APPENDIX 1: ACADEMIC ARTICLES FOR FURTHER REFERENCE

Genes and gestation in Australian regulation of egg donation, surrogacy and mitochondrial donation

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This article considers genetic and legal relatedness for the purposes of Australian regulation of egg donation, surrogacy and parentage by examination of that regulation through the lens of mitochondrial (mt) donation. The article addresses whether mt donors would be a child's genetic parents following clinical use in that child's conception should mt donation be legalised for such use in Australia. It then considers how genetic and gestational relatedness are relevant in the discourse around legal parentage following egg donation and surrogacy and argues that the current approach is in need of reform so that intending parents of all children are deemed to be the resulting child's legal parents at birth.

INTRODUCTION

Genes and gestation matter in individual reproductive choice, science and in the regulation of egg donation, surrogacy and parentage. However, while intending parents in donor conception cases are given the advantage of having the child's biological ties with others severed so that they are the resulting child's legal parents at birth, intending parents in gestational surrogacy arrangements are not. As this article explains below, both gestational surrogates and egg donors have significant clinical effects on the resulting child's genes but, pursuant to legislation in all Australian jurisdictions, a gestational surrogate will not be a genetic parent of the resulting child. Further, unlike genetic parents of donor-conceived children, gestational surrogates (and their partner, if any) are preferenced over intending parents in Australian parentage legislation.[1]

Regulatory scholars have previously identified that the law perennially faces problems when confronted with (bio)technology innovation.[2] On assisted reproductive technology (ART), Sheldon has pointed out the ability of new technology to "confuse and disrupt our understanding of parenthood".[3] Using a recent development in ART known as mitochondrial (mt) donation, this article offers a close analysis of the relevance of genetic and gestational relatedness to legal parentage of children born through donor conception or surrogacy in Australia. It also examines how the mt donation technique would fit within existing Australian regulation if it were to be legalised here. This tool shows inconsistencies in the law's response to the biological reality of genetic and gestational links.

The article begins by explaining the technique of mt donation and its place in the widening space of reproductive choice. The law's response to genetic and gestational links in its regulation of legal parentage is then examined to show first, that mt donors will be genetic parents and gestational surrogates will not. Further, and more importantly, parentage laws make that genetic link irrelevant in cases of donor conception but resurrect its importance in surrogacy arrangements. This inconsistency together with other confusion regarding the relevance of genetic relationships to parentage transfer decisions identified below, means the weight to be attached to genetic and gestational relatedness by courts addressing parentage transfer applications is unclear and that Australian regulation is

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[1] Surrogate is used for the woman who gestates and gives birth to the child and intending parent(s) refers to the person(s) who will parent the child. Different terms are used in the various Acts discussed in this article.

[2] See, for example, Roger Brownsword, "Regulating Human Genetics: New Dilemmas for a New Millennium" (2004) 12 Med L Rev 14.

[3] Sally Sheldon, "Fragmenting Fatherhood: The Regulation of Reproductive Technologies" (2005) 68 MLR 523, 524.

inadequate for ongoing developments in reproductive choice. Instead, this article suggests that legal parentage should be given to intending parent(s) upon a child's birth, regardless of the technique used to assist their conception and birth.

MITOCHONDRIAL DONATION AND REPRODUCTIVE CHOICE

The United Kingdom (UK) Parliament has now allowed clinical application of mt donation.[4] The entry into force of the *Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015* (UK) on 29 October 2015 allows licensing of the technique's use on embryos intended for implantation.[5] The United States (US) is similarly considering approving this technique for clinical application.[6] In late 2014, the US Food and Drug Administration tasked a US Institute of Medicine ad hoc committee (Committee on Ethical and Social Policy Considerations of Novel Techniques for Prevention of Maternal Transmission of Mitochondrial DNA Diseases) to consider the modern technique.[7] The Committee has begun holding public and closed sessions on the social and ethical issues raised by the technique. A consensus report will be produced at the end of that process.[8] Some forms of mt donation are allowed for research purposes in Australia but there are legal obstacles to its clinical use here.[9] Although in need of examination, such obstacles are not within the scope of this article. This article proceeds on the basis that mt donation may be legalised for clinical use here.

Mt donation aims to replace an intending mother's "faulty" mtDNA with the healthy mtDNA of another woman to allow the intending mother to have a genetically related child of her own. In simplistic terms, when an egg and sperm (known as gametes) combine to develop into an embryo, that embryo is endowed with a combination of DNA from its two genetic parents. Most of that DNA (over 20,000 genes) is in the cell's nucleus but a small amount (37 genes – about 0.1% of the cell's total DNA) is present in small packages (or organelles) called mitochondria in the surrounding environment (or cytoplasm) of the cell.[10] Each cell contains about 400 mitochondria, responsible for converting food energy into chemical energy and leading to mitochondria being referred to as a cell's "batteries".

[4] Research into mt donation has been licensed in the UK since 2005: Human Fertilisation & Embryology Authority (HFEA), "HFEA Grants Licence to Newcastle Centre at LIFE for Mitochondrial Research" (Press Release, 8 September 2005) <www.hfea.gov.uk/671.html>.

[5] The Regulations amend the *Human Fertilisation and Embryology Act 1990* (UK). There are objections to these changes on a number of bases, not considered here, including that such technique is eugenic, genetic modification, incompatible with human dignity and contrary to international law. See Department of Health (UK), *Mitochondrial Donation: Government Response to the Consultation on Draft Regulation to Permit the Use of New Treatment Techniques to Prevent the Transmission of a Serious Mitochondrial Disease from Mother to Child* (2014) <https://www.gov.uk/government/consultations/serious-mitochondrial-disease-new-techniques-to-prevent-transmission>; Parliamentary Assembly of the Council of Europe, *Creation of Embryos with Genetic Material from More than Two Progenitor Persons* (3 October 2013).

[6] An early form of partial mt donation was used in the US in the 1990s, which involved injecting cytoplasm from one woman's egg into the intending mother's egg. The US Food and Drug Administration eventually asserted that the cytoplasm was a drug for these purposes, needing approval for use. No approval has been granted. Jaques Cohen et al, "Birth of Infant after Transfer of AnucleateDonor Oocyte Cytoplasm into Recipients Eggs" (1997) 350(9072) *The Lancet* 186; Nuffield Council on Bioethics, *Novel Techniques for the Prevention of Mitochondrial Disorders: An Ethical Review* (2012) [2.8]-[2.14].

[7] Food and Drug Administration (US), Advisory Committees, *2014 Meeting Materials, Cellular, Tissue and Gene Therapies Advisory Committee* (25-26 February 2014) <www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/ CellularTissueandGeneTherapiesAdvisoryCommittee/ucm380047.htm>.

[8] On differences between the US and UK regulation of the mt donation technique, see I Glenn Cohen, Julian Savulescu and Eli Y Adashi, "Transatlantic Lessons in Regulation of Mitochondrial Replacement Therapy" (2015) 348(6231) *Science* 178.

[9] See, for example, *Prohibition of Human Cloning for Reproduction Act 2002* (Cth) ss 13, 20(3) and (4)(c) and mirroring State legislation. For research use, see *Prohibition of Human Cloning for Reproduction Act 2002* (Cth) s 23 and *Research Involving Human Embryos Act 2002* (Cth) s 10A(b)(ii) and mirroring State legislation.

[10] Nuffield Council on Bioethics, n 6, [1.5]-[1.6].

Faults, or mutations, occur in all DNA. In mtDNA, mutations cause severe non-curable neurological, muscular and other diseases in at least one per 10,000 individuals. Diseases linked to mtDNA mutations include muscular dystrophy and other life-threatening conditions. At least one in 250 Australians carry mtDNA mutations.[11]

Only maternal mitochondria are passed on to offspring in human reproduction.[12] Whether a woman's mutant mtDNA presents as disease in her offspring depends largely on the proportion of mutant, relative to total, mtDNA in the particular egg used in the conception of a particular child. Mutant mtDNA numbers vary between individual eggs. For some women, though, the chance of passing on mtDNA mutation is great. Alternatives such as genetic screening of embryos prior to implantation are insufficient to determine the risk to the embryo in all cases, particularly as the number of mutant mtDNA can differ between cells that makeup the embryo. A sample embryonic cell will therefore not necessarily represent all embryonic cells. Mt donation is an alternative in addressing the problem.

There are variations in the actual procedure – maternal spindle, pronuclear and polar body transfer[13] – but essentially the nuclear DNA, containing the bulk of the DNA, from the intending mother's egg (or from a zygote made with her egg and a sperm) is moved to an egg (or zygote) of a woman with healthy mtDNA. The nucleus of the "normal" egg or zygote is removed first, leaving the healthy mitochondria.[14] Any child born as a result of this procedure will have nuclear DNA from one man and woman and mtDNA from another woman. The child's DNA is accordingly from three individuals, including two women. Furthermore, and just as controversially, if the child is female, the changes will be inherited by each of that child's children and the descendants of her daughters.

An alternative for women who carry these mutations and do not want to risk passing them onto their children is to use both the nuclear and mtDNA from the one donated egg. As discussed below, egg donation for use in ART by another woman is allowed in all Australian jurisdictions, and legislation addresses the parentage of the resulting children. However, as noted in the 2014 review of the science for the UK ART regulator, using a donated egg this way "means that any resultant child will not be genetically related to the [intending] mother".[15]

Surrogacy is another option for women seeking to have a genetically related child. All Australian jurisdictions allow surrogacy in some circumstances[16] and all, except the Northern Territory (NT), have legislation providing for the parentage of such children.[17] However, surrogacy where the intending mother carries mtDNA mutation only addresses that problem if an entire donated egg (containing the donor's nuclear and mtDNA) or embryo is used, removing a genetic link between intending mother and child. The donated egg could be provided by the surrogate (called a genetic or

[11] David Thorburn in Australian Science Media Centre, "DNA Transfer Prevents Mitochondrial Disease in Humans – Experts Respond", *Rapid Roundup*, 15 April 2010 <www.smc.org.au/rapid-roundup-dna-transfer-prevents-mitochondrial-disease-in-humans-nature-experts-respond>.

[12] This paragraph is drawn from Daniel Paullet al, "Nuclear Genome Transfer in Human Oocytes Eliminates Mitochondrial DNA Variants" (2013) 493 *Nature* 632.

[13] See HFEA, *Third Scientific Review of the Safety and Efficacy of Methods to Avoid Mitochondrial Disease Through Assisted Conception: Update* (3 June 2014) <http://www.hfea.gov.uk/8807.html>. Regarding polar body transfer technique, see HFEA, *Review of the Safety and Efficacy of Polar Body Transfer to Avoid Mitochondrial Dsease. Addendum to "Third Scientific Review of the Safety and Efficacy of Methods to Avoid Mitochondrial Disease Through Assisted Conception: 2014 Update"* (2014). See also HFEA, *Mitochondrial Donation: An Introductory Briefing Note* (2014).

[14] Institute of Medicine (US), *Ethical and Social Policy Considerations of Novel Techniques for Prevention of Maternal Transmission of Mitochondrial DNA Diseases* <http://www.iom.edu/Activities/Research/MitoEthics.aspx>.

[15] HFEA, n 4, [3.1.1].

[16] *Parentage Act 2004* (ACT); *Surrogacy Act 2010* (NSW); *Surrogacy Act 2010* (Qld); *Family Relationships Act 1975* (SA); *Surrogacy Act 2012* (Tas); *Assisted Reproductive Treatment Act 2008* (Vic); *Surrogacy Act 2008* (WA). See also Jenni Millbank, "The New Surrogacy Parentage Laws in Australia: Cautious Regulation or '25 Brick Walls'?" (2011) 35 MULR 165; Paul Boers, "Surrogacy – The Varied Approaches of the States and Territories" (2011) 22 AFL 28.

[17] *Parentage Act 2004* (ACT); *Surrogacy Act 2010* (NSW); *Surrogacy Act 2010* (Qld); *Family Relationships Act 1975* (SA); *Surrogacy Act 2012* (Tas); *Status of Children Act 1974* (Vic); *Surrogacy Act 2008* (WA).

traditional surrogacy) either through ART in a clinical setting or informally without ART.[18] More commonly, though, the surrogate's egg is not used and instead an embryo created using ART is implanted into the surrogate's uterus.[19] The egg could be sourced from the intending mother or a donor.[20] Such surrogacies are referred to as gestational surrogacies.

Both egg donors, whether for use in mt donation or for conventional ART, and gestational surrogates have input into the resulting child's genetic makeup. Although mt genes are important for the reasons explained above, it is arguable whether the genetic influence of the third person is greater in surrogate pregnancies than in mt donation assisted pregnancies because "the environment of the womb is now recognised to program the way various genes are expressed and potentially affect health outcomes in later life".[21]

The article next examines how genetic relationships with children are understood in Australian regulation of egg donation, surrogacy and parentage and the relevance and prioritisation of such relationships in State and Territory parentage laws. The results of that examination are then used to inform later discussion.

HOW DO GENES AND GESTATION MATTER IN AUSTRALIAN REGULATION?

Introduction

Regulation of donor conception, surrogacy and legal parentage occurs on a State-by-State basis. Relevant parts of that regulation are summarised in the Table at the end of this article. Four States – New South Wales (NSW), South Australia (SA), Victoria and Western Australia (WA) – regulate donor conception through ART legislation. The remaining jurisdictions rely on the National Health and Medical Research Council (NHMRC) *Ethical Guidelines on Assisted Reproductive Technology in Clinical Practice and Research* (2007) and the accreditation requirements of the Fertility Society of Australia.[22] In summary, conception using donor eggs is permitted in all jurisdictions and the parentage of donor-conceived children is regulated through specific parentage legislation. That legislation legally severs the genetic link between donor and child, and parentage is instead endowed on the intending parent(s) through statutory presumption.[23]

All jurisdictions also allow altruistic surrogacy in some circumstances, regulating it through their ART legislation, specific surrogacy legislation or the NHMRC Guidelines. The exception is the NT which has no surrogacy legislation. As explored by Millbank, "genetics as determinative of the 'real' or 'biological' parents of children" was a prominent theme in both parliamentary and media accounts regarding the most recent wave of surrogacy law reforms.[24] However, despite the emphasis of a genetic link to legitimatise legalisation of surrogacy, the surrogate and not the genetic parents is the child's legal parent at birth in all jurisdictions.[25] Justification for this is most commonly that it is in the child's best interests, although in some cases it is also justified as allowing surrogates the opportunity

[18] Millbank, n 16, 170.

[19] Others have considered whether the separation of a genetic link by prohibiting the use of the surrogate's egg (or her partner's gamete) is appropriate: for example, Pip Trowse, "'Surrogacy': Is it Harder to Relinquish Genes?" (2011) 18 JLM 614.

[20] Millbank, n 16, 170.

[21] Thorburn, n 11.

[22] Reproductive Technology Accreditation Committee, *Code of Practice for Assisted Reproductive Technology Units* (Fertility Society of Australia, 2014) 13. These are relevant in all jurisdictions but subject to any contrary legislation. See generally, Belinda Bennett and Malcolm Smith, "Assisted Reproductive Technology" in Ben White, Fiona McDonald and Lindy Willmott (eds), *Health Law in Australia* (Thompson Reuters, 2nd ed, 2014).

[23] See Senate Legal and Constitutional Affairs References Committee, Parliament of Australia, *Donor Conception Practices in Australia* (February 2011).

[24] Jenni Millbank, "From Alice and Evelyn to Isabella – Exploring the Narratives and Norms of 'New' Surrogacy in Australia" (2012) 21 GLR 101, 105.

[25] The surrogate's partner may also be a parent, although there are differences between the States.

to change their mind regarding parenting the child.[26] While the surrogate's interests are very important, the strength of those interests is not within the scope of this article. Instead, the focus is on the inconsistencies such an approach creates when compared with parentage regulation in donor conception cases where consideration of the child's best interests has meant genetic links to adults other than intending parents are severed.

All jurisdictions (other than the NT) allow legal parentage to be transferred from the surrogate to the intending parents, but only after birth albeit with significant variation in the conditions required for transfer. The presence or absence of genetic relatedness between those involved creates a spectrum of legislative responses in regards to relevance for applications for parentage transfer. In some States, transfer of parentage requires at least one of the intending parents to be the genetic parent of the child. Another group of States prohibit parentage transfer if there is a genetic link between the surrogate and/or her partner and the child. Even in the remaining jurisdictions though, genetic connection is to be addressed by courts considering applications to transfer parentage.

For each jurisdiction, the concept of genetic relatedness used in their regulation of donor-conception and surrogacy and where mt donation fits within this is considered below. The relevance of genes and gestation to parentage presumptions and parentage transfer is also considered, providing the basis for consideration later of the areas in need of reform.

Australian Capital Territory

The ACT does not have ART legislation, the NHMRC Guidelines instead being relevant. The Guidelines make clear that donated gametes can be used in the conception of children and that the resulting child has the right to identifying information on the donor.[27] The same approach is taken in regards to donated embryos.[28] The Guidelines explain that disclosure is required because donor-conceived persons are entitled to know their genetic parents.[29] While the Guidelines use the terms genetic parent / offspring / sibling / material, these terms are not defined. The Guidelines also use the term gamete provider, defined as "[t]he person who is the biological (that is, genetic) source of the gamete".[30] This term is likely to include mt donors because, as in all jurisdictions, "gamete" is defined to mean a human sperm or egg.[31] Mt donors clearly provide an egg, even though it is eventually enucleated (nucleus removed).

On surrogacy, the Guidelines note that it is a controversial practice[32] and observe considerations needing further community discussion. Some of these considerations raise genetics-based issues. Supportive of surrogacy, for example, is the consideration that "the use of a surrogate mother who is also the genetic mother can prevent the transmission of serious genetic diseases by allowing a commissioning mother who is the carrier of that disease to avoid pregnancy".[33] Amongst considerations against surrogacy, the NHMRC notes that "surrogacy is less about the autonomous choices of the women involved than about enabling men to have children with whom they have a genetic connection".[34]

[26] The Standing Committee of Attorneys-General, Joint Working Group, Parliament of Australia, *A Proposal for a National Model to Harmonise Regulation of Surrogacy* (2009) 8-12.

[27] NHMRC, *Ethical Guidelines on Assisted Reproductive Technology in Clinical Practice and Research* (2007) Guideline 6.

[28] NHMRC, n 27, Guideline 7.

[29] NHMRC, n 27, Guideline 6.1.

[30] NHMRC, n 27, Explanation of Key Terms, 96.

[31] NHMRC, n 27, Explanation of Key Terms, 96.

[32] NHMRC, n 27, Guideline 13.2.

[33] NHMRC, n 27, Appendix C3, 92.

[34] NHMRC, n 27, Appendix C3, 92.

The *Parentage Act 2004* (ACT) provides for parentage of donor-conceived and surrogate born children. A child cannot have more than two parents at any one time,[35] parent being defined in the *Legislation Act 2001* (ACT) as the child's mother or father or someone else presumed under the *Parentage Act* to be parent.[36] Parent for these purposes is therefore the legal parent and there is no such restriction on the number of genetic parents.

For donor-conceived children, the intending parents (which will include the gestational mother) and not those who provide gametes used in the child's conception will be the legal parents upon birth because of a conclusive statutory presumption that if a woman becomes pregnant other than as a result of sexual intercourse,[37] she is the mother of any child born as a result of that pregnancy.[38] The Act goes on to clearly sever the genetic link for parentage purposes by providing that:

> If the ovum used in the procedure was produced by another woman, that other woman is conclusively presumed not to be the mother of any child born as a result of the pregnancy.[39]

In regards to children born through surrogacy arrangements, the ACT has mandatory requirements regarding genetic links before parentage transfer from surrogate to intending parents can occur. The legislation provides that an application for parentage transfer can be made if, inter alia, neither birth parent is a genetic parent *and* if at least one intending parent is a genetic parent.[40] Genetic parent of a child is defined to mean "a person whose gametes were used to create the embryo",[41] which would include mt donors but not gestational surrogates. Gamete is undefined.

Millbank observes that the ACT provisions were closely based on UK legislation[42] but the ACT added the need for the surrogate not to be genetically related to the child and prohibiting the use of the surrogate's partner as a gamete donor.[43] Millbank notes that no rationale for this variation was given in the parliamentary materials, the Explanatory Statement only noting the requirements for no genetic connection between surrogate and child but not explaining the reason for it.[44] She suggests that it may be because the practice of the only clinic that provided ART for surrogacy arrangements in the ACT at the time followed that practice.[45]

New South Wales

Pursuant to the *Assisted Reproductive Technology Act 2007* (NSW), donated gametes can be used in ART and the resulting child has a right to identifying information about the donor.[46] Gamete provider is defined broadly as "in relation to a gamete, means the individual from whom the gamete has been obtained and in relation to an embryo means an individual from whom a gamete used to create the embryo was obtained".[47] The term is similarly defined for the purposes of surrogacy[48] and would include mt donors. The Act does not use the term genetic parents, instead using biological parents which is undefined. Biological parents is used in the definition of offspring of a person, whereby

[35] *Parentage Act 2004* (ACT) s 14.

[36] *Legislation Act 2001* (ACT) Dictionary "parent".

[37] *Parentage Act 2004* (ACT) s 11(9) "procedure".

[38] *Parentage Act 2004* (ACT) s 11(2).

[39] *Parentage Act 2004* (ACT) s 11(3).

[40] *Parentage Act 2004* (ACT) s 24.

[41] *Parentage Act 2004* (ACT) s 3, Dictionary.

[42] *Human Fertilisation and Embryology Act 1990* (UK) s 30.

[43] See Millbank, n 16, 179.

[44] Millbank, n 16, 179.

[45] Millbank, n 16, 179-180.

[46] *Assisted Reproductive Technology Act 2007* (NSW) s 37.

[47] *Assisted Reproductive Technology Act 2007* (NSW) s 4(1).

[48] *Assisted Reproductive Technology Act 2007* (NSW) s 41A.

offspring means an individual to whom the person is a biological parent.[49] Both gestational surrogates and mt donors would arguably be biological parents for these purposes.

In the context of surrogacy arrangements, the term biological sibling is also used. It is defined by reference to blood as a brother or sister of a person, "whether the relationship is of the whole blood or half blood".[50] Children gestated by the same woman or conceived using eggs from the same mt or nuclear DNA donor would be within this definition.[51] Further, full identifying information on any surrogate and gamete provider for the pregnancy is to be recorded and available to the child.[52]

Pursuant to the *Status of Children Act 1996* (NSW) there is anirrebuttable statutory presumption of motherhood for any woman, including surrogates, that becomes pregnant other than as a result of sexual intercourse and that the egg donor is not the child's mother.[53] The *Surrogacy Act 2010* (NSW) provides for the transfer of parentage for children born under surrogacy arrangements. It requires applications for parentage orders to be accompanied by an independent counsellor's report on various matters, including their assessment on "any contact arrangements proposed in relation to the child and his or her birth parent or parents or biological parent or parents".[54] The term genetic parent is not used and biological parent is not defined but arguably includes mt donors but not gestational surrogates, who would instead be the birth parent.

Northern Territory

ART regulation in the NT is the same as in the ACT, namely the NHMRC Guidelines are relied on. NT parentage legislation, the *Status of Children Act 1978* (NT), addresses the status of children born through the use of donated gametes or embryos.[55] A woman who gives birth is the mother of the child, regardless of the source of the egg used in the child's conception.[56] The donor of an egg used in a fertilisation procedure[57] is not the mother of any resulting child.[58] NT has no provisions specifically concerning surrogacy. However, pursuant to the general "maternity" provision referred to above, a surrogate would be presumed to be the mother of any child she gives birth to.[59] The terms genetic, biological and gamete provider are not used. Parentage transfer would follow SA's legislation.

Queensland

Queensland also does not have ART legislation, instead relying on the NHMRC Guidelines as described in regards to the ACT. Its legislation concerning the parentage of donor-conceived children, the *Status of Children Act 1978* (Qld), provides for the same irrebuttable statutory presumptions as NSW.[60]

Of all jurisdictions, genes have the least relevance in surrogacy arrangements in Queensland. This is reflected in a guiding principle in its *Surrogacy Act 2010* (Qld), which provides that the same status, protection and support is to be available to children born as a result of surrogacy arrangements

[49] *Assisted Reproductive Technology Act 2007* (NSW) s 4(1).

[50] *Assisted Reproductive Technology Act 2007* (NSW) s 41A

[51] See *Assisted Reproductive Technology Act 2007* (NSW) s 41F and *Assisted Reproductive Technology Regulation 2014* (NSW) r 20. See also Legislative Council Standing Committee on Law and Justice, Parliament of New South Wales, *Legislation on Altruistic Surrogacy in NSW* (2009) [3.73]-[3.75].

[52] *Assisted Reproductive Technology Act 2007* (NSW) s 41F.

[53] *Status of Children Act 1996* (NSW) s 14.

[54] *Surrogacy Act 2010* (NSW) s 17(3)(d).

[55] *Status of Children Act 1978* (NT) Pt IIIA.

[56] *Status of Children Act 1978* (NT) s 5C.

[57] *Status of Children Act 1978* (NT) s 5A(1).

[58] *Status of Children Act 1978* (NT) s 5E.

[59] *Status of Children Act 1978* (NT) s 5C.

[60] *Status of Children Act 1978* (Qld) ss 19, 19E, 23.

regardless of whether there is a genetic relationship between the child and any of the parties to the arrangement.[61] There is no definition of genetic relationship.

When addressing an application for a parentage order, the *Surrogacy Act* requires the Court to be satisfied that a report by an independent counsellor supports the parentage transfer.[62] There is no express requirement that the report provide information regarding genetic relationships. However, as in the other jurisdictions, the report is required to address certain matters. These include each party's understanding of the social and psychological implications of parentage transfer and that openness and honesty about the child's birth parentage are needed for the wellbeing of the child.[63]

South Australia

The *Assisted Reproductive Treatment Act 1988* (SA) adopts the requirements of the NHMRC Guidelines and professional registration rules into law.[64] The terms genetic or biological parent are not used in that legislation. However, there is reference to donors of human reproductive material, that material being defined as a human embryo, human semen and a human ovum.[65] This would include mt donors.

In regards to children conceived following fertilisation procedures, whether donor-conceived or born through a surrogacy arrangement, as in the other States any woman that gives birth is the mother[66] and the egg donor is not the child's mother.[67]

Under the *Family Relationships Act 1975* (SA), recognition of a surrogacy agreement so that parentage transfer can occur requires that the agreement, inter alia, provide that the parties intend that at least one of the intending parents will provide "human reproductive material" with respect to creating an embryo for the purposes of the pregnancy,[68] unless the intending parents satisfy a medical-based exemption.[69] Such an exemption requires both intending parents to be infertile or unable to provide human reproductive material to create an embryo for medical reasons.[70] Like the State's ART legislation, the parentage legislation uses the term "human reproductive material" rather than genetic or biological material, and defines this as "human semen or a human ovum".[71] This would include mt donors but not gestational surrogates.

Tasmania

Tasmania does not have legislation regulating donor conception, instead adopting the same approach as the ACT. Its *Status of Children Act 1974* (Tas) provides that any woman becoming pregnant other than as a result of sexual intercourse is to be treated as the child's mother and the egg donor is not to be treated as the child's mother.[72]

The *Surrogacy Act 2012* (Tas) provides for the transfer of parentage from the birth mother to the intending parent(s) in certain circumstances. The Act includes the same guiding principle regarding genetic relatedness as the Queensland legislation.[73] However, unlike in Queensland, the Act permits a

[61] *Surrogacy Act 2010* (Qld) s 6(2)(b)(ii).

[62] *Surrogacy Act 2010* (Qld) s 22(2)(i). This can be dispensed with in exceptional circumstances pursuant to s 23(2).

[63] *Surrogacy Act 2010* (Qld) s 32(d).

[64] *Assisted Reproductive Treatment Regulations 2010* (SA) r 8.

[65] *Assisted Reproductive Treatment Act 1988* (SA) s 3.

[66] *Family Relationships Act 1975* (SA) s 10C(1).

[67] *Family Relationships Act 1975* (SA) s 10C(2).

[68] *Family Relationships Act 1975* (SA) s 10HA(2)(viii)(B).

[69] *Family Relationships Act 1975* (SA) s 10HA(2)(viii)(B), (5).

[70] *Family Relationships Act 1975* (SA) s 10HA(5).

[71] *Family Relationships Act 1975* (SA) s 10HA(1).

[72] *Status of Children Act 1974* (Tas) s 10C.

[73] *Surrogacy Act 2012* (Tas) s 3(2)(b)(ii).

Court addressing applications for parentage orders to request an independent counsellor's report on matters, including "any arrangements proposed for the child to have contact with his or her birth parent or birth parents or a person, other than an intending parent, who has provided some of the child's genetic material".[74] There is no definition of genetic relationship or genetic material but it is submitted these terms include mt donors.

Victoria

The *Assisted Reproductive Treatment Act 2008* (Vic) (ART Act) allows donor conception and provides for donor-conceived children to obtain identifying information on their donors.[75] It reinforces this right by providing in its guiding principles that "children born as result of the use of donated gametes have a right to information about their genetic parents".[76] Although the term genetic parents is used, the term is undefined. Donor gamete is defined to include donor eggs and so would include mt donors.[77] The *Status of Children Act 1974* (Vic) creates the same irrebuttable statutory presumptions regarding motherhood, as is the case with the NSW legislation.[78]

The provisions in the ART Act regarding surrogacy involving an ART provider result in a requirement for an absence of a genetic link between the surrogate and child if the intending parents want to become the legal parents of the resulting child. Unless and until a transfer of parentage occurs, the same presumptions under the *Status of Children Act* as described above apply.[79] Under the *Status of Children Act*, where an ART provider is involved in the child's conception, transfer of parentage from surrogate to the intending parents can only occur where the Victorian Patient Review Panel (PRP), the body responsible for decision-making regarding many ART procedures under the ART Act,[80] has pre-approved the ART procedure.[81] Pursuant to the ART Act, PRP approval of surrogacy arrangements requires, amongst other things, that the surrogate mother's egg not be used in conception,[82] although that can be waived in exceptional circumstances and if it is reasonable to do so.[83] Other considerations can also be considered by the Court. However, where an ART provider is not involved in the surrogacy, prior approval by the PRP is unnecessary and the restriction on genetic surrogacy will not apply. The *Status of Children Act* allows for parentage to be transferred from the surrogate to the intending parents by parentage order despite the genetic connection in those cases. There is no use of the term genetic or biological parent in the Victorian parentage legislation.

The restriction on the use of surrogates' eggs in ART-assisted surrogacy was a last minute addition to the parentage legislation.[84] It is justified in the *Parliamentary Debates* on the basis that it meant the surrogate "will not have her genetic or biological material in that child".[85] This was considered necessary to accommodate community expectations and concerns,[86] although there was no evidence the restriction was to the child's benefit. As this provision predates clinical use of mt donation, there is no discussion of the possibility of more than one egg donor being involved in a

[74] *Surrogacy Act 2012* (Tas) s 18(2)(d).

[75] *Assisted Reproductive Treatment Act 2008* (Vic) Pt 6.

[76] *Assisted Reproductive Treatment Act 2008* (Vic) s 5(c).

[77] *Assisted Reproductive Treatment Act 2008* (Vic) s 3.

[78] *Status of Children Act 1974* (Vic) ss 10E(2)(a), (b) and (3), 13(1)(a) and (2), 14(1)(a), (d) and (2), 16(1)(a), (c) and (2).

[79] *Status of Children Act 1974* (Vic) s 19.

[80] *Assisted Reproductive Treatment Act 2008* (Vic) Pt 9.

[81] *Status of Children Act 1974* (Vic) s 22(1)(b).

[82] *Assisted Reproductive Treatment Act 2008* (Vic) s 40(1)(ab).

[83] *Assisted Reproductive Treatment Act 2008* (Vic) s 41

[84] Trowse, n 19. See Victoria, *Parliamentary Debates*, Legislative Council, 4 December 2008, 5442 (Brian Tee).

[85] Victoria, n 84, 5442 (Brian Tee).

[86] Victoria, n 84, 5444 (Gavin Jennings).

child's conception. It is also noteworthy that justification for prohibiting a genetic link between surrogate and child entirely ignores the biological impact of the surrogate on the resulting child's genes.

Western Australia

The *Human Reproductive Technology Act 1991* (WA) addresses both ART and embryonic research. While this Act refers to genetic parents, it does not define the term. Instead, it defines biological parent by reference to genetic parent providing that a biological parent is a person who:

> (a) is the source of a human egg or human sperm used in an artificial fertilisation procedure; and
> (b) is the genetic parent of a human embryo developed, or of a child born, as a consequence of that procedure.[87]

This would include mt donors but not gestational surrogates.

The *Artificial Conception Act 1985* (WA) concerns "the status of persons conceived by artificial means". There is no definition of genetic material, but the legislation provides that the donor of genetic material has no status as parent.[88] Under the general rule regarding presumption of maternity, the birth mother is the child's mother.[89]

In regards to surrogacy, WA requires any surrogacy arrangement to have been approved by an oversight body (Western Australian Reproductive Technology Council), prior to the surrogacy taking place, if a court is to subsequently make a parentage order.[90] Amongst other things, the *Surrogacy Act 2008* (WA) provides that approval by the Council requires satisfaction of certain mandatory conditions. These include that the surrogacy arrangement is signed by all parties, including "any other person (a donor) whose egg or sperm is to be used for the conception of the child".[91] This would include mt donors. However, the court can dispense with certain requirements when making parentage orders (namely around the need for the surrogate to consent to the transfer, be counselled and receive legal advice regarding this, and the need for the child to be living with the intending parents at the time of the application)[92] if the child is genetically related to one or both intending parent and is not genetically related to the birth mother.[93] Genetic parent is defined for these purposes as "a person from whose egg or sperm the child is conceived" and would include mt donors but not gestational surrogates.[94] The purpose of these exceptions is to address cases where a surrogate refuses to surrender the child and privileges the genetic parent's interests over other considerations in the event of such a dispute.

Summary

The examination above shows that intending parent(s) in donor conception cases are the legal parents of the child and that genetic relationships between the child and gamete donors are irrelevant to legal parentage. This reflects society's expectations that such children be the legal children of those desiring to raise them and that it is in their best interests that this occur. In such cases, the birth mother who gestates the child will also be the intending mother so prioritisation between gestating and intending mother is unnecessary. In surrogacy arrangements, though, the law preferences the gestating mother by making her the child's legal parent at birth. However, in this case the gestating mother is not the intending mother and it is submitted that this preferencing is inconsistent with society's expectations regarding legal parentage as demonstrated in its regulation of the parentage of donor-conceived children.

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[87] *Human Reproductive Technology Act 1991* (WA) s 3.

[88] *Artificial Conception Act 1985* (WA) s 7.

[89] *Artificial Conception Act 1985* (WA) s 5(1).

[90] *Surrogacy Act 2008* (WA) s 16(1).

[91] *Surrogacy Act 2008* (WA) s 17(b)(iii).

[92] *Surrogacy Act 2008* (WA) ss 21(3) and 21(2)(e) respectively.

[93] *Surrogacy Act 2008* (WA) s 21(4).

[94] *Surrogacy Act 2008* (WA) s 21(5).

The above examination also shows that it can be expected that mt donors will be treated as genetic parents and therefore will not have legal parentage of resulting children. In contrast, the law endows gestational surrogates, who also have a biological relationship with the child, with legal parentage of the child. Confusingly, parentage legislation then instructs courts considering parentage transfer from the surrogate to the intending parents that genetic relationships are relevant without clearly explaining how so. These problems are discussed next by first considering the law's preferencing of genes over gestation in determining genetic parentage and then the law's preferencing of gestation over genes in regards to legal parentage.

DISCUSSION

Genetic parents: Preferencing genes over gestation

The concepts of genetic and biological relatedness are used interchangeably in State regulation of egg donation. For those jurisdictions relying on the NHMRC Guidelines to regulate egg donation (ACT, NT, Queensland and Tasmania), various genetic relationships, namely parent, offspring and sibling, are referred to and recognised but undefined. The term gamete provider is also used, defined as "the person who is the biological (that is, genetic) source of the gamete".[95] This would include mt donors but not gestational surrogates.

Amongst the four States with legislation regulating egg donation, two – NSW and SA – regulate without reference to genetic parent, although the NSW legislation uses the term biological parent, which is not defined. Like the NHMRC Guidelines, the legislation of both States instead refers to gamete provider (in NSW) or donor of human reproductive material (in SA) and this would include mt donors but not gestational surrogates. Victorian and WA legislation use the term genetic parents but do not define it. The WA legislation also uses biological parent, defined by reference to the genetic parent, providing that the biological parent is, inter alia, the genetic parent of the resulting child. The Victorian Act uses the defined terms donor and donor gamete but refers to the genetic parents of a child in its Guiding Principles. Neither the NHMRC Guidelines nor State legislation imposes a restriction on having more than two genetic parents.

Given that mt donation requires the donation of an egg, there is no scientific reason or regulatory language requiring that a distinction be drawn between nuclear DNA egg donors and mtDNA egg donors. There is no limit in science or law to one egg in relation to the conception of the same individual. Two egg donors can therefore each be treated as the genetic parents of the same child. However, genetic or biological relatedness for the purposes of egg donation regulation is dependent on the contribution of a gamete, such as an egg, towards a child's conception. Therefore, while science may treat gestational surrogates as a biological and possibly genetic parent because of the significant clinical effects of gestation on the child's genes, the law will not. Mt donors, on the other hand, while possibly having less impact than gestational surrogates on the child's genes, will be genetic parents for both scientific and Australian legal purposes.

In contrast, although the UK Government has acknowledged that three individuals contribute to the child's DNA where mt donation is used, mt donors are excluded as genetic parents by regulations providing that mt donors are not to be treated as a person who provided gametes for the creation of the embryo.[96] According to the Explanatory Note, the purpose of this is to clarify that there is no legal relationship between the donor and the resulting child and that the donor cannot apply for a parental order on the basis of that donation alone.[97] The Explanatory Memorandum explains that this reflects the government's position that mt donors do not have the same legal status as full gamete donors[98]

[95] NHMRC, n 27, Explanation of Key Terms, gamete and gamete provider.

[96] *Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015* (UK) reg 18, amending *Human Fertilisation and Embryology Act 1990* (UK) s 54.

[97] Explanatory Note, *Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015* (UK).

[98] Explanatory Memorandum, *Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015* (UK) [7.12].

because mtDNA does not impact the child's physical characteristics.[99] In the UK then, the impact of mt donation on the resulting child is considered to be of insufficient impact to justify any claim to genetic or legal parentage.

Before leaving donor conception, it should be noted that the NHMRC Guidelines and Victorian and WA legislation all expressly prohibit the deliberate confusion of children's biological parentage. Mixing gametes, embryos or eggs undergoing fertilisation from different donors in the same ART procedure so that it is not possible (without genetic testing) to know who is/are the genetic parents is prohibited.[100] This would not necessarily prevent mt donation but would require that mtDNA from the same woman be used in the creation of all embryos implanted at the same time in an intending mother.

Turning to surrogacy, all States again use the concepts of genetic or biological relatedness in their regulation, in particular in relation to parentage. Legislation in the ACT, SA and WA all use the concept of genetic parent (although SA's term is provider of human genetic material) defined essentially as a person whose gametes are used to create the embryo. NSW uses the term biological parent and Queensland uses genetic relationship but neither defines the terms. The Tasmanian Act refers to a person who provides some of the child's genetic material, but does not define genetic material. While one State, ACT, expressly provides that a child cannot have more than two parents at any one time, this is in regards to legal rather than genetic, parentage. Again, mt donors would be included in the concept of genetic parent for the purposes of surrogacy regulation but gestational surrogates would not.

The majority of the most recent round of parliamentary and law reform commission inquiries into surrogacy also treated genetic and biological relatedness as the same concept, and failed to acknowledge that gestation has an important biological impact on the resulting child's genetics.[101] However, the NSW and Queensland inquiries noted they had received submissions pointing out the biological link created by gestation[102] and the NSW body commented that for that reason care should be taken in using the terms in regards to surrogacy. More broadly, the Queensland report expressly considered the importance of a genetic connection concluding that "[i]t is clear to the committee that genetic connection means different things to different people".[103] However, as with all of these inquiries, the Queensland report predates the possibility of clinical use of mt donation and therefore genetic relatedness simply refers to the provision of a gamete. That more than two eggs may be involved in the creation of one embryo is not addressed. This means that mt donors will be genetic parents of both donor-conceived children and children born through surrogacy arrangements. The parentage laws around the use of donor gametes, however, sever those links for legal purposes. In the surrogacy legislation, though, statutory processes are provided to genetic parents that can lead to parentage transfer or at least make that relatedness a relevant consideration.

Whether mt donors are treated in the same way as other egg donors and considered a genetic (or biological) parent of the child is significant. Being a genetic parent creates legal obligations including providing identifying information, that information be recorded and disclosed to certain people, in particular the resulting child. The UK regulation means that mt donors will not be treated as persons

[99] Department of Health (UK), n 5, 15-16.

[100] NHMRC, n 27, Guideline 6.1; *Human Reproductive Technology Act 1991* (WA) s 17. Directions made for the purposes of the Act, provide that there is to be no deliberate confusion of biological parentage: *Human Reproductive Technology Act Directions* (2004) Direction 8.6 <http://www.slp.wa.gov.au/gazette/GAZETTE.NSF/gazlist/28FA432BECED857B48256F58002444B8/$file/gg201.pdf>; *Assisted Reproductive Treatment Act 2008* (Vic)s 27(1).

[101] Legislative Council Standing Committee on Law and Justice, n 51; Investigation into Altruistic Surrogacy Committee, Parliament of Queensland, *Report* (2008); Social Development Committee, Parliament of South Australia, *Inquiry into Gestational Surrogacy* (2007); Legislative Council Select Committee on Surrogacy, Parliament of Tasmania, *Report on Surrogacy* (2008); Victorian Law Reform Commission, *Assisted Reproductive Technology and Adoption: Final Report* (2007); Department of Health (WA), *Review of the Surrogacy Act 2008* (2014). The NSW Attorney-General is also currently undertaking a statutory review of the NSW Act.

[102] Legislative Council Standing Committee on Law and Justice, n 51, [3.69]; Investigation into Altruistic Surrogacy Committee, n 101, 45-46.

[103] Investigation into Altruistic Surrogacy Committee, n 101, 54.

who provided gametes for the creation of the embryo and so are excluded as genetic parents and only non-identifying information about them will be available to the child. The UK Government's view is that mt donation is fundamentally different to gamete donation and that "[a]s a matter of biological fact, the contribution made by a mitochondrial donor is quite different to that of a full genetic donor".[104] In effect, the mt donor is treated like a donor of non-reproductive tissue, such as kidneys or blood. Whether this is satisfactory for the resulting child will require more study into the ramifications of such conception in resulting children.[105] However, it is observed here that unlike non-reproductive tissue, for females at least, the mt genes are passed onto their offspring and this alone makes mt donation different.

If mt donors are recognised as genetic parents of the resulting child, new developments in science will continue to push this boundary. The media reported in April 2015 that overseas trials have replaced a single gene in a human embryo with a "healthy" gene from a donor.[106] If, and when, such modification becomes reality in children's conception, should the contribution of a single gene be sufficient to make the donor a genetic parent of any resulting child? Should it matter whether the gene concerned is part of the nuclear rather than mtDNA? The Nuffield Council on Bioethics review into mt donation observed that "[i]t is our view that the clear material difference between mitochondrial and nuclear genes means, in practice, that the adoption of [mt donation] would not necessitate the adoption of nuclear transfer or nuclear modification technologies if they were to emerge in future". The Council also noted that nuclear modification was outside their remit and did not comment on its desirability.[107] The amount and type of DNA contributed is not relevant to genetic relatedness under current State regulatory frameworks, except that there is a requirement that donors provide a gamete.[108]

Legal parents: Preferencing gestation over genes

The clear genetic link between mtDNA egg donor and the resulting child is rendered irrelevant to legal parentage in all jurisdictions by legislation providing that gamete donors have no claim to parentage. As noted above, this is also the case under the UK regulation of the mt technique. Before ART's development, it was medically impossible to separate maternal genetics from gestation. When egg or embryo donation became clinically possible, it was recognised that it was not clear in Australian law that gestation was sufficient to ensure that the gestating mother was the child's legal mother. All jurisdictions therefore amended their legislation to clarify that gestational mothers of donor-conceived children were the legal mothers without any formal legal process needing to be followed, even where there was no genetic relationship between gestational mother and child. This approach is generally thought to be appropriate because the gestational mother is the (or one of the) person(s) intending to parent the child and it reflects the view that it is usually in the child's best interests that the person who intends to parent them be recognised as legal parent, regardless of genetic parentage.[109]

The legislation around parentage in surrogacy, however, has the opposite result. The Victorian surrogacy inquiry concluded that intending parents should have the same powers and responsibilities as all other parents. Nevertheless, it recommended that "recognition of [intending parents'] parental

[104] Department of Health (UK), n 5, 36, also explaining why the concerns raised in the Nuffield Council on Bioethics, *Donor Conception: Ethical Aspects of Information Sharing Report* (2013), could be disregarded.

[105] The Victorian Law Reform Commission noted there had been little work around the "significance donor-conceived people attach to their donors and the absence of genetic connection with their parents": Victorian Law Reform Commission, n 101, 119.

[106] Reuters, "Chinese Experiment which 'Edits' DNA of Human Embryos", *ABC News*, 25 April 2015 <http://www.abc.net.au/news/2015-04-24/human-embryos-editing-experiment-ignites-ethical-furore/6418818>. See further Puping Liang et al, "CRISPR/Cas9 – Mediated Gene Editing in Human Tripronuclear Zygotes" (2015) 6 Protein & Cell 363; Ainsley J Newson and Anthony Wrigley, "Identifying Key Developments, Issues and Questions Relating to Techniques of Genome Editing with Engineered Nucleases" (Background Paper, Nuffield Council on Bioethics, 2015).

[107] Nuffield Council on Bioethics, n 6, [5.5].

[108] DNA modification of an early stage embryo is illegal under Australian law: *Prohibition of Human Cloning for Reproduction Act 2002* (Cth) s 15(1).

[109] See Susan B Boyd, "Gendering Legal Parenthood: Bio-genetic Ties, Intentionality and Responsibility" (2007) 25 Windsor YB Access Just 63, regarding competing claims of intentionality and genetic ties in legal parenthood.

status should be subject to court supervision".[110] This approach, taken in all States and the ACT, preferences the gestational surrogate's interests over those of the child and intending parents. Legislation makes the surrogate the child's legal mother unless and until there is a parentage transfer after birth regardless of the fact that there is no intention, at least at conception, that the surrogate parent the child and that a gestational surrogate is not the child's genetic parent for the purposes of egg donation, surrogacy and parentage legislation.[111] There is also a compulsory delay in all jurisdictions except NSW, before which a parentage transfer can occur.[112] Further, in all jurisdictions whether the child is living with the intending parents is a relevant consideration, and in three States (Queensland, Tasmania and WA) this is a requirement before parentage transfer can occur.[113] The child therefore must be raised by people who cannot be its legal parents and cannot make particular decisions regarding the child's welfare until a prescribed period has passed. As Sheldon has observed, this may leave some children particularly vulnerable and, it is submitted here, is not in their best interests.[114]

All jurisdictions (except NT) address genetic relatedness in regards to parentage transfer, in many cases instructing the court that it is a matter of relevance. The relationship created by mt donation would be included in these considerations. ACT, SA, Victoria and WA require the intending parents to be genetically related to the child to become the legal parent and/or no genetic relationship between surrogate and child for that to happen. WA goes the furthest, albeit in limited circumstances, allowing intending parents to override a surrogate's claim to legal parentage and have parentage transferred away from her if there is a genetic relationship between intending parents and child and not between surrogate and child. The genetic link is therefore prioritised.

In Queensland and Tasmania, legislation provides that children born through surrogacy arrangements have the same status, protection and support regardless of whether there is a genetic relationship between the child and any other parties to the arrangement. Genetic relationship is not defined, although the legislation's requirements mean that for this principle to be relevant where mt donation was used, the mt donor would have to be party to the surrogacy arrangement. When making a decision on parentage transfer, courts in NSW, Queensland and Tasmania may consider an independent counsellor's report which could address genetic relationship issues and in NSW and Tasmania this is expressly required to be included. The Tasmanian legislation expressly includes arrangements for the child to have contact with "a person, other than an intending parent, who has provided some of the child's genetic material" as a matter that a court may request the report to address. In NSW, a report must accompany transfer applications, which includes contact arrangements between the child and his or her biological parent(s).

While all States require parentage decisions to be made in the child's best interests, none of them clearly explain the prioritisation of genetic and intending parentage. In light of legislative responses to donor conception, it is arguable that intending parents should be given priority and that other third parties, whether mt donor or gestational surrogate, should not.

CONCLUSION

Although children's best interests support legal parentage by those who parent them, parentage legislation preferences gestating mothers over intending parents in surrogacy arrangements. The interests of the child, and intending parents, are intended to be met by allowing parentage transfer

[110] Victorian Law Reform Commission, n 101, 8.

[111] The Victorian Law Reform Commission also noted that making the surrogate the legal parent at birth meant that the surrogate may find herself responsible for a child not originally intended to be hers: Victorian Law Reform Commission, n 101, 173.

[112] *Parentage Act 2004* (ACT) s 25(3); *Surrogacy Act 2010* (NSW) s 16; *Surrogacy Act 2010* (Qld) s 21(1); *Family Relationships Act 1975* (SA) s 10HB(5); *Surrogacy Act 2012* (Tas) s 15; *Status of Children Act 1974* (Vic) s 20(2); *Surrogacy Act 2008* (WA) s 20.

[113] *Parentage Act 2004* (ACT) s 26(3)(a); *Surrogacy Act 2010* (NSW) s 33; *Surrogacy Act 2010* (Qld) s 22(2)(b); *Family Relationships Act 1975* (SA) s 10HB(9)(a); *Surrogacy Act 2012* (Tas) s 16(2)(j)(i); *Status of Children Act 1974* (Vic) s 22(1)(c); *Surrogacy Act 2008* (WA) s 21(2)(e).

[114] Sheldon, n 3, 83.

from surrogate to intending parent(s) after the child's birth. Further, in decision-making in such cases all State and Territory courts may (and in some jurisdictions, must) consider the presence or absence of genetic links between the surrogate and child or intending parent(s) and child.

This instruction to the courts sits uneasily with the approach taken in all jurisdictions to gamete donors, whereby genetic relatedness is dismissed to prevent claims to legal parentage by gamete donors. That tension creates confusion regarding the weight courts should give to the presence or absence of genetic and biological links and the contact the child has with such "relatives".

It would be better for both children and intending parents if gestational surrogates were treated in the same way as adults with genetic relationships with the child, and have their parentage claims severed at birth.[115] Such an approach would mean that families' reproductive choice to use surrogacy will not inevitably cause them to go through the emotional and economic costs of seeking court approval of parentage transfer. Instead, such families will have the same status and protection as families created using other reproductive methods and the law will reflect all parties' intentions at the time the surrogacy is arranged.

TABLE: GENETICS IN AUSTRALIAN REGULATION OF EGG DONATION, SURROGACY AND PARENTAGE

Jurisdiction	Use of donor eggs	Use of surrogacy	Parentage – Donor eggs used	Parentage – Surrogacy used
ACT	NHMRC Guidelines on ART 2007 • "gamete provider" defined as "[t]he person who is the biological (that is, genetic) source of the gamete" • "In these guidelines, the term 'donated gametes' is used when the gametes are provided by a third person who, while being the genetic parent of the person born, will not be the social parent" • "genetic parent/offspring/ sibling/ material" used but not defined	NHMRC Guidelines on ART 2007 • genetic and gestational surrogacy controversial • notes genetic relatedness considerations in surrogacy debate	*Parentage Act 2004* • conclusive statutory presumption of motherhood for any woman becoming pregnant other than as result of sexual intercourse • conclusive statutory presumption that egg donor is not child's mother	*Parentage Act 2004* • parentage order application can be made if inter alia: - neither birth parent is a genetic parent - at least one intending parent is genetic parent • "genetic parent" defined as "a person whose gametes [undefined] were used to create the embryo"

[115] Exceptional procedures could be introduced to allow for parentage transfer to the surrogate to address those cases where a surrogate changes her mind regarding parenting of the child.

Jurisdiction	Use of donor eggs	Use of surrogacy	Parentage – Donor eggs used	Parentage – Surrogacy used
NSW	*Assisted Reproductive Technology Act 2007* • "gamete provider" defined as "in relation to a gamete, means the individual from whom the gamete has been obtained and in relation to an embryo means an individual from whom a gamete used to create the embryo was obtained" • "genetic" not used • "biological parent" used but not defined	*Assisted Reproductive Technology Act 2007* • "biological sibling" used and defined by reference to "blood"	*Status of Children Act 1996* • irrebuttable statutory presumption of motherhood for any woman becoming pregnant other than as result of sexual intercourse • irrebuttable statutory presumption that egg donor is not child's mother	*Surrogacy Act 2010* • parentage order application to be accompanied by independent counsellor's report on matters, including "any contact arrangements proposed in relation to the child and his or her birth parent or parents or biological parent or parents" • "genetic parent" not used • "biological parent" used but not defined
NT	See ACT	See ACT	*Status of Children Act 1978* • any woman who gives birth is child's mother • egg donor is not mother of any donor-conceived child • does not use "genetic", "biological" or "gamete provider"	*Status of Children Act 1978* • general "maternity" provisions mean birth mother is legal mother • no legislation providing for parentage transfer
QLD	See ACT	See ACT	*Status of Children Act 1978* See NSW	*Surrogacy Act 2010* • guiding principle that same status, protection and support available to children born as result of surrogacy arrangements regardless of whether there is a genetic relationship between child and any parties to the arrangement • "genetic relationship" used but not defined • independent counsellor's report required with parentage application but no express requirement regarding discussion of genetic relationship • "genetic" or "biological parent" not used

Jurisdiction	Use of donor eggs	Use of surrogacy	Parentage – Donor eggs used	Parentage – Surrogacy used
SA	*Assisted Reproductive Treatment Act 1988* • adopts NHMRC Guidelines – see ACT • "genetic" or "biological parent" not used • "donor of human reproductive material" used, such material defined as including "a human ovum"	See SA – Use of donor eggs	*Family Relationships Act 1975* • for children conceived following fertilisation procedures, woman that gives birth is mother • egg donor is not child's mother	*Family Relationships Act 1975* • recognition of surrogacy agreement to enable parentage transfer requires at least one intended parent be genetic parent of child (subject to medical based exceptions) • provider of "human reproductive material" (defined to mean sperm or an ovum) used rather than genetic parent
TAS	See ACT	See ACT	*Status of Children Act 1974* • any woman becoming pregnant other than as result of sexual intercourse is treated as mother • egg donor treated as not being child's mother	*Surrogacy Act 2012* • same guiding principle as QLD • Court may request independent counsellor's report on matters including "any arrangements proposed for the child to have contact with his or her birth parent or birth parents or a person, other than an intended parent, who has provided some of the child's genetic material" • "genetic relationship / material" not defined
VIC	*Assisted Reproductive Treatment Act 2008* • guiding principle that "children born as the result of the use of donated gametes have a right to information about their genetic parents" • "genetic parents" not defined • "donor gametes" includes donor eggs	*Assisted Reproductive Treatment Act 2008* • surrogacy involving ART provider can only be approved if surrogate's egg not used or requirement waived by Panel • "genetic" or "biological parent" not used • surrogacy not involving ART provider has no requirements re genetic parentage	*Status of Children Act 1974* See NSW	*Status of Children Act 1974* • "genetic" or "biological" parent not used • can transfer parentage where ART provider involved, only if PRP pre-approved ART procedure • "other" relevant considerations can be taken into account by court • if ART provider not involved in surrogacy, parentage transfer can occur regardless of genetic link between surrogate and child

Jurisdiction	Use of donor eggs	Use of surrogacy	Parentage – Donor eggs used	Parentage – Surrogacy used
WA	*Human Reproductive Technology Act 1991* • "genetic parents" used but not defined • "biological parent" used and defined by reference to "genetic parent" as: "a biological parent is a person who: (a) is the source of a human egg or human sperm used in an artificial fertilisation procedure; and (b) is the genetic parent of a human embryo developed, or of a child born, as a consequence of that procedure"	*Surrogacy Act 2008* • pre-approval of arrangement requires, inter alia, signed written agreement by "any other person (a donor) whose egg … is to be used for conception of the child"	*Artificial Conception Act 1985* • birth mother is mother of child • donor of "genetic material" has no status as parent • "genetic material" not defined	*Surrogacy Act 2008* • parentage transfer requires pre-approval of surrogacy arrangement • court can dispense with certain requirements including surrogate's consent if: - surrogate is not a genetic parent and - at least 1 arranged parent is a genetic parent • "genetic parent" defined for these purposes as "a person from whose egg or sperm the child is conceived"

SYMPOSIUM

THE POLICY AND REGULATORY CONTEXT OF U.S., U.K., AND AUSTRALIAN RESPONSES TO MITOCHONDRIAL DONATION GOVERNANCE

Karinne Ludlow*

ABSTRACT: Jurisdictions are beginning to respond to growing demands to begin the clinical use of mitochondrial donation in human embryos. This form of directed modification of human embryos is intended to prevent mitochondrial disease in future members of families with a known history of such disease. At least one child has already been born after the technique was used during his conception. The United Kingdom has legalized such use and the United States has undertaken high level reviews of the legal and ethical issues that arise from it. Other jurisdictions, such as Australia, continue to prohibit the clinical use of the technique. Using these three distinct responses, this article identifies three fundamental issues raised by the clinical use of mitochondrial donation that must be addressed by jurisdictions considering their own governance responses and analyzes the policy and regulatory contexts that impact how these issues are or will be responded to. Drawing on this analysis, the article discusses how the studied frameworks can inform future governance arrangements in other jurisdictions considering clinical mitochondrial donation.

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The April 2016 birth in Mexico of a boy conceived using mitochondrial donation (mtD),[1] and the March 2017 licensing of a U.K. clinic to use the same technique are recent public developments of this form of directed modification

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1. Other names are also applied to the technique, including mitochondrial replacement therapy and nuclear transfer.

of human embryos.[2] The United Kingdom was the first jurisdiction to expressly legalize the technique's clinical use. Other jurisdictions, such as the United States, have also begun to respond to these developments. Most jurisdictions though, have no specific laws around the technique's clinical use or, like Australia, expressly prohibit such use.

Governance responses to any innovative technology are always dependent, in part, on the background policy and regulatory frameworks relevant to that technology.[3] That background may even impede a jurisdiction's freedom to respond.[4] Nevertheless, studying the responses of other jurisdictions demonstrates possible reforms and expected difficulties. It can also highlight explicit and implicit assumptions about, and possible deficiencies in, a particular jurisdiction's own regulatory framework.[5] When deciding whether to allow mtD, it is likely that jurisdictions will look to the United Kingdom and United States as early movers. Australia, a jurisdiction where public demand for reform in this area is already occurring, is an example of this and is used as a case study here.[6]

After a brief introduction to mtD in Part I, Part II outlines the regulatory background in the United States, United Kingdom and Australia against which changes to legalize the clinical use of mtD have or will occur. Part III identifies three fundamental issues raised by the clinical use of mtD that must be addressed by all jurisdictions and analyzes the policy and regulatory contexts that impact how these issues are, or will be, responded to in the studied jurisdictions. Finally, Part IV discusses how the studied frameworks inform future governance arrangements in other jurisdictions considering clinical mtD.

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2. *See* John Zhang et al., *Live Birth Derived from Oocyte Spindle Transfer to Prevent Mitochondrial Disease*, 34 REPROD. BIOMEDICINE ONLINE 361, 361–62, 364 (2017) http://dx.doi.org/10.1016/j.rbmo.2017.01.013. The license was issued by the U.K. regulator, the Human Fertilisation and Embryology Agency (HFEA), to Newcastle Fertility Centre. Press Release, Human Fertilisation & Embryology Auth., HFEA Statement on Mitochondrial Donation (Mar. 15, 2017), https://www.hfea.gov.uk/about-us/news-and-press-releases/2017-news-and-press-releases/hfea-statement-on-mitochondrial-donation/ [https://perma.cc/JX5X-HBGN].

3. *See* NUFFIELD COUNCIL ON BIOETHICS, EMERGING BIOTECHNOLOGIES: TECHNOLOGY, CHOICE, AND THE PUBLIC GOOD 140 para. 8.18 (2012); *see also* Roger Brownsword & Han Somsen, *Law, Innovation and Technology: Before We Fast Forward—A Forum for Debate*, 1 L. INNOVATION & TECH. 1 (2009); Lyria Bennett Moses, *How to Think About Law, Regulation and Technology: Problems with 'Technology' as a Regulatory Target*, 5 LAW, INNOVATION & TECH. 1 (2013).

4. *See* Roger Brownsword, *Regulating Human Genetics: New Dilemmas for a New Millennium*, 12 MED. L. REV. 14, 35, 39 (2004).

5. *See* Moses, *supra* note 3, at 10.

6. *Mitochondrial Donation—How You Can Help*, AUSTL. MITOCHONDRIAL DISEASE FOUND., http://www.amdf.org.au/mito-donation-how-you-can-help/ [https://perma.cc/YB64-XNPE] (located under the "Get Involved" tab); Tracy Bowden, *Three-Parent Babies: Calls to Allow Controversial Mitochondrial Donation Procedure in Australia*, ABC NEWS (Nov. 19, 2017, 8:42 PM), http://www.abc.net.au/news/2017-11-20/three-parent-babies-and-mitochondrial-donation/9100228 [https://perma.cc/JA8G-7GS3] (last updated Nov. 20, 2017, 12:15 AM).

I. MITOCHONDRIAL DONATION

Most human cellular DNA is in the nucleus (in the chromosomes), which contains approximately 20,000–30,000 coding genes.[7] But a small amount, 37 genes or about 0.1% of the cell's total coding genes, is in small packages or organelles in the cell's surrounding environment (cytoplasm).[8] These organelles are called mitochondria.[9] Amongst other things, mitochondria are crucial to generating energy for cell function by converting food energy to chemical energy.[10] Each individual cell contains many mitochondria and an individual mitochondrion can contain many copies of the mitochondrial DNA (mtDNA).[11]

Like all DNA, mtDNA can have faults or mutations.[12] If such mutations cause failure in the energy supplying functions of mitochondria, chronic loss of cellular energy results.[13] This adversely affects many organs and tissues but particularly those with high energy demand, such as the brain, heart, eyes, ears and skeletal muscles, with catastrophic consequences including blindness, cardiac failure, deafness, exercise intolerance, premature death, or stroke.[14] About 50 or so metabolic disorders display as severe noncurable neurological, muscular and other diseases.[15] These include MELAS (mitochondrial encephalomyopathy, lactic acidosis, and stroke-like episodes) and Leigh syndrome, a devastating pediatric-onset disease causing regression of mental and motor skills leading rapidly to death.[16] The child born in Mexico discussed above was conceived with the assistance of mtD to avoid maternally inherited Leigh syndrome.[17]

There is currently no cure for mitochondrial disease, which is troubling given that 152, 778, and 56 children are born with the disease each year in the United Kingdom, United States, and Australia respectively.[18] It is estimated that

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7. COMM. ON THE ETHICAL & SOC. POL'Y CONSIDERATIONS OF NOVEL TECHNIQUES FOR PREVENTION OF MATERNAL TRANSMISSION OF MITOCHONDRIAL DNA DISEASES, NAT'L ACADS. OF THE SCIS., ENG'G & MED., MITOCHONDRIAL REPLACEMENT TECHNIQUES: ETHICAL, SOCIAL, AND POLICY CONSIDERATIONS 33 (Anne Claiborne et al. eds., 2016) [hereinafter U.S. NAS REPORT].

8. *Id.* at 19, 33.

9. *Id.* at 33.

10. Extensive contribution from nuclear DNA is also essential for mitochondrial activity and structure. *Id.*

11. *Id.* at 33–34.

12. mtDNA acquires mutations at a much greater rate than nuclear DNA. *Id*. at 35.

13. Samvel Varvaštian, *UK's Legalisation of Mitochondrial Donation in IVF Treatment: A Challenge to the International Community or a Promotion of Life-Saving Medical Innovation to Be Followed by Others?*, 22 EUR. J. HEALTH L. 405, 408 (2015).

14. *Id.*

15. For a summary of mitochondrial disorders, see NEVA HAITES ET AL., HUMAN FERTILISATION & EMBRYOLOGY AUTH., SCIENTIFIC REVIEW OF THE SAFETY AND EFFICACY OF METHODS TO AVOID MITOCHONDRIAL DISEASE THROUGH ASSISTED CONCEPTION 25–26 tbl.1 (2011) [hereinafter HFEA 2011] (UK) (citing Robert W. Taylor & Doug M. Turnbull, *Mitochondrial DNA Mutations in Human Disease*, 6 NATURE REVS. GENETICS 389, 394 (2005)).

16. U.S. NAS REPORT, *supra* note 7, at 38–39.

17. Zhang et al., *supra* note 2, at 362.

18. U.S. NAS REPORT, *supra* note 7, at 41–42 (citing Gráinne S. Gorman et al., Letter to the Editor, *Mitochondrial Donation—How Many Women Could Benefit?*, 372 NEW ENG. J. MED. 885,

about 1 in 200 people carry pathogenic mtDNA mutations without displaying symptoms, but between 1 in 5000–10,000 go on to develop serious disease conditions.[19] Direct medical costs for hospitalization in the United States alone for mitochondrial disease patients is about US$113 million per year.[20]

MtD aims to prevent such diseases in future family members.[21] In simple terms, mtDNA affected by mutations is replaced with healthy mtDNA by transferring the nuclear DNA of the intending mother's egg or fertilized egg into a healthy enucleated egg from a donor.[22] That is, the nucleus of a "normal" egg or zygote is removed, leaving the healthy mitochondria in the cell. The nuclear DNA from the woman wanting the child is transferred into that egg or zygote. The result is a child with nuclear DNA from the parental egg and sperm but mtDNA from another woman. If successful, it is hoped the technique will allow women with faulty mtDNA to have a healthy, genetically related child.[23]

II. REGULATORY BACKGROUND

MtD research using human embryos is legal in the United States, United Kingdom, and Australia. But while embryo research is publically funded and governed by specific legislation in the United Kingdom and Australia, this is

886 (2015)); *Mitochondrial Donation*, AUSTL. MITOCHONDRIAL DISEASE FOUND., https://www.amdf.org.au/mitochondrial-donation/ [https://perma.cc/YUE5-RTPN] (located under the MITO Info tab).

19. Disease prevalence rates vary across "different countries, regions, population groups and mutation expressions" but it is generally agreed that mtDNA diseases are amongst the most common human genetic disorders. Varvaštian, *supra* note 13, at 408–09.

20. Shana E. McCormack et al., *Hospitalization for Mitochondrial Disease Across the Lifespan in the U.S.*, 121 MOLECULAR GENETICS & METABOLISM 119, 124 (2017).

21. Whether a particular child displays disease depends on the proportion of mutant mtDNA relative to total mtDNA in the particular egg used to conceive that child. *See* Varvaštian, *supra* note 13, at 3.

22. The three most developed forms of the technique are maternal spindle transfer (MST), pronuclear transfer (PNT) and polar body transfer. *See* HFEA 2011, *supra* note 15, at 3; *see also* ANDY GREENFIELD ET AL., HUMAN FERTILISATION & EMBRYOLOGY AUTH., ANNEX VIII: SCIENTIFIC REVIEW OF THE SAFETY AND EFFICACY OF METHODS TO AVOID MITOCHONDRIAL DISEASE THROUGH ASSISTED CONCEPTION: UPDATE 9 (2013) [hereinafter HFEA 2013] (UK); ANDY GREENFIELD ET AL., HUMAN FERTILISATION & EMBRYOLOGY AUTH., THIRD SCIENTIFIC REVIEW OF THE SAFETY AND EFFICACY OF METHODS TO AVOID MITOCHONDRIAL DISEASE THROUGH ASSISTED CONCEPTION: 2014 UPDATE 3 (2014) [hereinafter HFEA 2014] (UK); U.S. NAS REPORT, *supra* note 7, at 45. The child born in Mexico was conceived using MST as well as other assisted reproductive technologies (ART) including egg donation, intracytoplasmic sperm injection (ICSI) and prenatal genetic diagnosis (PGD). *See* Zhang et al., *supra* note 2, at 363.

23. An earlier technique involved cytoplasmic or ooplasmic transfer and was used in the United States in the late 1990s. Jason A. Barritt et al., *Mitochondria in Human Offspring Derived from Ooplasmic Transplantation,* 16 HUM. REPROD. 513, 513 (2001). This was halted by the identification of serious safety concerns for the children and the U.S. FDA in 2001 declaring the procedure required its approval. Jennifer L. Rosato, *The Children of ART (Assisted Reproductive Technology): Should the Law Protect Them from Harm?*, 57 UTAH L. REV. 57, 74 n.120 (2004).

not the case in the United States.[24] However, despite not being prohibited by federal law (although state legislation may prohibit such research) publically funded mtD research using human embryos is limited.[25] The Dickey-Wicker amendment (a rider on the annual U.S. Department of Health and Human Services appropriation bill) prohibits using the Department's funding "for research in which embryos are created for research purposes or destroyed, discarded, or subjected to risks with no prospect of medical benefit for the embryo."[26] As noted, such research is publicly funded in the United Kingdom and Australia, but it must be licensed.[27] Australian researchers are also limited in the types of human embryos that can be used for this purpose.[28] In particular, embryos created through fertilization of an egg by sperm cannot be expressly created for research purposes.[29] Researchers may only use embryos that are excess assisted reproductive technology (ART) embryos or created by means other than by fertilization of a human egg by a human sperm such as somatic cell nuclear transfer (cloned) embryos.[30]

The U.K. regulator, the Human Fertilisation and Embryology Agency (HFEA), regulates the use of human embryos in both research and treatment, including ART.[31] Work by HFEA to move mtD from the laboratory to the clinic took a significant step forward in 2008 with legislative amendments to allow

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24. There is some federal regulation of conception through ART—through 21 C.F.R. § 1271 (2011)—but this addresses the risks associated with communicable diseases. *FDA Regulation of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/P's) Product List*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/BiologicsBloodVaccines/TissueTissueProducts/RegulationofTissues/ucm150485.htm [https://perma.cc/69Z3-385B] (last updated Feb. 02, 2018) (cited in U.S. NAS REPORT, *supra* note 7, at 22).

25. States have responded to the rider in different ways. California, for example, has addressed the rider by creating and funding the California Institute for Regenerative Medicine to fund stem cell research. *History*, CAL. INST. FOR REGENERATIVE MED., https://www.cirm.ca.gov/about-cirm/history [https://perma.cc/L9PJ-42YE].

26. U.S. NAS REPORT, *supra* note 7, at 23. The report also recommends the development of ethical standards for the procurement of gametes and embryos for mtD. *Id.* at 125.

27. In the United Kingdom, such licenses are issued by the HFEA under the Human Fertilisation and Embryology Act 1990 c. 37, § 11 (1), sch. 2 (UK). The first application for a license to undertake research in mtD was made in late 2004. Rosa J. Castro, *Mitochondrial Replacement Therapy: The UK and US Regulatory Landscapes*, 3 J.L. & BIOSCIENCES 726, 730–735 (2016). That license was issued to the Newcastle Centre for Mitochondrial Research in 2005. Press Release, Human Fertilisation & Embryology Auth., *supra* note 2. In Australia mtD research must be licensed by the Embryo Research Licensing Committee of the National Health and Medical Research Council. *Prohibition of Human Cloning for Reproduction Act 2002* (Cth) pt 2 div 2 s 23 (Austl.). Licenses are issued pursuant to the Research Involving Human Embryos Act. *Research Involving Human Embryos Act 2002* (Cth) pt 2 div 2 ss 10–11, div 4 s 20 (1) (c) (Austl.). The Licensing Committee is established by the same legislation. *Id.* at div 3 s 13.

28. Researchers must also comply with the current NHMRC. NAT'L HEALTH & MED. RESEARCH COUNCIL ET AL., AUSTL. GOV'T, NATIONAL STATEMENT ON ETHICAL CONDUCT IN HUMAN RESEARCH (2007) (updated 2015), https://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/e72_national_statement_may_2015_150514_a.pdf [https://perma.cc/V24J-KHGB].

29. *See Prohibition of Human Cloning for Reproduction Act 2002* (Cth) s 12 (1) (Austl.).

30. *Research Involving Human Embryos Act 2002* (Cth) s 20 (1) (Austl.).

31. HFEA is an independent regulatory agency established pursuant to the Human Fertilisation and Embryology Act. Human Fertilisation and Embryology Act 1990 c. 37, § 5 (UK).

regulations legalizing the technique's clinical use to be enacted at a later date.[32] Such regulations came into effect in October 2015 after three major scientific reviews and two rounds of public consultation.[33] These regulations made the United Kingdom the first jurisdiction in the world to expressly legalize the clinical use of mtD.[34] On December 15, 2016, the HFEA decided it was comfortable with the scientific evidence for the technique's safety and the first license under those regulations was issued on March 16, 2017.[35] Note, however, that patients wanting to undergo mtD must still apply for licenses on a case-by-case basis.[36]

In contrast with the United Kingdom, where such matters are the subject of national legislation, regulation of assisted conception and parentage in the United States is reserved to the states and governance of ART is largely through self-regulation by the profession.[37] However, the U.S. Food and Drug Administration (FDA) has some involvement in the regulation of mtD's clinical use because such use is considered a clinical investigation requiring FDA approval.[38] For that reason, the U.S. clinic, involved in the birth of the boy referred to in the introduction, performed the embryo transfer to the intending mother's uterus in Mexico.[39] The FDA has subsequently notified the clinic that the creation of the embryo violated regulation around human subject research involving

32. *See generally* Human Fertilisation and Embryology Act 2008 (UK), *amending* Human Fertilisation and Embryology Act 1990 c. 37 (UK).

33. *See* HFEA 2011, *supra* note 15, at 3; HFEA 2013, *supra* note 22, at 3; HFEA 2014 *supra* note 22, at 3. Public consultations: HEALTH SCI. & BIOETHICS DIV., DEP'T OF HEALTH, MITOCHONDRIAL DONATION: DRAFT REGULATIONS TO PERMIT THE USE OF NEW TREATMENT TECHNIQUES TO PREVENT THE TRANSMISSION OF A SERIOUS MITOCHONDRIAL DISEASE FROM MOTHER TO CHILD (2014) [hereinafter U.K. DEP'T OF HEALTH REPORT] (UK); HUMAN FERTILISATION & EMBRYOLOGY AUTH., DEP'T OF HEALTH, MITOCHONDRIA REPLACEMENT CONSULTATION: ADVICE TO GOVERNMENT (2013) (UK); *see also* NUFFIELD COUNCIL ON BIOETHICS, NOVEL TECHNIQUES FOR THE PREVENTION OF MITOCHONDRIAL DNA DISORDERS: AN ETHICAL REVIEW (2012).

34. James Gallagher, *UK Approves Three-Person Babies*, BRIT. BROADCAST CORP. (Feb. 24, 2015), http://www.bbc.com/news/health-31594856.

35. Ian Sample, *First UK Licence to Create Three-Person Baby Granted by Fertility Regulator*, GUARDIAN (Mar. 16, 2017, 7:51 AM), https://www.theguardian.com/science/2017/mar/16/first-licence-to-create-three-person-baby-granted-by-uk-fertility-regulator [https://perma.cc/L3VM-E84Z].

36. Press Release, Human Fertilisation & Embryology Auth., *supra* note 2.

37. Human Fertilisation and Embryology Act 1990, *amended by* Human Fertilisation and Embryology Act 2008 (UK); THE PRESIDENT'S COUNCIL ON BIOETHICS, REPRODUCTION & RESPONSIBILITY: THE REGULATION OF NEW BIOTECHNOLOGIES 51–54, 71–74 (2004), Amy B. Leiser, Note, *Parentage Disputes in the Age of Mitochondrial Replacement Therapy*, 104 GEO. L.J. 414, 422–26 (2016).

38. *See generally* Human Cells, Tissues, and Cellular and Tissue-Based Products, 21 C.F.R. § 1271.3 (2017) (including the use of "human cells or tissues that are intended for implantation . . . into a human" as covered by the Act).

39. Emily Mullin, *The Fertility Doctor Trying to Commercialize Three-Parent Babies*, MIT TECH. REV. (June 13, 2017), https://www.technologyreview.com/s/608033/the-fertility-doctor-trying-to-commercialize-three-parent-babies/ [https://perma.cc/V27J-GMBW].

intentional creation of genetically modified embryos and the embryo's export violated licensing requirements for the export of certain biological products.[40]

Australia's regulatory framework for reproductive technology is splintered between federal, state and professional governance. In contrast to the United Kingdom, where the crossing of the mtD technique from experimental to clinical use did not need regulatory responsibility to pass to a different body, multiple regulatory or governance bodies will be involved in Australia should the legalization of mtD's clinical use be sought. Federal legislation regulates the creation and use of human embryos in research—and to a limited extent in treatment—but there is no federal regulation of ART.[41] This is where regulatory responsibility splinters: Only four of the eight Australian states and territories have their own ART legislation.[42] Self-regulation by the profession provides a minimal level of consistency between states because the federal legislation on embryo use requires clinics using embryos in ART to be accredited.[43] Accreditation, which is the responsibility of a professional body, in turn requires compliance with ethical guidelines written by the Australian National Health and Medical Research Council, the federal statutory agency for health and medical research.[44] This arrangement gives the guidelines some legal weight. These guidelines do not directly impact mtD governance because the newly released 2017 Guidelines expressly note that they do not address mtD. However, they are relevant to the use of donated gametes, something that is necessary in mtD.[45]

If legalized in Australia, mtD will be the first significant innovative genetic technology to cross the boundary between the federal scheme regulating embryo research and use generally to the state schemes regulating clinical ART. Earlier innovative genetic technologies have not crossed that boundary—Australia only permits human cloning as licensed research, not as a reproductive technology. ART was used as a clinical technology before the splintered regulatory system was established. Discussions around clinical use of mtD will need to address

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40. Letter from Mary A. Malarkey, Dir., Office of Compliance & Biologics Quality, Ctr. for Biologics Evaluation & Research, to John Zhang, Chief Exec. Officer, Darwin Life, Inc. & New Hope Fertility Ctr. (Aug. 4, 2017), https://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ComplianceActivities/Enforcement/UntitledLetters/UCM570225.pdf [https://perma.cc/8JVZ-36LQ].

41. *See Research Involving Human Embryos Act 2002* (Cth); *Prohibition of Human Cloning for Reproduction Act 2002* (Cth) s 2. For constitutional law reasons, the federal legislation is replicated in state legislation in each state and territory. *See Australian Constitution* s 109.

42. The states with legislation are New South Wales, South Australia, Victoria and Western Australia. *See Assisted Reproductive Technology Act 2007* (N.S.W); *Assisted Reproductive Treatment Act 1988* (S.Austl.); *Assisted Reproductive Treatment Act 2008* (Vict.); *Human Reproductive Technology Act 1991* (W. Austl.).

43. *Research Involving Human Embryos Act 2002* (Cth) s 10.

44. *Id.* at s 8. The professional body that does the accreditation requires ART clinics to comply with professional ethical guidelines. NAT'L HEALTH & MED. RESEARCH COUNCIL, ETHICAL GUIDELINES ON THE USE OF ASSISTED REPRODUCTIVE TECHNOLOGY IN CLINICAL PRACTICE AND RESEARCH 13 (2017). These provide an overarching framework for the conduct of ART in both clinical practice and research. *Id.*

45. NAT'L HEALTH & MED. RESEARCH COUNCIL, *supra* note 44, at 134.

what is necessary for a technology to cross that boundary. Further complicating any move to legalize the clinical use of mtD in Australia is the fragmented approach taken to the regulation of genetics. As discussed below numerous regulatory frameworks are relevant and discussions around mtD highlight the gaps and inconsistencies in those frameworks.

III. U.S. AND U. K. MTD POLICY —TWO ENDS OF THE SPECTRUM

Both the United States and United Kingdom have responded to the public's concerns over mtD.[46] Of particular significance are the U.K. Department of Health's 2014 responses to the public's concerns around mtD regulation in its *Mitochondrial Donation* Report (U.K. Dep't of Health Report) and the 2016 consensus paper by the U.S. National Academies of Sciences, Engineering and Medicine on policy issues associated with mtD, *Mitochondrial Replacement Techniques: Ethical, Social, and Policy Considerations* (U.S. NAS Report).[47] Drawing on these reports, Table 1 brings together the conclusions of policy analyses on behalf of government in the United Kingdom and United States in regards to the characterization of mtD.[48] Table 1 also includes this author's conclusions on these issues with respect to Australia.

Table 1 highlights the extreme divergence between the United Kingdom and United States on three fundamental issues raised by mtD: whether mtD is germline modification, whether mtD is human genetic modification, and what mtD means for kinship and identity. The following Sections consider the policy and regulatory contexts that explain these differences and lead to the conclusions suggested for Australia.

Table 1. Characterization of mtD

	United Kingdom	United States	Australia
Human germline modification	√	X	√
Human genetic modification	X	√	√
Kinship status of Mt donor and identity of child	X	?	√

46. Johanna Schandera & Tim K. Mackey, *Mitochondrial Replacement Techniques: Divergence in Global Policy*, 32 TRENDS GENETICS 385, 386 (2016).

47. U.K. DEP'T OF HEALTH REPORT, *supra* note 33; U.S. NAS REPORT, *supra* note 7.

48. To some extent the differences in the conclusions reflect the different tasks given to the investigative bodies but also reflect the background regulations of the two nations.

A. Human Germline Modification

The U.K. Dep't of Health Report concludes that mtD is human germline modification because changes will be passed onto future generations.[49] In contrast, the U.S. NAS Report concludes that mtD is *not* human germline modification.[50] For the U.S. NAS Report's purposes, germline modification is defined as "human *inheritable* genetic modification."[51] As such, the U.S. NAS Report recommends limiting the use of mtD to male embryos because this limitation avoids the technique being germline modification.[52] Confinement to male embryos reflects the science that mitochondria are inherited maternally. That is, in almost all cases only maternal mitochondria are passed on (through the egg) to the resulting child, and the father's mitochondria, although present in sperm, are not passed on.[53] Therefore, if the resulting child conceived using mtD is female, the changes will be inherited by that child's own children and descendants of her daughters; if it is male, the changes will impact only the particular resulting child.

Interestingly, the FDA may not agree with that interpretation of regulations under its authority, having warned the U.S. clinic discussed above that the creation of the male embryo was a violation of the prohibition on the creation of embryos with a *heritable* genetic modification.[54] Australian law prohibits intentional heritable changes to the human genome.[55]

The approach taken by the United States is not easily available in the United Kingdom and Australia, where embryo or gamete selection is prohibited unless necessary to *prevent* a child being born with a serious disease or disability.[56] In the case of mtD, the purpose of selection of male embryos would be to prevent inheritance of a modification made with the intention of assisting the resulting child, albeit that the modification may pose unknown risks to that child or their descendants.[57] It is unlikely that selection for such a purpose would satisfy current United Kingdom and Australian governance requirements.

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49. U.K. DEP'T OF HEALTH REPORT, *supra* note 33, at 15.

50. U.S. NAS REPORT, *supra* note 7, at 6–7.

51. *Id.* at 6 (emphasis added).

52. *Id.* at 89, 119–21.

53. *Id.* at 34.

54. Letter from Mary A. Malarkey to John Zhang, *supra* note 40.

55. *Prohibition of Human Cloning for Reproduction Act 2002* (Cth) s 15.

56. Human Fertilisation and Embryology Act 1990, *amended by* Human Fertilisation and Embryology Act 2008 c. 22 § 3, sch. 2 (UK). As to when a license will be granted for such selection, see Human Fertilisation and Embryology Act 1990 §§ 3(1)–(1A), 11 & sch. 2, ¶¶ 1ZA–B (UK); *Assisted Reproductive Treatment Act 2008* (Vict.) s 28; *Human Reproductive Technology Act 1991* (W. Austl.) ss 7 (1) (b), and 14 (2b); NAT'L HEALTH & MED. RESEARCH COUNCIL, *supra* note 44, at 69–72.

57. *See* U.S. NAS REPORT, *supra* note 7, at 119.

B. Human Genetic Modification

As Table 1 demonstrates, the U.S. NAS Report concludes that mtD is human genetic modification of human germ cells.[58] The U.S. NAS Report defines genetic modification as "changes to the genetic material within a cell" and does not require direct modification or editing of DNA.[59] Its conclusion on this classification as genetic modification was reached because mtD results in a novel combination of nuclear DNA and mtDNA that could not occur through unassisted sexual reproduction.[60] Australian legislation similarly excludes sexual reproduction from the definition of gene technology, which is its name for the technology that creates genetically modified organisms.[61]

In direct contrast with the conclusions in the U.S. NAS Report, the U.K. Dep't of Health Report concludes that mtD is not human genetic modification.[62] According to the U.K. Dep't of Health Report, genetic modification requires "germline modification of *nuclear* DNA . . . that can be passed on to future generations."[63] This does not occur in mtD. The U.K. Dep't of Health Report suggests that mtD is instead similar to organ transplants, blood donations, or somatic cell gene therapy, which are not genetic modification of an individual although a third person's DNA is present in the patient's body.[64] This conclusion was likely reached for two reasons. First, having conceded that mtD is heritable and therefore germline modification, the United Kingdom was in peril of legalizing inheritable changes[65] to the human genome if it also agreed that mtD is genetic modification. This would be an issue because the United Kingdom—along with the United States and Australia—is a Member State of the United Nations Educational, Scientific and Cultural Organization (UNESCO). UNESCO's *Universal Declaration on the Human Genome and Human Rights* suggests that human germline intervention could be contrary to human dignity.[66] Although, as noted in the U.K. Dep't of Health Report, the Declaration is not an international treaty and therefore contains no mandatory provisions, it does set

58. *See infra* Table 1

59. U.S. NAS REPORT, *supra* note 7, at 6.

60. *Id.* at 88.

61. *Gene Technology Act 2000* (Cth) s 10(1) (defining "gene technology").

62. U.K. DEP'T OF HEALTH REPORT, *supra* note 33, at 15.

63. *Id.* (emphasis added).

64. *Id.*

65. Notably, Australia similarly legislatively prohibits such changes. *Prohibition of Human Cloning for Reproduction Act 2002* (Cth) s 15 (Austl.).

66. U.N. Educational, Social and Cultural Organization Twenty-Ninth General Conference, *Universal Declaration on the Human Genome and Human Rights*, 41, U.N. Doc. 29 C/Res.16 (Nov. 11, 1997) (adopted by the U.N. General Assembly through G.A. Res. 53/168 (Feb. 11, 1999)). Article 24 of the Resolution states that the UNESCO International Bioethics Committee "should make recommendations, in accordance with UNESCO's statutory procedures, addressed to the General Conference and give advice concerning the follow-up of this Declaration, in particular regarding the identification of practices that could be contrary to human dignity, such as germ-line interventions." *Id.* at 46. This is not limited to germline interventions in nuclear DNA and the Declaration does not distinguish between mtDNA and nuclear DNA. *See id.* at 41–46.

out a framework of principles intended to guide Member States in the development of their national legislation.[67] The United Kingdom and Australian prohibitions on inheritable changes to the human germline reflect the Declaration's principles. Importantly, the United States is not in peril of acting contrary to the principles if the U.S. NAS Report's conclusions are correct that restricting mtD to male embryos prevents mtD being an inheritable change.

A second reason for the difference between the conclusions of the U.K. Dep't of Health Report and U.S. NAS Report on this point concerns the term *genetic modification*. The use of the term genetic modification in the two reports demonstrates the contrasting attitudes to that use. The U.S. NAS Report is upfront in stating on its first page that mtD is genetic modification.[68] In contrast, this issue is discussed much later in the U.K. Dep't of Health Report and even then, only to note that opponents to the proposed regulations allowing the clinical use of mtD, claim that mtD is genetic modification.[69] As noted above, the U.K. Dep't of Health Report then rejects that conclusion.

The United Kingdom and Australia have "baggage" associated with that term. Both jurisdictions have specific legislation addressing genetically modified organisms (GMOs).[70] That legislation is triggered by the process used to produce an organism. This is in contrast to the U.S. regulatory approach to GMOs, which focuses on the final product rather than the process or organism used to produce it. Australia's GMO legislation is particularly problematic here. The U.K. legislation has long excluded humans from the meaning of GMO.[71] With the moves towards legalization of the clinical use of mtD, the legislation was further amended in 2008 to ensure that it was clear humans and embryos that have undergone mtD are not GMOs.[72] On the other hand, Australian GMO legislation includes humans within the definition of regulated GMOs if they have been genetically modified, although it excludes humans where modification is through somatic gene therapy.[73] The Australian GMO legislation could safely take this approach to regulating human GMOs in the past because, as noted above, other federal legislation prohibits heritable changes to the human genome if that change is intended to be heritable.[74]

Experts in both the United States and United Kingdom have recognized significant confusion about the boundary between genetic modification to germline cells (causing heritable genetic changes) and somatic cells (causing

67. U.K. DEP'T OF HEALTH REPORT, *supra* note 33, at 16.

68. U.S. NAS REPORT, *supra* note 7, at 1.

69. *Id.* at 6, 14.

70. *Gene Technology Act 2000* (Cth) (Austl.); Environmental Protection Act 1990 c.43 (UK).

71. Environmental Protection Act 1990 (UK) (defining genetically modified organisms).

72. Human Fertilisation and Embryology Act 2008 section 60 added a reference to human embryos and human admixed embryos in section 106(2). Human Fertilisation and Embryology Act 2008 c. 22 §§ 60, sch. 3 (UK). A new subsection was also included in the Environmental Protection Act. *See id.* Together, these provisions make it clear that humans (and embryos) are not GMOs for the purposes of the legislative scheme protecting the environment when GMOs are released.

73. *Gene Technology Act 2000* (Cth) s 10 (defining GMO, genetically modified organism, and organism, but containing no definition for somatic gene therapy).

74. *Prohibition of Human Cloning for Reproduction Act 2002* (Cth) s 15.

nonheritable genetic changes).[75] The clinical use of mtD makes decisions on that boundary more urgent. The U.K. Dep't of Health Report's discussion of that boundary in the context of mtD rewards closer examination in light of this. It found that "[mtD] would be a new and distinct form of donation that falls somewhere between gamete donation and organ/tissue donation."[76]

If Australia chooses to legalize clinical use of mtD, it could do this by repealing the prohibition on heritable changes to the human genome. This is clearly not an available option given Australia's membership of the UNESCO Declaration. Alternatively, it could amend relevant legislation to allow embryo selection on the basis of sex to allow selection intended to avoid passing on the benefits and possible unknown risks of mtD. It is unclear whether the Australian public would agree with such a change, given the recent rejection of legalizing such selection, at least in the context of sex selection for family planning purposes.[77]

A third—and the most likely to be successful—alternative for Australia should it choose to allow the clinical use of mtD is to exclude mtDNA from the meaning of the human genome, a similar approach to that of the U.K. Dep't of Health Report. The Australian legislation prohibiting such changes (and the legislation which regulates research using human embryos) does not define genome or genetic material.[78] Similarly and relevantly, when addressing human embryo clones, the legislation makes no distinction between nuclear DNA and mtDNA. Instead a human embryo clone is defined in part as "a human embryo that is a genetic copy of another living or dead human" without express recognition that a "clone" would have different mtDNA to its founder, because creation of the clone would use a different egg to that used to create the founder.[79] Importantly, the legislation goes on to instruct that in establishing whether an embryo is a genetic copy of another (and therefore a clone), it is sufficient if the nuclear genes are copied, although it is not necessary to show the copy is an identical one.[80] MtDNA accordingly seems irrelevant in the legislation's understanding of genome and genetic material. Finally, recalling Australia's fragmented approach to the regulation of genetics, Australian GMO legislation (which, as noted above, applies to humans) defines gene technology as "any technique for

75. The U.S. NAS Report notes there needs to be clarification of the line between somatic cell genetic modification and germline modification, U.S. NAS REPORT, *supra* note 7, at 88, and further public deliberation on the acceptability of and moral limits to heritable genetic modification, *id.* at 13. The U.K. House of Commons Science and Technology Committee has noted the regulatory distinction between germline and somatic editing is the area of human genomics most in need of further investigation. SCIENCE AND TECHNOLOGY COMMITTEE, GENOMICS AND GENOME-EDITING: FUTURE LINES OF INQUIRY, 2016–17, HC 854, at 6 (UK).

76. U.K. DEP'T OF HEALTH REPORT, *supra* note 33, at 29.

77. NAT'L HEALTH & MED. RESEARCH COUNCIL, *supra* note 44, at 69.

78. *See Prohibition of Human Cloning for Reproduction Act 2002* (Cth); *Research Involving Human Embryos Act 2002* (Cth) s 7.

79. *Prohibition of Human Cloning for Reproduction Act 2002* (Cth) s 8(1) (defining "human embryo clone").

80. *Id.* at s 2.

the modification of genes or other genetic material."[81] Although it uses the term genetic material often, it has no definition of genetic material.[82] Because none of these frameworks differentiate between nuclear DNA and mtDNA, it is likely that the Australian legislature could exclude mtDNA from future definitions of the human genome.

C. What mtD Means for Kinship and Identity?

Jurisdictions regulate the various forms of kinship, such as adoption, surrogacy, gamete and embryo donation, differently to reflect their own cultural and policy concerns. Nevertheless, all will be challenged by the novel relationships created by mtD. In particular, issues around parentage and identity arise because the mtDNA donor's donation of an egg for use in mtD creates a genetic relationship between the resulting child and two women—the intending mother through nuclear DNA and mtDNA donor through mtDNA.

The U.S. NAS Report concludes the relevance of the contribution of genetic material from two women is "a matter for reflection by families" considering using the technique, and "for societal discussions related to conceptions of identity, kinship, and ancestry."[83] This is consistent with parentage in donor conception not being regulated by federal law, whether for mtD or not, although a model parentage Act has been adopted in eleven U.S. states in various forms.[84] Other states have their own legislation or rely on their courts to solve novel parentage disputes. Anonymous gamete donation is permitted in some U.S. states, even though some children may want to know their donor's identity.[85]

Pursuant to the model parentage Act, egg donors who do not intend to become a parent are not recognized as legal parents.[86] Genetic parentage in such cases is not addressed. However, the recent 2017 version of the model Act changes the provisions around parentage of children born with the assistance of ART.[87] All gamete donors, rather than only sperm donors as in the previous version, will now be a legal parent provided the gamete is provided with the

81. *Gene Technology Act 2000* (Cth) s 10(1) (defining "gene technology").

82. *See id.*

83. U.S. NAS REPORT, *supra* note 7, at 8, 102.

84. Leiser, *supra* note 37, at 423, 426. The relevant Act is the Uniform Parentage Act. UNIF. PARENTAGE ACT §§ 701–07 (UNIF. L. COMM'N 2002). Various parts of that Act have been adopted by Alabama, Delaware, Illinois, Maine, North Dakota, New Mexico, Oklahoma, Texas, Utah, Washington, and Wyoming. *Parentage Act*, UNIFORM L. COMMISSION, http://www.uniformlaws.org/Act.aspx?title=Parentage%20Act [https://perma.cc/AT8S-KP5L].

85. *See* June Carbone, *Negating the Genetic Tie: Does the Law Encourage Unnecessary Risks?*, 79 UMKC L. REV. 333, 338–40 (2010). The Uniform Parentage Act, 2017 includes a new article (Article 9) which requires gamete banks and fertility clinics to ask donors whether they consent to identifying information being disclosed when the resulting child attains 18 years of age. UNIF. PARENTAGE ACT §§ 901–06 (UNIF. L. COMM'N 2017).

86. *See* UNIF. PARENTAGE ACT §§ 701–07 (UNIF. L. COMM'N 2002) (particularly § 7.02).

87. UNIF. PARENTAGE ACT § 703 (UNIF. L. COMM'N 2017).

intent that the gamete provider be a parent.[88] Whether there can be more than two genetic parents of one child is not addressed.[89]

The United Kingdom, on the other hand, has a nationally applicable regulatory framework providing for parentage in donor conception.[90] The framework includes statutory donor linking regulations, allowing children to have identifying information about their genetic donors.[91] However, the U.K. Dep't of Health Report concludes that although the resulting child following mtD will have DNA from three individuals, the mtDNA donor is not a genetic donor for the law's purposes.[92] Resulting children, therefore, will *not* have a right to know the mtDNA donor's identity.[93] The new U.K. regulations are consistent with the report's conclusions. MtDNA donors are not treated as gamete providers despite the fact that they provide the egg used to create the embryo.[94] Only nuclear DNA donors are treated as gamete providers.[95] This means mtDNA donors have no genetic or legal parental status with respect to resulting children.[96] Instead, mtDNA donors are treated like organ donors and their identity is not disclosed.[97]

As noted above, clinical use of mtD is prohibited in Australia. If such use occurred though, in contrast with both the United States and United Kingdom, mtDNA donors are likely to be considered gamete providers and therefore would be a resulting child's genetic parent.[98] However, mtDNA donors would not be legal parents of the child because state legislation severs the legal relationship between the resulting child and gamete donors (including mt

88. *Compare* UNIF. PARENTAGE ACT § 703 (UNIF. L. COMM'N 2017) ("An individual who consents under Section 704 to assisted reproduction . . . is a parent of the child."), *with* UNIF. PARENTAGE ACT § 703 (UNIF. L. COMM'N 2002) ("A man who provides sperm for, or consents to, assisted reproduction . . . is a parent of the resulting child."). As of early 2018, no state has adopted the new version of the legislation, but three states—Washington, Rhode Island, and Vermont—have introduced it. *Parentage Act (2017)*, UNIFORM L. COMMISSION (2017), http://www.uniformlaws.org/Act.aspx?title=Parentage%20Act%20(2017) [https://perma.cc/PRB4-GTLM].

89. UNIF. PARENTAGE ACT § 703 (UNIF. L. COMM'N 2017).

90. *See* Human Fertilisation and Embryology Act 2008, c. 22 (UK). Part 2 regulates parenthood in ART. *Id.* at §§ 33–58 (UK).

91. Human Fertilisation and Embryology Act 1990, § 31 (UK).

92. U.K. DEP'T OF HEALTH REPORT, *supra* note 33, at 29–30.

93. *Id.* at 30.

94. Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015, SI 2015/562 6–7, ¶ 18 (U.K.), *amending* Human Fertilisation and Embryology Act 1990, c. 22 § 54 (UK).

95. *Id.*

96. Explanatory Memorandum to the Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015, at 4, ¶ 7.9 (UK).

97. U.K. DEP'T OF HEALTH REPORT, *supra* note 33, at 29–30.

98. Legal parentage in donor conception in Australia is a matter for states and territories. All jurisdictions have their own legislation. *See Parentage Act 2004* (Austl. Cap. Terr.); *Status of Children Act 1996* (N.S.W.); *Status of Children Act 1978* (N. Terr.); *Status of Children Act 1978* (Queensl.) s 8(6); *Family Relationships Act 1975* (S. Austl.) s (6)(1); *Status of Children Act 1974* (Tas.); *Status of Children Act 1974* (Vict.); *Artificial Conception Act 1985* (W. Austl.); *see also* Karinne Ludlow, *Genes and Gestation in Australian Regulation of Egg Donation, Surrogacy and Mitochondrial Donation* 23 J. L. & MED. 378, 381–87 (2015).

donors).[99] In stark contrast with the United Kingdom's final approach on the issue of identification of mtDNA donors, because mtDNA donors would be genetic parents under Australian state law, the resulting child would be entitled to know the donor's identity.[100]

Other legislative difficulties arise with the clinical use of mtD in Australia. While current state legislation and professional guidelines do not impose a restriction on a child having more than two genetic parents, federal legislation prohibits the creation of human embryos with genetic material from more than two persons.[101] If Australian regulatory frameworks are amended to exclude mtDNA from the definition of genetic material as discussed above, this prohibition will not apply to the clinical use of mtD. However, given that the prohibition was included specifically to prevent the clinical use of mtD,[102] it is more likely the provision will be repealed if the clinical use of mtD is legalized. Such an approach leaves the child's rights to know the mtDNA donor's identity intact.

The impact of mtD and the nonidentification of the mtDNA donor on the resulting child's identity and their self-perception is still largely unknown, although children's experiences following conception through gamete donation provide some insight.[103] The U.S. NAS and U.K. Dep't of Health Reports' conclusions around this issue are, as with the issues discussed in Sections III.A and III.B above, at different ends of the spectrum of possibilities. Again, this can be explained by reference to the policy and regulatory context in both jurisdictions. In particular, the U.K. Dep't of Health Report's approach can be explained by reference to the issues around the term genetic modification discussed above, which are not relevant to the U.S. context. Nevertheless, for the reasons discussed below, it is observed here that the U.K. Dep't of Health Report is disingenuous in its justification of its conclusions around identity.

Both reports note that the traits carried in nuclear DNA are those the public most closely associates with the core of genetic relatedness.[104] However, while the U.K. Dep't of Health Report concludes that mtDNA does not determine

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99. *Parentage Act 2004* (Austl. Cap. Terr.) s 11(3); *Status of Children Act 1996* (N.S.W.) s 14; *Status of Children Act 1978* (N. Terr.) s 5E; *Status of Children Act 1978* (Queensl.) s 17; *Family Relationships Act 1975* (S. Austl.) s 10C(2); *Status of Children Act 1974* (Tas.) s 10C; *Status of Children Act 1974* (Vict.) ss 10E, 13, 14, 15, 19; *Artificial Conception Act 1985* (W. Austl.) s 7.

100. *Assisted Reproductive Technology Act 2007* (N.S.W.) s 37; *Assisted Reproductive Treatment Act 2008* (Vict.) ss 49–68; *Human Reproductive Technology Act 1991* (W. Austl.) s 49; *see also* NAT'L HEALTH & MED. RESEARCH COUNCIL, *supra* note 44, at 45, ¶ 5.6 & 46–7, ¶ 5.9 for other states.

101. *Prohibition of Human Cloning for Reproduction Act 2002* (Cth) ss 13, 23. Implantation of such embryos into the body of a woman or animal is also prohibited. *Id.* at s 9; *see also Research Involving Human Embryos Act 2002* (Cth) s 10A.

102. PETER HEEREY ET AL., LEGISLATION REVIEW COMM., REPORT OF THE INDEPENDENT REVIEW OF THE PROHIBITION OF HUMAN CLONING ACT 2002 AND RESEARCH INVOLVING HUMAN EMBRYOS ACT 2002 57–61 (2011) (Austl.).

103. NUFFIELD COUNCIL ON BIOETHICS, *supra* note 33, at 70–72; U.S. NAS REPORT, *supra* note 7, at 99–101.

104. U.K. DEP'T OF HEALTH REPORT, *supra* note 33, at 26–30; U.S. NAS REPORT, *supra* note 7, at 8.

"personal characteristics or traits" of resulting child,[105] the U.S. NAS Report is more open in its acknowledgment that some traits result from mtDNA, such as energicity or athleticism.[106] Relevantly here, the U.K.'s Nuffield Council on Bioethics concluded it was difficult to draw a distinction between the impact of nuclear or mtDNA therapy and the effect on identity.[107] The Council also observed that if a person benefited from mtD so that they were born without the risk of mitochondrial disease, this may impact significantly on their idea of self-conception of identity and genetic identity.[108] Notably, while the U.S. NAS Report refers to the Council's conclusions on the impact of mtD on identity, the U.K. Dep't of Health Report does not.[109]

The U.K. Dep't of Health Report goes on to use its conclusions on the lack of impact of mtDNA on the identity, personal characteristics, or traits of the resulting child to justify its conclusions in regards to genetic parentage and the sharing of identifying information about the mtDNA donor.[110] The U.S. NAS Report does not do this largely because it does not address the issue of genetic parentage in great detail given that this is a matter for state regulation in the United States.[111] In particular, the U.K. Dep't of Health Report justifies its conclusion that mtDNA donors are not the resulting child's genetic parents by using legal parentage status.[112] For the purposes of consultation, the U.K. public was asked the following question on the subject of mtDNA donors: "Do you agree that people donating eggs and embryos for the purposes of mitochondrial donation should *not* have the same status as those donating eggs and embryos for use in fertility treatment, but rather be regarded more like organ or tissue donors?"[113] It is not made clear by the consultation paper[114] nor the U.K. Dep't of Health Report itself, whether status here is intended to refer to genetic or legal parentage. The reference to organ donation is unhelpful in clarifying this given it raises no parentage issues. However, from the surrounding statements in each document it seems genetic parentage was the intended subject.[115]

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105. U.K. DEP'T OF HEALTH REPORT, *supra* note 33, at 29–30. Evidence given by the U.K. Chief Medical Officer, Professor Dame Sally Davies, to the U.K. House of Commons Science and Technology Committee when it was considering mtD, took an approach similar to that of the U.K. Dep't of Health Report. SCIENCE AND TECHNOLOGY COMMITTEE, MITOCHONDRIAL DONATION, 2014–15, HC 730, at 25 (UK).

106. U.S. NAS REPORT, *supra* note 7, at 107.

107. NUFFIELD COUNCIL ON BIOETHICS, *supra* note 33, at 57, ¶ 4.27.

108. SARAH BARBER & PETER BORDER, STANDARD NOTE SN/SC/6833: MITOCHONDRIAL DONATION 23 (2015) (UK) (citing NUFFIELD COUNCIL ON BIOETHICS, *supra* note 33, at 56–57).

109. U.S. NAS REPORT, *supra* note 7, at 99.

110. U.K. DEP'T OF HEALTH REPORT, *supra* note 33, at 29–30.

111. *See* U.S. NAS REPORT, *supra* note 7, at 101–02.

112. U.K. DEP'T OF HEALTH REPORT, *supra* note 33, at 27, 29.

113. *Id*. at 26; *see also* HEALTH SCI. & BIOETHICS DIV., DEP'T OF HEALTH, MITOCHONDRIAL DONATION: CONSULTATION ON DRAFT REGULATIONS TO PERMIT THE USE OF NEW TREATMENT TECHNIQUES TO PREVENT THE TRANSMISSION OF A SERIOUS MITOCHONDRIAL DISEASE FROM MOTHER TO CHILD 20 (2014) [hereinafter U.K. DEP'T OF HEALTH CONSULTATION PAPER] (UK).

114. U.K. DEP'T OF HEALTH CONSULTATION PAPER, *supra* note 113.

115. U.K. DEP'T OF HEALTH REPORT, *supra* note 33, at 27–29; *see also* U.K. DEP'T OF HEALTH CONSULTATION PAPER, *supra* note 113, at 20–22.

The criticism arises because the U.K. Dep't of Health Report alternates between genetic and legal parentage when the two are not necessarily tied together. It notes that egg donors are not *legal* parents of any resulting child despite contributing 50 per cent of the child's genes.[116] It does not explain that egg donors are nevertheless the *genetic* parents of such child and that it is only through legislative intervention that egg donors are not also the child's legal parents. Instead, the U.K. Dep't of Health Report explains the background around the mtDNA donor's status in the following way.

> The regulations clarify that a mitochondrial donor is *not* to be treated as a person who would or might be the parent of a resulting child if it was not for the provisions in the 1990 and 2008 Acts removing parenthood. This is in contrast to the legal position for sperm and egg donors, who *are* treated as people who would or might be the legal parent of a child born from their donation but for the provisions in the 1990 and 2008 Acts.[117]

The lack of legal parentage together with the dismissal of any material impact on personal traits are then used in the U.K. Dep't of Health Report to justify characterization of the genetic link between a child and its mtDNA donor as remote and the consequential recommendation to share only nonidentifying information of the mtDNA donor as in organ donation scenarios.[118]

The characterization of mtDNA donation as more like organ donation than nuclear DNA donation is not criticized here. However, the reliance on the lack of impact of mtDNA on the resulting child's personal traits is a weakness in the U.K. Dep't of Health Report. Gestational surrogate mothers, through the gestation of a child and consequential epigenetic impacts on the child, can have serious impacts on the resulting child's identity, personal characteristics and traits. Yet, while such mothers are not recognized under U.K. law as genetic parents, they are nevertheless the legal parent at birth.[119] The U.K. Dep't of Health Report's reasoning demonstrates an inconsistency in U.K. genetics policy around the relevance of a genetic link in predicting parentage.

IV. SUMMARY AND CONCLUSIONS

Many jurisdictions will look to the first-mover responses of the United States and United Kingdom in deciding whether to legalize clinical mtD. However, while the science behind mtD is universal, regulatory responses are not. The United Kingdom and United States have divergent approaches to the fields

116. U.K. DEP'T OF HEALTH REPORT, *supra* note 33, at 29.

117. *Id.* at 27.

118. *Id.* at 29–30.

119. Pursuant to Human Fertilisation and Embryology Act 2008, the birth mother is the legal mother. *See* Human Fertilisation and Embryology Act 2008, c. 22 § 33 (UK). Intending parents can apply for a parental order if one of the intending parents provided gametes to create the relevant embryo. *Id.* at § 54; *see also* Samantha Nicholson & Caroline Nicholson, *I Used to Have Two Parents and Now I Have Three? When Science (Fiction) and the Law Meet: Unexpected Complications*, 35 MED. & L. 423, 432 (2016).

relevant to mtD: ART and embryo research. The United Kingdom has been described by others as having a "robust regulatory framework" for ART and embryo use, while the United States has no such framework.[120] It is therefore no surprise they differ in their approach to mtD governance.

Nevertheless, the studied approaches can inform future governance arrangements in other jurisdictions considering clinical mtD. As demonstrated by the analysis above, the central issue for decision-making around clinical mtD is classification of mtD's characteristics. One fundamental classification choice is whether to distinguish between nuclear and mitochondrial DNA. This is particularly important to the decision on whether mtD is human genetic modification. Jurisdictions will need to assess the implications of that choice for their regulation of embryo research and genetic modification technology more generally. As the Australian position demonstrates, for example, consideration should be given to whether legislation is consistent in addressing (or not) the distinction between nuclear and mitochondrial DNA.

Further classification choices arise because the relevant DNA is in human germ cells. Decisions around whether mtD is therefore germline modification highlight assumptions made in the past in this area of regulation. For example, Australia's exclusion of human somatic cell genetic modification from its genetic modification regulations is useful if it is assumed that there are only two forms of genetic modification—germline and somatic. But as the U.K. Dep't of Health Report explains, additional classifications may be needed for mtD. The choice by the United States to use embryo sex selection to prevent mtD causing permanent changes to the human genome is another example of reliance on particular assumptions. This approach assumes sex selection is acceptable for purposes other than preventing a disease or disability in the resulting child. That may not be acceptable to all jurisdictions.

Finally, choices must be made around the classification of the relationship between mtDNA donors and the resulting child as genetic or legal parentage. It may be that when the traits which nuclear and mtDNA respectively code are more properly understood by both science and the public, assumptions like those made by the U.K. Dep't of Health Report (i.e., genetic disease and disability do not impact a child's phenotype, and mtDNA donation does not warrant identification of the donor to the resulting child) will need revision.

Looking at human genomics more broadly, mtD is not the only emerging technology challenging current regulation: Genome editing and stem cell science raise further challenges. The U.S. National Academy of Science has recently completed a thorough review of the science, ethics and governance of human genome editing.[121] Similarly, the United Kingdom began an inquiry into genomics and genome editing in 2016, but this was closed prematurely because

120. U.K. DEP'T OF HEALTH REPORT, *supra* note 33, at 41.

121. *See* COMM. ON HUMAN GENE EDITING: SCI., MED., & ETHICAL CONSIDERATIONS, U.S. NAT'L ACADS. OF SCIS., ENG'G, & MED., HUMAN GENOME EDITING: SCIENCE, ETHICS, AND GOVERNANCE (2017).

of the June 2017 general election in that country.[122] The Australian Health Ministers' Council recently released a draft consultation paper, *National Health Genomics Policy Framework 2017–2020*, recognizing that Australia lags behind other countries in "developing national genomic policies, regulations, and capacity building."[123]

Any amendments responding to mtD should therefore be part of a broader review of a nation's genomic policies and regulations. It has been over a decade since the World Health Assembly urged Member States to frame genomics policies.[124] Developments in human genome editing increase the need to pursue such policies. While mtD is a novel technology, it is not unique in the pressure it places on policy makers to ensure governance keeps pace with science.

122. *See Genomics and Genome-Editing Inquiry—Publications*, PARLIAMENT.UK, https://www.parliament.uk/business/committees/committees-a-z/commons-select/science-and-technology-committee/inquiries/parliament-2015/inquiry2/publications/ [https://perma.cc/Q7GT-FNLN]; *see also* SCIENCE AND TECHNOLOGY COMMITTEE, GENOMICS AND GENOME-EDITING: FUTURE LINES OF INQUIRY, 2016–17, HC 854 (UK).

123. AUSTRALIAN HEALTH MINISTERS' ADVISORY COUNCIL, DEP'T OF HEALTH, NATIONAL HEALTH GENOMICS POLICY FRAMEWORK 2017–2020 (CONSULTATION DRAFT) 14 (2016).

124. Fifty-Seventh Session of the World Health Assembly, *Genomics and World Health*, 16, U.N. Doc. WHA57/2004/REC/1 (May 22, 2004).