-treatment counselling.[92]

2.76 The Mito Foundation told the committee that mandatory counselling would allow families to make informed decisions about mitochondrial donation and permit them appropriate reproductive choice.[93]

2.77 ANZICA suggested that counselling requirements for donors should be explicitly recognised.[94] Best practice, according to ANZICA, would require each party having at least two counselling sessions – plus an additional joint session in the case of known donation.[95]

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88 Australian Christian Lobby, *Submission 23*, p. 9.

89 Australian Christian Lobby, *Submission 23*, p. 9.

90 Australian and New Zealand Infertility Counsellors Association (ANZICA), *Submission 46*, p. 1.

91 Explanatory Memorandum, p. 10.

92 See Bill, Item 17, proposed subsection 28P; Explanatory Memorandum, p. 33.

93 Mito Foundation, *Submission 16*, p. 11.

94 ANZICA, *Submission 46*, p. 1.

95 Ms Rebecca Kerner, ANZICA, *Committee Hansard*, 6 August 2021, p. 23.

2.78 The committee heard that there are currently different requirements for counselling in states and territories, and it was suggested that there should be further clarification about counselling requirements at a national level.[96]

2.79 According to the NHMRC, the Australian Health Ethics Committee (AHEC) will be reviewing its *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research* to incorporate guidance specifically for mitochondrial donation.[97]

2.80 The guidelines cover information counselling and consent and the use of donated gametes in assisted reproductive technology. The NHMRC told the committee:

> … whether there's anything specific that needs to be considered for mitochondrial donors—will be picked up as part of the targeted review that the Australian Health Ethics Committee will do if the legislation passes. The committee intends to do a limited, targeted review to pick up mitochondrial donation implementation considerations to support the implementation of the bill.[98]

2.81 The Department of Health noted that there is no limit in the bill as to the number of counselling sessions that could be required.[99]

2.82 Finally, several inquiry participants recommended the bill should require pre-treatment counsellors to be independent and not involved in the research program.[100] ANZICA commented that rather than require independent counsellors, there should be a requirement for counsellors to be accredited.[101]

Privacy

2.83 Submitters were supportive of the protections for individual privacy in the bill. It was noted that children born of mitochondrial donation may attract media and public attention, and that the privacy wishes of families must be respected and upheld.[102]

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96 Ms Rebecca Kerner, Chair, Australian and New Zealand Infertility Counsellors Association (ANZICA), *Committee Hansard*, 6 August 2021, p. 24; Dr Iolanda Rodino, Committee Member, ANZICA, *Committee Hansard*, 6 August 2021, p. 24.

97 NHMRC, *Submission 17*, p. 8.

98 Ms Prue Torrance, NHMRC, *Committee Hansard*, 6 August 2021, pp. 37–38.

99 Ms Bronwyn Field, Department of Health, *Committee Hansard*, 6 August 2021, p. 50.

100 Ethicentre, *Submission 7*, p. 7; Australian Christian Lobby, *Submission 23*, p. 9.

101 Ms Rebecca Kerner, ANZICA, *Committee Hansard*, 6 August 2021, p. 24

102 Professor Ainsley Newson & Dr Christopher Rudge, *Submission 49,* p. 1; Mito Foundation, *Submission 16*, p. 11.

2.84 The committee also heard support for the bill not requiring children born of mitochondrial donation to be subject to 'unnecessary or routinely invasive monitoring'.[103]

Reporting and review

2.85 The committee heard from several submitters that there should be a parliamentary review before proceeding to Stage 2.[104]

2.86 Currently in the bill, there would be a requirement for an independent review every seven years.[105]

2.87 This is in addition to any review of the outcome of the clinical trial, which, as discussed above, is expected to run over 10 years, and will be used to inform any further legislative changes that would be required to progress to clinical practice.[106]

[103] Mito Foundation, *Submission 16*, p. 11.

[104] Ethicentre, *Submission 7*, p. 7; Australian Christian Lobby, *Submission 23*, p. 9.

[105] See Bill, Item 103, proposed section 47B; Explanatory Memorandum, pp. 59 – 60.

[106] See discussion at paragraph 2.15 above.

Chapter 3
Ethical, social and scientific considerations

3.1 The introduction of mitochondrial donation in Australia, as proposed by the bill, raises a number of ethical, social and scientific issues. Many of these issues are deeply personal and manifest in strong and opposing views.

3.2 The committee has heard from a range of submitters and witnesses who strongly support the introduction of mitochondrial donation to enable women with mitochondrial disease to bear biological children and reduce the risk of passing it on to future generations, and the burden of the disease on families and communities.

3.3 The committee also heard strong opposition to the bill, underpinned by concerns that mitochondrial donation would involve the creation and destruction of embryos, that there are existing legal options to have children thereby making this technology unnecessary, and that it would cause distress and confusion to a child born from the biological material of three people.

3.4 In addition, a range of scientific issues have been raised with the bill. The committee heard concerns about a lack of publicly available research on mitochondrial donation and its use in other jurisdictions, and the potential for unknown intergenerational effects. There were also strongly held concerns that legalising mitochondrial donation could open the door to human cloning or other inappropriate uses of the technology.

Ethical and social considerations

Reducing the risk of mitochondrial disease

3.5 Those in support of the bill told the committee that the introduction of mitochondrial donation would help reduce the risk of a woman with mitochondrial disease passing it on to her biological child.[1]

3.6 Witnesses and submitters described the devastating impact of mitochondrial disease on individuals and multiple generations within families, and the desire to reduce the risk of the disease being passed on to future generations.[2]

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[1] See, for example, Mito Foundation, *Submission 16*, p. 12; The Lily Foundation, *Submission 25*, p. 1; Progress Educational Trust, *Submission 27,* p. 1; Name withheld, *Submission 38*, p. 1; Professor Mary Herbert, *Submission 40*, p. 1; Name withheld, *Submission 42*, p. 1 Name withheld, *Submission 45*, p. 1; Name withheld, *Submission 50*, p. 1.

[2] See, for example, Name withheld, *Submission 50*, p. 1; The Lily Foundation, *Submission 25,* p. 1; Mrs Shelley Beverley, private capacity, *Committee Hansard,* 6 August 2021, p. 3; Mr Sean Murray, Chief Executive Officer, Mito Foundation, *Committee Hansard,* 6 August 2021, p. 1.

3.7 The Mito Foundation explained that the opportunity to have a healthy child through mitochondrial donation offers some families the only means to have a child genetically related to both parents who is healthy.[3] One witness, who suffers from mitochondrial disease, told the committee:

> This law would be an absolute ray of hope, a miracle, to me because I don't have any other options and I feel that I'm running out of time. This is the only way I would be able to have my own healthy biological child. If anything were to happen to me, I know that my husband would be able to see part of me in our own children, and this would mean the world—to have this legalised within my time frame or at least for future families.[4]

3.8 This perspective was strongly reinforced by several submitters to the inquiry who shared their experiences living with mitochondrial disease, some with children who could potentially benefit from the option of mitochondrial donation.[5]

3.9 The Mito Foundation noted that introducing mitochondrial donation in Australia could also address the risk of people traveling overseas for mitochondrial donation procedures in jurisdictions with unregulated health systems and for conditions not related to the avoidance of mitochondrial disease.[6]

Mitochondrial donation is not a cure

3.10 However, some submitters and witnesses stressed to the committee that mitochondrial donation does not cure mitochondrial disease, and that some 'diseased' mitochondria can still be transferred through the procedure.[7] Mrs Wendy Francis of the Australian Christian Lobby made the comment:

> Mitochondrial transfer doesn't cure mitochondrial disease. It engages in genetic manipulation and it ensures that people with mitochondrial disease are not born.[8]

3.11 Several witnesses noted that the introduction of mitochondrial donation will not prevent children being born of mitochondrial disease.[9] This is because a

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3 Mito Foundation, *Submission 16*, p. 12.

4 Mrs Shelley Beverley, private capacity, *Committee Hansard,* 6 August 2021, p. 3.

5 Name withheld, *Submission 38*, p. 1; Name withheld, *Submission 42*, p. 1; Name withheld, *Submission 45*, p. 1; Name withheld, *Submission 50*, p. 1.

6 Mito Foundation, *Submission 16*, p. 13.

7 Mrs Wendy Francis, Australian Christian Lobby, *Committee Hansard*, 6 August 2021, p. 9; Australian Catholic Bishops Conference, *Submission 11*, pp. 4–5.

8 Mrs Wendy Francis, Australian Christian Lobby, *Committee Hansard*, 6 August 2021, p. 9.

9 See, for example, Mrs Wendy Francis, Australian Christian Lobby, *Committee Hansard*, 6 August 2021, p. 9; Associate Professor Megan Best, Director, Ethicentre, *Committee Hansard*, 6 August 2021, p. 10.

mother may not know that she carries a mutation, or because a new mutation could appear, or because the mutation is in the woman's nuclear DNA and therefore cannot be treated with this procedure.[10] Associate Professor Megan Best, Director at Ethicentre, added:

> Rather than spending our money and efforts on experimental ART techniques, I believe we should seek to develop genetic treatments for those born with mitochondrial disease. Children will still be born with mitochondrial disease, even if this bill is passed.[11]

3.12 However, other witnesses gave evidence that mitochondrial donation, although not a cure, would significantly reduce the defective mitochondrial DNA in offspring, and overall, decrease the burden of the disease within the community.[12]

3.13 The Murdoch Children's Research Institute, argued that '[t]he fact that [mitochondrial donation] won't remove the disease burden entirely is clearly not a reason to oppose the legislation'.[13] Professor David Thorburn explained:

> This is offering families who know they are at risk of mitochondrial DNA disease a reproductive option. There's no expectation that one can wipe out genetic diseases from the community.[14]

3.14 Although there is currently no cure for mitochondrial disease, the Department of Health noted that the Government has also spent considerable funding on research to find a cure.[15]

3.15 On the issue of the potential carry over of defective mitochondria through the procedure, witnesses acknowledged that further research was needed. However they argued that current evidence already shows that mitochondrial donation significantly reduces the defective mitochondria.[16]

3.16 According to Dr George Daley, a member of the International Society for Stem Cell Research (ISSCR):

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[10] Associate Professor Megan Best, Director, Ethicentre, *Committee Hansard*, 6 August 2021, p. 10.

[11] Associate Professor Megan Best, Director, Ethicentre, *Committee Hansard*, 6 August 2021, p. 10.

[12] Professor David Thorburn, Co-Group Leader, Brain and Mitochondrial Research, Murdoch Children's Research Institute (MCRI), *Committee Hansard*, 6 August 2021, p. 32; Dr Christopher Gyngell, Team Leader/Research Fellow, Biomedical Ethics, MCRI, *Committee Hansard*, 6 August 2021, p. 32.

[13] Professor David Thorburn, MCRI, *Committee Hansard*, 6 August 2021, p. 32.

[14] Professor David Thorburn, MCRI, *Committee Hansard*, 6 August 2021, p. 32.

[15] Ms Bronwyn Field, First Assistant Secretary, Portfolio Strategies Division, Department of Health, *Committee Hansard,* 6 August 2021, p. 51.

[16] Professor Rebecca Robker, Biomedical Scientist, Robinson Research Institute, University of Adelaide, *Committee Hansard*, 6 August 2021, p. 25; Dr George Daley, Member, ISSCR, *Committee Hansard*, 6 August 2021, pp. 25–26.

> What we're really encouraged by, however, is that the evidence to date is that these strategies actually do reduce the burden of defective mitochondria quite significantly—not perfectly, but quite significantly.[17]

Options for building a family

3.17 The committee heard from several inquiry participants that introducing mitochondrial donation is unnecessary. This is because there are already legal options available to a woman with mitochondrial disease concerned about passing it on to her offspring.[18] These options would include adoption, use of a donor egg, or pre-implantation genetic diagnosis (PGD).[19]

3.18 Dr Bernadette Tobin of the Plunkett Centre for Ethics told the committee that families should be looking at ways to have a healthy child that are already legal in Australia:

> It's perfectly possible to have a child, using a donated egg without then taking that egg, which is perfectly healthy, and then modifying it in ways that are very risky for future generations, and, therefore, the child will have three biological parents et cetera. That's my point, that someone in that position could simply use IVF with a donor egg.[20]

3.19 However the committee heard a different perspective from those who suffer from mitochondrial disease and the organisations and clinicians that support them. The Mito Foundation summarised:

> While some people do not consider genetic relationship to be of significant importance, evidence indicates that this is not the case for a large number of people. This was upheld throughout the consultations mentioned above and has also been highlighted by members of the Australian mitochondrial disease community who are clear that they are not seeking to have a 'designer baby' but simply a child related to both parents and one who will not suffer from mitochondrial disease.[21]

3.20 A witness, who suffers from mitochondrial disease, gave evidence about her strong connection with her biological mother, and the desire to have that with her own biological child:

> … when I do something in the day or I look in the mirror or I say something, I realise that that's come from my mum. That was her personality. She was conscientious, she was persistent and determined, she was compassionate. Those are all things that I inherited from her and that

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17 Dr George Daley, ISSCR, *Committee Hansard*, 6 August 2021, pp. 25–26.

18 Ethicentre, *Submission 7*, p. 2; Australian Catholic Bishops Conference, *Submission 11*, p. 7; Feminist International Network of Resistance to Reproductive and Genetic Engineering, *Submission 23*, p. 2.

19 Ethicentre, *Submission 7*, p 2. Ethicentre notes that PGD can be used to identify levels of faulty mitochondrial DNA in the embryo prior to implantation to reduce risk of passing it on, however it will not be suitable for severe forms of disease.

20 Dr Bernadette Tobin, Director, Plunkett Centre for Ethics, *Committee Hansard*, 6 August 2021, p. 10.

21 Mito Foundation, *Submission 16*, p. 12.

> I'm so grateful for. For me, this process would allow me to continue to pass that on to my children and for us to have that unique bond in that biological way.[22]

Creation and destruction of embryos

3.21 In the course of the inquiry, concerns were raised regarding the creation and destruction of human embryos involved in mitochondrial donation techniques.[23]

3.22 As discussed in Chapter 2, inquiry participants specifically objected to some of the proposed mitochondrial donation techniques in the bill (pronuclear transfer and polar body transfer techniques), because they involve the creation of a human embryo 'for its parts', and would result in higher rates of embryo wastage.[24]

3.23 According to the Australian Catholic Bishops Conference, mitochondrial donation techniques do not respect the human dignity of embryos:

> The Conference objects to the disposing of any human embryos because such actions would instrumentalise human embryos, treating them as part of a production process where they can be kept or disposed of subject to arbitrary judgements.[25]

3.24 The committee heard competing evidence on whether the introduction of mitochondrial donation would result in significantly more embryos being created or destroyed.[26]

3.25 Professor David Thorburn of the Murdoch Children's Research Institute argued there would not be a substantial number of excess embryos generated with the mitochondrial donation as compared to other assisted reproductive technologies.[27]

'Three parent child'

3.26 Inquiry participants told the committee that the techniques used for mitochondrial donation would result in a 'three parent child' because the

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[22] Mrs Shelley Beverley, private capacity, *Committee Hansard*, 6 August 2021, p. 6.

[23] Australian Catholic Bishops Conference, *Submission 11*, p. 2, Family Voice Australia, *Submission 12*, p. 2.

[24] Ethicentre, *Submission 7*, p. 6; Australian Christian Lobby, *Submission 24*, p. 5.

[25] Australian Catholic Bishops Conference, *Submission 11*, p. 9.

[26] Professor David Thorburn, *Committee Hansard*, 6 August 2012, p. 35.

[27] Professor David Thorburn, *Committee Hansard*, 6 August 2012, p. 35.

individual born of the procedure would have three genetic parents (mother, father, donor).[28]

3.27 Dr Bernadette Tobin of the Plunkett Centre for Ethics explained that a fundamental objection to mitochondrial donation is that the techniques would require three people to produce a child:

> … the point is that the embryo will be formed from biological material from three people. That confuses the child's biological heritage. That's the point about the biological material from three people—it's genomically confusing. Children ought to be able to look back to their origins of one untampered-with sperm and one untampered-with egg.[29]

3.28 According to the Australian Christian Lobby, mitochondrial donation represents a significant departure from current assisted reproductive technology (ART) practices:

> Until the advent of mtDNA transfer, children have always been born as the result of two biological parents. Even the small minority conceived with the assistance of donor eggs or donor sperm still have only 2 genetic parents. This technology represents a significant change from the way ART is currently practiced in Australia. Children born of mtDNA transfer have two biological mothers and one biological father. This creation of an embryo with three biological parents crosses a new frontier in human experimentation.[30]

3.29 Inquiry participants expressed concern about the confusion and distress that would be caused to a child born of mitochondrial donation who is trying to understand their origins and self-identity.[31]

3.30 As discussed in Chapter 2, inquiry participants stressed that if the bill were to be passed, it would be important to retain the donor register which would allow a person born from mitochondrial donation to receive identifying information about their donor when they turn 18.[32]

3.31 The Australian Catholic Bishops Conference argued that mitochondrial donation techniques would involve the transmission of personal characteristics between the donor and the resultant offspring. In their submission, they state:

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[28] See, for example, Ethicentre, *Submission 7*, p. 6; Australian Catholic Bishops Conference, *Submission 11*, p. 11; Family Voice Australia, *Submission 12*, p. 3; Feminist International Network of Resistance to Reproductive and Genetic Engineering, *Submission 23,* [p. 2].

[29] Dr Bernadette Tobin, Director, Plunkett Centre for Ethics, *Committee Hansard*, 6 August 2021, p. 11.

[30] Australian Christian Lobby, *Submission 24*, p. 6.

[31] Australian Catholic Bishops Conference, *Submission 11*, p. 9; Mrs Wendy Francis, Australian Christian Lobby, *Committee Hansard*, 6 August 2021, p. 9; Name withheld, *Submission 43,* pp. 1–3.

[32] See for example, MitoCanada, *Submission 10*, p. 1; Ethicentre, *Submission 7*, p. 6; Australian Christian Lobby, *Submission 24*, p. 7. See further discussion in Chapter 2 from paragraph 2.66. See also discussion in Dr Greg Pike, *Submission 53,* pp. 3–4.

> A person's identity depends on more than appearance and other characteristics, but mtDNA is also an important influence on characteristics such as ageing, memory and combatting disease.[33]

3.32 However, other inquiry participants refuted the claim that mitochondrial donation would result in a 'three parent child'.[34] For example, Science and Technology Australia, argued that placing the DNA of a mother's nucleus into a donor egg does not significantly change the genetic makeup of the child:

> The nuclear genome contains just over 20,000 genes that encode for a protein, mitochondria only have 13 genes and code for proteins exclusively in the mitochondria (Salzberg 2018). While mitochondria do contain its own DNA, the function of this DNA is to allow the proper function of the mitochondria - to produce energy for the cell.[35]

3.33 The Murdoch Children's Research Institute acknowledged that the term 'parent' is obviously complex.[36] According to Dr Christopher Gyngell, a research fellow in biomedical ethics with the institute, the distinction between nuclear DNA and mitochondrial DNA is relevant:

> One reason we might refer to a provider of sperm or egg as a genetic parent is that they provide a lot of the personal characteristics of that person. The nuclear DNA codes personal characteristics and can explain things like our likes and dislikes. Mitochondrial donation doesn't provide for those personal characteristics, so for that reason it would be my view that it would be inappropriate to label a mitochondrial donor as a parent.[37]

Commercial exploitation and risks to donors

3.34 The committee heard concerns about the potential for commercial exploitation by in vitro fertilisation (IVF) clinics through the introduction of mitochondrial donation.[38] Inquiry participants highlighted a shortage of donor eggs in Australia, and the risk of commercialisation, and exploitation of women for their eggs.[39]

3.35 The Australian Christian Lobby recommended that a clause be inserted in the bill to prohibit the use of human eggs obtained by commercial means, either in

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[33] Australian Catholic Bishops Conference, *Submission 11*, p. 8.

[34] See, for example, Science and Technology Australia, *Submission 18*, p. 3; Dr Christopher Gyngell, Team Leader/Research Fellow, Biomedical Ethics, Murdoch Children's Research Institute (MCRI), *Committee Hansard*, 6 August 2021, p. 30.

[35] Science and Technology Australia, *Submission 18*, p. 3.

[36] Dr Christopher Gyngell, MCRI, *Committee Hansard*, 6 August 2021, p. 30.

[37] Dr Christopher Gyngell, MCRI, *Committee Hansard*, 6 August 2021, p. 30.

[38] See, for example, Feminist International Network of Resistance to Reproductive and Genetic Engineering, *Submission 23,* p. 1; Womens Bioethics Alliance, *Submission 37*, p. 3.

[39] Australian Catholic Bishops Conference, *Submission 11*, p. 11; Family Voice Australia, *Submission 12*, p. 3.

Australia or overseas. In addition, that IVF clinics should be banned from offering inducements to clients to donate excess eggs obtained through their own treatments.[40]

3.36 Concerns were also raised about the health risks to donor women, and the lack of understanding of the long-term health risks involved in donation.[41] According to the Australian Christian Lobby:

> The call on egg donors also contributes to the objectification of women. Increasingly women are being called on to donate eggs for therapeutic practices as the applications of ART widen. Women are not 'spare parts' providers. The demands made of these women in these processes is costly in time and in terms of health risks.[42]

Sex selection

3.37 Several inquiry participants raised concerns about the provisions of the bill that would enable a woman to select the sex of embryos.[43]

3.38 The bill outlines that under a clinical trial licence and clinical practice licence, and following counselling, a woman and her spouse (if any) can request for only male embryos be selected for implantation.[44] The rationale is that, experts consider there is potentially an additional risk of mitochondrial disease re-emerging in the children of daughters born through mitochondrial donation.[45]

3.39 In the Mitochondrial Donation Expert Working Committee's Statement to the National Health and Medical Research Council (NHMRC) CEO, sex selection was specifically addressed:

> The Committee noted that, while there is scope to prevent the transmission of genetic changes resulting from mitochondrial donation by restricting the clinical procedure to male offspring only, there are ethical, scientific and practical considerations that make this practice problematic.[46]

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40 Australian Christian Lobby, *Submission 24*, p. 7.

41 Womens Bioethics Alliance, *Submission 37*, p. 3; Australian Catholic Bishops Conference, *Submission 11*, p. 2; Dr Karen Crawley, *Submission 41*, p. 1.

42 Australian Christian Lobby, *Submission 24*, p. 7.

43 Australian Christian Lobby, *Submission 24*, p. 16; mitoCandada, *Submission 10*, pp 1–2; Australian Catholic Bishops Conference, *Submission 11*, p. 10; Womens Bioethics Alliance, *Submission 37*, p. 3.

44 Bill, Item 17, proposed subsection 28Q; Explanatory Memorandum, p. 34.

45 Explanatory Memorandum, p. 34. The proposed approach is optional, and aligns with the UK and the findings of the previous Senate inquiry, which determined mandatory sex selection is not necessary to manage the risk. The explanatory memorandum also notes that currently in Australia, sex selection can be legally undertaken to reduce the risk of transmission of a serious genetic condition.

46 National Health and Medical Research Council (NHMRC), *Submission 17*, p. 3.

3.40 Inquiry participants told the committee that the United Kingdom (UK) does not allow sex selection in its mitochondrial donation regime.[47] Several international submitters, the Wellcome Centre for Mitochondrial Research in the UK, and MitoCanada, were not supportive of mandatory male preferential sex selection.[48]

3.41 In addition, according to the Wellcome Centre for Mitochondrial Research, sex selection would create a risk to the viability of the embryo and is unnecessary:

> … determination of sex would currently require an additional manipulation of the embryo at an extremely early stage of development, potentially compromising viability of that embryo.[49]

3.42 Several submitters recommended amending the bill to remove the ability to select the sex of embryos.[50] One noted that, given the differences of opinion internationally and amongst 'experts', it is unreasonable to expect families contemplating mitochondrial donation to make this decision.[51]

3.43 The Feminist International Network of Resistance to Reproductive and Genetic Engineering expressed strong opposition to the 'selective erasure of female embryos, hence future girls and women'.[52]

Scientific considerations

Scientific evidence

3.44 A key concern raised by those who object to the bill was the lack of publicly available scientific evidence about the safety and efficacy of mitochondrial donation, and the unknown risks to children subject to the procedure and to future generations.[53]

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47 See, for example, Wellcome Centre for Mitochondrial Research, *Submission 26*, p. 1.

48 MitoCanada, *Submission 10*, pp 1–2; Wellcome Centre for Mitochondrial Research, *Submission 26*, p. 1.

49 Wellcome Centre for Mitochondrial Research, *Submission 26*, p. 1.

50 Australian Christian Lobby, *Submission 24*, p. 15; Professor Ainsley Newson & Dr Christopher Rudge, *Submission 49*, p. 3.

51 Professor Ainsley Newson & Dr Christopher Rudge, *Submission 49*, p. 3.

52 Feminist International Network of Resistance to Reproductive and Genetic Engineering, *Submission 23*, p. 2. See also Womens Bioethics Alliance, *Submission 37*, p. 3.

53 See, for example, Family Voice Australia, *Submission 12*, p. 4; Australian Catholic Bishops Conference, *Submission 11*, p. 2; Australian Christian Lobby, *Submission 24*, p. 14; Womens Bioethics Alliance, *Submission 37*, p. 4; Dr Greg Pike, *Submission 53*, p. 2; Ethicentre, *Submission;* pp. 3–4.

3.45 The Australian Catholic Bishops Conference noted that mitochondrial donation has been legal in the UK for five years, with no reported live births, and no clear evidence the procedure is safe or practical.[54]

3.46 The Australian Christian Lobby shared similar concerns about the lack of published evidence from the UK. They noted in their submission that:

> … considerations regarding client confidentiality and parental wishes have also apparently obscured public insight into the outcomes of the UK scheme to some extent. This makes it difficult to assess other potential moral and ethical implications relating to the procedures which have been performed in the UK to date.[55]

3.47 It was suggested that the Mitochondrial Donation Expert Working Committee's Statement to the NHMRC CEO highlighted a lack of evidence regarding the safety of mitochondrial donation.[56] The statement notes:

> … incremental developments have been made on some aspects of the science since the 2016 UK Human Fertilisation and Embryology Authority (HEFA) scientific review. However, there is no significant new evidence about the safety and efficacy of mitochondrial donation since the 2016 HEFA scientific review.[57]

3.48 Inquiry participants voiced strong concerns about the unknown impacts of mitochondrial donation on the health of the person born of the procedure.[58] For example, the Australian Christian Lobby said:

> Questions regarding the long-term implications of the procedure into adulthood may potentially remain under-researched in practice for many years'.[59]

3.49 The Robinson Research Institute recommended further research in large animals to determine the relative safety and efficacy of mitochondrial donation techniques. It also recommended further research to understand the risk of mitochondrial disease re-emerging in children of mitochondrial donation and the consequences of any mitochondrial DNA being carried over to the prospective mother.[60]

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54 Australian Catholic Bishops Conference, *Submission 11*, p. 2;

55 Australian Christian Lobby, *Submission 23*, p. 14.

56 Australian Catholic Bishops Conference, *Submission 11*, p. 5. See also discussion in Dr Peter McCullogh, *Submission 14*, p. 9. See also discussion in Geneethics, *Submission* 36, p. 14.

57 NHMRC, *Submission 17*, p. 3.

58 Feminist International Network of Resistance to Reproductive and Genetic Engineering, *Submission 23*, p. 2; Australian Christian Lobby, *Submission 24*, pp. 4–5; Mrs Wendy Francis, National Director, Politics, Australian Christian Lobby, *Committee Hansard*, 6 August 2021, p. 9.

59 Australian Christian Lobby, *Submission 23*, p. 12.

60 Robinson Research Institute, *Submission 32*, p. 2

3.50 In contrast to these concerns, the committee heard from several witnesses arguing that there is sufficient scientific evidence to proceed with mitochondrial donation in Australia.[61] The ISSCR told the committee that clinicians and scientists believe the preponderance of evidence suggests moving forward:

> Our position at the International Society for Stem Cell Research is that there is sufficient evidence to justify first-in-human clinical studies.[62]

3.51 Professor Megan Munsie, Member and past Chair of the ISSCR, added that preclinical experiments including those undertaken in large animals, demonstrate the safety of mitochondrial donation techniques:

> Our guidelines stipulate the laboratory and clinical research involving mitochondrial replacement therapies for the purpose of preventing transmission of serious diseases is scientifically justifiable. We acknowledge that more research must be undertaken to refine optimised techniques but conclude that preclinical experiments performed to date, including the birth of healthy macaque monkeys, demonstrate adequate safety of mitochondrial replacement techniques to justify first-in-human clinical experiments.[63]

3.52 Other submitters noted that the bill itself will allow for important research, which will help demonstrate the safety and efficacy of mitochondrial donation.[64] Dr George Daley of the ISSCR told the committee:

> Through the provisions of the bill before us, I think there's a reasonable approach to rigour, to prudence, to safety and to what we hope will ultimately advance our understanding so that it can be even safer and more effective in the future.[65]

Human germline manipulation

3.53 Another key concern raised in the inquiry is that mitochondrial donation, if introduced through the bill, would result in human germline manipulation. That is, altering genetic material that is inherited by the next generation.[66]

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[61] Professor David Thorburn, Co-Group Leader, Brain and Mitochondrial Research, MCRI, *Committee* Hansard, 6 August 2021, p. 33; Professor Megan Munsie, ISSCR, *Committee* Hansard, 6 August 2021, p. 20; Dr George Daley, ISSCR, *Committee Hansard*, 6 August 2021, p. 25.

[62] Professor Megan Munsie, ISSCR, *Committee* Hansard, 6 August 2021, p. 20.

[63] Professor Megan Munsie, ISSCR, *Committee* Hansard, 6 August 2021, p. 20.

[64] See, for example, Dr Christopher Gyngall, MCRI, *Committee Hansard*, 6 August 2021, p. 31; Professor Carolyn Sue, Fellow, Australian Academy of Health and Medical Sciences, *Committee* Hansard, 6 August 2021, p. 28; Mito Foundation, *Submission 16*, p. 12;.

[65] Dr George Daley, ISSCR, *Committee Hansard*, 6 August 2021, p. 25.

[66] Ethicentre, *Submission 7*, p. 4, Australian Catholic Bishops Conference, *Submission 11*, p. 2; Australian Christian Lobby, *Submission 23*, p. 8; Plunkett Centre for Ethics, *Submission 31*, p. .2; GeneEthics, *Submission 36*, p. 4; Dr Greg Pike, *Submission 53*, p. 3.

3.54 According to the Robinson Research Institute, mitochondrial donation is a form of genome modification combining the DNA of three people in the conception of a child:

> … this genome modification is a heritable germline manipulation, meaning that the children of any females conceived by Mitochondrial Donation will inherit the two female genomes, as mtDNA is passed through the female germline relatively unchanged.[67]

3.55 Submitters noted that there is currently an international moratorium on human germline manipulation, due to the limits of genetic knowledge in this area.[68] Associate Professor Megan Best explained the rationale behind the moratorium:

> The motivation behind this whole idea is that we really don't know what the full impact of changing the germ line would be on the human gene pool, because of the limits of our genetic knowledge.[69]

3.56 It was also suggested that 'interference with human germline has consequences for history, anthropology and the social sciences'. This is because research into human populations, migration and demographic history uses mitochondrial DNA analysis.[70]

3.57 Inquiry submitters also raised issue with those who have equated mitochondrial donation to an organ transplant.[71] One submitter noted that an organ transplant would only affect the recipient and not her descendants, and that mitochondrial donation makes heritable changes to a person's genome that will be passed on to future generations.[72]

3.58 The committee heard concerns around the current limits of human understanding of mitochondrial DNA, and that it may contribute to personal characteristics in a person in ways not yet recognised.[73] The committee was directed to the Government's consultation paper on the bill which acknowledges that 'the immediate and long term risks for the child and

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67 Robinson Research Institute, *Submission 32,* p. 1.

68 Ethicentre, *Submission 7*, p. 4; Robinson Research Institute, *Submission 32,* p. 1.

69 Associate Professor Megan Best, Director, Ethicentre, *Committee Hansard,* 6 August 2021, p. 12.

70 Australian Christian Lobby, *Submission 23*, p. 10. See also discussion in Feminist International Network of Resistance to Reproductive and Genetic Engineering, *Submission 23,* p. 2; Dr Greg Pike, *Submission 53,* p. 3.

71 Associate Professor Megan Best, Director, Ethicentre, *Committee Hansard,* 6 August 2021, p. 10; GeneEthics, *Submission 36*, p. 8.

72 GeneEthics, *Submission 36*, p. 8.

73 Plunkett Centre for Ethics, *Submission 31,* p. 2.

longer-term implications for subsequent generations are not yet fully understood'.[74]

3.59 Finally, submitters raised concerns that mitochondrial donation would 'open the door to other germ-line manipulations' which have been condemned internationally.[75]

3.60 In contrast to these concerns, evidence was also presented to the committee which disputed the claim that mitochondrial donation would result in human germline manipulation.[76]

3.61 At a hearing, the ISSCR told the committee that there is a clear distinction between the current scientific understanding of mitochondrial donation techniques and heritable editing of the human genome:

> [ISSCR] scientists believes that heritable genome editing, where changes are made to nuclear DNA of an embryo, is not ready for clinical testing at this time. In contrast, mitochondrial replacement techniques as described in Maeve's Law are ready.[77]

3.62 The Mito Foundation argued that the bill clearly rules out intentional modification of either nuclear or mitochondrial DNA during mitochondrial donation. That is, mitochondrial donation as outlined in the bill, can only be used to minimise the risk of Australian parents passing on mitochondrial disease to their children.[78]

3.63 In their statement to the CEO of the NHMRC, the Mitochondrial Donation Expert Working Committee specifically addressed the question of whether mitochondrial donation is distinct from germline genetic modification. The committee advised:

> … the term "germline genetic modification" has conceptual drawbacks and would not be appropriate for classifying mitochondrial donation… however, that it is essential to recognise that mitochondrial donation introduces changes to the genome of the embryo with the potential to be inherited by future generations.[79]

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74 Plunkett Centre for Ethics, *Submission 31*, p. 2.

75 Feminist International Network of Resistance to Reproductive and Genetic Engineering, *Submission 23*, p. 2; Australian Catholic Bishops Conference, *Submission 11*, p. 6; Dr Greg Pike, *Submission 53*, p. 3.

76 Professor Megan Munsie, ISSCR, *Committee Hansard*, 6 August 2021, p. 20.

77 Professor Megan Munsie, ISSCR, *Committee Hansard*, 6 August 2021, p. 20.

78 Mito Foundation, *Submission 16*, p. 10.

79 See NHMRC, *Submission 17*, p. 3.

Cloning

3.64 The committee heard concerns about the bill amending the *Prohibition of Human Cloning for Reproduction Act 2002* and enabling techniques to be practiced that are used in cloning.[80] For example, the Feminist International Network of Resistance to Reproductive and Genetic Engineering submitted that such change would be 'highly unethical':

> … it is less than 20 years since the Australian parliament voted against human cloning. This was a good decision because, as we predicted, cloning has not produced any of the 'miracle cures' that were promised at the time.[81]

3.65 The committee heard that the use of Pronuclear Transfer and Second Polar Body Transfer techniques, proposed in the bill, use techniques similar to that used in cloning.[82] At a hearing, Associate Professor Megan Best of Ethicentre argued:

> It is true that pronuclear transfer as described in the bill is not cloning per se, however the technique used is a parallel of what is used in nuclear transfer, or cloning. Do we really want people to get better at the techniques? The difference between pronuclear transfer and cloning is just the cells that you use. The techniques are the same.[83]

3.66 Other witnesses, however, stressed that mitochondrial donation is not cloning and its purpose is not to produce identical copies.[84] According to Professor Megan Munsie of the ISSCR:

> The distinction here is that in cloning technology you're attempting to make the copy of existing nuclear DNA, and in the case of mitochondrial replacement techniques you're either taking across the maternal chromosomes, the chromosomes of the woman with the diseased mitochondria, or the pronuclei—that is, before the male and the female chromosomes unite to form a new nucleus. So I don't see it as cloning an individual.[85]

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[80] See, for example, Australian Catholic Bishops Conference, *Submission 11*, p. 2; Ethicentre, *Submission 7*, p. 6; Feminist International Network of Resistance to Reproductive and Genetic Engineering, *Submission 23,* p. 2.

[81] Feminist International Network of Resistance to Reproductive and Genetic Engineering, *Submission 23*, p. 2.

[82] Australian Catholic Bishops Conference, *Submission 11*, p. 2; Ethicentre, *Submission 7*, p. 6.

[83] Associate Professor Megan Best, Director, Ethicentre, *Committee Hansard*, 6 August 2021, p. 17.

[84] Professor Anne Kelso, Chief Executive Officer, National Health and Medical Research Council (NHMRC), *Committee Hansard*, 6 August 2021, p. 38; Professor Megan Munsie, ISSCR, *Committee Hansard*, 6 August 2021, p. 21; Professor George Daley, ISSCR, *Committee Hansard*, 6 August 2021, pp. 21–22.

[85] Professor Megan Munsie, ISSCR, *Committee Hansard*, 6 August 2021, p. 21.

3.67 Scientists that gave evidence to the committee stressed the distinction between nuclear and mitochondrial DNA.[86] Dr Christopher Gyngell of the Murdoch Children's Research Institute explained that with mitochondrial donation:

> … you're getting the mitochondrial DNA, which is shared by many, many different people, that only really affects the functioning of the mitochondria, not the personal characteristics that are contained in our nuclear DNA. I think the term 'designer babies' is really referring to changes in nuclear DNA, which affect our personal characteristics, rather than changes to our mitochondrial DNA.[87]

Other uses for mitochondrial donation techniques

3.68 In addition to fears about cloning posed by the bill, concerns were raised that mitochondrial donation, if legalised, would open the floodgates for other uses of mitochondrial donation techniques that are outside the initially narrow remit in the bill.[88]

3.69 The committee heard that the technology used in mitochondrial donation has been promoted as a way to address infertility.[89] There were also concerns the technology would be used to treat other rare diseases or as a way to choose desirable traits in children.[90]

3.70 In reply to these concerns, the Murdoch Children's Research Institute argued that mitochondrial donation techniques are unlikely to be used as a viable option for infertility, and are completely irrelevant for the treatment of other diseases or the selection of desirable traits that might result in 'designer babies'.[91] According to Professor David Thorburn:

> The concept of mitochondrial donation being used to treat infertility has been raised. I think most credible authorities conclude that there is no hard evidence that it would work and think that the risk-benefit ratio is inappropriate for mitochondrial donation to be used in that context. To me, that's the only spillover of mitochondrial donation into other uses, and that seems to me to be clearly blocked in the legislation, by requiring it to be only used for the prevention of severe disease. It cannot be used for the prevention of any other inherited disorders—Down syndrome, cystic

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86 Dr Christopher Gyngell, MCRI, *Committee Hansard,* 6 August 2021, p. 36; Dr George Daley, ISSCR, *Committee Hansard*, 6 August 2021, pp. 21–22; Professor Megan Munsie, ISSCR, *Committee Hansard*, 6 August 2021, p. 21.

87 Dr Christopher Gyngell, MCRI, *Committee Hansard,* 6 August 2021, p. 36.

88 Australian Christian Lobby, *Submission 23*, p. 13.

89 Victorian Assisted Reproductive Treatment Authority, *Submission 30*, p. 3; Plunkett Centre for Ethics, *Submission 31*, p. 3.

90 See, for example, GeneEthics, *Submission 36*, p. 10; Womens Bioethics Alliance, *Submission 37*, p. 3.

91 Professor David Thorburn, MCRI, *Committee Hansard,* 6 August 2021, p. 35; Professor Christopher Gyngell, MCRI, *Committee Hansard,* 6 August 2021, p. 36.

> fibrosis. It is completely irrelevant; changing the mitochondria would not do anything.[92]

3.71 More broadly, as discussed in Chapter 2, inquiry participants told the committee that the changes to cloning and embryo research legislation proposed by the bill are sufficiently narrow to prevent any use of the techniques beyond the treatment of mitochondrial disease.[93]

3.72 The Department of Health also gave evidence at the hearing that any further use of the techniques beyond mitochondrial donation would require additional legislative change and consideration by the Parliament.[94]

Concluding comments

3.73 The committee acknowledges the devastating impact of mitochondrial disease on individuals and whole families. The committee was deeply moved by evidence from those who suffer from mitochondrial disease, who have lost family members to the disease, and who have a strong desire to prevent the burden of the disease in future generations.

3.74 The proposed introduction of mitochondrial donation in Australia, as set out in the bill, engages difficult ethical, social and scientific issues. The committee notes that the changes proposed are significant and that the bill would amend existing laws that strictly control embryo research and prohibit cloning.

3.75 The committee acknowledges and respects the diverse views held in relation to the bill. This is reflective of broader views on mitochondrial donation in the community, and reinforces the importance of allowing for a conscience vote. The task of the committee in this inquiry has been to explore the issues raised by the bill, and present them to the Parliament to assist in its deliberations.

3.76 Should the bill be passed, the committee highlights several areas where additional clarification, amendment or further consideration may be appropriate. These include in relation to:

- the proposed donor register, and exploring the possibility of enabling children under the age of 18 the right to information about the donor in appropriate circumstances;
- pre-treatment counselling for all parties involved in mitochondrial donation, and providing further clarity on the requirements for counselling for donors;

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92 Professor David Thorburn, MCRI, *Committee Hansard,* 6 August 2021, p. 35.

93 See Chapter 2, paragraph 2.8.

94 Ms Bronwyn Field, First Assistant Secretary, Portfolio Strategies Division, Department of Health, *Committee Hansard,* 6 August 2021, p. 48.

- in relation to sex selection, whether the provisions of the bill that would enable a woman the option of selecting the sex of embryos is necessary and appropriate; and
- monitoring and evaluation of the outcome of the clinical trial, and providing further clarification on the requirements for longer term outcomes monitoring and reporting. In particular, ensuring that the privacy of families is protected, but also providing assurance that the evidence needed to consider the safety and efficacy of mitochondrial donation will be available for the community, and the Parliament, to assist in considering the possibility of clinical practice in Stage 2.

3.77 The committee makes no recommendations as this is a conscience matter. The report is simply a summary of the submissions and views available at the time of reporting.

Senator Wendy Askew
Chair

Appendix 1
Submissions and additional information

Submissions

1 Murdoch Children's Research Institute
2 Human Genetics Society of Australasia
3 Research Australia
4 Rare Voices Australia
5 Monash IVF Group Limited
6 Australian Genomics Health Alliance
7 Ethicentre Ltd.
8 Childhood Dementia Initiative
9 The International Society for Stem Cell Research
10 MitoCanada
11 Australian Catholic Bishops Conference
12 FamilyVoice Australia
13 Professor John Christodoulou
14 Dr Peter McCullagh
15 Professor Michael Ryan
16 Mito Foundation
- Supplementary to submission 16

17 National Health and Medical Research Council
18 Science & Technology Australia
19 Genetic Alliance Australia
20 Dr Suzanne Sallevelt
21 Professor David Thorburn
22 Professor John Carroll
23 Feminist International Network of Resistance to Reproductive and Genetic Engineering
24 Australian Christian Lobby
25 The Lily Foundation
26 Wellcome Centre for Mitochondrial Research
27 Progress Educational Trust
28 Professor David Albert Jones
29 Professor Carolyn Sue
30 Victorian Assisted Reproductive Treatment Authority
31 Plunkett Centre for Ethics
32 Robinson Research Institute
33 The Australian Academy of Science & The Academy of Health and Medical Sciences
34 Department of Health

35 Australian Society for Medical Research
36 GeneEthics
- Supplementary to submission 36
- Supplementary to submission 36

37 Women's Bioethics Alliance
38 *Name Withheld*
39 *Name Withheld*
40 Professor Mary Herbert
41 Dr Karen Crawley
42 *Name Withheld*
43 *Name Withheld*
44 Professor Stuart Newman
45 *Name Withheld*
46 Australian and New Zealand Infertility Counsellors Association
47 Right to Life Australia
48 Associate Professor Karinne Ludlow, Ms Esther Lestrell and Professor Catherine Mills
49 Professor Ainsley Newson & Dr Christopher Rudge
50 *Name Withheld*
51 Ms Giselle Newton
52 Ms Sarah Dingle
53 Dr Greg Pike
54 *Name Withheld*
55 Professor Julian Savulescu
56 Dr Cathy Herbrand

Answer to Question on Notice

1 Answer to question taken on notice during 6 August public hearing, received from the Department of Health, 16 August 2021

Appendix 2
Public Hearings

Friday, 6 August 2021
Committee Room 2S2
Parliament House
Canberra

Mito Foundation

- Mr Sean Murray, Chief Executive Officer
- Mrs Shelley Beverley, Lived Experience
- Professor Carolyn Sue AM FAHMS, Founding Director and Chair - Scientific & Medical Advisory Panel

Australian Genomics Health Alliance

- Ms Tiffany Boughtwood, Managing Director
- Professor John Christodoulou, Chief Investigator

Plunkett Centre for Ethics

- Dr Bernadette Tobin, Director

Australian Christian Lobby

- Ms Wendy Francis, National Director - Politics

Ethicentre Ltd.

- Associate Professor Megan Best, Director

The International Society for Stem Cell Research

- Professor Megan Munsie, Member – ISSCR Ethics Committee and ISSCR Guidelines on Stem Cell Research and Clinical Translation Taskforce
- Dr George Daley, Dean of the Faculty of Medicine - Harvard Medical School

Robinson Research Institute

- Professor Rebecca Robker, Executive - Theme Leader Early Origins of Health

Australian and New Zealand Infertility Counsellors Association

- Ms Rebecca Kerner, Chair
- Ms Iolanda Rodino, Committee Member

The Academies

- Professor Carolyn Sue AM FAHMS, Fellow - Australian Academy of Health and Medial Sciences

Murdoch Children's Research Institute

- Professor David Thorburn, Co-Group Leader - Brain & Mitochondrial Research
- Dr Christopher Gyngell, Team Leader

National Health and Medical Research Council

- Professor Anne Kelso, Chief Executive Officer
- Ms Prue Torrance, Executive Director

Department of Health

- Mr Paul McBride, Acting Deputy Secretary - Strategy, Evidence and Research Group
- Ms Bronwyn Field, First Assistant Secretary - Portfolio Strategies Division
- Ms Angela Wallbank, Assistant Secretary - Strategic Policy Branch