Chapter 4

Ethics of mitochondrial donation

4.1 A number of submitters to this inquiry expressed ethical concerns about the techniques used in mitochondrial donation. Noting that different people have different ethical frames of reference, this chapter examines the ethical issues that have been raised during the inquiry.

4.2 The ethical issues can be broadly categorised under three themes:

- Moral issues: including questions about the moral status of embryos and who should be considered to be a parent;
- Medical and health ethics: including questions about whether a child has a right to know the genetic contributors; how donors are treated; whether consent can be anticipated and the degree to which medical science intervenes in the life of a child born to the technique; and
- Scientific ethics: including questions about when a technology should be considered to be safe for use; whether the technology will affect future generations and the degree of risk to them and whether the technology could inadvertently be used for other things.

4.3 All witnesses and submitters to this inquiry agree that mitochondrial disease is a terrible disease, with devastating impacts to individuals and their families. Submitters with an ethical objection to mitochondrial donation expressed great compassion for families impacted by mitochondrial disease:

> Our hearts go out to families dealing with these diseases and who have the understandable desire that their children should not also be born with these burdens. It is a natural human longing to spare children of illness and suffering.[1]

Moral issues

Moral status of human embryos

4.4 As discussed in chapter three, the pronuclear transfer technique requires two fertilised eggs, one from the mother with the mutated mitochondrial deoxyribonucleic acid (mtDNA) and one from a donor with healthy mtDNA. The pronuclear transfer technique results in a reconstituted egg with the parents' nuclear DNA, but it requires the disposal of the fertilised pronuclei that were contained in the donor egg.[2]

4.5 Submitters such as the Social Issues Committee of the Anglican Church Diocese of Sydney, the Plunkett Centre for Ethics, the Australian Catholic Bishops

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1 Australian Catholic Bishops Conference, *Submission 28*, p. 2.

2 Dr Petra Wale, Board Member, Fertility Society of Australia, *Committee Hansard*, 17 May 2018, p. 44; Professor Justin St John, Professor and Head, Mitochondrial Genetics Group, Hudson Institute of Medical Research, *Committee Hansard*, 17 May 2018, p. 44.

Conference and Catholic Health Australia raised an ethical concern that the creation of an embryo for the purpose of destroying it violates the dignity that is owed to the embryo.[3] The legislative changes required to permit the pronuclear transfer technique of mitochondrial donation in Australia would represent the only permissible creation of an embryo with no potential to develop into a viable pregnancy, outside of somatic cell nuclear transfer (SCNT) research conducted under license.

4.6 The Australian Catholic Bishops Conference explained that its objection about the ethical use of embryos was not limited to mitochondrial donation, but was a common concern about all forms of assisted reproductive technology (ART):

> Human beings have inherent dignity and their rights as people must be respected including their right to life from the moment the first cell of the human zygote is formed by whatever means it comes to be.
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> A logical ethical sequence of this dignity is that the life of each human embryo is to be considered inviolable. [ART] may involve the discarding of human embryos and may involve the formation of an embryo of a laboratory procedure replacing…marital intercourse…with a technical procedure.[4]

4.7 The Plunkett Centre for Ethics raised a similar concern about the creation of an embryo to obtain the donor egg and mitochondria:

> Treating an embryo merely as a *means* and not also as an *end in itself* violates the respect owed to embryonic human life.[5]

4.8 For these submitters, the end to which the procedure is directed is irrelevant.[6] Their belief in the dignity of the embryo means that their opposition is not specific to mitochondrial donation, but to any interference with human embryos that leads to their destruction:

> I think, of course, that we should never have legalised research on human embryos that involves their destruction, and I have no doubt there will be plenty more destructive research on human embryos to develop any of these techniques. There's no doubt about that.[7]

4.9 Other submitters recognised that questions about the moral status of embryos were neither new nor particular to mitochondrial donation.[8]

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3 Social Issues Committee, Anglican Church Diocese of Sydney, *Submission 56*, p. 2; Plunkett Centre for Ethics, *Submission 30*, p. 2; Australian Catholic Bishops Conference, *Submission 28*, p. 3; Catholic Health Australia, *Submission 60*, pp. 1–2.

4 Australian Catholic Bishops Conference, *Submission 28*, p. 3.

5 Plunkett Centre for Ethics, *Submission 30*, p. 2 (emphasis in original).

6 Plunkett Centre for Ethics, *Submission 30*, p. 1.

7 Dr Bernadette Tobin, Director, Plunkett Centre for Ethics, *Committee Hansard*, 17 May 2018, p. 65. The Plunkett Centre for Ethics is a collaboration between the Australian National University, St Vincent's Health Network Sydney and Calvary Health Care.

8 Mr Ash Howlett and Dr Steve Mercer, *Submission 40*, [p. 4]; Associate Professor Ainsley Newson, *Submission 29*, p. 5.

4.10 As noted in earlier chapters, one current option that is available to women who live with a mitochondrial disease who are considering having children is to have the embryos tested through a process known as pre-implantation genetic diagnosis. In their submission to the committee, Mr Ash Howlett and Dr Steve Mercer explained that they could see little ethical difference between the mitochondrial donation techniques and other procedures that had already been legalised, such as pre-implantation genetic diagnosis:

> Perhaps the most similar technique on ethical terms currently employed in Australia is Preimplantation Genetic Diagnosis (PGD). With PGD, many embryos are created for the purpose of removing cells for genetic testing. Embryos that are deemed unfit are destroyed, likely many more than are destroyed during a single mtDNA donation process depending on the number of embryos tested during PGD. This leads us to an ethical area that is contested by people who believe that life begins at the embryonic stage of development, and those that believe that it is more ethically justifiable to suggest that life begins later on during pregnancy, around when neural structures are forming. A government that allows PGD as well as other embryo or foetal destroying procedures such as abortion, should not be swayed by appeals to the moral status of an embryo.[9]

4.11 Bioethicist Dr Ainsley Newson also noted that current ART already requires the destruction of a number of embryos and the introduction of mitochondrial donation would not add substantially to the number of embryos that are destroyed each year:

> We also have quite small numbers here. This is a background of a technology where fewer than 100 people a year are likely to use it, compared to the 13,000 cycles of assisted reproductive techniques. Embryo discard in that context would be significantly higher. If your position is one where that is problematic too then that is not going to be information that is convincing or of comfort.[10]

4.12 In summary, while there are a range of views about the moral status of embryos, there is little about mitochondrial donation that is different to other forms of ART. As Dr Newson submitted to the committee:

> There are a range of views on embryo moral status in Australia. Mitochondrial donation does not add anything new to existing issues regarding the ethics of the use of embryos in research and clinical treatment, from the perspective of the moral status of the embryo.[11]

Committee view

4.13 The committee understands that some people will have ethical concerns about the destruction of human embryos. That is an understandable concern; however, the question is whether those concerns should preclude the progression of mitochondrial

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9 Mr Howlett and Dr Mercer, *Submission 40,* [p. 4].

10 Associate Professor Ainsley Newson, *Committee Hansard*, 17 May 2018, p. 58.

11 Associate Professor Newson, *Submission 29,* p. 5.

donation techniques. The committee has reached a view that the ethical concerns should not prohibit further scientific review and community consultation on the use of mitochondrial donation in Australia.

4.14 The committee has received evidence that all forms of ART result in some destruction of embryos and pregnancy screening techniques present parents with a choice of continuing a pregnancy or undergoing a termination. As concerning as that may be, ART has been available in Australia for a number of decades and is well accepted. The committee accepts that arguments against mitochondrial donation based solely on the absolute moral status of the embryo are a continuation of an older debate over reproductive rights.

4.15 However, mitochondrial donation does potentially raise new and different ethical concerns regarding embryos that must be considered. The legislative changes required to permit the pronuclear transfer technique of mitochondrial donation in Australia would represent the only permissible creation of unique and potentially viable embryos with no potential to develop into a viable pregnancy outside of SCNT research conducted under license. This is a new moral question that would require community consultation as well as a change to the legal prohibition of such activity under current law.

4.16 The committee considers that mitochondrial donation techniques do not present new ethical concerns, but they do present a scientifically supported source of hope that future generations of Australians may be able to live free of the diseases that have plagued generations of their families.

mtDNA parent or mtDNA donor?

4.17 One of the ethical concerns about mitochondrial donation is the inclusion of genetic material from a third person in the creation of the embryo. The phrase that has sometimes been used in the media is that mitochondrial donation creates 'three-parent babies'.[12]

4.18 The ethical concern about the use of a third person's genetic material was expressed by Dr Bernadette Tobin, Director of the Plunkett Centre for Ethics as a violation of 'the child's right to a natural biological heritage'.[13]

4.19 This argument can be separated into two parts: the first part is an argument that the introduction of a third genetic donor violates the dignity of the unborn child and the second is that the child will be confused or will experience distress because

12 Dr John A Duley, *Submission 7*, [p. 2]; Associate Professor Catherine Mills, Associate Professor Karinne Ludlow, Professor Robert Sparrow and Dr Narelle Warren, *Submission 20*, [p. 9]. See for example: Tracy Bowden, 'Three-parent babies: calls to allow controversial mitochondrial donation procedure in Australia', *ABC News*, 19 November 2017, http://www.abc.net.au/news/2017-11-20/three-parent-babies-and-mitochondrial-donation/9100228 (accessed 29 May 2018).

13 Dr Tobin, *Committee Hansard*, 17 May 2018, p. 65.

they are uncertain about their parentage.[14] Central to both arguments is a question about whether an mtDNA donor is or should be considered to be a parent.

4.20 Dr Newson notes that there is a difference between genetic and social parenting:

> …the term 'three parent baby' has numerous problems. It conflates genetic and social parenting. It overlooks that the genetic contribution from the 'third parent' is vastly smaller than the commissioning couple's and that an epigenetic contribution from a woman pregnant with a foetus conceived via oocyte donation could also be said to be a 'genetic contribution'.[15]

4.21 From a genetic perspective, some submitters suggested that the phrase is misleading. The Wellcome Trust, in an attachment to its submission, explained that children who are born using these techniques will only have nuclear DNA from the mother and the father:

> In mitochondrial donation, almost all of the child's genes will come from its parents; the mitochondrial donor will only contribute 37 genes (0.1% of total DNA), which enable the mitochondria to produce energy. The donor mitochondrial DNA will not affect the child's appearance, personality or any other features that make a person unique – it will simply allow the mitochondria to function normally and the child to be free of mitochondrial DNA disease. Mitochondrial donation involves two-parent fertilisation in the same way that IVF does, and any child would be genetically unique, with a natural combination of nuclear genes from both parents…
>
> The term "three-parent children" is misleading. These children will only have two biological parents…[16]

4.22 Professor John Christodoulou, Chair of Genomic Medicine at the Department of Paediatrics at the University of Melbourne suggested that the fact that mtDNA does not contribute to physical, cognitive or behavioural characteristics was relevant to considering whether the mtDNA donor should be considered to be a parent:

> Certainly, it's DNA that is different from the parent's, but it is 0.1 per cent of the total amount of genetic material in terms of what makes us us. As I said, the mitochondrial DNA really is only involved in making energy; it's not about other physical, cognitive or behavioural characteristics.[17]

4.23 Associate Professor Damian Dowling from the School of Biological Sciences at Monash University also thought that the genetic contribution of the mtDNA donor was so small that the donor should not be considered to be a third parent:

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14 Dr Tobin, *Committee Hansard*, 17 May 2018, p. 65; Australian Christian Lobby, *Submission 51*, p. 5.

15 Associate Professor Ainsley Newson, *Submission 29*, p. 4.

16 Wellcome Trust, *Submission 1—Attachment 3*, [p. 4].

17 Professor John Christodoulou, Chair of Genomic Medicine, Department of Paediatrics, University of Melbourne, *Committee Hansard*, 17 May 2018, p. 16.

> From a technical genetic point of view, if we just consider the nuclear chromosomes and ignore the mtDNA, the children produced will clearly be two-parent babies. But, as others have pointed out, if we consider all of the unique protein-coding genes dispersed across the nuclear and mitochondrial genome—of which there are 37 mitochondrial and close to 20,000 nuclear genes—the children produced would be 2.002-parent babies.[18]

4.24 If the three-parent issue is considered from a social perspective, in the United Kingdom (UK) the mtDNA donor is not considered to be a parent, but the equivalent of an organ donor.[19]

4.25 Some submitters observed that organ donation and tissue donation includes a complement of DNA being placed into the body of the recipient.[20] Professor Christodoulou noted that the additional genetic complement does not change the way society views that person:

> Bone marrow transplantation can be considered to have DNA from three individuals. That's very acceptable; we don't call that person a three-person bone marrow recipient.[21]

4.26 Similarly, according to Professor Carolyn Sue, Director of the Mitochondrial Research Centre at the Kolling Institute of Medical Research based at the Royal North Shore Hospital in Sydney, surveys of patients who live with mitochondrial disease indicates that they conceive of the procedure as being similar to organ or tissue donation:

> When you hear the 'three parent' terminology, I guess they want you to hear that it's like a bone marrow transplant or a heart transplant. Those patients also have three components of DNA within their body, but really that doesn't impact on their day-to-day lives, apart from the fact that it's improved their health outcomes.[22]

4.27 Fears that transplantation or an infusion might change a person are also not new. Dr John Duley, a scientist who has worked in the area of mitochondrial disease, recalled that similar fears were raised when heart transplants were first conducted:

> In people's minds this organ was endowed with almost mystical qualities—it was the seat of love and other emotions… Its transfer from one person to

18 Associate Professor Damian Dowling, School of Biological Sciences, Monash University, *Committee Hansard*, 17 May 2018, p. 53.

19 Wellcome Trust, *Submission 1—Attachment 3*, [p. 4].

20 Professor Carolyn Sue, Director, Kolling Institute of Medical Research, Mitochondrial Research Centre, *Committee Hansard*, 17 May 2018, p. 23; Professor Christodoulou, *Committee Hansard*, 17 May 2018, p. 16.

21 Professor Christodoulou, *Committee Hansard*, 17 May 2018, p. 16.

22 Professor Sue, *Committee Hansard*, 17 May 2018, p. 21.

> another was regarded as an unnatural act, meddling with 'personhood' and trespassing into territory that had a spiritual quality.[23]

4.28 Science and the ethical debates about transplantation have evolved since that time and transplants are now a standard part of medical practice. The broader Australian community accepts that organ donation is ethical and it is something that the medical community actively promotes:

> In Australia, we already support organ donation; it is legal, it is common practice and we actively promote it. Somebody who has an organ donated has more DNA from somebody else than we are talking about in mitochondrial donation.[24]

4.29 Concepts around the genetic contribution of mtDNA versus nuclear DNA have broader application than simply a question of contribution to the parentage of a particular child. It also reflects on whether mtDNA donation is considered to be a germline genetic modification in the same way that some nuclear DNA modifications can be. This is an issue that will be considered in greater detail below.

Committee view

4.30 The committee understands that there are people who have concerns that mitochondrial donation techniques may lead to children having three genetic parents. This is not the case. The benefit of mitochondrial donation is that it affords people living with mitochondrial disease the opportunity to have a genetically related child whilst dramatically reducing the child's chance of developing a serious mitochondrial disease.

4.31 The committee considers that an mtDNA donor should be conceptualised as being similar to an organ donor. The committee notes that there are already procedures being performed, such as bone marrow or organ transplants, that results in genetic material being transferred to a person who needs it for a medical reason. These do not appear to have led to adverse consequences for the individuals involved in the transplant procedures. There may be reasons to hold concerns about mitochondrial donation, but the committee does not have any reservation that the children born of this technique will have only two parents. The question of whether mtDNA donation should be anonymous, similar to organ donation, is discussed below.

Medical and health ethics

4.32 Four main ethical questions were raised by submitters that can be broadly categorised as concerning medical and health ethics:

- should mtDNA donation be anonymous?
- will the mtDNA donors be exploited?

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23 Raymond Hoffenberg, 'Christian Barnard: his first transplants and their impact on concepts of death', *British Medical Journal*, vol. 324, 2001, pp. 1478–1480 quoted in Dr Duley, *Submission 7*, [p. 2].

24 Ms Monica Ferrie, Chief Executive Officer, Genetic Support Network of Victoria, *Committee Hansard*, 17 May 2018, p. 2.

- would a child consent to be conceived by mitochondrial donation?
- should a child be required to participate in ongoing follow up?

4.33 Each of these questions is considered below.

Should mtDNA donation be anonymous?

4.34 Another ethical concern raised by submitters was whether mtDNA donors should be anonymous or whether the child has a right to know the identity of the donor. This question needs to be considered from the perspective of the donor and from the perspective of the child who may be born of the technique. In the UK, the regulations allow a child born of the technique to discover only non-identifying information about the donor from the age of 16, making mtDNA donation anonymous.[25] A donor is entitled to know how many children have been born from their donated material, the sex of those children, and what years the children were born.[26]

4.35 Dr Newson explained that the rationale for making mtDNA anonymous in the UK was that mitochondrial donation is more akin to organ or tissue donation than reproductive donation and the preference for anonymity reflects that fact.[27]

4.36 However, opinions on whether mtDNA donors should be anonymous vary. Professor John Christodoulou supported anonymous mtDNA donation because he considered it to be important to the donor.[28] Professor Sue informed the committee that some people living with mitochondrial disease have indicated that they would prefer mitochondrial donation to be anonymous because they considered that the techniques were akin to organ or tissue donation and because they were concerned about the risk of stigma.[29]

4.37 Other submitters to the inquiry argued that, if Australia allowed mtDNA donation, the child should be entitled to know the identity of the mtDNA donor. Dr Petra Wale, a board member of the Fertility Society of Australia told the committee that most donor-conceived people want to know their genetic heritage:

> People want to know where they come from. As a society and as a practice we don't have anonymous donation anymore. Anybody donating in the current climate, and this has been for many years—whether it be a sperm donor, an egg donor or an embryo donor—is made aware that that resulting offspring will know who you are and have the opportunity to have identifying information about you. I struggle to think that there will be a lot circumstances where this would be anonymous. There would probably be a

25 Professors David Thorburn, John Christodoulou, Carolyn Sue, John Carroll, Mike Ryan and Aleksandra Filipovska, *Submission 59—Attachment 1*, [33.28].

26 Professors Thorburn, Christodoulou, Sue, Carroll, Ryan, Filipovska, *Submission 59—Attachment 1*, p. 191.

27 Associate Professor Newson, *Submission 29*, p. 4.

28 Professor Christodoulou, *Committee Hansard*, 17 May 2018, p. 13.

29 Professor Sue, *Submission 24*, p. 4.

> lot of people who have people helping them out. That's what happens now with egg donation. It's usually altruistic from other family members and from best friends. There are always stories. Their best friends and other people help them out. Making it anonymous will come back to bite us.[30]

4.38 Some submitters, such as the Australian Christian Lobby and the Australian Catholic Bishops Conference, considered that the child's right 'to know and be cared for by his or her parents' includes a moral right to know the circumstances of a person's conception.[31]

4.39 Archbishop Fisher drawing on the experiences of adopted children, pointed to the psychological distress that can result from a lack of knowledge about their genetic history:

> When we think of what confusion that might create in a child regarding their lineage, their genetic heritage, the families they belong to, we know already the problem of genealogical bewilderment or children that go searching for donor parents or searching for their natural parents when they been adopted. We would risk creating another group of children in search of their genealogy.[32]

4.40 Dr Tobin from the Plunkett Centre agreed the move away from anonymous donation was to be commended and that it should not be considered for mtDNA donation:

> To add to what you said, that we have gotten rid of anonymous donation is a great Australian ethical development that has been picked up in some parts of the world. This was a wonderful achievement of the NHMRC 10 or 15 years ago. I do hope that nothing that the legislators consider will have us back-sliding on that one.[33]

4.41 In her submission, Dr Newson explained that she conducted a citizen's jury to understand community attitudes to mitochondrial donation. According to Dr Newson, one of the issues that many of the jurors were concerned about was ensuring that children had a right to know their donor if they wished to do so.[34]

4.42 Dr Newson noted that allowing the mtDNA donor to be known also validates the contribution that the mtDNA donor made to the child's life:

> Women who choose to donate oocytes for mitochondrial donation are making a small but very fundamental contribution to this process and also to the genetic complement of any children who are born as a result. The

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30 Dr Wale, *Committee Hansard*, 17 May 2018, p. 46.

31 Australian Catholic Bishops Conference, *Submission 28*, p. 3; Australian Christian Lobby, *Submission 51*, p. 5.

32 Archbishop Anthony Fisher, Vice President, Catholic Bishops Conference and Chairman, Bishops Commission for Family, Youth and Life, *Committee Hansard*, 17 May 2018, p. 64.

33 Dr Tobin, *Committee Hansard*, 17 May 2018, p. 68.

34 Associate Professor Newson, *Submission 29*, p. 8. Additional information about the citizen's jury process can be found in Associate Professor Newson's submission.

> presumption that this complement is too small to warrant recognition of the donor, to me, overlooks the significance of the physical process of donation and also that the donated material makes a significant difference between someone having mitochondrial disease and not in the future.[35]

4.43 Professor John Christodoulou told the committee that, like other ethical issues involving mitochondrial donation, the committee needs to consider carefully about community morals and expectations regarding the process:

> [T]his is an area where we need to understand what the community by and large wants or finds acceptable. Certainly, everyone is entitled to their own individual want and desire, but I guess if we are talking about changing legislation for the whole community we have to take into account what the whole community's desire is.[36]

Committee view

4.44 The committee understands that people have different views about whether mtDNA donation should be anonymous. The committee considers that a child's right to know their biological heritage should be paramount. The committee acknowledges that there has been a shift in Australian attitudes towards making information about a person's biological heritage known in both the adoption space and in other forms of ART. The committee considers that children who are born from a mitochondrial donation technique should be entitled to know their donor if they want to.

4.45 The committee notes that it proposes treating mtDNA donation differently from either gamete or organ donation. The committee considers that an mtDNA donor should be conceptualised as being similar to an organ donor because they are donating non-nuclear genetic material. However, recognising that biological or heritage questions may arise for children born of this process, the committee considers that mtDNA donors should not be anonymous.

4.46 Women who donate their mtDNA should be made aware that if a child is born from their donated mtDNA then the child may be given identifying information about the donor at an appropriate time.

Will mtDNA donors be exploited?

4.47 Mitochondrial donation requires human eggs that contain healthy mitochondria. Some submitters expressed concerns about where the eggs would come from and whether the egg donor would be exploited.[37]

4.48 The Social Issues Committee of the Anglican Church Diocese of Sydney raised concerns that women may be financially coerced into donating their eggs for this purpose:

> …there are also ethical issues pertaining to the egg donor herself. It is known that egg donation is potentially dangerous due to the risks of

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35 Associate Professor Newson, *Committee Hansard*, 17 May 2018, p. 50.

36 Professor Christodoulou, *Committee Hansard*, 17 May 2018, p. 14.

37 Social Issues Committee of the Anglican Church Diocese of Sydney, *Submission 56*, p. 2.

> associated hormonal stimulation. As a result, egg donors can be difficult to find. This leads to pressure from lobby groups to introduce payment for gamete donation, which leads to vulnerable women being financially coerced into undergoing a potentially life-threatening harvesting procedure. This is unethical.[38]

4.49 This concern was shared by the Catholic Church. Archbishop Anthony Fisher, the Catholic Archbishop of Sydney and Chairman of the Bishops Commission for Family, Youth and Life told that committee that he was concerned that eggs needed to be obtained from women through invasive procedures:

> The availability of human ova is often assumed when people talk about reproductive technology as if they were somehow there in a cupboard to be used. In fact, it means women have to be used to obtain these eggs. They are extracted by invasive procedures that do carry some risk.[39]

4.50 Professor David Thorburn, Head of Mitochondrial Research and Diagnostic Laboratories at the Murdoch Children's Research Institute and Victorian Clinical Genetic Services told the committee that the eggs required for these procedures would most likely come from excess eggs that were donated after in vitro fertilisation procedures or from women who were close to the family.[40]

4.51 Professor Sue told the committee that her research indicated that most women would be happy to be able to donate their excess eggs after in vitro fertilisation:

> In this case it is going to be donor women, who are presumably and most commonly donating their eggs because they've had an IVF procedure themselves. When we asked those patients, we found a huge level of altruism about this. The women who were having IVF procedures for infertility reasons, for example, would most commonly be the donors, and the excess eggs would probably be the donor material. There was this altruistic feeling. They were delighted, happy, that their excess eggs had, first of all, a purpose or could have a legal purpose and also that they would be helping other people who faced a similar but slightly different dilemma from theirs.[41]

4.52 The *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research, 2017* (ART Guidelines) made by the National Health and Medical Research Council (NHMRC) relevantly provides that both commercial trading and direct and indirect inducements are prohibited by legislation to prevent this type of exploitation:

> The current situation in Australia is that gamete donation must be altruistic, and that commercial trading in human gametes or the use of direct or

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38 Social Issues Committee of the Anglican Church Diocese of Sydney, *Submission 56*, p. 2.

39 Archbishop Fisher, *Committee Hansard*, 17 May 2018, p. 64.

40 Professor David Thorburn, Head of Mitochondrial Research and Diagnostic Laboratories, Murdoch Children's Research Institute and Victorian Clinical Genetic Services, *Committee Hansard*, 17 May 2018, p. 19.

41 Professor Sue, *Committee Hansard*, 17 May 2018, p. 31.

> indirect inducements is prohibited by legislation. This position reflects concerns about the potential exploitation of donors (particularly egg donors) and the potential risks to all parties.[42]

4.53 However, the ART Guidelines permit the reimbursement of some out-of-pocket expenses that are directly incurred by the donor.[43]

4.54 Another potentially concerning form of exploitation could stem from overuse of the same donor's genetic material. Currently, the ART Guidelines specify that only a limited number of families can be created from a single egg or sperm donor and that consideration must be given to the number of persons already born from the donor's donated genetic material in deciding whether to use that donor's material.[44] The same standards may be applied to egg donors who donate eggs for mtDNA donation.

Committee view

4.55 The committee understands the concerns about the potential exploitation of mtDNA donors. However, the committee has confidence that the existing ethical standards for egg donation are consistent with community expectations. The committee expects that the same ethical safeguards that protect egg donors would be applied to egg donors who donate their eggs for mtDNA donation if it was introduced in Australia. The regulatory aspects of mitochondrial donation are discussed in greater detail in chapter five.

Would a child consent to mitochondrial donation?

4.56 Consent is an important ethical principle that is derived from the rights of autonomy and dignity. Some submitters raised concerns that a child that is yet to be born cannot, and, if they had the requisite capacity, may not consent to such a procedure.

4.57 The Australian Christian Lobby noted that anticipated consent is an important principle in considering whether mitochondrial donation should be permitted:

> …children with three biological parents are a brave experiment which will have a significant effect on a person not-yet-born who is unable to consent to the procedure. Ethicist Margaret Sommerville speaks of the principle of 'anticipated consent' where a person is affected by a decision to which they cannot give consent. Such a decision, made by the parents on behalf of the child, may have serious consequence for the child and their sense of self.[45]

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42 National Health and Medical Research Council (NHMRC), *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research, 2017* (ART Guidelines), p. 43, https://www.nhmrc.gov.au/_files_nhmrc/file/guidelines/ethics/16506_nhmrc_-_ethical_guidelines_on_the_use_of_assisted_reproductive_technology-web.pdf (accessed 7 June 2018).

43 NHMRC, ART Guidelines, pp. 43–44.

44 NHMRC, ART Guidelines, p. 43.

45 Australian Christian Lobby, *Submission 51*, p. 5.

4.58 This is a principle that can have practical implications and can be an important ethical guide for people who are making decisions about the care of people who are unable to provide consent. However, Dr Tobin questioned whether the principle would apply in the case of a person born because of a mitochondrial donation technique:

> We came up with a formula which said: … if you could anticipate that they would consent—then it would be legitimate... it's obviously very relevant here. All we can really do is do thought experiments, because, if you ask me what I think a child so manufactured will think when he or she grows up, I don't know.[46]

4.59 People who live with a mitochondrial disease and their children had little difficulty imagining whether a person who was born from a mitochondrial donation technique would consent. Mary, a person living with a mitochondrial disease, asked her children whether they thought they would have consented to the procedure:

> In the process of preparing my submission, I talked to my children about this and I said to them: 'What do you think?' They said, 'If we had a child with mitochondrial disease, we would love that child we would understand what the child was going through.' But their view was that everyone who has mitochondrial disease, their families that are affected by it, should have this choice.[47]

4.60 Justin, who also lives with a mitochondrial disease, told the committee that he believes that a child who was born of the technique would understand the choice that had been made for them:

> What I have learned over the last 2½ years is that having a disability or a sickness like we've got is about compromise. You are compromising the whole time about what you used to have in your life that you don't have anymore. Being part of a family where the other members of the family are disabled or are sick and is also about compromise—you can't do the things you need to do. So I'm confident that any child, if this technology was to go forward, born through mitochondrial donation would understand that life is about compromises when you are in this situation. If that means that I can't participate in recreational genetics, if that means that a second woman gave me the slightest part of my DNA, I think that would be a compromise I would be able to live with.[48]

Committee view

4.61 The committee acknowledges that some submitters have ethical concerns about whether a child would consent to a medical procedure that had the potential to prevent it from having a debilitating illness. The committee considers that the child's consent could be anticipated. Whilst we cannot know for certain, the evidence from

46 Dr Tobin, *Committee Hansard*, 17 May 2018, p. 67.

47 Mary, *Committee Hansard*, 17 May 2018, p. 38.

48 Justin, *Committee Hansard*, 17 May 2018, p. 37.

submitters living with the disease is that they and their children would like to have the choice to determine whether or not the technique is right for them and their child.

Ongoing follow up

4.62 Scientific and medical research depends on data. Submitters told the committee that they considered that follow up should be conducted with the children who are born to these techniques. A number of submitters told the committee that there should be a rigorous follow-up study conducted by the fertility clinics to inform the scientific evidence base.[49]

4.63 The NHMRC told the committee that obtaining the best data about people born to this technique will requires significant long-term follow up, potentially over multiple generations:

> Ideally, this monitoring would be multi-generational, that is, children born following mitochondrial donation would be monitored into adulthood and their children, if any, would also be monitored.[50]

4.64 In the UK, the team at the Wellcome Centre for Mitochondrial Research developed an innovative clinical method through the National Health Service's routine check-ups:

> Feedback from [patient focus] groups states that patients wanted to be involved in long term follow up but at the same time, did not want to 'medicalise' an otherwise healthy child. Taking this into consideration, the follow up pathway takes advantage of the routine NHS health checks offered to all children born in the UK, with only a small amount of extra information collected during these appointments.[51]

4.65 In Australia, the NHMRC acknowledged that obtaining data may be difficult to obtain if a child does not wish to be monitored into the future:

> However, while the parents may have consented to ongoing monitoring on behalf of the child, the child has not been involved in this decision and may not consent to long-term follow-up. Therefore, while the importance of follow-up for the safety and well-being of the child can be emphasised, there are significant ethical issues associated with ongoing monitoring that would need to be explored further.[52]

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49 Professor John Carroll, Director, Monash Biomedicine Discovery Centre, *Committee Hansard*, 17 May 2018, p. 30; Dr Nadine Richings, Vice-Chair, Scientists in Reproductive Technology (SIRT), *Committee Hansard*, 17 May 2018, p. 42; Professor Aleksandra Filipovska, *Submission 17*, p. 2; Biomedical Ethics Research Group, Murdoch Children's Research Institute, *Submission 34*, [p. 2]; Australian Academy of Sciences, *Submission 35*, p. 5; Nuffield Council on Bioethics, *Submission 43*, [p. 2].

50 NHMRC, *Submission 4*, p. 4.

51 Wellcome Centre for Mitochondrial Research, *Submission 45*, [p. 5].

52 NHMRC, *Submission 4*, p. 4.

4.66 Dr Newson raised concerns regarding the child's right to privacy, noting that 'the balance between monitoring and invasiveness should be carefully considered'.[53]

4.67 Professor Sheryl de Lacey, a Professor of Nursing at Flinders University, noted that it may be possible to ask the parents to participate in a study about the health and wellbeing of their children:

> Taking part in a clinical trial necessitates an agreement to participate in follow-up studies. This is a view that a child should not be created so as to be identifies as 'different' and subjected to mandatory procedures in the interests of science. However my experience in social research suggests that it is possible to track the progress and development of children through enrolment of the parents in the trial.[54]

4.68 Professor de Lacey noted that the failure to conduct a long-term study can make it challenging to understand the effects of a particular technology for a substantial period of time:

> Follow up of children was never successfully achieves when IVF was introduced and we are now reliant on retrospective epidemiological studies to indicate the health outcomes for children.[55]

4.69 The NHMRC's ART Guidelines currently require clinics to record and retain certain information for the purposes of follow up.[56] Clinics are required to make this data available in a non-identifiable format to ensure accountability and for research purposes.[57] Similar and additional requirements may be imposed if mitochondrial donation is legalised for clinical use in Australia.

Committee view

4.70 The committee considers that clinical follow-up is important to monitor the health of children born to the technique and for epidemiological health reasons it is important to know about the risks that may be presented by the technology. The committee acknowledges the concerns that unnecessary or intrusive follow up risks 'medicalising' an otherwise healthy child. The committee considers that this is a matter that needs to be considered in the regulatory design if the government decides to legalise mitochondrial donation.

Scientific ethical considerations

4.71 The most important stakeholder in any discussion about mitochondrial donation is the child whose life will be affected by the use of the technique. In this section, the following questions will be discussed:

- should the technology be used if there is a potential for harm?

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53 Associate Professor Newson, *Submission 29*, p. 5.

54 Professor Sheryl de Lacey, *Submission 55*, p. 2.

55 Professor Sheryl de Lacey, *Submission 55*, p. 2.

56 NHMRC, ART Guidelines, pp. 83–85.

57 NHMRC, ART Guidelines, p. 85.

- is mitochondrial donation germline genetic modification?
- is it ethically relevant that mitochondrial donation is not a cure?
- could allowing mitochondrial donation lead to a 'slippery slope'?

Should the technology be used if there is a potential for harm?

4.72 In chapter three, it was noted that there are still some aspects of the science of mitochondrial donation that are not completely known and that there could potentially be some harm to the children born to the technique if some of the concerns are realised.

4.73 The question that needs to be considered is whether the technology should be authorised for use if there is some risk of harm. The Murdoch Children's Research Institute and Victorian Clinical Genetic Services consider that the potential risks and the potential benefits need to be weighed up in considering whether to authorise any technique:

> It is unlikely that any IVF technique or most other medical advances could ever have been introduced if absolute certainty was a pre-condition of their application to human subjects. It is thus necessary to consider the balance of potential benefits and potential harms to decide whether application to human subjects is appropriate and what types and duration of monitoring should be in place to assess safety and efficacy if the benefits outweigh the harms.[58]

4.74 The Biomedical Ethics Research Group at the Murdoch Children's Research Institute noted that the potential to avoid passing on a devastating and life-threatening illness to an unborn child was a clear ethical imperative that weighed in favour of allowing mtDNA donation.[59]

4.75 The countervailing factor that the Biomedical Ethics Group at the Murdoch Children's Research Institute pointed out was that there were factors that suggested that the science was not yet certain and potentially unsafe:

> [Mitochondrial Replacement Therapy] is a new technology. It could have unexpected and harmful consequences, which should be fully investigated before MRT is used clinically. Concerns have been raised about the potentially harmful effects that could arise as a result of a genetic misalignment between mitochondrial and nuclear DNA.[60]

4.76 Distinguished Professors Jenni Millbank and Isabel Karpin and Professor Anita Stuhmcke argued that a harm minimisation approach balanced the rights of parents against the potential safety risks:

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58 Murdoch Children's Research Institute and Victorian Clinical Genetic Services, *Submission 23*, p. 4.

59 Biomedical Ethics Research Group, Murdoch Children's Research Institute, *Submission 34*, [p. 2].

60 Biomedical Ethics Research Group, Murdoch Children's Research Institute, *Submission 34*, [p. 2].

> In the interests of protecting and supporting Australians we believe that a harm minimisation approach is urgently needed that ensures the health and well-being of both the family and their future offspring. Such an approach accords with human rights principles and the well accepted right to form a family. In the case of those seeking treatment for mitochondrial disease a legal prohibition is both onerous and discriminatory towards people who carry the gene for this disabling condition.[61]

Committee view

4.77 The committee considers that a harm minimisation approach is appropriate in the circumstances. The committee accepts that the potential to alleviate significant suffering is a morally compelling reason to permit mitochondrial donation, though it notes that the hope for the technology needs to be balanced against the potential risks. At this point, the risks appear to be sufficiently manageable to allow the use of the technology. However, it is not the role of a Senate committee to make definitive scientific or medical findings. The committee considers that formal review and potential endorsement of the UK scientific findings should be made by a panel of Australian experts with relevant scientific and medical knowledge. The committee considers that an independent panel of Australian scientists and medical practitioners should be asked to consider whether the science is sufficiently certain for clinical use.

Germline alteration

4.78 Some submitters raised ethical concerns about whether mitochondrial donation would alter the human germline and whether that should be permitted. In gene therapy, a distinction can be drawn between somatic gene therapy, an alteration of a cell that only affects the current generation, and germline gene therapy which alters a gene that is passed on to future generations.[62] In most jurisdictions, heritable gene alteration, or germline gene therapy, is not permissible.[63] It is thought of as a 'bright line' in terms of both safety and ethics.[64]

4.79 Different jurisdictions have come to different positions on whether mitochondrial donation should be considered to be an inheritable gene alteration or replacement. In chapter three it was noted that the National Academies of Sciences, Engineering and Medicine in the United States of America proposed the implantation of only male embryos for a period of time to monitor the effects of mitochondrial donation while effectively removing the potential for the mitochondria to passed on to future generations.[65] In the UK, mitochondrial donation was considered to be a

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61 Distinguished Professor Jenni Millbank, Distinguished Professor Isabel Karpin and Professor Anita Stuhmcke, *Submission 57*, [p. 5].

62 Associate Professor Catherine Mills, *Committee Hansard*, 17 May 2018, p. 50.

63 Associate Professor Newson, *Committee Hansard*, 17 May 2018, p. 55; Murdoch Children's Research Institute and Victorian Clinical Genetic Services, *Submission 23*, p. 8; Dr Newson, *Submission 29*, p. 3.

64 Associate Professors Mills and Ludlow, Professor Sparrow and Dr Warren, *Submission 20*, p. 3.

65 NHMRC, *Submission 4*, p. 5.

germline therapy because the mitochondria will be inherited by future generations from a female born to the technique if she has children, but it was not considered to be a form of human genetic modification.[66] However, these terms generally relate to nuclear genes rather than organelles, like mitochondria.

4.80 Submitters to the inquiry who supported mitochondrial donation considered that the question about whether mitochondrial donation was a germline alteration did not arise because it was separate from the nuclear genes. Dr Newson suggested that mitochondrial replacement should be considered neither germline or somatic gene therapy but as 'conditionally inheritable genomic modifications'.[67] Mitochondria is conditionally inheritable because it can only by passed through the female line; in a male embryo the mitochondrial donation is similar to somatic gene therapy. In a female embryo, the mitochondria is inheritable and forms part of the genetic information that is passed on to future generations.

4.81 Professors Thorburn, Christodoulou, Sue, Carroll, Ryan and Filipovska noted that mitochondrial donation should be thought of ethically as being distinct from germline genetic modification because mtDNA is distinct from the nuclear genes.[68]

4.82 These submitters also noted that mtDNA was not unique to individuals, but was shared with the other members of the maternal haplogroup.

4.83 Submitters who were concerned about germline alteration were most concerned about the effects of mtDNA donation on future generations.[69] For these submitters, the scientific uncertainty raised a moral concern about whether the lives of people who are not yet born may be affected by the carrying out of the mitochondrial donation procedure.[70] These concerns were prompted by some of the scientific questions that were raised in chapter three, such as questions about possible mito-nuclear interactions.

4.84 Dr Tobin from the Plunkett Centre told the committee that she had no principled objection to altering a person's genes to correct a genetic defect even if there was a risk that the modification could be inherited, if it could be shown it could be done safely:

> It may be that with some of the new genetic techniques, so-called CRISPR, where, at least theoretically, it may be possible to correct a genetic defect in

66 Associate Professors Mills and Ludlow, Professor Sparrow and Dr Warren, *Submission 20*, [pp. 16–17]. See Karinne Ludlow, 'The policy and regulatory context of U.S., U.K., and Australian responses to mitochondrial donation governance', *Jurimetrics*, vol. 58, p. 256.

67 Associate Professor Newson, *Submission 29*, p. 3. See Ainsley Newson and Anthony Wrigley, 'Is mitochondrial donation germ line gene therapy? Classifications and ethical implications', *Bioethics*, vol. 31, pp. 55–67.

68 Professors Thorburn, Christodoulou, Sue, Carroll, Ryan and Filipovska, *Submission 59*, pp. 8–9.

69 Australian Christian Lobby, *Submission 51*, p. 7.

70 Australian Christian Lobby, *Submission 51*, p. 8; Catholic Health Australia, *Submission 60*, [p. 2].

> a young human being or adult human being such that that person no longer has that disease or susceptibility to disease, and that affects that person's germ line, a time comes when that is safe. If so, I don't see an in-principle objection to that. I don't think we're there now.[71]

4.85 Dr Newson told the committee that mitochondrial donation was the first process that would be permitted to deliberately alter heritable characteristics, but it was up to the committee to determine whether that was ethically important:

> Senator Brockman's question was around if this is the first thing that we know of that will lead to these kind of changes in a deliberately intervening way; my answer to that is yes. The questions from an ethical perspective are, 'What does that matter? What do we make [of] this from a moral perspective?'[72]

4.86 Whether Australia determines that mtDNA amounts to germline modification or not will have implications for how mitochondrial donation can be legalised in Australia. This will be discussed in greater detail in chapter five.

Committee view

4.87 The committee recognises that there are many ethical views regarding mitochondrial donation. In particular, the committee understands that some submitters have concerns about whether mitochondrial donation constitutes a form of germline gene therapy. The committee understands mtDNA is inherited from the mother and that changes to mtDNA of an egg or embryo will affect future generations. However, the committee accepts that there is an ethical difference between the manipulation of nuclear DNA and the manipulation of mtDNA, primarily because mtDNA does not contribute to the characteristics of inheritable genetics in the manner traditionally thought of, at the time such manipulations were prohibited through anti-cloning laws.

4.88 The committee acknowledges that there is a degree of scientific uncertainty as to how to characterise the modification of mtDNA, and that these definitions might have unanticipated impacts, such as legalising other techniques of gene manipulation. As with other areas of science discussed in this report, the committee acknowledges it does not have the expertise to make a formal finding, but recognises that further exploration is required.

4.89 Therefore, the committee considers that the questions of whether mtDNA should be considered a germline genetic modification, and does that preclude it use, should be considered by a panel of expert Australian scientists and bioethicists as a foundational question to be answered prior to any legalisation of mitochondrial donation.

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71 Dr Tobin, *Committee Hansard*, 17 May 2018, p. 66.

72 Associate Professor Newson, Committee Hansard, 17 May 2018, p. 55.

Does it matter if it is not a cure for mitochondrial disease?

4.90 There is currently no cure for mitochondrial disease.[73] Mitochondrial donation is also not a cure for mitochondrial disease; it prevents the transmission of the mitochondrial disease to the next generation.[74]

4.91 Some submitters considered that it was morally relevant that mitochondrial donation was not a 'cure' for mitochondrial disease. For these submitters, a distinction could be drawn between alleviating the suffering of a living person and intervening to prevent a person from acquiring a mitochondrial disease.

4.92 The Australian Christian Lobby clearly told the committee that interference at a genetic level was of concern:

> Mitochondrial donation does not cure mitochondrial disease. It is not 'treatment'. It is genetic manipulation to ensure that mutant mtDNA is not transmitted to future generations. This has serious ethical implications.[75]

4.93 Dr Tobin from the Plunkett Centre elaborated on this concern:

> I think it is important to note that, were you to recommend the legalisation of this procedure, it is a procedure that doesn't cure anyone of this disease, even in its mild forms let alone in its severe forms. The risks that it involves are, strictly speaking, unnecessary. I think there are alternative ways in which people with this disease, which can be so debilitating, can have children.[76]

4.94 For these submitters, the fact that mitochondrial donation was not a cure militated against its legalisation, but the Australian Mitochondrial Disease Foundation (AMDF) argued that the lack of any cure for mitochondrial diseases gave ethical weight to the argument in favour of legalising mitochondrial donation:

> Unfortunately at this time there is no cure and few treatments for mitochondrial disease which is one of the reasons its impacts on patients and families are so devastating and why the community is seeking the

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73 Wellcome Trust, *Submission 1—Attachment 3*, [p. 2]; Professor Filipovska, *Submission 17*, p. 1; Associate Professors Mills ans Ludlow, Professor Sparrow and Dr Warren, *Submission 20*, p. 249; Professor Sue, *Submission 24*, p. 2; Associate Professor Dowling, *Submission 25 — Attachment 1*, [p. 1]; Australian Mitochondrial Disease Foundation (AMDF), *Submission 26*, [p. 2]; Australian Academy of Sciences, *Submission 35*, p. 2; Lily Foundation, *Submission 44*, [p. 2]; Wellcome Centre for Mitochondrial Research, *Submission 45*, [p. 5]; Dr Shanti Balasubramaniam, *Submission 52*, [p. 6]; Professor Sheryl de Lacey, *Submission 55*, p. 1; Dr Robin Lovell-Badge, *Submission 58—Attachment 1*, p. 1060.

74 NHMRC, *Submission 4*, p. 9; Plunkett Centre for Ethics, *Submission 30*, p. 1; Australian Christian Lobby, *Submission 51*, p. 3; Dr Cathy Herbrand, *Submission 54*, p. 3; Professors Thorburn, Christodoulou, Sue, Carroll, Ryan and Filipovska, *Submission 59*, p. 1; Catholic Health Australia, *Submission 60*, [p. 1].

75 Australian Christian Lobby, *Submission 51*, p. 4.

76 Dr Tobin, *Committee Hansard*, 17 May 2018, p. 65.

> opportunity for Australia to adopt mitochondrial donation as an option for affected families.[77]

4.95 AMDF's argument was supported by a number of leading scientists in the field who told the committee:

> The fact that there is no cure for mitochondrial disease emphasizes the need and the urgency for allowing women from affected families to have the best chance of having biologically related children who are unaffected by mitochondrial disease...Like almost all assisted reproduction approaches, it should be regarded as mitigating risk, rather than eliminating it. It is worth noting that about 3% of all births are affected by a serious genetic anomaly or disorder.[78]

Committee view

4.96 The committee understands that mitochondrial donation is not a cure, but it presents an opportunity to prevent a child from developing a specific disease. Whilst there are ethical questions about whether this should be permitted for nuclear cells, the committee considers that correcting the mtDNA may be ethically permissible.

The start of the slippery slope?

4.97 Some submitters raised concerns that the same reasoning that is used to allow the replacement of mtDNA to avoid a disease could be used to justify the alteration of nuclear genes of unborn children to alleviate disease. These submitters were concerned that this would be a step towards genetic engineering and a lack of human diversity.

Committee view

4.98 While the committee understands this argument, it is not the proposition before the committee. The committee is satisfied that mitochondrial donation can be legalised in a manner that does not permit the alteration of nuclear germline genes.

Concluding committee view

4.99 The report, so far, has considered the evidence presented to the committee by submitters, including prominent members of the scientific and medical community who work in fields relevant to mitochondrial disease, and concluded that mitochondrial donation is a safe and effective treatment to prevent transmission of mitochondrial disease to the next generation in cases where the disease develops because of mutated mtDNA.

4.100 Chapter one outlined that this treatment has been legalised in the UK, after an extensive 12 year path of scientific and ethical review, combined with community education and consultation.

4.101 Chapter two discussed mitochondrial disease and its impact to individuals and families, as well as provided some estimates of the health costs associated with this

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77 AMDF, *Submission 26.1*, [p. 4].

78 Professors Thorburn, Christodoulou, Sue, Carroll, Ryan and Filipovska, *Submission 59*, p. 1.

disease. Compelling evidence was presented to this committee on the devastating impacts of this disease on families, particularly as its genetic nature means it tends to impact multiple members of the same family, with high child mortality.

4.102 Chapter three discussed the evidence provided on the science and safety of mitochondrial donation. Evidence to the committee noted that while there are still some unknown risks associated with mitochondrial donation, they are far outweighed by the known risks of mitochondrial disease.

4.103 The committee recognises the clinicians' argument that most new medical therapies involve a degree of risk and the last stage of the development of medical treatments usually involve controlled clinical trials. The committee considers that mitochondrial donation has reached this stage. As discussed in chapter three, the committee believes that a formal determination that the science of mitochondrial donation is ready for clinical trial in Australia should be made by independent experts with relevant scientific and medical expertise.

4.104 This chapter discussed the ethics of mitochondrial donation. Many of the ethical concerns considered the mechanics of mitochondrial donation because it necessitates the destruction of embryos and interferes with dignity of natural conception. The committee recognises that these concerns are not specific to mitochondrial donation, and can be applied to any form of ART. However, the committee acknowledges that the creation of viable, distinct embryos with no potential to develop into a viable pregnancy is a new moral question that would require community consultation as well as a change to the legal prohibition of such activity under current law.

4.105 One key ethical concern specific to mitochondrial donation remains unresolved: whether or not mitochondrial donation is genetic engineering of the human genome similar to germline modification, and if so, whether that in itself is enough to reject mitochondrial donation as a medical therapy to prevent children being born with a high risk of developing mitochondrial disease.

4.106 The committee heard evidence that mitochondrial donation is not a form of germline modification as that term was understood at the time genetic modification was prohibited under Australian law. However, the committee recognises that an independent determination that mitochondrial donation is not a form of germline modification would most appropriately be made by a panel of scientists and bio-ethicists.

4.107 These foundational questions remain to be answered before the committee can make a finding that mitochondrial donation is a medical therapy that is safe to be introduced into Australia in the form of a clinical trial, which could lead to clinical practice.

4.108 To achieve this, legislative change must occur at commonwealth and state level to make mitochondrial donation lawful, and a regulatory regime must be created to oversee research, clinical trial and later public rollout. The next chapter discusses the evidence presented to the committee on the most effective ways to regulate for Australia.