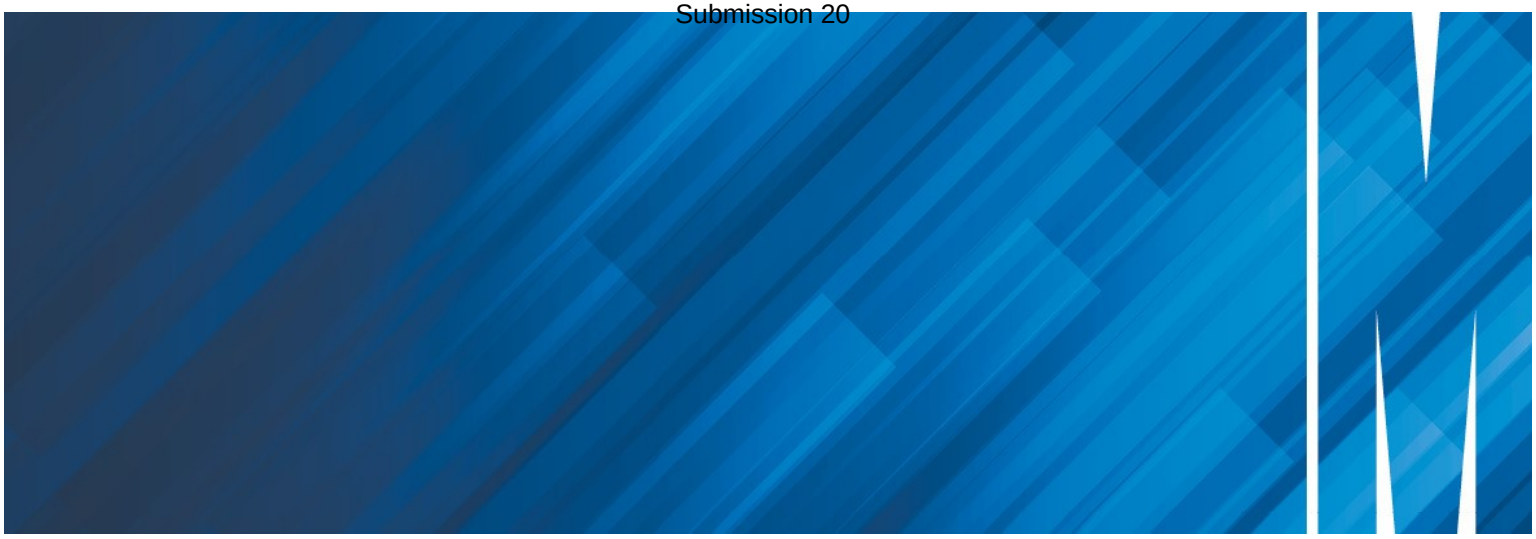

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11 May 2018

Dear Committee Members.

Thank you for the opportunity to contribute to the Inquiry into the Science of Mitochondrial Donation and Other Matters.

We are the Chief Investigators of an ongoing Australian Research Council-funded study into 'The legal and ethical aspects of the inheritable genetic modification of humans: The Australian context' (ARC DP170100919). This project focuses on the ethical and legal aspects of mitochondrial donation and CRISPR-Cas9.

We hope our research to date assists the Committee in considering the legal and ethical aspects of mitochondrial donation and associated matters.

Sincerely,

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OVERVIEW

Mitochondrial donation is a relatively new scientific advance in the sphere of assisted reproductive technologies. It allows for the replacement of mitochondrial DNA affected by mutations in a human egg (ovum) or zygote by transferring the nuclear DNA into a healthy donated egg that is not affected. The aim of this is to stop the transmission of mitochondrial disease that is inherited from the maternal line.

In 2015, the British Parliament legalised the clinical use of mitochondrial donation. Significantly, these techniques allow for interventions that may be inherited by all subsequent generations of offspring of the person that the modified embryo may grow to be. Further, the embryo created using mitochondrial donation contains the genetic material of three people. The USA is cautiously moving in a similar direction, though with some key differences.

These international developments raise significant questions about the moral and legal permissibility of mitochondrial donation, which Australia must address now in order to moderate undesirable effects and capitalise on positive ones. Clinical use of this technique is currently prohibited under Australian legislation, as are some forms of basic research. However, the breadth of that prohibition and the legal consequences of amendment to legalise some or all uses of these techniques are unclear. Further, the normative justification for continuing prohibition or amending the law must be examined in light of the new realities of human genetic modification.

Given the uniquely interdisciplinary nature of our research team, we are able to provide insight across the Senate Inquiry terms of reference. In the following submission, we particularly address topic B - safety and efficacy, and ethical considerations, as well as topic E - legal changes that may be required if mitochondrial donation is introduced in Australia. Other topics, such as the impact on Australian families, are also touched on throughout our discussion.

Our study also comprises qualitative interviews with scientists, policy makers, disability representatives, and people living with mitochondrial disease. Interviewees are asked to speak to how viable heritable genetic modification techniques are, what ethical issues might be associated with them, what the arguments in favour and against are, and how effective the Australian ethics and policy landscape is in this context. Data collection and analysis is currently underway. However, we present select preliminary findings for the Committee's consideration in this submission.

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1. B: ETHICAL CONSIDERATIONS, INCLUDING SAFETY AND EFFICACY CONCERNS

1.1 Genetic interventions in assisted reproduction have traditionally been seen as characterised by a moral 'bright line' that separates **somatic (non heritable) from germline (heritable) modifications**. Many see heritable modification as objectionable on grounds of safety and ethics. Mitochondrial donation sits in an ambiguous position to this distinction, due to the uncertain status of mitochondrial DNA.

There are **notable differences in how the UK, US, and Australia respond to fundamental questions** related to mitochondrial donation. For example, both Australia and the UK treat mitochondrial donation as a kind of germline modification, unlike in the US. Somewhat in contradiction, UK regulation does not treat mitochondrial donation as a form of inheritable *genetic* modification, which they limit to heritable changes to nuclear DNA.

The US have sidestepped the issue of heritability by recommending that only male embryos are selected following mitochondrial donation, to ensure that no modified mitochondrial DNA is later passed on. This effectively nullifies the most widely acknowledged issue with germline modification, that it has roll-on effects for future generations. However, this option requires the sex selection of embryos for non-medical reasons, which is currently not permitted in Australia.

For the purposes of this submission, we consider mitochondrial donation under the umbrella of 'heritable genetic modifications', which we define as genetic changes that can be passed on to subsequent generations.

- However, our interviews suggest mitochondrial donation is not seen as posing the same 'slippery slope' risks as, for example, gene editing (eg. using CRISPR-Cas9), which risks being misused to enhance personal characteristics. Our respondents considered mitochondrial donation as more difficult to misuse than gene editing.

1.2 Much of the public debate of mitochondrial donation focuses on the issue of **safety**; however, these concerns are unlikely to rule out the use of the technology in the longer term.[1] It is never possible to know in advance whether new reproductive technologies will risk the health of the children born as a result, or their descendants. **The first use of any new reproductive technology will be essentially experimental and risk unanticipated consequences for those children born of it**, no matter how carefully it has been tested *in vitro* or in animal models. Presuming that it is implausible to argue that it would *never* be ethical to trial a new reproductive technology, the real question about risk, then, is**:** *when* it is ethical to impose unknown risks on future children?

- Interviewees for our project agree that ensuring the **safety of mitochondrial donation** is paramount, and also point out that some degree of uncertainty at the time that this technology enters clinical use will be unavoidable. One interviewee suggested that a licensing model similar to that used in the UK would help to ensure a sound and well regulated environment for mitochondrial donation in practice.

In determining the appropriate balance of risks and benefits, mitochondrial donation has to be assessed in the **context of existing (medical) options for potential users**, ie women affected by mutations in mitochondrial DNA who wish to reproduce and seek to ensure that their child does not inherit mitochondrial mutations from them. Existing reproductive options, such as Preimplantation Genetic Diagnosis (PGD), may be objectionable to some prospective parents on religious grounds, since it entails the destruction of embryos. Moreover, PGD is not reliable for the detection of mitochondrial disease, since PGD tests one cell of a very early embryo, and mitochondrial diseases may not appear in all cells. Nevertheless, there are safe reproductive options available, such as the use of donor gametes (eggs), or in some circumstances, adoption. The promotion of mitochondrial donation as the only option for prospective parents affected by these conditions is premised on the unquestioned value of genetic parenthood (see further on this below).

We believe it is important to maintain transparency and accuracy in discussions about the **therapeutic efficacy** of mitochondrial donation. Mitochondrial diseases can be caused by mutations in nuclear DNA that control mitochondria, as well as mitochondrial DNA. While the latter of these is inherited maternally, the former follows Mendelian patterns of inheritance. Further, in some cases, mitochondrial disease results from new (de novo) mutations in genes and occurs in people without any family history of the disease. It is important in discussions of mitochondrial donation that its capacity to 'cure' mitochondrial disease is not overstated. In fact, this technology only addresses mitochondrial disease that arises from mitochondrial DNA. There are also efficacy and safety issues to consider here, such as the current incomplete understanding of the interaction of donor DNA with nuclear DNA.

For mitochondrial donation to be performed as safely and ethically as possible, the whole of a patient's medical team (including specialists, general practitioners, genetic counsellors, etc) will need regularly updated **training and education about the technology**. As mitochondrial donation would enter the clinical sphere as a novel medical technology, it should not be assumed that this expertise would be currently available. Potential introduction of the technology also requires developing expertise in the clinical setting in advance.

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1. 3 Other ethical considerations beyond safety and efficacy also arise with mitochondrial donation. One concern is the relatively **unquestioned moral value of its therapeutic purpose.** The perceived benefits and moral permissibility of mitochondrial donation and other genetic modification technologies typically rest on their utility in correcting genetic disorders in human embryos. Indeed, it has been argued that it would be morally negligent not to use genetic technologies for this reason where possible.[2]

However, the identification of a condition as a disability or disease, and thus as eligible for treatment, is informed by cultural and medical conceptions of normality. While these may have a profound impact on the experience of living with a condition, they do not necessarily determine that experience.[3] The perspectives of persons living with disabilities may challenge the "therapeutic imperative" that drives much discussion of inheritable genetic modification.[4] In fact, inheritable genetic modification raises questions not only about the first-person valuation of life with disability, but wider societal valuations as well.

Disability scholars have argued that using genetic selection technologies constitutes a form of **discrimination against people with disabilities** insofar as it 'sends a message' to persons with disability that their lives are not worth living.[5] This expressive characteristic may also be born out by inheritable genetic modifications, including mitochondrial donation. Further, inheritable genetic modification also raises the possibility of a world in which some genetic conditions no longer exist. For most commentators, this seems an unmitigated good. But from another perspective, it raises questions about the social value of disability and the loss entailed in its elimination, and the correlative reduction in genetic diversity. Garland Thomson has recently made a case for the importance of conserving disability, while Sparrow has criticized this idea.[6]

The "therapeutic imperative" is underpinned by a **conception of disability and disease** that sees these as necessarily a harm that ought to be prevented or avoided.[7] It is often taken for granted in contemporary debates that procreators should be at liberty to make decisions about reproduction – including when, how, with whom – based on their own values. But typically this autonomy is limited to actions that do not cause significant harm to others, prompting questions about what constitutes harm, and what is significant enough as to place limits on liberty. These questions are especially complicated in regards to reproduction, where harm may be considered either 'person affecting' or 'non-person-affecting'. This distinction emerges from the so-called 'non-identity problem', which indicates that, so long as a congenital condition is not so bad as to make life not worth living, then no harm is done to the person born with that condition (since otherwise they would not be born at all). In relation to mitochondrial donation, one question this raises is about the extent to which women affected by mitochondrial disease who are seeking to reproduce would be obliged to or feel pressured to use the technology of mitochondrial donation if it were available.

While there is currently no data about **attitudes toward mitochondrial donation** from persons with mitochondrial disease themselves in Australia [such data will be compiled as part of this project], there is some data from the UK. This suggests that attitudes toward mitochondrial donation of women affected by mitochondrial disease is varied. For instance, while some women were not opposed to making mitochondrial donation available, they expressed reluctance about using the technology themselves. This was because of concerns about safety and not wanting to undertake what is essentially an experimental procedure, or a more general sense that mitochondrial donation overly technologized pregnancy. For these reasons, women sometimes expressed a preference for safer alternative options such as donated gametes and/or adoption.[8]

1. 4. The prospect of the clinical use of mitochondrial donation has generated significant concern about **the genetic parenthood of children created using the technique**. There has been much media and bioethics discussion of '3-parent babies', and the implications this might have for the resulting children and for ideas of parenthood. Some commentators worry that, if used widely, such techniques would precipitate a rupture in familial and personal narratives, possibly in ways that do damage to personal identity, especially to the children born of the technology.[9] However, this line of thinking remains underdeveloped, and the normative implications of such a rupture in narratives of identity are unclear.

Further, it remains unclear **whether mitochondrial donors should be considered parents**, at least in a minimal genetic sense. UK legislation treats mitochondrial donors as equivalent to organ, rather than gamete (egg or sperm), donors. This means that they have no rights to a parental relationship with the recipient of their mitochondrial DNA (or parental obligations to them). However, the reasoning behind this decision is inconsistent it hinges on the supposedly inconsequential status of mitochondrial DNA, at the same time as mitochondrial donation is seen as necessary because of the significant consequences of mitochondrial DNA.[10] Other analysts, including the US National Academies and the Nuffield Council of Bioethics, acknowledge that mitochondrial DNA might also contribute to personal characteristics in ways that are not yet well understood.

Concerns about the capacity of assisted reproductive technologies to "**confuse and disrupt" our understanding of kinship, parenting and familial identity** have been central to bioethical discussion of genetics for some time. This capacity is further increased with mitochondrial donation, since it not only raise questions about the value of genetic relatedness, but also fundamentally disrupts our understanding of what it entails (ie. two genetic progenitors rather than three). While it has long been recognised that being a genetic progenitor is not *necessary* to establish parenthood (as in adoption), it is something else again to suggest that being a genetic progenitor is not *sufficient* to establish genetic parenthood.

Establishing parenthood has significant implications, both ethical and legal. For instance, recent interventions consider the obligations parents acquire in bringing children into the world.[11] It may be that inheritable genetic modification technologies

extend the obligations that parents have to their own children in various ways. For instance, if a genetic modification affects not only the resultant child, but also that child's offspring, what, if any, obligations do the parents have to the 'more than next' generation? Legally, the status of parenthood may potentially allow children born of mitochondrial donation to find out information about their donor. This is discussed further in the following section of this submission.

E: LEGAL FRAMEWORKS AND CHANGES THAT WOULD BE REQUIRED IF MITOCHONDRIAL DONATION WAS TO BE INTRODUCED IN AUSTRALIA

Consideration of these moral topics has direct bearing on the legal frameworks that regulate research and clinical application of technologies using human embryos and assisted reproductive technologies in Australia. However, the relevant legislation and NHMRC Guidelines were developed in a context where inheritable genetic modification technologies such as mitochondrial donation were not yet clinically feasible. In light of recent technological and legal developments, a question arises as to whether, and if so how, Australian and State legislation ought to be reformed in order to meet this new reality.

If legalised, regulation of mitochondrial donation will **span federal regulation of embryo use and state regulation of clinical assisted reproductive technologies** in a novel fashion. Multiple governance bodies will be implicated in any attempt to legalise clinical use of mitochondrial donation.

2.1 LEGALITY OF TECHNIQUE'S USE - We draw the Committee's attention to a forthcoming publication by Ludlow (2018), which analyses possible governance responses to mitochondrial donation, noting in particular the following:

- The most straightforward legal route would be to treat mitochondrial DNA as separate from the human genome. This approach parallels the UK process and resonates with existing legislation of embryos and cloning, as well as current legal definitions of genetic material and the genome, which are highly opaque. There are alternative approaches but these raise their own, not necessarily insurmountable, challenges:
    - Repeal the prohibition on heritable genetic changes or include an exception allowing the technique, which may contravene UNESCO's Universal Declaration on the Human Genome and Human Rights, to which Australia is a signatory; or
    - Revise regulation around embryo sex selection to enable the technique's use only in male embryos, which could attract opposition given the recent public rejection of sex selection in family planning contexts.
- **Key definitional issues must be resolved before legislation can be developed around mitochondrial donation** include:
    - Whether this technology constitutes genetic modification / gene technology according to current definitions;
    - Whether it can be considered either germline or somatic modification, and whether this distinction remains useful; and
    - How mitochondrial and nuclear DNA should be defined and regulated.
- A regulatory framework for clinical use will need development, addressing governance issues such as access to the technique for reasons other than to address mitochondrial disease.

2.2 PARENTAGE AND KINSHIP - We draw the Committee's attention to a publication by Ludlow (2015), which summarises current legislation across Australian federal and state jurisdictions regulating Australian genetic and legal parentage through the lens of mitochondrial donation, noting in particular the following:

- **Parentage and kinship in Australia is regulated at the state level**. By current definitions, a mitochondrial DNA donor would likely be considered to be the resulting child's genetic, though not legal, parent in all jurisdictions. In such an arrangement, the child would have access to information on the donor's identity.

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- All jurisdictions require that the genetic origins of the resulting child be certain. This does not prevent mitochondrial donation but constrains the implantation of more than one embryo into one woman where mitochondrial donation has been used.

There are lessons to be taken from the development of legislation around mitochondrial donation in other countries. For example, the UK, US, and Australia differ in many critical respects: the UK treats mitochondrial donation as germline modification, yet UK regulation does not consider it to be *genetic* modification. UK legislation also positions mitochondrial DNA donors as more analogous with organ rather than gamete (egg or sperm) donors, redacting any rights to a parental relationship with the resulting child. However, the reasoning behind these decisions is inconsistent and does not align with the views of some international bodies, for example the US National Academies and the Nuffield Council of Bioethics.

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[1] Lanphier, E. et al. 2015. Don't Edit the Human Germ Line. *Nature*. 519(26 March): 410-411. Harris, J. 2015. Germline Manipulation and Our Future Worlds. *Am J Bioeth*. 15(12): 30-4.

[2] Harris, J. 2007. Enhancing Evolution: The Ethical Case for Making Better People. Princeton: Princeton UP.

[3] Warren, N. and L. Manderson. eds. 2013. *Reframing Disability and Quality of Life: A Global Perspective*. Springer: Dordrecht.

[4] Scully, J.L. 2006. IGM and Disability: Normality and Identity. In *The Ethics of Inheritable Genetic Modification: A Dividing Line?*. J.E.J. Rasko, G.M. O'Sullivan, and R.A. Ankeny (eds). Cambridge: Cambridge UP: 175-192.

[5] Parens, E. and A. Asch. 2000. *Prenatal Testing and Disability Rights.* Washington D.C: Georgetown UP.

[6] Garland Thomson, R. 2012. The Case for Conserving Disability. *J Bioeth Inq*. 9(3): 339-55. Sparrow, R. 2015. Imposing Genetic Diversity. *Am J Bioeth*. 15(6): 2-10.

[7] Mills, C., 2011. *Futures of Reproduction: Bioethics and Biopolitics.* Dordrecht: Springer.

[8] Herbrand, C. 2017. Mitochondrial replacement techniques: who are the potential users and will they benefit? *Bioethics*. 31(1): 46-54

[9] Baylis, F. and J.S. Robert, 2006. Radical Rupture: Exploring Biological Sequelae of Volitional Inheritable Genetic Modification. In *The Ethics of Inheritable Genetic Modification: A Dividing Line*?, J.E. Rasko. et.al, eds. Cambridge: Cambridge UP: 131-148.

[10] For a fuller discussion, see Ludlow, K. 2018. The policy and regulatory context of US, UK and Australian responses to mitochondrial donation governance. Jurimetrics. Forthcoming

[11] DeGrazia, D. 2012. *Creation Ethics: Reproduction, Genetics and Quality of Life*. New York: Oxford UP. Prusack, B.G. 2013. *Parental Obligations and Bioethics: The Duties of a Creator*. New York: Routledge.

APPENDIX 1: ACADEMIC ARTICLES FOR FURTHER REFERENCE

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.

CITATION: Karinne Ludlow, *The Policy and Regulatory Context of U.S., U.K., and Australian Responses to Mitochondrial Donation Governance*, 58 JURIMETRICS J. 247–265 (2018).

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

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).

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

Karinne Ludlow*

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".

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[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"

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Target Article

Imposing Genetic Diversity

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The idea that a world in which everyone was born "perfect" would be a world in which something valuable was missing often comes up in debates about the ethics of technologies of prenatal testing and preimplantation genetic diagnosis (PGD). This thought plays an important role in the "disability critique" of prenatal testing. However, the idea that human genetic variation is an important good with significant benefits for society at large is also embraced by a wide range of figures writing in the bioethics literature, including some who are notoriously hostile to the idea that we should not select against disability. By developing a number of thought experiments wherein we are to contemplate increasing genetic diversity from a lower baseline in order to secure this value, I argue that this powerful intuition is more problematic than is generally recognized, especially where the price of diversity is the well-being of particular individuals.

Keywords: disability, diversity, ethics, human enhancement, PGD, prenatal testing

The idea that a world in which everyone was born "perfect" would be a world in which something valuable—a certain richness that flows from diversity—was missing often comes up in debates about the ethics of technologies of prenatal testing and preimplantation genetic diagnosis (PGD). Our imperfections and our deviations from the norm are, it is commonly held, part of what makes life interesting. This thought plays an important role in the "disability critique" of prenatal testing (Wendell 1996, 82–83).[1] However, the idea that human genetic variation is an important good with significant benefits for society at large is also embraced by a wide range of figures writing in the bioethics literature, including some who are notoriously hostile to the idea that we should not select against disability.

In this article I argue that this powerful intuition is more problematic than is generally recognized, especially where the price of diversity is the well-being of particular individuals. The article makes use of an argumentative strategy advocated by Bostrom and Ord (2006), which they call the "reversal test." In order to detect and compensate for the human tendency toward "status quo bias," these authors suggest that whenever we are inclined to evaluate negatively a possible change to our circumstances we should try to imagine how we would feel if the situation were the reverse: that is, if we were contemplating a change from the imagined future to our current circumstances. Thus, so as to become clearer about the value of genetic diversity and how we should feel about the prospect of a loss of diversity as a result of the use of technologies of genetic selection, I propose a number of thought experiments wherein we are to contemplate increasing genetic diversity from a lower baseline in order to secure this value. After discussing the implications of these thought experiments and surveying possible responses to them, I conclude that, although the idea that there is a value in genetic diversity is compelling, precisely how much value there is and what we should be prepared to sacrifice to achieve it remains mysterious.

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1. The "disability critique" of prenatal testing contains a number of different argumentative strands (Parens and Asch 1999) and the claim I discuss here is only one—and perhaps not even the most compelling—of these. In particular, the argument of this article leaves untouched the matter of whether or not the use of technologies of prenatal testing and/or preimplantation genetic diagnosis "sends a message" that the lives of disabled individuals are of less value than those of healthy individuals (see, e.g., Asch 1989; 2000; Kaplan 1993; Saxton 1997). I have discussed this question elsewhere (Sparrow 2008). Note also that respect for the reproductive liberty of parents—the importance of which disability advocates have rightly emphasized—may mitigate any threat to diversity posed by regimes of prenatal testing and/or preimplantation genetic diagnosis, if sufficient numbers of parents are willing to resist the social pressures to have "perfect" children; my concern here is with a particular philosophical defense of the value of diversity in the face of these pressures.

THE VALUE OF GENETIC DIVERSITY

Garland-Thomson and the Case for Conserving Disability

In a fascinating and important paper entitled "The Case for Conserving Disability," Rosemarie Garland-Thomson (2012) responds to contemporary bioethical enthusiasm for technologies of genetic selection with a passionate defense of the value of what would be lost were these technologies to become widely adopted. Instead of understanding disability merely as a tragedy to be overcome or eliminated, Garland-Thomson suggests, we should recognize it as a valuable resource to be conserved. According to Garland-Thomson, disability is a *narrative* resource insofar as the encounter with "freakish" bodies teaches the nondisabled how to be more human, and the experience of disability facilitates and underpins narratives that unite the human community (2012, 344–345). Disability is an *epistemic* resource because the experiences of "variant bodies" produce distinctive "ways of knowing" and make possible new forms of aesthetic expression and evaluation (2012, 346–347).[2] Finally, disability is an *ethical* resource because the existence of disability requires us to be open to "the unbidden" and to be creative and flexible in our relation to the world; it also reminds and prepares us for the "inevitable growing into disability inherent in the human condition" (2012, 348–349).

There is a lot going on in Garland-Thomson's paper and I am unable to do justice to all of her arguments here. Garland-Thomson is also working with an expansive definition of disability, as "the transformation of flesh as it encounters world. . . . Disability occurs when the shape and function of bodies come into conflict with the shape and stuff of the world" (2012, 340), so her argument is presumably intended to have implications for therapeutic practice more generally and not just for the ethics of genetic selection. However, Garland-Thomson explicitly develops her argument against what she describes as "eugenic logic" (Garland-Thomson 2012, 340; see also Mitchell and Snyder 2003) and situates it in relation to contemporary debates about genetic testing and selective abortion. Moreover, the case she makes for disability as a resource relies crucially on the idea that disabled bodies are *different* bodies: it is because, and to the extent that, disabled bodies vary from (imagined) "normal" bodies that disability generates new narratives, ways of knowing, and ethical insights. Thus, while Garland-Thomson may be willing to endorse more expansive claims, at the very least she holds that genetic variation, including variations that produce impairment, should be seen as a resource to be conserved.

2. See also Scully (2008) and Wendell (1996, 68–76).

Savulescu and the Value of Individual Variation

I originally conceived of this article solely as a response to Garland-Thomson. However, as I was writing it, I became increasingly conscious that the value of genetic diversity is recognized much more widely and that appeals to the value of this diversity pop up in the most surprising places in debates about the ethics of genetic selection.[3]

Julian Savulescu is a conscious and enthusiastic advocate of what Garland-Thomson describes as "eugenic logic." Indeed, Savulescu is notorious for defending the existence of a generalized obligation of "procreative beneficence" (Savulescu 2001; Savulescu and Kahane 2009). According to Savulescu, not only are intending parents morally obligated to make use of preimplantation genetic diagnosis in order to prevent the birth of children with disabilities, but they have an obligation to use technologies of genetic selection to have the "best child possible."

In a number of critical responses to Savulescu's work, I have argued that an obligation to have the best child possible would require all parents in a given environment to reproduce using clones of the same embryo, selected to possess the best genome for that environment (Sparrow 2007; Sparrow 2011a; Sparrow 2014a). While there may be reasonable disagreement among parents as to what counts as the "best" genome in a given environment, any plausible "obligation" of procreative beneficence must require parents to do what actually is best for the child, rather than merely to do what they think to be best (Sparrow 2007). Moreover, because "best" is a maximizing notion, parental choices should converge on whichever genome will provide a child with the highest possible expected

3. One important version of this claim argues that genetic diversity should be preserved for the benefit of the species. Thus, John Harris (2011) and Paula Casal (2013) have argued (in response to Sparrow [2010a; 2010b; 2011b]) that we should be prepared to sacrifice the welfare of our children in order to reduce the risk that a decline in sexual diversity will threaten the capacity of human beings to reproduce, while Chris Gyngell (2012) has argued that it might be necessary to restrict access to genetic enhancement technologies in order to maximize the chance that descendants of some human beings at least will flourish under as large a range of selective pressures as possible (see also Powell 2012). However, the appeal to the welfare of the species in this argument—rather than the individuals of which it is composed—is problematic for reasons that would take me to too far from my interests in the current article to discuss, so I do not consider it here (but see Sparrow 2011c). Note, however, that the argument I develop in the following would also seem to apply to this version of the claim.

welfare in the environment they are expected to grow up in.[4]

Savulescu has resisted this attempted *reductio* at a number of levels—and I have not space available here to assess the adequacy of each response (Savulescu 2014; Savulescu and Sparrow 2013; Sparrow 2014b). However, one of Savulescu's arguments has been an appeal to the value of diversity: a world full of clones would, he suggests, be "boring" (Savulescu and Sparrow 2013, 53). Even this most enthusiastic advocate of reshaping the human genome to maximize well-being is moved to embrace the value of diversity when confronted by the logical conclusion of his arguments—which is a world of striking uniformity.[5]

An Observation

Note that while Garland-Thomson and Savulescu both argue that some diversity is justified, they need not—and probably do not—agree on the precise nature of the benefits that genetic diversity provides. As a committed consequentialist, Savulescu would presumably argue that the existence of the sorts of diversity he endorses increases both total and (if the population size does not change) average welfare over what it would have been in its absence. Garland-Thomson suggests that disability is a resource that "generates circuits of meaning making in the world" (2012, 344). Other defenders of diversity have claimed that it "is necessary for creating a vibrant and sustainable society" (Hurst 2009) or is a good simply in itself (Murphy 1994; Parens 1995) without, explicitly at least, committing themselves to the further claim that these qualities result in improvements in the well-being of any individual.[6]

Interestingly, though, both Garland-Thomson's and Savulescu's arguments have the character of theodicies, of the sort so ably satirized by Voltaire in *Candide* (Voltaire 2005). Although they disagree about precisely how much genetic diversity we should celebrate, Savulescu and Garland-Thomson agree that, with regard to some forms of genetic variation at least, this world is the best of all possible worlds: were these forms of genetic variation to be eliminated, the world would be a poorer place.[7]

APPLYING THE REVERSAL TEST

I now want to set out two hypothetical scenarios that suggest that the appeal to the value of diversity in the arguments just discussed is much more problematic than generally recognized. What follows, then, is a philosopher's thought experiment—or, rather, series of thought experiments—with all the dangers of oversimplification, misrepresentation, and distortion of our judgments that this involves.[8] Moreover, in order to draw out the intuitions that interest me—and that are, I believe, central to the plausibility of the argument about the value of diversity—the scenarios I describe are necessarily rather farfetched. Nevertheless, I believe that they accurately represent the structure of the argument involved when each of the authors I have discussed appeals to the value of

4. The emphasis on maximization in the key papers on procreative beneficence and the references to "the best" in the text of these papers—and occasionally in their titles (Savulescu 2001; Savulescu and Kahane 2009)—encourages readers to understand procreative beneficence as extremely demanding and as requiring parents to select the single "best" embryo of the embryos available to them. However, in a recent exchange with the author (Savulescu 2014; Sparrow 2014a; Sparrow 2014b), Savulescu has clarified his position to acknowledge that in many circumstances there may be a number of embryos with "equally good" genomes (Savulescu 2014; even in this paper, however, Savulescu's opening sentence affirms "that couples have a moral obligation to use genetic selection to have *the* best child, of the possible children they could have"! [my emphasis]). Where this is the case, procreative beneficence requires parents only to choose a child from among the set of children with an expected welfare not worse than that of any of the others available to them. Acknowledging this possibility renders the principle of procreative beneficence both much more plausible and much less controversial; moreover, one wonders how much this concession is compatible with any case for "human enhancement" given that (one presumes that) most normal individuals would have genomes that are equally good as each other—and as good as those of putatively enhanced individuals. To the extent that some genetic diversity is compatible with individuals having equal expected welfare, Savulescu's arguments will only imply a reduction in the extent of genetic diversity, rather than the complete collapse thereof. However, it is also clearly possible that one embryo might have a genome that was clearly superior over all others in a given environment—in which case his arguments will have the implication I explore here.

5. Interestingly, in a paper that I only became aware of after having finished a draft of this article, Savulescu's former PhD supervisor, Peter Singer, also refers to the possibility that the aggregate impact of parents' decisions in relation to genetic selection might result in a loss of diversity as a reason to objecting to the "genetic supermarket" (Singer 2003). Like Savulescu, Singer is usually associated with the idea that we should strive to eliminate disability through genetic selection rather than conserve it. My thanks to Robert Ranisch for drawing this paper to my attention.

6. As well as insisting that "the diversity of human forms" is a good in itself (149), Parens (1995) also suggests that diversity is necessary for our "experience of some forms of the beautiful" (145) and "the good that is some relationships of care" (149); the latter two are more obviously benefits that accrue to individuals.

7. Strictly speaking, it is open to Garland-Thomson to hold that a world with even more genetic diversity would be still better—and in this sense our world is not the best of all possible worlds. Nevertheless, insofar as she presents her argument as a case for conservation rather than promotion of disability, I take it that she would be reluctant to claim this.

8. For a useful reminder of the dangers involved in these sorts of thought experiments see Scully (2008, 172–174).

diversity. I therefore ask the reader to bear with me in considering what we should think about these admittedly very artificial cases before we return to the larger question of the significance and value of genetic diversity when it comes to policy around, for instance, PGD, genetic screening, and genetic testing.

The scenarios are intended to facilitate the "reversal test" advocated by Bostrom and Ord to detect and remedy the effects of "status quo bias" in human reasoning (Bostrom and Ord 2006). Human beings are subject to a number of well-documented cognitive biases, which distort our judgments and decision making (Kahneman and Tversky 2000; Tversky and Kahneman 1974). One of these is "status quo bias," which is the tendency to overvalue—and consequently rationalize—the state of affairs that currently exists and with which we are most familiar (Samuelson and Zeckhauser 1988). The mere fact that things "are this way" makes us more likely to believe that they should be this way. Bostrom and Ord suggest that status quo bias plays a major role in motivating popular—and sometimes philosophical—resistance to the use of science and technology to transform our current circumstances. In order to test whether this is the case or not, they suggest that we should compare our intuitions about moving from our current circumstances to some future possible state of affairs with what we would find it plausible to say about a case wherein we were contemplating a move from the possible future state of affairs to our current circumstances. If it would be implausible not to regret the change from the possible future state of affairs to our current circumstances, Bostrom and Ord argue, then resistance to moving from our current circumstances to the possible future state of affairs should be understood as the result of status quo bias.

In order to become clearer on the value of genetic diversity, then, the following scenarios encourage the readers to consider how they would feel if the choice were not about conserving genetic diversity but rather imposing it.

Scenario I: Imposing Disability

Imagine that . . .

> On April 7, 2050, a mysterious seismic upheaval was recorded occurring deep within the earth's core and was later recognized to be correlated with dramatic and perplexing consequences for human health; since that date the rate of a wide range of congenital impairments due to genetic factors has declined to the point where it is now effectively zero. Scientists are still arguing about the precise mechanism whereby this change has had such a profound influence on human genetic variation, with the leading theory involving a hitherto unrecognized role played by trace amounts of radionucleotides diffusing into the water supply from the earth's mantle. Nevertheless, its effects are undeniable. Children are no longer being born with Down syndrome, cystic fibrosis, congenital adrenal hyperplasia, many forms of cleft palate, and so on. Of course, despite ongoing advances in medical care, people are still injured in accidents and suffer the effects of ageing. Moreover, unfortunately, whatever process or processes have led to the decline in these conditions have not led to similar decline in the rates of more debilitating genetic illnesses, such as Lesch–Nyhan syndrome—conditions where one might well think that it would have been better for the affected individuals if they had never been born at all.[9] Nevertheless, while the world is not entirely bereft of people with disabilities, the number of people with disabilities has been drastically and—it would appear—permanently reduced.

Garland-Thomson and others swayed by her arguments arguably should hold that this is a change for the worse. If we have reason to conserve disability then we have reason to regret this change. Thus, we might imagine . . .

> A group of public-spirited bioethicists has come up with the idea of introducing a mutagen into the water supply, with the intention of restoring the rate of genetic variation—and congenital impairment—to what it was before the recent precipitous decline and thus ensuring a more diverse world. They are confident that this policy would not directly harm anyone; rather, it would bring it about that different people (with disabilities rather than without disabilities) will be born (the mutagen works by making it easier for sperm carrying genetic disorders to fuse with ova, rather than by damaging genes in existing embryos: it does not affect the rate of birth of persons with the most severe genetic conditions).

Scenario II: Imposing Variation

Now, imagine, instead, that . . .

> The year is 2131. In the second and third decades of the 21st century, the Oxford–Uehiro Centre for Practical Ethics went from strength to strength: its publications became eagerly awaited by policymakers and the public alike; its members were treated like rock stars, with their every utterance dissected and discussed all over the world. The idea that parents should have "the best child possible" passed into folk wisdom. Consequently, in 2030 a powerful popular movement arose that demanded that national governments identify those traits that would provide children with the highest expected welfare and/or openness of future and make cloned embryos, with the genetics most associated with those traits, available to intending parents. For the last 100 years, all children born have had this cloned genome and lived in unsullied health,

9. This feature of the scenario is intended to facilitate restriction of the discussion of the value of diversity to cases where the imposition of diversity would not be "person affecting" (Parfit 1984, 351–379), where I believe it is most plausible, for reasons that will become clear in the following. In fact, Garland-Thomson's paper contains an extended discussion of the value of even very severe disability, including consideration of the lessons that might be drawn from the life of Emily Rapp's son Ronan, who was born with Tay–Sachs syndrome (Rapp 2013), in which she emphasizes that we are often too quick to make the judgment that the lives of others are "not worth living" (Feinberg 1986). Nevertheless, it is striking that Emily Rapp herself admits—as Garland-Thomson acknowledges—that had her son's condition been diagnosed in pregnancy she would have chosen to terminate the pregnancy.

> with a cheery disposition, an IQ of 160 (relative to today's baseline), and with the same blue eyes, chiseled cheekbones, and perfect teeth.[10] Genetic diversity has been entirely eliminated from this society.

Savulescu's published remarks suggest that the lack of diversity in this world is something to be regretted. However, we might also imagine that . . .

> A renegade group of scholars remains convinced that these circumstances have established a dystopia and is plotting a daring raid on the government clone banks, with the aim of substituting a diverse population of embryos for the official clone. While all of these embryos have been chosen so that the child can expect a long, healthy and happy life, only one of these embryos is "the best"—the rest are suboptimal in one way or the other, if not dramatically so. Some individuals will be less good-looking than others, some more inclined to musicality but also to moodiness, some will have blond or red hair and be more prone to sunburn than others, and so on.

DISCUSSION

Although these two hypotheticals are fanciful, it is relatively easy to imagine real-world analogues to at least the first of them. Instead of manipulating the water supply after a mysterious seismic event, we might consider, for instance, outlawing the use of PGD and of prenatal testing and selective abortion from a society in which these technologies had become a matter of routine in the course of reproduction. The dilemma in the second scenario merely tests our intuitions about how much we should try to "perfect" our children through whatever technologies are available to us.

In any case, the two scenarios need not map directly onto real-world cases for the intuitions they evoke to be relevant to real-world problems. It is therefore, I suggest, worth thinking about should we feel about the policy of imposing diversity in these hypotheticals. The answer to this question is not straightforward, and for that reason I begin by setting out what might be said for, and then against, imposing diversity in these cases. Note that the structure of the two scenarios, as I have described them, is the same. In both cases, we are confronted with the choice as to whether or not to impose diversity and thus realize its value by bringing it about that some people are born with (what looks to be) lower expected welfare than others and with lower welfare than other people who might have been born in their place; the choice to impose diversity would not directly harm or benefit any individuals but would rather alter who came into the world. The fact that the cases have the same structure strongly suggests that—unless we can find a convincing way of drawing a line between them—we should treat them alike.

The Case Against Imposing Diversity

One possible—and not implausible—response to these scenarios is to deny that the proposed change would be justified in either of the hypothetical cases. There are, I think, three reasons why one might have this intuition.

First, one might simply deny that diversity in and of itself has any value at all: Why should mere variation be something that we care about? The value of diversity is so often lauded that we may lose sight of the fact that it is not self-evident. Note, however, that while Garland-Thomson and/or some other disability advocates may do so, neither of the authors I've discussed need hold that diversity is an intrinsic good. Savulescu, for instance, seems to hold that its value is instrumental; we enjoy diversity and thus its presence contributes to our welfare. The claim that diversity makes the world more interesting, or existence richer, may also interpreted as a claim that diversity is an instrumental good.

Second, even if we are willing to allow that diversity is intrinsically valuable or is instrumentally valuable in achieving some other good, we may be reluctant to act so as to secure such diversity at the cost of some individuals having lower expected welfare than others at birth and having lower expected welfare than other individuals that might have been born in their place. One version of this objection would concede that we might be justified in principle in imposing diversity in some cases but deny that it would be justified in either or both of those that I have outlined here; the obvious question to ask then is, what grounds we have for making this discrimination? A stronger version of the objection would deny that we are ever justified in sacrificing the welfare of some individuals in this fashion in order to generate benefits for others; I explore this latter intuition further in the following.

Obviously, genetic diversity is not the only kind of diversity. A third option, then, is to argue that because diversity will still exist in both of these scenarios as a result of various contingencies across the course of the human life span, there is no need to impose it. Garland-Thomson argues, quite correctly, that "disability is inherent in the human condition" and that "we will all become disabled if we live long enough" (2012, 339).[11] If diversity is ineliminable, though, then arguments about its value are inapposite. A concern for the value of diversity gives us no reason to try to impose or conserve it, as this value will be realized regardless.

10. For an argument that this would be the endpoint of the pursuit of the "best child possible" given social pressures in many societies today, see Sparrow (2011a). However, because, as I stated earlier, the "best genome" will always be relative to an environment, it is in fact unlikely that clones of one embryo would be the best child possible everywhere in the world. Nevertheless, the basic point that in any given environment Savulescu's arguments should motivate parents to choose the same set of genes for their children at the expense of diversity remains valid, and I hope I will be forgiven the rhetorical exaggeration here for the sake of simplicity and the larger argument.

11. See also Asch (1999) and Davis (1995, 8–9).

The Case for Imposing Diversity

On the other hand, nor is it entirely implausible, I think, to bite the bullet and support the imposing of diversity in each case. Many people might support the actions of the rogue bioethicists in Scenario II, for instance, in order to avoid the uneasiness associated with a world of clones and because the difference in the welfare of the worst off citizens afterward remains relatively minor. Where people may recoil, however, is at the idea of imposing disability, in Scenario I. We typically think of disability as something to be avoided—as something that is bad for the people who suffer it. Thus the idea that we should impose it in order to make the world a better place seems troubling.

Of course, if, as disability advocates have sometimes seemed to suggest, disability need have no implications for individuals' expected welfare (see, e.g., Swain and French 2000), then perhaps we should not flinch at imposing even genetic diversity that leads to disability. Yet because we are typically not indifferent to changes in our children's capacities as a result of environmental influences (Harris 2007, 1–2), I suspect that it is implausible to hold that differences in capacities as a result of genetic factors have no implications for well-being over the course of an individual's life. If I am confident that my infant daughter's life would go worse were she to lose both her legs, then it seems I should also believe that it would have been worse if she had been born without legs rather than with legs.[12] Our attitudes toward changes in our own circumstances also imply that we are willing to extrapolate from capacities to expected welfare. Thus, as Tom Shakespeare has observed, even those disability advocates who deny that impairments need correlate with any reduction in well-being are typically reluctant to allow their own capabilities to diminish further (Shakespeare 2006).

Moreover, it is difficult to see how genetic diversity could generate the goods that Garland-Thomson lists without it also having implications for well-being. Disability (and genetic diversity) is a narrative resource precisely because and insofar as it shapes the experiences of those who encounter it both in themselves and in others. Similarly, disability is an epistemic resource to the extent that it generates differences in the way we experience the world. The different experiences produced by being disabled are ones that one might reasonably desire to seek out or avoid. More importantly, as suggested earlier, they are experiences that one might reasonably evaluate when it comes to the decision about whether one should seek them out or avoid them on behalf of one's children. Indeed, Garland-Thomson (2012, 349–351) is explicit that the disability that generates these goods may also involve extensive suffering. Suffering—or, at the very least, a reduction in welfare—would also appear to be necessary in order for disability to serve as an ethical resource by providing the opportunity to "build solidarity with others . . . [and] cultivate human sympathies" (Garland-Thomson 2012, 348). Even when it comes to the diversity Savulescu endorses in the service of making the world less "boring," it would be surprising if genetic differences that did not matter at all to the welfare of individuals were sufficient to do much by way of achieving this goal. Again, it is precisely because small differences like hair color also make a (small) difference to individuals' experiences over the course of their lives that they are of interest to us; diversity in absolutely trivial things does not do much, if anything, to enrich our experience of the world.[13]

However, the fact that no one is harmed by imposing diversity makes the counterintuitive choice more palatable than might first appear even in Scenario II.[14] Those people with disabilities who do come into existence as a result of the presence of the mutagen in the water will have good lives, which they would not have had otherwise, and will therefore be happy for the fact. Given that the world is made better (more diverse) and no one is harmed by the policy, imposing even genetic disability is arguably the right thing to do.

Kantian Concerns

Note that for a sufficiently committed consequentialist, the decision to impose diversity in each case will be straightforward: if the more diverse world contains a greater amount of whatever we value, we should impose diversity.[15] However, as is often the case, this clear statement of a consequentialist argument also draws our attention to a competing and compelling intuition that seems Kantian in nature: achieving diversity in this way seems to require us to sacrifice the welfare of some individuals for the sake of a social good and thus to "use" them in a manner that seems problematic. The force of this thought may be clarified by considering one final thought experiment.

12. Again, this is not to deny that, as disability activists have argued, many of the implications of not having legs for the welfare of individuals are a product of the social environment and could be addressed through social and institutional reforms (Oliver 1996).

13. Savulescu's main philosophical ally in the argument for human enhancement, John Harris, is very clear that small differences in capacities may have implications for welfare (Harris 2007, 93).

14. Where imposing diversity involves harming existing persons (e.g., by injuring them so they become disabled) in order to make the world a more diverse place, then it is, I think, obviously indefensible. For this reason, I suspect that any larger claim that we should conserve disability by, for instance, not curing injury and illness in existing persons where we can, which Garland-Thomson may intend, is likely to be implausible.

15. Utilitarians will typically be concerned with *total* or *average* welfare. As noted earlier, if Savulescu is right, these may both be higher after the imposition of diversity in Scenario II; nor is it implausible to believe that if Garland-Thomson is right, these are both higher after the imposition of diversity in Scenario I (although Garland-Thomson does not herself make this argument).

Scenario III: The "Genetic Scapegoat"

Imagine that . . .

> The world of "cosmetic" diversity advocated by Savulescu has come about, as the result of universal adoption of PGD and prenatal testing (and selective abortion) to prevent the birth of children with less than perfect health. However, a group of empirically minded bioethicists, inspired by disability advocates, have conducted a careful study and established that levels of both total *and average* well-being are actually significantly less now than they were when the same number of people existed but there were just a few very severely disabled people present in the community. They hypothesize that this is because the presence of some people with severe disabilities produced benefits for the other members of the community, who were able to cultivate and display various virtues in their relations with these people and to lead richer and happier lives because of it. More problematically, the recognition among the majority of the community that they were (much) better off than the people with disabilities may also have enhanced their welfare insofar as having a higher welfare than others may itself be a (status) good.

Thus . . .

> These bioethicists propose that the government should deliberately bring into existence a small number of people with very severe disabilities, who will have lives that are only barely worth living, instead of the same number of healthy individuals. The contribution of the presence of these individuals to the welfare of others will greatly increase total and average well-being.

I am inclined to believe that imposing diversity in this case would be repugnant. To deliberately create persons with very severe disabilities to increase aggregate and average social welfare in this way would be to sacrifice the welfare of these persons in order to serve the interests of others.[16] Of course, to talk of the welfare of particular individuals being sacrificed is not strictly speaking accurate, as these individuals will be no better off if the government decides not to bring them into existence. Nevertheless, there is a clear sense in which the existence of the disabled persons and the nature of their circumstances would be a function of their contribution to the social good rather than a concern for their welfare; they would be "genetic scapegoats." This is not true of other citizens, whose perfect genetic health is a product of a concern for their welfare. The genetic scapegoats would be a means to a utopian (dystopian?) social end.

Importantly, any willingness to endorse the creation of the genetic scapegoats would also appear to license other types of genetic social engineering that are equally if not more horrific. Thus, for instance, we might imagine selecting individuals for their capacity to perform menial labor and to be happy while doing it, on the grounds that it is better for everyone that those people who perform these tasks are happy while doing so (Huxley 1970). Alternatively, we might bring individuals into existence who were genetically predisposed to die at 13 to serve as sources of organs for other citizens. Like the creation of genetic scapegoats, these initiatives would provide great social benefits without harming anyone. Yet such initiatives are paradigmatic instances of the sorts of policies that people decry when they worry that the development and application of technologies of genetic selection will usher in a "Brave New World" (Appleyard 1998, 62–64).

However, if we reject imposing diversity in the "genetic scapegoat" scenario, this strongly suggests that we should also reject imposing it in the other scenarios, as the structure of the choice involved is the same in each case. That is, arguably in all of the scenarios in the preceding, the cost of achieving diversity is to bring about the existence of some individuals who have lower welfare than others and also lower welfare than other individuals who might have been born in their place.[17] Moreover, the lower welfare of these individuals is a consequence of their having been brought into existence as a means of producing a social good, which is enjoyed primarily by other persons.

The case of the genetic scapegoat—and the Kantian intervention it motivates—therefore suggests to me that the imposition of diversity for the sake of its benefits should be profoundly controversial. This implies in turn that the argument for the conservation of diversity is equally problematic.

Conservation Versus Imposition

An important line of thought in response to the larger argument I have made here is to deny the relevance of the intuitions summoned by the reversal test. Garland-Thomson (2012, 341) explicitly describes her own argument as an argument for conservation, rather than, for instance, protection, and situates it alongside the case for conservation of biodiversity and historical architecture, noting that

> These conservation initiatives are based on the concept of valuing a historically sedimented environment as it has materialised over time and in response to both random and intentional influences that shape that environment. The principle of honouring the "is" rather than the "ought," the contingent rather than the intentional nature of an environment, is what I wish to capture with the word conservation.

16. Notice that in this case the lower welfare of the person with the genetic disorder is necessary to the production of the goods associated with "diversity." Those who wish to deny that differences in capacities correlate with differences in well-being will presumably need to deny the very possibility of this scenario.

17. The example of the "genetic scapegoat" is therefore a key test case in evaluating the plausibility of recent arguments that parents have an obligation to consider the welfare of parties other than the child themselves when making decisions about reproduction. See, for instance, Douglas and Devolder (2013) and Elster (2011).

Thus, it might be argued that diversity that we have imposed would be different from the diversity that we find in the world as it is—and therefore that we should not conclude from a reluctance to impose diversity that we have no reason to conserve it. I have a good deal of sympathy for this line of thought, which resonates interestingly with recent arguments about the virtues of "species relativism" developed by Agar (2010). However, arguably this strategy works—if it works—by, in effect, embracing status quo bias. One might well question why the mere fact that people happen to have been born with some particular range and set of disabilities means that we should cherish the situation. Insisting on the value of the existing extent of diversity at birth seems especially tendentious, given how much this distribution is itself already a product of the history of improvements in public health, midwifery and obstetrics, diet, and medical technologies. Moreover, were this principle to be applied more broadly, it would argue against any change in the human condition. Absent a further, satisfying, account as to the moral significance of particular contingencies, I regret that I cannot see that this line of argument succeeds in establishing why we should conserve what we would be unwilling to impose.[18]

CONCLUSION: WHAT PRICE DIVERSITY?

The intuition that something important would be lost should everyone come to be born "perfect" as a result of the use of technologies of genetic selection is a compelling one. Diversity clearly makes the world a more interesting place and the idea that we should conserve genetic diversity is therefore tempting. Yet when we imagine imposing genetic diversity to secure this same good, its value is revealed as elusive, especially if we concede that it must be achieved at the cost of the well-being of some individuals whose existence has been used to produce a benefit enjoyed mainly by others. If we would be unwilling to impose diversity in order to realize its value, this also suggests that, despite Garland-Thomson's provocative exposition of the case for conservation of disability, we have little reason to conserve genetic diversity by restricting the use of technologies of genetic selection.[19] Thus, perhaps the most interesting implication of my own investigation, then, is that, insofar as the value of diversity offers little ground for resisting the "eugenic logic" that Garland-Thomson deplores, the logical outcome of such eugenic logic—a world of striking uniformity—would appear both more likely and more disturbing.

18. One obvious way of defending the conservation of diversity where we would not be willing to impose it is to insist on the moral significance of the distinction between acts and omissions. Yet, again, it is hard to see how this differs from simply asserting the moral significance of the status quo; moreover, the significance of the acts/omissions distinction is itself controversial.

19. Moreover, as is suggested in note 14 earlier, the case for conserving disability at the cost of the welfare of existing individuals is even more tendentious.

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