Genetic identity concerns in the regulation of novel reproductive technologies

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ABSTRACT

Confusion concerning a child’s genetic identity is a common objection to the application of novel technologies to human embryos. Unsurprisingly then, concern for genetic identity has been used to justify successive waves of regulatory activity and is again appearing in debates about regulatory responses to emerging reproductive technologies. By examining the history of Australian law’s understanding and responses to so-called genetic identity in the context of past and current scientific developments in reproductive technology, this paper investigates regulatory reform needed for still emerging reproductive technologies. While this paper presents and analyzes in some detail Australian regulation and the policy deliberations and scientific developments that led to them, the identified inconsistencies in the regulatory responses, and recommended reforms to address emerging reproductive technologies offered, address issues relevant to many countries responding to the same technologies.

KEYWORDS: regulation, reproductive technology, genetic identity, innovation

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Novel reproductive technologies raise concerns about children’s genetic identity. As Douglas and Devolder explain, such technologies create widening opportunities for children to inherit genomes in ways substantially different from standard forms of human reproduction. The use of donated gametes, development of reproductive cloning, clinical use of mitochondrial replacement, genome editing of human embryos, and creation of stem cell-derived (SCD) gametes are part of an expanding repertoire of such technologies. But despite extensive debates on the morality of altering a future individual’s essential characteristics through reproductive technologies, the meaning of genetic identity remains unclear. Indeed, the term identity is itself subject to numerous understandings.

Turning to the law’s understanding of genetic identity, while concern for children’s genetic identity is often used to justify regulatory responses to reproductive technologies, the components of an individual’s genetic identity and the relationships included by the term is unresolved. The Singaporean Bioethics Advisory Committee places genetic identity as one aspect of personal identity, but what the Committee includes in genetic identity is unclear. A specialist committee of the US National Academies of Sciences, Engineering and Medicine identified the issue of confusion about identity in its discussion of policy considerations relevant to mitochondrial replacement, arising because of the presence of DNA from two women. That Committee said confusion could arise in multiple ways: around whether the child had ‘some shared identity’ with those women, information about the identity or evolutionary origin of the egg (oocyte) provider, and the alteration of the child’s identity as compared with what it would have been without the intervention. The Nuffield Council uses genetic identity to include both parentage and genetic traits. Scully describes these components as direct identity effects (namely, the individual’s genetic makeup) and indirect identity effects (namely, impacts on the individual’s family relationships). These views perhaps resonate with concerns about ‘the child’s right to a natural biological heritage’ raised with the Australian Senate committee which...

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1 Thomas Douglas & Katrien Devolder, A Conception of Genetic Parenthood, 33 BIOETHICS 54, 54 (2019).
2 These technologies are explained in Section 2.
3 See, for example, Donald S. Rubenstein et al., Germ-Line Therapy to Cure Mitochondrial Disease: Protocol and Ethics of In Vitro Ovum Nuclear Transplantation, 4 CAMBRIDGE QUARTERLY OF HEALTHCARE ETHICS 316 (1995); Annelien L. Bredenoord, et al., Ethics of Modifying the Mitochondrial Genome, 37 JOURNAL OF MEDICAL ETHICS 97 (2011).
4 Nuffield Council on Bioethics, Novel techniques for the prevention of mitochondrial DNA disorders: An ethical review (2012), at para 4.21.
5 Understandings include numerical identity, self-conception, and qualitative identity. These are not considered in this paper. The broader context is discussed in Section 3.
6 Bioethics Advisory Committee, Singapore, Ethical, legal and social issues arising from mitochondrial genome replacement technology. Consultation Paper (Bioethics Advisory Committee. 2018), at para 69.
7 Anne Claiborne et al. (eds.), Mitochondrial replacement techniques: Ethical, social, and policy considerations (National Academies Press. 2016).
8 Id. at 99–100.
9 Nuffield Council on Bioethics, Genome editing and human reproduction: social and ethical issues (2018), at para 1.1.
10 Jackie Leach Scully, A Mitochondrial Story: Mitochondrial Replacement, Identity and Narrative, 31 BIOETHICS 37, 38 (2017).
recently considered mitochondrial replacement. However, the Australian committee interpreted these concerns as being limited to confusion or distress over parentage.

This paper adopts the approach suggested by Ravitsky et al. and uses the term genetic identity to refer to the genetic components of an individual’s identity and relationships. Like the approach of the Nuffield Council, genetic identity is used here to include the genetic contributors to the creation of the individual, possession of distinctive genetic traits, and social information or narrative related to a specific, limited element of a person’s origins. But even this suggested approach needs exploration. Genetic traits could be limited to those genetic compositions that affect identity-forming characteristics (phenotype) most commonly associated with identity—such as physical appearance and personality. As discussed below, this was the approach of the Australian Senate committee which considered mitochondrial replacement. However, this paper uses Scully’s broader understanding of genetic identity to include cultural narratives around the relevant technology. Such narratives, in this context, arise from the portrayal of a technology, the resulting child, and their family in the public arena and within the family itself. This paper agrees with Scully’s assertion that the impact of such narratives on identity should be considered by regulators. In a broader form, genetic identity includes the child’s right to an open future, which was included by the Nuffield Council as a key ethical consideration in the context of mitochondrial replacement.

Despite the opaqueness around the meaning of genetic identity, concern about children’s genetic identity has been used to justify the three successive waves of Australian reproductive technology regulatory activity. That activity includes both national and state regulation and discussion about future regulatory changes. As a federation, constitutional responsibility in Australia is split between national and state governments. The national parliament has only those powers given to it by the Commonwealth

11 Dr Bernadette Tobin, Director Plunkett Centre for Ethics, Submission, cited in Australian Senate Standing Committee on Community Affairs, Inquiry into the science of mitochondrial donation and related matters (2018), at para 4.18. The U.S. President’s Council on Bioethics similarly observed in relation to advances such as cloning, that respect for children required legislation ensuring that all children have a ‘natural connection to two human genetic parents.’ President’s Council on Bioethics, REPRODUCTION AND RESPONSIBILITY, THE REGULATION OF NEW BIOTECHNOLOGIES: A REPORT OF THE PRESIDENT’S COUNCIL ON BIOETHICS (Government Printing Office. 2004), at 199.
12 Australian Senate Standing Committee on Community Affairs, Inquiry into the science of mitochondrial donation and related matters (2018), at para 4.19.
13 Vardit Ravitsky et al., The Conceptual Foundation of the Right to Know One’s Genetic Origins, BIOWEWS June 5, 2017.
14 Nuffield Council on Bioethics, NOVEL TECHNIQUES supra note 4, at paras 4.20–3.
15 Scully, supra note 10, at 39.
16 Id. at 44–45.
17 Id. at 45.
18 Nuffield Council on Bioethics, NOVEL TECHNIQUES, supra note 4, at 56. The right to an open future cautions against violation of the autonomy of the future adult when irreversible decisions are made for or about a child during its childhood. Jeremy R. Garrett et al., Rethinking the ‘Open Future’ Argument Against Predictive Genetic Testing of Children, 21 GENETICS IN MEDICINE 2190, 2191 (2019).
19 Whether confusion about genetic identity is actually experienced by the resulting child is best assessed through empirical studies and is outside the scope of this paper. Both Claiborne, et al., supra note 7, at 99 and 101, and Nuffield Council on Bioethics, NOVEL TECHNIQUES supra note 4, at 70–72, identify the need for empirical evidence on this issue.
Constitution. All other powers are left to the states. Regulation of assisted reproductive technology (ART) and parentage, for example, are matters for the state governments. National regulatory schemes, such as the one around research embryos, require intergovernmental agreement, the passing of national legislation, and the adoption of that legislation by each state jurisdiction. Unlike the United Kingdom where the same body is responsible for the regulation of reproductive clinics and embryo research, Australia has a splintered regulatory framework for reproductive technology, where states are responsible for parentage and ART regulation and a national scheme regulates the creation and use of human embryos for research and, to a limited extent, reproduction. Concerns about genetic identity, however, cross these regimes. Any regulatory changes in response to emerging reproductive technologies must therefore be appropriate for all regimes.

The first wave of Australian reproductive technology regulatory activity saw state regulation of ART and legal parentage. Introduced in the 1980s, this was intended to prevent confusion for ‘those concerned about the genetic background of any child born.’ The second wave responded to advances in the creation of human life outside the body, such as cloning. As part of this second wave, a national scheme was created in 2002 prohibiting certain embryo research activities and creating a licensing scheme for others. This scheme was justified (in part at least) as being necessary to avoid ‘confusion of genetic identity for the person born.’ The important distinction here though, compared with the ART regulations, is that the relevant embryos could never be used in reproduction. Nearly two decades later, emerging technologies are again raising concerns about the resulting child’s genetic identity. Cell reconstruction techniques (whether affecting an embryo’s mitochondrial (mt) or nuclear DNA), for example, have been observed as impacting a child’s genetic identity because the resulting child will be ‘genetically distinct from the person who might have been naturally conceived by his or her parents.’ In contrast, an Australian Senate committee recently concluded that mtDNA is not relevant to the resulting child’s genetic identity. Whichever response is correct, it can be expected that concerns about children’s genetic identity will be relevant to the third wave of regulatory responses, preparing for emerging technologies such as mitochondrial replacement, genome editing, and SCD gametes.

20 Michael Kirby, *IVF—The Scope and Limitation of Law* (Conference on Bioethics and the Law of Human Conception, London, UK 1983).

21 For further details, see Karinne Ludlow, *The Policy and Regulatory Context of US, UK, and Australian Responses to Mitochondrial Donation Governance*, *JURIMETRICS: THE JOURNAL OF LAW, SCIENCE AND TECHNOLOGY* 247, 253 (2018).

22 Louis Waller, Committee to consider the Social, Ethical and Legal issues arising from In Vitro Fertilisation, *Report on Donor Gametes in IVF* (Victoria, Australia 1983) at 29. The subsequent legislation, discussed below, reflected this. For the background and history leading to this legislation, see Loane Skene, *Moral and Legal Issues in the New Biotechnology*, *Australiann Law Journal* 379, 385–389 (1985); B. Gaze & P. Kasimba, *Embryo Experimentation: The Path and Problems of Legislation in Victoria, in EMBRYO EXPERIMENTATION* (Peter Singer & Stephen Buckle eds., 1993).

23 Australia Legislation Review Committee, *Issues Paper: Outline of existing legislation and issues for public consultation: Legislation Review of Australia’s Prohibition of Human Cloning Act 2002 and Research Involving Human Embryos Act 2002. (2005)* at 14.

24 Nuffield Council on Bioethics, *NOVEL TECHNIQUES*, supra note 4, at para 4.25.

25 Australian Senate Standing Committee on Community Affairs, *supra note 12*, at para 1.17 (footnotes omitted).
This paper investigates regulation of novel reproductive technologies through an examination of Australian law’s understanding of children’s genetic identity and its attempts to protect that identity. Informed by that investigation, the paper then considers how regulations can best respond to still emerging reproductive technologies. The next section, Section 2, briefly explains the relevant technologies and their legal status in Australia. Section 3 places genetic identity and regulation justified using concerns about that identity in the context of the broader literature about identity, kinship and connection, and the regulation of reproduction. Sections 4 and 5 consider successive generations of regulatory reform. Each section assesses what the relevant regulations tell us about Australian law’s understanding of children’s genetic identity and how that identity is protected.

The first-generation regulation, considered in Section 4, requires that genetic contributors be identifiable and legal parentage be certain. The use of donated gametes (eggs and sperm) and embryos is particularly relevant here. Newer technologies such as mitochondrial replacement challenge this regulation by prompting discussion of regulatory distinctions between nuclear and mt DNA contributions in the context of genetic contribution and genetic identity. In Section 5, second-generation regulation is considered, subsection 5.1 examining the maximum on the number of genetic contributors. Mitochondrial replacement and genome editing challenge this regulation through their combination of DNA from three individuals. The minimum number on genetic contributors imposed by second-generation regulation is considered in subsection 5.2. This restriction was imposed in response to the possibility of human cloning, but the development of mitochondrial replacement, genome editing, and SCD gametes all challenge this lower limit. Regulation of heritable changes is addressed in subsection 5.3. The results of the analysis in Sections 4 and 5 are discussed in Section 6, with conclusions being drawn together in Section 7. The paper demonstrates how existing regulations will be challenged by emerging reproductive technologies and that third-generation regulatory reform is needed. It concludes that control of the maximum number of genetic contributors to human embryos is no longer appropriate and should be repealed or at least amended; that control of the minimum number needs strengthening because of vulnerabilities; and that decisions are urgently needed on whether a distinction should be made between mtDNA and nuclear DNA and on how much genetic contribution is needed before a person is considered a genetic contributor. All of these reforms impact children’s genetic identity consistently with Australian law’s approach to that concern.

II. THE EXPANSION OF REPRODUCTIVE TECHNOLOGIES
The desire for a child is strong, and therefore the significant uptake of ART should be no surprise. One in 25 Australian children is now born with the assistance of in vitro fertilization (IVF). Australian regulation of IVF began in 1984 although IVF had been

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26 There are ongoing debates about the appropriate name for this technology. See, for example, Ainsley J. Newson et al., Ethical and Legal Issues in Mitochondrial Transfer, 8 EMBO MOLECULAR MEDICINE S89, S89 (2016).
27 See, for example, World Health Organisation, Mother or Nothing: The Agony of Infertility, 88 BULLETIN OF THE WORLD HEALTH ORGANIZATION 877 (2010).
28 K. Aubusson, Australia’s IVF Rates Revealed: One in Every 25 Births an IVF Baby, THE SYDNEY MORNING HERALD, Sept. 9, 2018. The first live Australian birth following IVF was in 1980, in Melbourne. John Leeton,
used in Australian clinics since 1972.\textsuperscript{29} Artificial insemination (AI), which has a longer history, is regulated in the same way as IVF but only when administered by a medical practitioner.\textsuperscript{30} Where infertility because of medical or social factors (such as same sex relationships or single individuals) makes it necessary, donated gametes or embryos may be used in IVF or AI. This enables same sex couples, single persons, and infertile heterosexual couples access ART.\textsuperscript{31}

Reproductive cloning [also known as somatic cell nuclear transfer (SCNT)] could be an alternative for some would-be parents, such as those unable to produce viable gametes. Reproductive cloning involves transferring a somatic cell nucleus to an enucleated egg, which is then used in an IVF procedure to produce a baby. However, as discussed below, clinical use of this technique is prohibited in Australia although licensed use to create embryos for research is permitted.

For other would-be parents, there may be a known fault with their mtDNA. This means that while they may be able to conceive, there is a risk of their children inheriting that fault.\textsuperscript{32} Mitochondrial DNA is passed along the maternal line, and mitochondrial replacement allows an intending mother’s ‘faulty’ mtDNA to be replaced with healthy mtDNA of another woman to stop the transmission of mitochondrial disease.\textsuperscript{33} A variety of techniques are used, but essentially the nuclear DNA is transferred from the intending mother’s egg (or zygote made with her egg and a sperm) to an enucleated egg (or zygote) of a woman with healthy mtDNA.\textsuperscript{34} The first birth of a child conceived using mitochondrial replacement occurred in Mexico in 2016.\textsuperscript{35} After public calls

\textsuperscript{29} Victorian Hansard, supra note 28. The world’s first ART legislation was the Infertility (Medical Procedures) Act 1984 (Vic) (now repealed).

\textsuperscript{30} See, for example, Assisted Reproductive Treatment Act 2008 (Vic) s 9.

\textsuperscript{31} Assisted Reproductive Treatment Act 1988 (SA) s 9(1); Assisted Reproductive Treatment Act 2008 (Vic) s 10; Human Fertilisation and Embryology Act 1991 (WA) s 23 (but note the requirement for a ‘medical’ reason for infertility). For other jurisdictions, see National Health and Medical Research Council, Ethical Guidelines on Assisted Reproductive Technology in Clinical Practice and Research (Canberra 2017) guideline 3.7 and the parentage legislation discussed in Section 4. Note though that discrimination on the basis of sexuality or relationship status in providing ART is not prohibited in Queensland.

\textsuperscript{32} The proportion of mutant mtDNA relative to total mtDNA in the particular egg used to conceive the child determines whether the child displays disease. See Samvel Varvastian, 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 European Journal of Health Law 405, 408 (2015).

\textsuperscript{33} Mitochondria are passed along the maternal line, the sperm contributing only nuclear DNA to an embryo.

\textsuperscript{34} The three most developed forms of the technique are MST, PNT, and polar body transfer. See N. Haites et al., Human Fertilisation and Embryology Authority, Scientific Review of the Safety and Efficacy of Methods to Avoid Mitochondrial Disease Through Assisted Conception (2011), at 3; see also A. Greenfield et al., Human Fertilisation and Embryology Authority, Annex VIII: Scientific Review of the Safety and Efficacy of Methods to Avoid Mitochondrial Disease Through Assisted Conception: Update 9 (UK 2013); A. Greenfield et al., Human Fertilisation and Embryology Authority, Third scientific review of the safety and efficacy of methods to avoid mitochondrial disease through assisted conception: Update 3 (UK 2014); and Claiborne et al., supra note 7, at 45.

\textsuperscript{35} John Zhang et al., Live Birth Derived from Oocyte Spindle Transfer to Prevent Mitochondrial Disease, 34 Reproductive Biomedicine Online 361, 361–362 (2017).
to allow the clinical use of mitochondrial replacement in Australia, an Australian Senate committee inquiry endorsed such use in 2018. The Committee called for the Australian Government to prepare a consultation paper on the technique’s introduction to clinical practice, including options for necessary legislative change. The Australian Government has responded to these calls, by confirming the process it will adopt for further consultation around decision-making on issues raised by mitochondrial replacement.

The controversial 2018 announcement by He Jiankui of the clinical use of genome editing in reproductive embryos hastens the need for Australia to also consider its response to this emerging technology. Genome editing allows precise and targeted changes to be made to DNA, changing the functioning of a targeted gene or noncoding sequence. The predominant genome editing technique uses site-directed nuclease (SDN) techniques. CRISPR/Cas is a well-known example of the simplest form of the SDN technique. Using CRISPR, the chosen DNA sequence is found in the cell’s genome. The SDN (Cas) then cuts both strands of the DNA at that sequence. The cell in turn recognizes there is a break in its DNA and repairs the break using normal cellular repair mechanisms. The precision of those repair mechanisms can be improved by introducing a piece of DNA to act as a template. That template could be from a third person’s DNA. The desired change could be a small deletion or insertion, or a large DNA sequence can be inserted to either replace or add to the existing DNA. While the United Kingdom has legalized both the clinical use of mitochondrial replacement and research on human embryo genome editing and policy reviews on both these technologies have been completed in the USA, there has been no formal consideration of amending Australian regulation to allow embryo genome editing.

36 Alisha Dow & Melissa Cunningham, Call for Change to Human Cloning Law to Prevent Genetic Disorder, THE AGE (Sept. 21, 2017), https://www.theage.com.au/national/victoria/call-for-change-to-human-cloning-law-to-prevent-genetic-disorder-20170920-gylgyo.html (accessed Feb. 13, 2020).
37 Australian Senate Standing Committee on Community Affairs, supra note 12.
38 Id. at rec. 1 para 5.99. The Committee also called for the Council of Australian Governments (COAG) Health Council to progress the Committee’s findings with all states and territories. Id. at rec. 3 para 5.103.
39 Australian Government, AUSTRALIAN GOVERNMENT RESPONSE TO THE SENATE COMMUNITY AFFAIRS REFERENCES COMMITTEE INQUIRY INTO: THE SCIENCE OF MITOCHONDRIAL DONATION AND RELATED MATTERS (2019).
40 Statement by the Organizing Committee of the Second International Summit on Human Genome Editing (Nov. 29, 2018), http://www.nationalacademies.org/gene-editing/2nd_summit/index.htm (accessed Apr. 5, 2019).
41 SDN is a generic term and includes a range of nuclease (a type of enzyme) techniques. Enzymes are proteins that carry out some function in the cell, in this case cutting DNA. For more details, see European Food Safety Authority Panel on Genetically Modified Organisms, SCIENTIFIC OPINION ADDRESSING THE SAFETY ASSESSMENT OF PLANTS DEVELOPED USING ZINC FINGER NUCLEASE 3 AND OTHER SITE-DIRECTED NUCLEASES WITH SIMILAR FUNCTION, 10 EFSA JOURNAL 2943 (2012).
42 Council for Agricultural Science and Technology, ISSUE PAPER: GENOME EDITING IN AGRICULTURE: METHODS, APPLICATIONS, AND GOVERNANCE (2018), at 4.
43 U.K.: Clinical use of mitochondrial replacement in human embryos was legalized in October 2015, with the passing of the Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015; research use of genome editing in human embryos was legalized in 2016. U.S.: Claiborne et al., supra note 7; U.S. NATIONAL ACADEMIES OF SCIENCES, ENGINEERING AND MEDICINE, HUMAN GENOME EDITING: SCIENCE, ETHICS, AND GOVERNANCE (National Academies Press. 2017). As to necessary regulatory changes to allow such editing, see Michelle Taylor-Sands & Christopher Gyngell, LEGALITY OF EMBRYONIC GENE EDITING IN AUSTRALIA, 26 JOURNAL OF LAW AND MEDICINE 356 (2018).
SCD gametes are another emerging reproductive technology that can be expected to challenge existing Australian regulation. This technology offers an alternative to the creation of embryos using naturally derived gametes and has successfully created non-human embryos. SCD gametes could be useful for would-be parents unable to produce viable gametes but who want to conceive a child with their DNA. Both embryonic stem cells (ESC) and induced pluripotent stem cells (iPSC) have been used for this purpose. In each case, the stem cells are differentiated into gametes. ESCs can be obtained from surplus IVF embryos or from embryos created via cloning (SCNT). iPSCs are derived by reprogramming somatic cells to an embryonic state. iPSCs are particularly significant because of their potential to allow gametes to be created from any body cell (such as a skin cell). Further advances show that it may be possible to generate counter-gender gametes from a stem cell of a particular sex. That means male stem cells could be differentiated into artificial eggs or female stem cells into artificial sperm. If this development is successful in humans (and legalized), it could enable same sex couples to have a child genetically related to both of them. As explained below, the legality of this technology in Australia is unclear.

III. IDENTITY AND REGULATION OF REPRODUCTION

Reproductive technologies disrupt our understanding of identity, kinship, and familial connections, concepts underpinning most known cultures and societies. Franklin, who describes kinship as having been 'conventionally imagined as the natural flow of reproductive substance,' points out that reproductive technologies mean that kinship is no longer based on a pre-existing natural mechanism. Instead, as Rao observes, kinship and family are as much the product of social choices as the reflection of

44 S. Bhattacharya, Stem Cells Can End Infertility, Say IVF Pioneers New Scientist. com News Service at https://www.newscientist.com/article/dn3980-stem-cells-can-end-infertility-say-ivf-pioneers/ (accessed Feb. 13, 2020).
45 Saskia Hendriks et al., Artificial Gametes: A Systematic Review of Biological Progress Towards Clinical Application, 21 Human reproduction update 285 (2015). A. Smajdor & D. Cutas, Artificial Gametes (The Nuffield Council on Bioethics. 2015). See also Seppe Segers et al., In Vitro Gametogenesis and Reproductive Cloning: Can We Allow One While Banning the Other?, 33 Bioethics 68, 69 (2019).
46 Kazutoshi Takahashi et al., Induction of Pluripotent Stem Cells from Adult Human Fibroblasts by Defined Factors, 131 cell 861 (2007).
47 Monya Baker, iPSC Cells Make Mice That Make Mice Nature Reports: Stem Cells, https://www.nature.com/articles/stemcells.2009.106 (accessed Feb. 13, 2020).
48 Barbara Advena-Regnery et al., Framing the Ethical and Legal Issues of Human Artificial Gametes in Research, Therapy, and Assisted Reproduction: A German Perspective, 32 Bioethics 314, 316 (2018).
49 Giuseppe Testa & John Harris, Ethical Aspects of ES Cell-Derived Gametes, 305 SCIENCE 1719 (2004).
50 Anne-Maree Farrell et al., Health Law: Frameworks and Context (2017). Recent developments have shown that haploid embryonic SCD from female mice and altered using genome editing have allowed the production of healthy offspring after being injected into another female’s egg. Zhi-Kun Li et al., Generation of Bimaternal and Bipaternal Mice from Hypomethylated Haploid ESCs with Imprinting Region Deletions, 23 CELL STEM CELL 1 (2018).
51 Nuffield Council on Bioethics, NOVEL TECHNIQUES, supra note 4, at 71 citing evidence given by Brenda Almond. See generally Martin Richards, The Development of Governance and Regulation of Donor Conception in the UK, in REGULATING REPRODUCTIVE DONATION (Susan Golombok et al. eds., 2016).
52 Sarah Franklin, BIOLOGICAL RELATIVES: IVF, STEM CELLS, AND THE FUTURE OF KINSHIP (Duke University Press. 2013) 151–152.
biological facts.\textsuperscript{53} Given that the meaning and shape of kinship and other connections are determined by society, society can create and has created new kin ties as well as, as Franklin observes, ‘categories of biological relatives.’\textsuperscript{54} Reproductive technology both drives and enables many of these changes, with regulation recording and facilitating those changes.

Most relevant here is the role of genetic relatedness.\textsuperscript{55} For some, genetic relatedness between intending parents and the resulting child is sufficiently important to justify the medical, social, and ethical risks raised by reproductive technologies. Regulation responds to some of these risks, but because regulations reflect the cultural and policy concerns of the jurisdiction concerned, there are important differences between countries.\textsuperscript{56} Even within a particular jurisdiction, regulation cannot reflect the spectrum of its citizens’ views. Attitudes to technologies such as genome editing and mitochondrial replacement which could enable correction of genetic disorders are a good example here. The possibility of genetic change to an embryo makes such technologies unacceptable to some, while others assert that it imposes additional legal and moral obligations on intending parents to use reproductive technology.\textsuperscript{57} There are also differences in the focus of concern, which may be broader society, the resulting child or intending parents, or particular segments of the community, such as those with a disability.

But establishing ‘harm’ in the context of reproduction is fraught with difficulty. The use of reproductive technologies and/or regulation of it must be justifiable. A central flashpoint here is the nonidentity problem.\textsuperscript{58} In simplistic terms, this posits that no harm is done to a child where that child is a different child to the one that would have been born without the technology (or regulation) being considered, because otherwise the child would not have been born at all. This is the case even where the child has a congenital condition, provided that condition does not make the child’s life not worth living.\textsuperscript{59} In regard to the regulation of reproductive technologies (rather than the technology itself), Cohen has observed that the nonidentity problem provides insight that justifications based on ‘the best interests of the resulting child’ fail when regulation

\textsuperscript{53} Radhika Rao, Assisted Reproductive Technology and The Threat to The Traditional Family, 47 HASTINGS LAW JOURNAL 951, 959 (1996).
\textsuperscript{54} Franklin, supra note 52, at 159.
\textsuperscript{55} See Seppe Segers, Guido Pennings & Heidi Mertes, Getting What You Desire: The Normative Significance of Genetic Relatedness in Parent-Child Relationships, 22 MEDICINE, HEALTH CARE AND PHILOSOPHY 487 (2019).
\textsuperscript{56} Ludlow, supra note 21, at 13–14. Regulation is itself the subject of critique. See I. Glenn Cohen, Regulating Reproduction: The Problem with Best Interests, 96 MINN. L. REV. 423 (2011). I. Glenn Cohen, Beyond Best Interests, 96 MINN. L. REV. 1187 (2012).
\textsuperscript{57} For commentary against the technology see, for example, Inmaculada de Melo-Martin, Rethinking Reprogenetics: Enhancing Ethical Analysis of Reprogenetic Technologies (2017). In support, see, for example, Christopher Gyngell, Hilary Bowman-Smart & Julian Savulescu, Moral Reasons to Edit the Human Genome: Picking Up from the Nuffield Report, 45 J. MED. ETHICS 514 (2019).
\textsuperscript{58} See generally Rob Lawlor, Questioning the Significance of the Non-Identity Problem in Applied Ethics, 41 JOURNAL OF MEDICAL ETHICS 893 (2015).
\textsuperscript{59} Proper assessment of the value of this purpose requires valuation of life with disability, an issue not considered here. See Jackie Leach Scully, Inheritable Genetic Modification and Disability: Normality and Identity in The Ethics of Inheritable Genetic Modification: A Dividing Line? (John E. J. Rasco, Gabrielle J. O’Sullivan & Rachel A. Ankeny eds., 2006). More broadly see Rosamund Scott, CHOOSING BETWEEN POSSIBLE LIVES. LAW AND ETHICS OF PRENATAL AND PREIMPLANTATION GENETIC DIAGNOSIS (2007).
impacts when, whether, or with whom individuals reproduce. This is because the resulting child is a different child to the one that would otherwise be born. For reproductive technologies that facilitate conception, in some cases avoiding genetic disorders, these are not therapeutic in the sense of helping an existing person nor can they be said to harm a person, in light of the nonidentity problem. Nevertheless, some technologies (such as genome editing and particular forms of mitochondrial replacement) may be at least pre-emptively curative because a particular embryo is selected for reproduction before use of the technology. Additional to that challenge to justification is the debate around whether such change changes the resulting child’s identity, including genetic identity. With this brief description of the ethical and social science literature, the regulatory responses to that concern are now addressed.

IV. FIRST-GENERATION REGULATION

A. Identifiable Genetic Contributors and Parentage

The relationship between genetic contributors and resulting children is one of the most controversial and fundamental matters around the regulation of reproductive technologies. It is also fundamental to children’s genetic identity. As the Singaporean Bioethics Advisory Committee notes:

There is an emerging concept that understanding one’s genetic origins is of great importance in one’s personal identity, thereby justifying the mandatory disclosure of selective identifying information relating to gamete donors in assisted reproductive treatments in some jurisdictions.

Gamete and embryo donation and the legal parentage of resulting children are regulated in Australia on a state-by-state basis. All jurisdictions (except the Northern Territory) have parentage legislation. Four states [New South Wales (NSW), South Australia (SA), Victoria, and Western Australia (WA)] regulate ART with their own legislation with the other jurisdictions relying on guidelines from the National Health and Medical Research Council (NHMRC), called the Ethical Guidelines on Assisted Reproductive

60 I. Glenn Cohen, Regulating Reproduction: The Problem with Best Interests, 96 MINN. L. REV. 423, 457 (2011).
61 As to whether genetic modification gives rise to the nonidentity problem, see I. Glenn Cohen, Intentional Diminishment, The Non-Identity Problem, and Legal Liability, 60 Hastings L. J. 347, 350–359 (2008). Contra Kirsten Smolensky, Creating Children with Disabilities: Parental Tort Liability for Preimplantation Genetic Interventions, 60 Hastings L. J. 299, 331 (2008).
62 Wrigley et al., assert that this means in some circumstances there may be a stronger obligation to use one form of mitochondrial replacement over another. Anthony Wrigley, Stephen Wilkinson & John B. Appleby, supra note Mitochondrial Replacement: Ethics and Identity, 29 BIOETHICS 631, 636 (2015).
63 See, for example, Robert Sparrow, Orphaned at Conception: The Uncanny Offspring of Embryos, 26 BIOETHICS 173 (2012). Karinne Ludlow, Genes and Gestation in Australian Regulation of Egg Donation, Surrogacy and Mitochondrial Donation, 23 JOURNAL OF LAW AND MEDICINE 378 (2015). Douglas & Devolder, supra note 1.
64 Singapore, Bioethics Advisory Committee, supra note 6, at para 6, citing the Nuffield Council on Bioethics, NOVEL TECHNIQUES, supra note 4, at para 4.106.
65 For further details, see Ludlow, supra note 61.
66 Parentage Act 2004 (ACT); Status of Children Act 1996 (NSW); Status of Children Act 1978 (NT); Status of Children Act 1978 (Qld); Family Relationships Act 1975 (SA); Status of Children Act 1974 (Tas); Status of Children Act 1974 (Vic); Artificial Conception Act 1985 (WA).
Technology in Clinical Practice and Research (2017). These Guidelines (and their predecessors) have legislative force throughout Australia because of a national accreditation system for reproductive clinics created by national legislation.

Parliamentary debates in the early 1980s leading to this first wave of reproductive technology regulations reflect public controversy over whether donated gametes should be used at all: one member of parliament referring to their use as genetic engineering and the Anglican Church claiming such use was inconsistent with the Christian understanding of marriage. Beyond personal and professional morality concerns, other public concerns included that gamete donation was possibly grounds for divorce (where no fault divorce was not available), and there were concerns for children’s legitimacy and that donor half-siblings could unwittingly marry. Legal concerns included donors’ liability for child maintenance, falsification of birth records by intending parents and doctors when registering the child’s legal parents, and liability of doctors for negligence or conspiracy in cases involving inheritance. Some 7 years before those debates, the Council of Australian Social Welfare Ministers had discussed the legal and social aspects of AI by donor (AID), referring these matters to the Standing Committee of Attorney-Generals. That Committee prepared draft model legislation addressing children’s parentage rather than regulation of their conception, by ensuring children born using donated gametes or embryos were recognized as ‘legitimate’ children of the intending parents. All states adopted that legislation. Any genetic link between the child and donor was and continues to be irrelevant for legal parentage purposes. Although the parentage legislation severs the link between legal and genetic parentage, it does not address children’s genetic identity. Children’s genetic identity is instead protected by the state ART regulations and NHMRC Guidelines. This occurs through the prevention of confusion for resulting children over their genetic contributors. Two known human genetic contributors

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67 Assisted Reproductive Technology Act 2007 (NSW); Assisted Reproductive Treatment Act 1988 (SA); Assisted Reproductive Treatment Act 2008 (Vic); Human Reproductive Technology Act 1991 (WA). National Health and Medical Research Council, Ethical Guidelines on Assisted Reproductive Technology in Clinical Practice and Research (Canberra 2017).

68 As the NHMRC submission to Australian Senate Standing Committee on Community Affairs, supra note 12, at 1 explains federal legislation (the Research Involving Human Embryos Act 2002 (Cth) ss 8 and 11) requires all ART clinics to be accredited by the Reproductive Technology Accreditation Committee (RTAC) of the Fertility Society of Australia. Accreditation in turn requires clinics to comply with the RTAC Code of Practice and that Code requires clinics to comply with the NHMRC Guidelines.

69 Victorian Hansard, supra note 28, Mr McNamara (Benalla) 1838.

70 G. Downe, Anglican Commission Against Artificial Insemination by Donor, CANBERRA TIMES (Feb. 9, 1983).

71 See Richards, supra note 51.

72 This followed a recommendation by the Australian Law Reform Commission, HUMAN TISSUE TRANSPLANTS (1977), at para 42.2. The Committee added the issue of the legal status of children born with the assistance of IVF after it had commenced considering the status of AID children.

73 Relevant to the discussion below, the model parentage legislation proceeded on the basis that it was acceptable that sperm from two men be mixed and included such practices within its scope. Attorney-Generals Model Bill (Model Artificial Conception Bill 1984) cl 4(1) (to be found as Appendix 2 to J. Cornwall, REPORT OF THE WORKING PARTY ON IN VITRO FERTILISATION AND ARTIFICIAL INSEMINATION BY DONORS 1984). Clause 5(1) (d) and subsequent legislation provided that the male partner of the couple undergoing treatment would be presumed to have caused the pregnancy and to be the father of any child born as a result of the pregnancy.

74 Ludlow, supra note 48.
to each human embryo are required.75 Prior to ART regulation, the sperm of male intending parents was sometimes mixed with donor sperm to increase the chances of conception.76 As explained below, this is now prohibited throughout Australia. However, sperm mixing continues in some overseas clinics. For example, a Canadian surrogacy consultancy offers male same sex couples the opportunity for both partners to be ‘genetically linked’ to their children.77 In reality, only one sperm can fertilize an egg, and therefore only one male will be genetically linked to the resulting child. The genetic link referred to in the consultancy’s advertising (and potential confusion for the child) is the possibility that either male could be the genetic contributor.78

Each state held a committee of inquiry prior to the introduction of ART regulation. All committees agreed that gamete mixing should be prohibited.79 The Tasmanian Committee, for example, recommended that ‘the practice of mixing gametes so as to confuse the identity of resulting children should not be conducted in this State.’80 Inquiries in three states (Queensland, SA, and WA) recommended an

75 National Health and Medical Research Council, supra note 52, at guidelines 5.6.2 and 6.1.2. Vic: Assisted Reproductive Treatment Act 2008 (Vic) s 27. WA: Human Reproductive Technology Act Directions 2004 (WA), Direction 8.6 made under the Human Reproductive Technology Act 1991 (WA) s 17. NSW legislation (Assisted Reproductive Technology Act 2007 (NSW)) does not address this issue because the NHMRC Guidelines already do so and SA legislation [Assisted Reproductive Treatment Regulations 2010 (SA)] made under the Assisted Reproductive Treatment Act 1988 (SA) requires the NHMRC Guidelines be followed.

76 Special Committee Appointed by the Queensland Government to Enquire into the Laws Relating to AI In Vitro Fertilization and other Related Matters, REPORT OF THE SPECIAL COMMITTEE APPOINTED BY THE QUEENSLAND GOVERNMENT TO ENQUIRE INTO THE LAWS RELATING TO ARTIFICIAL INSEMINATION, IN VITRO FERTILIZATION AND OTHER RELATED MATTERS (1984) (Demack Report), at 32. The Report notes (at 32) that this practice had become discredited as good medical practice.

77 Such couples are given the choice of using multiple embryos fertilized by each would-be parent or mixing the sperm of both men to fertilize available eggs. Proud Fertility, Whose Sperm Did Those Gay Guys Use, Anyway?, http://proudfertility.com/2017/05/03/whose-sperm-gay-guys-use-anyway/ (accessed July 27, 2018). See also FindSurrogateMother, What if Both of Us Want to Have a Biological Connection?, https://www.findsurrogatemother.com/gay-sperm/men/biological-connection (accessed July 4, 2018). WIN Fertility, Gay Men: How to Have a Biological Child, http://www.winfertility.com/gay-men-how-to-have-a-biological-child/ (accessed July 12, 2018). See further Dana Berkowitz & William Marsiglio, Gay men: Negotiating Procreative, Father, and Family Identities, 69 JOURNAL OF MARRIAGE AND FAMILY 366, 378 (2007).

78 Deliberate creation of uncertainty over paternity by mixing semen was practiced before the regulation of ART to avoid possible legal consequences. See Martin, supra note S8 at 18.

79 NSW: Law Reform Commission: REPORT ON HUMAN ARTIFICIAL INSEMINATION (Sydney, 1986), NSW Law Reform Commission: REPORT ON IN VITRO FERTILISATION (Sydney, 1986); Law Reform Commission, REPORT ON IN VITRO FERTILISATION (Sydney, 1988). Qld: Demack Report supra note 59. SA: Cornwall supra note 57; Select Committee of the SA Legislative Council, REPORT ON ARTIFICIAL INSEMINATION BY DONOR, IN VITRO FERTILISATION AND EMBRYO TRANSFER PROCEDURES AND RELATED MATTERS IN SOUTH AUSTRALIA (Parl. House, Adelaide, 1987). Tas: D. Chalmers, Committee to Investigate Artificial Conception and Related Matters, INTERIM (1984) AND FINAL REPORT OF THE COMMITTEE TO INVESTIGATE ARTIFICIAL CONCEPTION AND RELATED MATTERS (Govt. Printer Tasmania, 1985) (Chalmers Report). Vic: L Waller, INTERIM REPORT OF THE COMMITTEE TO CONSIDER THE SOCIAL, ETHICAL AND LEGAL ISSUES ARISING FROM IN VITRO FERTILISATION (1982); L. Waller, COMMITTEE TO CONSIDER THE SOCIAL, ETHICAL AND LEGAL ISSUES ARISING FROM IN VITRO FERTILISATION, ISSUES PAPER ON DONOR GAMETES IN IVF (April 1983); Waller supra note 20; L. Waller, Committee to consider the Social, Ethical and Legal issues arising from In Vitro Fertilisation, REPORT ON THE DISPOSITION OF EMBRYOS PRODUCED BY IN VITRO FERTILISATION (1984) (Waller Report). WA: C. Michael, INTERIM REPORT OF THE IVF ETHICS COMMITTEE OF WA (1984) (Michael Report); FINAL REPORT OF THE COMMITTEE APPOINTED BY THE WESTERN AUSTRALIAN GOVERNMENT TO ENQUIRE INTO THE SOCIAL, LEGAL AND ETHICAL ISSUES RELATING TO IN VITRO FERTILISATION AND SUPERVISION (Perth, 1986).

80 Chalmers Report, supra note 77, at rec. 12 and Section 3.5.11.
additional method to limit confusion—namely, the prohibition of embryo donation.\textsuperscript{81} However, this approach was not adopted in any state.

ART regulations were enacted in three states following the state inquiries.\textsuperscript{82} Although each permitted gamete and embryo donation, they adopted the recommendations of the expert committees and acted to prevent confusion for resulting children over their genetic contributors. As the Victorian Explanatory Memorandum explains, ‘[t]hese provisions are designed to ensure that the genetic origins of any resultant child is not in doubt because the sperm or oocyte used were produced by more than one person.’\textsuperscript{83} The use of multiple (or donated) embryos in one procedure was permitted but only if the gametes from which each embryo was derived were from the same two persons.\textsuperscript{84} The mixing of semen from more than one man when fertilizing an egg intended for use in ART or when carrying out AI was prohibited.\textsuperscript{85} Subsequent legislation continues to prohibit the same practices.\textsuperscript{86} The WA provisions go further, by requiring that donors and recipients are also to be given information about, among other things, ‘the need to refrain from unprotected sexual intercourse during the course of treatment to avoid confusion about the biological parentage of any child born.’\textsuperscript{87}

At the same time as the state committees were undertaking their inquiries, the Ethics Committee of Melbourne’s Queen Victoria Medical Centre approved a scheme allowing women to donate eggs to infertile patients.\textsuperscript{88} A short-lived moratorium on egg donation was imposed by the Victorian government, but this ended in December 1983, around the same time as the birth of the world’s first egg donor-conceived baby in Melbourne.\textsuperscript{89} Nevertheless, the use of eggs from more than one woman, where donated

\textsuperscript{81} The Demack Report (SA), supra note 74, recommended prohibition of embryo donation, while the Michael Report, supra note 77 (WA), recommended embryo donation be permitted only in rare cases.

\textsuperscript{82} SA: Reproductive Technology Act 1988 (SA) (as it was then known) and Reproductive Technology Code of Ethical Clinical Practice 1995, Schedule to Reproductive Technology (Code of Ethical Clinical Practice) Regulations 1995 (SA) (now revoked); Vic, Infertility (Medical Procedures) Act 1984 (Vic) (now repealed), superseded by the Infertility Treatment Act 1995 (Vic) (now repealed); WA, Human Reproductive Technology Act 1991 (WA).

\textsuperscript{83} Victoria, Explanatory Memorandum for Infertility Treatment Bill (1995) 10.

\textsuperscript{84} SA: Reproductive Technology Code of Ethical Clinical Practice 1995 c L 6, Schedule to Reproductive Technology (Code of Ethical Clinical Practice) Regulations 1995 (SA) (now revoked) made under the Reproductive Technology Act 1988 (SA) (as it was then known); Vic, Infertility (Medical Procedures) Act 1984 (Vic) (repealed) ss 13(1) and 3(e); Infertility Treatment Act 1995 (Vic) (now repealed) s 46; WA, Human Reproductive Technology Act Directions 2004 (WA), Direction 8.6 made under the Human Reproductive Technology Act 1991 (WA) s 17.

\textsuperscript{85} SA, Reproductive Technology Code of Ethical Clinical Practice 1995 c L 6, Schedule to Reproductive Technology (Code of Ethical Clinical Practice) Regulations 1995 (SA) (now revoked) made under the Reproductive Technology Act 1988 (SA) (as it was then known); Vic, Infertility (Medical Procedures) Act 1984 (Vic) (repealed) s 26; Infertility Treatment Act 1995 (Vic) (now repealed) s 46; WA, Human Reproductive Technology Act Directions 2004 (WA), Direction 8.6 made per Human Reproductive Technology Act 1991 (WA) s 17.

\textsuperscript{86} SA: Assisted Reproductive Treatment Regulations 2010 (SA) (made under the Assisted Reproductive Treatment Act 1988 (SA)) revoke the Code of Practice and require the NHMRC Guidelines to be followed. As discussed below, these also prohibit mixing. Vic: Assisted Reproductive Treatment Act 2008 (Vic) s 27. WA: Human Reproductive Technology Act Directions 2004 (WA), Direction 8.6 made under the Human Reproductive Technology Act 1991 (WA) s 17. NSW subsequently introduced ART legislation in 2007. The NSW legislation [Assisted Reproductive Technology Act 2007 (NSW)] does not address this issue because the NHMRC Guidelines already do so.

\textsuperscript{87} Human Reproductive Technology Act Directions 2004 (WA), Direction 4.2(e).

\textsuperscript{88} Kirby supra note 20, at 6.

\textsuperscript{89} Leeton, supra note 28, at 497. For more details on the moratorium, see Kirby supra note 20, at 6.
eggs but not donated sperm were used, was not originally prohibited in Victoria. It was prohibited in the other two states which originally enacted ART legislation.\textsuperscript{90} Presumably this omission from the Victorian legislation was because at that time, it was considered that egg freezing techniques had not been sufficiently developed for egg mixing to be a real problem.\textsuperscript{91} However, the regulations imposed in 1995 to replace the original Victorian legislation prohibited mixing eggs from more than one person in the one treatment procedure.\textsuperscript{92} This followed the introduction of gamete intrafallopian transfer into clinical practice during the 1980s, in which donated eggs are transferred into an intending mother, where they are fertilized.\textsuperscript{93}

Like the state ART legislation, the initial version of the NHMRC Guidelines expressly prohibited the deliberate confusion of children’s biological parentage.\textsuperscript{94} In any case, as the NSW Department of Health noted, ‘legislative regulation was not called for in relation to the use of mixed semen from two or more semen donors’ because such use and any other action aimed at causing confusion about a child’s parentage had fallen outside the bounds of good medical practice.\textsuperscript{95} Subsequent versions of the NHMRC Guidelines have continued to prohibit mixing gametes, embryos, or eggs undergoing fertilization from different donors in the same ART procedure so that it is not possible (without genetic testing) to know who is or are the genetic parents of the resulting child.\textsuperscript{96}

However, while the original ART regulations allowing the use of donated gametes intended to protect children’s genetic identity, it did not give children the right to know the name of their genetic contributor(s). Records were required to be kept of contributors’ identity, but that information could be passed onto the child only with the contributor’s consent. Whether, what, and how information is shared between

\textsuperscript{90} See Vic: Infertility (Medical Procedures) Act 1984 (Vic) (repealed) s 12, regarding ART using donated eggs, and s 26 which refers only to semen and not eggs. SA: Reproductive Technology Code of Ethical Clinical Practice 1995 cl 6, Schedule to Reproductive Technology (Code of Ethical Clinical Practice) Regulations 1995 (SA) (now revoked) made under the Reproductive Technology Act 1988 (SA) (as it was then known). WA: Human Reproductive Technology Act Directions 2004 (WA), Direction 8.6 made under the Human Reproductive Technology Act 1991 (WA) s 17.

\textsuperscript{91} Waller Report, supra note 77, at paras 1.6.3–1.6.5. However, note that the prohibition in s 13 referred to donated ova.

\textsuperscript{92} Infertility Treatment Act 1995 (Vic) (now repealed) s 46.

\textsuperscript{93} The technique is now rarely used. Victorian Assisted Reproductive Treatment Authority, Types of Assisted Reproductive Treatment, https://www.varta.org.au/information-support/assisted-reproductive-treatment/types-assisted-reproductive-treatment (accessed Oct. 10, 2017)

\textsuperscript{94} National Health and Medical Research Council, Ethical guidelines on assisted reproductive technology. (Australia 1996) (now rescinded) guideline 11.6.

\textsuperscript{95} NSW Department of Health, Review of the Human Tissue Act 1983 Discussion Paper. Assisted Reproductive Technologies (1997) at 35. The Department explained the Victorian and Western Australian ban on mixing gametes or embryos from more than one person in the following way: ‘This is to prevent an embryo being formed whose genetic heritage is uncertain. For example, fertilizing an ovum using a mixture of semen produced from two or more donors will make it difficult to determine which donor is the genetic father of the child.’

\textsuperscript{96} National Health Medical Research Council, Ethical guidelines on the use of assisted reproductive technology in clinical practice and research (Australia, 2004) (now rescinded) guidelines 6.1 and 7.2; National Health Medical Research Council, Ethical guidelines on the use of assisted reproductive technology in clinical practice and research 2004 (as revised in 2007 to take into account the changes in legislation) (Australia, 2007) (now rescinded) guidelines 6.1 and 7.2; National Health and Medical Research Council supra note 52, at guidelines 5.6.2 and 6.1.2.
Genetic identity concerns of novel reproductive technologies

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Donors, intending parents and people conceived with donated material, are a long running and divisive matter. As Segers et al. have observed, ‘it has been argued from the child’s perspective that access to one’s genetic family history is important for one’s identity formation and that knowledge of one’s genetic origins may contribute to developing a sense of who we are.’ However, while some of the secrecy surrounding donor conception in its earliest days has disappeared, regulatory responses are still contentious. In Australia, the right to know the identity of their genetic contributors was eventually extended to donor-conceived children throughout the country. For example, current NHMRC Guidelines (2017) state that ‘[p]ersons born from donated gametes are entitled to know the details of their genetic origins.’ Victoria has gone the furthest of the Australian jurisdictions (and quite possibly internationally) by expanding the right to identifying information about genetic contributors regardless of when the donation was made and whether the donor consented to that disclosure.

97 For more details, see John B. Appleby, Regulating the Provision of Donor Information to Donor-Conceived Children. Is There Room for Improvement? in Regulating Reproductive Donation (Susan Golombok et al. eds., 2016). In relation to what this extension means for ‘naturally’ conceived children, see An Ravelingien and Guido Pennings, The Right to Know Your Genetic Parents: From Open-Identity Gamete Donation to Routine Paternity Testing, 13(5) American J. of Bioethics 33 (2013). Glenn Cohen, Response: Rethinking Sperm-Donor Anonymity: Of Changed Selves, Non-Identity, and One-Night Stands, 100 Geo. L. J. 431 (2012).

98 Seppe Segers, Guido Pennings & Heidi Mertes, Getting What you Desire: The Normative Significance of Genetic Relatedness in Parent-Child Relationships, 22 Medicine, Health Care and Philosophy 487, 488 (2019).

99 Parliament of Victoria, Law Reform Committee Inquiry into Access by Donor-Conceived People to Information about Donors—Final Report (2012), 26.

100 In support, see the extensive work by Naomi Cahn, including Naomi Cahn, The New ‘ART’ of Family: Connecting Assisted Reproductive Technologies & Identity Rights, 2018 U. ILL. L. REV. 1443 (2018). Naomi Cahn, What’s Right about Knowing?, 4 J. L. & Biosci. 377 (2017). Naomi Cahn, Do Tell! The Rights of Donor-Conceived People, 42 Hofstra Law Review 1077 (2014). Compare literature supporting anonymity, including Inez Raes, An Ravelingien, and Guido Pennings, Donor Conception Disclosure: Directive or Non-Directive Counselling?, 13 J. of Bioethical Inquiry 369 (2016). An Ravelingien, Veerle Provoost, and Guido Pennings, Open-Identity Sperm Donation: How does Offering Donor-Identity Information Relate to Donor-Conceived Offspring’s Wishes and Needs?, 12 J. of Bioethical Inquiry 503 (2015). Inez Raes, An Ravelingien, and Guido Pennings, The Right of the Donor to Information About Children Conceived from His or Her Gametes, 28 Human Reproduction 560 (2013). Vanessa L. P., Regulating Sperm Donation: Why Requiring Exposed Donation is Not the Answer, 16 Duke Journal of Gender, Law and Policy 379 (2009). For views of donors themselves, see I. Glenn Cohen et al., Sperm Donor Anonymity and Compensation: An Experiment with American Sperm Donors, 3 J. L. & Biosci. 468 (2016). Maggie Kirkman et al., Gamete Donors’ Expectations and Experiences of Contact with Their Donor Offspring, 29 Human Reproduction 731 (2014). Regarding views of donor-conceived children, see Guido Pennings, Disclosure of Donor Conception, Age of Disclosure and the Well-Being of Donor Offspring, 32 Human Reproduction 969 (2017); Naomi Cahn, Legal Parent Versus Biological Parent: The Impact of Disclosure, 19 J. of Law and Medicine 790 (2012); and Susan Golombok et al., Children Conceived by Gamete Donation: Psychological Adjustment and Mother-Child Relationships at Age 7, 25 J. of FAMILY PSYCHOLOGY 230 (2011).

101 NSW: Assisted Reproductive Technology Act 2007 (NSW) s 37; SA, Assisted Reproductive Treatment Regulations 2010 (SA) reg 8(4); Vic, Assisted Reproductive Treatment Act 2008 (Vic) ss 56 and 59; WA: Human Reproductive Technology Act 1991 (WA) s 49. Other countries have also moved to require openness. See, for example, Human Fertilisation and Embryology Authority (Disclosure of Donor Information) Regulation 2004/1511 (UK).

102 National Health and Medical Research Council, supra note 67, at guideline 5.6.

103 Assisted Reproductive Treatment Amendment Act 2016 (Vic) amending the Assisted Reproductive Treatment Act 2008 (Vic). For criticism of such an approach, see Guido Pennings How to Kill Gamete Donation: Retrospective Legislation and Donor Anonymity, 27 Human Reproduction 2888 (2012). Where openness about donors’ identity is required, legal protections around obligations and rights must be addressed by regulation. See Vanessa Grubben and Angela Cameron, Donor Anonymity in Canada: Assessing the Obstacles to Openness and
B. Provision of Gametes

While the approach described above is satisfactory in protecting children’s genetic identity when IVF or AI is used, it is not sufficient to address newer reproductive technologies, particularly genome editing and mitochondrial replacement. ART regulations refer variously to gamete providers (NSW and NHMRC Guidelines), donor of human reproductive material (SA), biological parent (WA), and gamete donors (Victoria). Reliance on the provision of a gamete rather than impact on the child’s genetic identity to attract regulation means that neither the parentage legislation nor ART regulations distinguish genetic contribution based on the kind (nuclear or mitochondrial) or amount (major or minor contribution) of genetic material contributed.

As explained in Section 2, DNA template sequences from a third person can be used in genome editing. This would not contravene the prohibition on mixing under ART regulations because the third person is not contributing a gamete. However, the child would not be entitled to know the identity of the third person for the same reason.

Mitochondrial replacement also involves a third person’s DNA in the conception of an embryo. This technology results in children conceived with DNA from three individuals, including two women who each provide a gamete. The consequences of this in Australian law (which is triggered by the provision of a gamete and does not define genetic ties) are discussed below. Relevant to protection of the genetic identity of such children, the Nuffield Council dismissed distinctions ‘about the ethical acceptability of interventions on different genomes [nuclear v mitochondrial] in notions of identity.’ As noted in Section 3, others have argued that genetic ties, including for the child herself/himself, are social rather than natural constructs. In contrast, the Australian Senate inquiry into mitochondrial replacement in part justified its endorsement of...
the legalization of the technology on the basis that mtDNA is not relevant to genetic identity ‘because mtDNA only provides energy to the cells. Nuclear DNA is responsible for a person’s physical, cognitive and behavioral characteristics.’\textsuperscript{111} Similarly, the UK Government (in contrast to the Nuffield Council) based its decision to legalize mitochondrial replacement on the conclusion that mtDNA does not affect personal characteristics and that traits come solely from nuclear DNA.\textsuperscript{112} The UK regulations enabling clinical mitochondrial replacement mean that mtDNA contributors are not genetic or legal parents of the child and, further, that the contributor’s identity will not be disclosed to the child.\textsuperscript{113}

If clinical use of mitochondrial replacement was legalized in Australia, the mtDNA contributor would be a gamete donor or provider (or, to use the newer terminology, part of the child’s genetic origins) under existing state law.\textsuperscript{114} Unlike nuclear DNA, there are only about 25 different major variations (or haplotypes) in mtDNA.\textsuperscript{115} This makes it possible to use donor mtDNA that is the same as the non-mutated mtDNA of the intending mother. In any case, because the uniqueness of the child’s final genetic makeup is irrelevant to the application of the state ART regulations and NHMRC Guidelines, it is irrelevant whether the donated mtDNA is the same haplotype as that of the intending mother. The expected regulatory response is appropriate because although no ‘new’ genetic sequence may be present in the resulting embryo where the intending mother’s and mtDNA contributor’s eggs are from the same haplotype, the origins of mtDNA and cultural narratives about the child’s conception will be different.\textsuperscript{116}

The inclusion of the mtDNA contributor as a genetic contributor has a number of important legal consequences for children’s genetic identity. Most importantly, the child would have the right to know the identity of their genetic contributors, including the mtDNA donor.\textsuperscript{117} Secondly, Australian clinics would need to use mtDNA from the same woman to create all embryos implanted in the one procedure, into an intending mother, to avoid prohibitions on mixing. Finally, regulatory restrictions on the number

\begin{itemize}
\item \textsuperscript{111} Australian Senate Standing Committee on Community Affairs, \textit{supra} note 12, at para 1.17.
\item \textsuperscript{112} U.K. Department of Health, \textit{Mitochondrial Donation. Government response to the 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} (2014) at 15–16. The response does not refer to the Nuffield Council’s conclusions on the impact of mitochondrial replacement on identity.
\item \textsuperscript{113} Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015/572. Cf U.K. Joint Committee on the Human Tissue and Embryos (Draft) Bill (2007) \textit{Human Tissue and Embryos (Draft) Bill: Volume I—Report}, <http://www.publications.parliament.uk/pa/lt200607/ltselect/ltembryos/169/169.pdf?protect$\relax$> (accessed Apr. 8, 2019). The report concluded that children should be able to discover the identity of the mtDNA donor.
\item \textsuperscript{114} Ludlow, \textit{supra} note 63. See also T. C. de Campos & C. Milo, \textit{Mitochondrial Donations and the Right to Know and Trace One’s Genetic Origins: An Ethical and Legal Challenge}, 32 \textit{International Journal of Law, Policy and The Family} 170 (2018).
\item \textsuperscript{115} Australian Senate Standing Committee on Community Affairs, \textit{supra} note 12, at para 3.67.
\item \textsuperscript{116} This assumes the intending mother’s egg from which the nuclear DNA is taken was heteroplasmic and so contained at least some ‘normal’ copies of the same mtDNA.
\item \textsuperscript{117} For arguments relevant to whether the identity of mtDNA donors should be disclosed to the child, see Newson et al., \textit{supra} note 26, at 290.
\end{itemize}
of families to whom the one donor can donate would apply. This may not be practically significant, although the United Kingdom has not limited the number of mt donor siblings, deciding that mtDNA is insufficient to cause problems of consanguinity. The introduction of a third person’s DNA into human embryos also challenges second-generation regulation, a matter to which this paper now turns.

V. SECOND-GENERATION REGULATION

A. Maximum Number of Genetic Contributors

Australia’s national scheme regulating the creation and use of human embryos for research was the second wave of Australian reproductive technology regulatory activity. The scheme consists of two federal Acts and complementary legislation in all states and territories. The Prohibition of Human Cloning for Reproduction Act 2002 (Cth) as it is now called creates a series of offenses including prohibiting certain human embryos from being created or placed in a woman. The Research Involving Human Embryos Act 2002 (Cth) controls embryo research through a licensing process. Development of the national scheme changed Australian law’s approach to children’s genetic identity in two ways: the law’s role in protecting children’s genetic identity was expanded, and secondly, concerns about genetic identity were applied to embryos used in research.

Australia’s regulatory approach to embryo research could be categorized as being between Rosario Isasi and Bartha Knoppers’ intermediate and liberal policy groups. Adapting Joseph Straus’ explanation of these approaches, the use and creation of embryos for research is permitted, provided procedural rules and governance are strictly followed, and the embryos are either surplus embryos from IVF or created by cloning, but human reproductive cloning is banned. Further, particular embryos are prohibited for implantation. This is in contrast to the approach of other jurisdictions, such as the United Kingdom, which specifies ‘permitted’ gametes or embryos for

118 For example, Assisted Reproductive Treatment Act 2008 (Vic) s 29(1). The Nuffield Council noted that this was a consequence if the United Kingdom treated mtDNA donors as egg donors. Nuffield Council on Bioethics, NOVEL TECHNIQUES, supra note 4, at para 3.19.

119 The scheme was created pursuant to the COAG, Research Involving Human Embryos and Prohibition of Human Cloning Inter-Governmental Agreement (Apr. 5, 2002). State legislation: Human Cloning and Embryo Research Act 2004 (ACT); Human Cloning for Reproduction and Other Prohibited Practices Act 2003 (NSW); Research Involving Human Embryos and Prohibition of Human Cloning for Reproduction Act 2003 (Qld); Prohibition of Human Cloning for Reproduction Act 2002 (SA); Human Cloning for Reproduction and Other Prohibited Practices Act 2003 (Tas); Prohibition of Human Cloning for Reproduction Act 2008 (Vic); Research Involving Human Embryos Act 2008 (Vic); Human Reproductive Technology Act 1991 (WA). Legislation is being drafted in the Northern Territory.

120 The original state ART regulations had included some provisions around embryo research. D. R. C. Chalmers, Researching on Embryos: Australian Standards (Centre for Law & Genetics 2001 Symposium, Hobart 2002) at 125, 128. See, for example, Infertility Treatment Act 1995 (Vic) Part 3. See also Senate Select Committee on the Human Embryo Experimentation Bill 1985, Human Embryo Experimentation in Australia (Senator M. Tate, chairman) (Commonwealth Parliament Australia, AGPS, Canberra, 1986); Gaze and Kasimba, supra note 22, at 202–212.

121 Rosario M. Isasi & Bartha M. Knoppers, Beyond the Permissibility of Embryonic and Stem Cell Research: Substantive Requirements and Procedural Safeguards, 21 HUMAN REPRODUCTION 2474 (2006).

122 Joseph Straus, Research, Exploitation and Patenting in the Area of Human Embryonic Stem Cells in Europe—A Case of Concern Causing Inconsistency, 25 EUROPEAN REVIEW 107, 110 (2017).
As discussed above, such uses were expanded in the United Kingdom in 2015 to enable clinical use of mitochondrial replacement.

The national scheme included controls on the maximum number of genetic contributors to human embryos to avoid ‘confusion of genetic identity for the person born.’124 The Parliamentary Committee (the Andrews Committee) which prepared the scheme’s blueprint was aware that US clinics had used an earlier form of mitochondrial replacement, called cytoplasmic transfer.125 It was also aware that the United Kingdom had moved towards allowing embryo research that combined the DNA of three individuals while continuing to prohibit clinical use.126 Nevertheless, the original scheme prohibited the creation of embryos by fertilization of a human egg by a human sperm containing genetic material provided by more than two persons.127 Australia’s prohibition was intentionally broad ‘to include other techniques, current or emerging, that may also involve the presence in a human embryo of a third party’s DNA.’128 In light of this, it is arguable that the national scheme includes mitochondrial and nuclear DNA donors as well as those whose somatic cells may be used to create SCD gametes in its understanding of genetic contributors. A third person who provides a genetic sequence as a template in genome editing is also likely to be a genetic contributor for these purposes. This is because the legislation regulating decision-making around embryos with genetic material from more than two people defines ‘responsible person’ to mean ‘each person whose reproductive material, genetic material or cell was used, or is proposed to be used, in the creation or use of the embryo.’129 There is no distinction made on the basis of the kind or amount of genetic material used. This is different to

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123 Human Fertilisation and Embryology Act 1990 (UK) ss 3(2), 3ZA, and 35A.
124 Legislation Review Committee, Issues Paper: Outline of existing legislation and issues for public consultation, Legislation Review of Australia’s Prohibition of Human Cloning Act 2002 and Research Involving Human Embryos Act 2002 (2005), at 14.
125 In 2001, there were reports of children born in the USA following the use of cytoplasmic transfer in embryos. The Commonwealth, House of Representatives Standing Committee on Legal and Constitutional Affairs, Human Cloning: Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem Cell Research (2001) (Andrews Report) briefly refers to such transfers (para E8). The parameters for the legislation were provided by the decisions of the COAG as set out in the COAG Communique and Attachment, Arrangements for Nationally-consistent Bans on Human Cloning and other Unacceptable Practices, and Use of Excess Assisted Reproductive Technology (ART) Embryos (Apr. 5, 2002). The legislation was developed in consultation with all states and territories, relevant Commonwealth agencies, the NHMRC, and the executive committee of the Australian Health Ethics Committee. A national program of consultation was also undertaken in all capital cities with people nominated by each jurisdiction.
126 Andrews Report, supra note 126, at para 10.86. Mitochondrial replacement (called ooplasmic transfer in the Report) is referred to as a new method that may lead to new cloning technologies, but the Report notes that it is too new to be the focus of report (para 2.61). Later (at para 6.16), the Report notes that reproductive cloning could be used to ‘enable people to avoid passing on genetic diseases such as mitochondrial diseases.’ Whether mitochondrial replacement is reproductive cloning is discussed in Section 5.2.
127 Prohibition of Human Cloning Act 2002 (Cth) (as it then was) s 15. Placing such an embryo in the body of a woman was also prohibited (s 22). These provisions were deleted and replaced with Prohibition of Human Cloning for Reproduction Act 2002 (Cth) ss 13 and 23.
128 Commonwealth, Senate, Revised Explanatory Memorandum for Prohibition of Human Cloning Bill 2002 (2002) at 9. This is repeated in Commonwealth, House of Representatives, Explanatory Memorandum for Research Involving Embryos and Prohibition of Human Cloning Bill 2002 (2002) at 11.
129 Research Involving Human Embryos Act 2002 (Cth) s 8 definition of ‘responsible person’ (b).
the language used in the NHMRC Guidelines and state ART regulations, where genetic contributors are the gamete providers.\textsuperscript{130}

The original prohibition on embryos containing genetic material from more than two persons also applied to all embryos, those intended for reproductive and research use. It is strongly arguable that the expressed concerns about the genetic identity of resulting children were not intended to be relevant to embryos created for research. The agreement between the Commonwealth and state governments leading to the scheme was that ‘a person must not create or develop an embryo for \textit{assisted reproduction} that contains genetic material from more than two people.’\textsuperscript{131} It is submitted that the prohibition on research embryos containing DNA of more than two people was a drafting artifact rather than because of concern about genetic identity. Unlike the UK legislation which allowed the creation of human embryos by fertilization of egg by sperm for certain research purposes, the Australian national scheme originally prohibited creation of human embryos for research purposes by ‘any’ means.\textsuperscript{132} It therefore made sense for the restriction on the number of genetic contributors to apply to all embryos despite expressed concerns about genetic identity not being relevant to research embryos.

Amendments in 2006 allowed embryos to be created for research purposes but only using techniques other than fertilization of an egg by sperm (that is, cloning).\textsuperscript{133} Such embryos can contain the genetic material of more than two persons.\textsuperscript{134} However, it remains an offense to implant any embryo containing genetic material provided by more than two people into a woman’s body or to allow it to develop for longer than 14 days.\textsuperscript{135} It is also an offense to import such embryos, meaning mitochondrial

\textsuperscript{130} The WA regulations are an exception here, using the undefined term of biological parent. See notes 104–107.
\textsuperscript{131} COAG Communique and Attachment \textit{supra} note 126, at cl 2.2 (emphasis added).
\textsuperscript{132} The Warnock Committee report that led to the UK legislation recommended this be allowed. Dept. of Health & Social Security (UK), \textit{REPORT OF THE COMMITTEE OF INQUIRY INTO HUMAN FERTILISATION AND EMBRYOLOGY}, Chair Dame Mary Warnock (HMSO, London, Cmnd 9314, July 1984) (Warnock Report), at rec. 44.
\textsuperscript{133} These amendments were made following the first of two statutory reviews of the national scheme in 2005. Legislation Review Committee, \textit{PROHIBITION OF HUMAN CLONING ACT 2002 AND THE RESEARCH INVOLVING HUMAN EMBRYOS ACT 2002, FINAL REPORT} (Australia, Dec. 2005) (Lockhart Review), at rec. 26. Subsequent changes to the Commonwealth legislation were made by the \textit{Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006} (Cth).
\textsuperscript{134} \textit{Prohibition of Human Cloning for Reproduction Act 2002} (Cth) s 13. These changes allow the creation of human embryos by cloning for research purposes. In all cases though, that creation must be licensed (s 23). See also \textit{Research Involving Human Embryos Act 2002} (Cth) s 10A(b)(ii). Licenses for such research can be granted pursuant to \textit{Research Involving Human Embryos Act 2002} (Cth) s 20(1)(c).
\textsuperscript{135} \textit{Prohibition of Human Cloning for Reproduction Act 2002} (Cth) ss 14, 20(3) and (4)(c). Equivalent state and territory legislation was also amended (except in WA) to follow the same approach as the federal legislation. \textit{Human Cloning and Embryo Research Act 2004 (ACT)} ss 11 and 21; \textit{Human Cloning for Reproduction and Other Prohibited Practices Act 2003} (NSW) ss 8 and 18; \textit{Research Involving Human Embryos and Prohibition of Human Cloning for Reproduction Act 2003} (Qld) ss 9 and 19; \textit{Prohibition of Human Cloning for Reproduction Act 2002} (SA) ss 8 and 18; \textit{Human Cloning for Reproduction and Other Prohibited Practices Act 2003} (Tas) ss 11 and 20B; \textit{Prohibition of Human Cloning for Reproduction Act 2008} (Vic) ss 9 and 19. The \textit{Human Reproductive Technology Act 1991} (WA) s 53I does not permit human embryos of any kind to contain genetic material provided by more than two people. The relevant amending bill failed to pass the WA upper house on a conscience vote 18:15 in May 2008.
replacement could not be undertaken overseas and the embryo imported into Australia for clinical use.136

The practical results of this change for the development of reproductive technologies are not great. With respect to research embryos, at most the changes allow research into only one of the two most promising forms of mitochondrial replacement.137 Research into maternal spindle transfer (MST) but not pronuclear transfer (PNT) continues to be prohibited due to differences in the timing of the transfer of nuclear DNA. MST moves nuclear DNA from the intending mother’s egg to an unfertilized enucleated donor egg. The recombined egg is then fertilized with sperm to produce an embryo. That embryo will comprise DNA from the intending mother, the egg donor, and the sperm contributor. Importantly for the purposes of the legislation, it is created by fertilization of a reconstructed egg and is therefore prohibited.138

In contrast, licenses to create reconstructed embryos using PNT are available.139 In PNT, two eggs (one from the intending mother and the other from a donor) are fertilized by sperm. Fertilized eggs do not meet the definition of embryo until they divide.140 Before the fertilized eggs have divided, and therefore before they have become embryos, the now combined nuclear DNA of the intending parents is transferred from the intending mother’s egg to the enucleated donor egg and allowed to develop into a reconstructed embryo. That development is characterized as creation other than by fertilization of an egg by sperm and is therefore allowed with a license.141 The NHMRC advised the Senate mitochondrial replacement inquiry that the initial creation and destruction of the two fertilized eggs could be licensed as could the creation of the reconstructed embryo.142 As the NHMRC submission observed:

In other words, the two methods have the same aim, and lead to the same outcome, but under Australian law research into one technique is prohibited and the other is allowed.143

136 Prohibition of Human Cloning for Reproduction Act 2002 (Cth) s 20.
137 NHMRC Submission to Australian Senate Standing Committee on Community Affairs, supra note 12, at 7. However, as the NHMRC (the body responsible for licensing embryo research) has observed, there is little benefit in doing such research because use of the resulting embryos for reproduction continues to be prohibited. The NHMRC has said that ‘research to refine the technique of PNT could be conducted under license in Australia. While not without some doubt, the same legislative provisions may allow a clinic to apply for a license to conduct training and validate the technique, although there would be little benefit in doing this if mitochondrial donation for reproduction was prohibited.’ NHMRC Submission to Australian Senate Standing Committee on Community Affairs, supra note 12, at 7.
138 Id.
139 Pursuant to Research Involving Human Embryos Act 2002 (Cth) s 20(1)(c). Such licenses are granted by the Embryo Research Licensing Committee, a Principal Committee of NHMRC established under the Research Involving Human Embryos Act 2002 (Cth).
140 Research Involving Human Embryos Act 2002 (Cth) s 7(1) definition ‘human embryo.’
141 Prohibition of Human Cloning for Reproduction Act 2002 (Cth) s 22.
142 Pursuant to Research Involving Human Embryos Act 2002 (Cth) s 20(1)(e). The embryo could be maintained in culture to assess the success of the procedure for up to 14 days (Prohibition of Human Cloning for Reproduction Act 2002 (Cth) s 14).
143 NHMRC Submission to Australian Senate Standing Committee on Community Affairs, supra note 12, at 7. It added ‘[t]his highlights the difficulty of prohibiting particular techniques in legislation, given evolving research which may offer several routes to achieve the same end result. If the legislation were to be amended, consideration should be given to regulating outcomes rather than techniques.’
The NHMRC raised this issue in its submission to the most recent statutory review of the national scheme in 2011 (the Heerey Review). The NHMRC also submitted that mtDNA should be excluded from the meaning of genetic material for the purposes of the offense of creating embryos with more than two people's DNA. Unfortunately, the Heerey Review did not address these issues because the techniques were not considered sufficiently advanced to be permitted. Returning to genetic identity, a minority view of the Heerey Review Committee went further, concluding that PNT was hype, unproven, and too risky. The minority view drew on objections based on genetic identity to argue that mitochondrial replacement focused too much on the wishes of prospective parents, ignored the rights of the child, and might compromise the child’s right to be conceived with a natural biological inheritance. There is no explanation of what a natural biological inheritance is, but the main report later quotes from the work by Margaret Somerville on a different issue, which uses the same language. The central report says:

Somerville proposes a right ‘to be conceived with a natural biological heritage’—that is, ‘a right to be conceived from a natural sperm from one identified, living, adult man and a natural ovum from one, identified, living, adult woman.’

This was not an issue included in genetic identity concerns when the prohibition was originally introduced. The governmental agreement establishing the scheme explained that the restriction on the maximum number of genetic contributors was because of concern for the person born. But that concern was about the clinical safety and efficacy of cytoplasmic transfer. In any case, by 2011 the majority of the Heerey Review Committee concluded that it was not clear that the Australian community endorsed Somerville’s view. The majority’s discussion was part of the Committee’s consideration of another matter addressed by the second-generation regulations—the minimum number of contributors.
B. Minimum Number of Genetic Contributors

Through its prohibition on reproductive human cloning, the national scheme prohibits children having only one genetic contributor.\(^{152}\) In language that echoed earlier objections based on genetic identity, the Heerey Review noted that this was because ‘cloning of a human being for reproduction contravenes the most basic understanding of human identity and individuality.’\(^{153}\) As one activist group argued, there were concerns that ‘[t]he resultant lack of individual genetic identity, . . . may lead a child to face confusion, bewilderment, tension, self-consciousness and psychological problems relating to individual identity and incompleteness.’\(^{154}\) As will be discussed though, Australia’s regulatory response and lack of clarity on genetic identity creates uncertainty on this boundary.

A human embryo clone is ‘a human embryo that is a genetic copy of another living or dead human.’\(^{155}\) Importantly for understanding genetic contribution, the legislation instructs that it is sufficient if the nuclear genes are copied and it is not necessary to show the copies are identical.\(^{156}\) The final qualification was intended in part to future proof this provision by ensuring that genome editing of an early embryo (that is, purposeful interference with the nuclear DNA) does not prevent the resulting entity from being a clone.\(^{157}\)

Returning to the restriction on the maximum number of genetic contributors discussed above, this definition may mean that mitochondrial replacement does not offend the prohibitions around combining the genetic material of more than two people. Rather, it could be argued that the definition demonstrates that mtDNA is to be ignored when assessing the genetic makeup of an embryo. However, this is not the case because the definition of a human embryo clone is intended to assist in determining whether there is sufficient copying to constitute cloning; it does not mean that mtDNA is irrelevant in determining whether more than two people’s genetic material has been combined.\(^{158}\) As the Explanatory Memorandum explains, the qualification to the definition of clone ensures that the presence of mtDNA that is not identical to that of the human from whom the nuclear DNA is taken, as occurs in cloning, does not prevent the resulting embryo from being a clone.\(^{159}\)

Nevertheless, the exclusion of mtDNA when assessing whether an embryo is a clone, may mean that mitochondrial replacement contravenes the controls around the

\(^{152}\) The restriction was first introduced in Victoria, although cloning was not defined. Infertility (Medical Procedures) Act 1984 (Vic) (now repealed) ss 6(1) and (2)(a). Human cloning was also prohibited by the Human Reproductive Technology Act 1991 (WA) s7 and Reproductive Technology (Code of Ethical Research Practice) Regulations 1995 (now revoked) reg 6, made under the Reproductive Technology Act 1988 (SA) (as it was then known). The Gene Technology Act 2000 (Cth) s 192B (section now repealed) and the complementary state legislation also prohibited human cloning until the passage of the national scheme.

\(^{153}\) Heerey Review, supra note 146, at 42.

\(^{154}\) Andrews Report, supra note 126, at para 6.48 quoting Pro-Life Victoria, Submissions, S673–674. See also para 6.4.

\(^{155}\) Prohibition of Human Cloning for Reproduction Act 2002 (Cth) s 8(1) definition ‘human embryo clone.’

\(^{156}\) Prohibition of Human Cloning for Reproduction Act 2002 (Cth) s 8(2).

\(^{157}\) Commonwealth, House of Representatives, EXPLANATORY MEMORANDUM FOR RESEARCH INVOLVING EMBRYOS AND PROHIBITION OF HUMAN CLONING BILL 2002 (2002) at 6–7.

\(^{158}\) The definition says ‘in establishing whether one embryo is a genetic copy of another human (and therefore a clone)...’

\(^{159}\) Commonwealth, House of Representatives, EXPLANATORY MEMORANDUM, supra note 159, at 6.
minimum number of genetic contributors. This will be the case if embryos created through mitochondrial replacement are clones. As noted in Section 3, there is a division in the ethics community on when identity is fixed.\textsuperscript{160} However, it is unlikely mitochondrial replacement would be cloning for legal purposes. Instead, as Reznichenko et al. conclude in the context of South African law, the ‘resulting child will be the first of its kind and not a clone of an already existing human.’\textsuperscript{161} Where MST is used, the reconstructed egg created on the way to producing an embryo is not a genetic copy of another human, such eggs being haploid cells (that is, containing a single set of chromosomes in the nuclear DNA). In PNT the two fertilized eggs produced during the technique are not embryos pursuant to Australian law because they have not yet undergone their first mitotic division.\textsuperscript{162} Therefore the fact that the nuclear DNA of the reconstructed fertilized egg is the same as the nuclear DNA of the intending mother’s fertilized egg is insufficient to be a human embryo clone for the purposes of the legislation.

Other uncertainties exist at this boundary besides that concerning the scope of germline modification. Despite the prohibition of cloning for reproduction, it is not clear that Australian law requires more than one genetic contributor to human embryos. This will depend upon whether the prohibition is intended to prevent asexual reproduction (that is, clone refers to the method of reproduction as one not involving the combination of two gametes) or the outcome of the technique (an organism that is genetically identical to another entity). If it is the latter, then pursuant to the definition of human embryo clone, only the nuclear genome is relevant.\textsuperscript{163} This uncertainty is of growing importance as another reproductive technology develops—that of SCD gametes.\textsuperscript{164}

\textsuperscript{160} For example, Hoppe and Rensten assert that mitochondrial replacement is aimed ‘at replacing the sick child with a healthy child.’ They go on to note that ‘The genuinely interesting question here would actually be why a scientifically informed interference with the “raw material” is more problematic than a subsequent discarding of a morphologically undesirable embryo.’ N. Hoppe & K. Rensten, The Draft Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015, I CORAM CHAMBERS GENETICS LAW JOURNAL 19, 21 (2015). The Singaporean Bioethics Advisory Committee goes further on this issue. It sees one form of the therapy (MST) as a form of selective reproduction involving egg manipulation and therefore a less ethically acceptable option than the other form (PNT) on the basis of eugenics. Singapore, Bioethics Advisory Committee, supra note 6, at para 81. See also Wrigley et al., supra note 62.

\textsuperscript{161} A. S. Reznichenko et al., Mitochondrial Transfer: Ethical, Legal and Social Implications in Assisted Reproduction, 8 SOUTH AFRICAN JOURNAL OF BIOETHICS AND LAW 32, 32–33 (2015).

\textsuperscript{162} Prohibition of Human Cloning for Reproduction Act 2002 (Cth) s 8(1) definition ‘human embryo.’ Under the previous definition of ‘human embryo’ [Prohibition of Human Cloning Act 2002 (Cth) (as it was then known) s 8(1) definition ‘human embryo’], it was arguable that such entities would be embryos and the reconstructed embryo resulting from PNT would then be a clone of the fertilized egg from the intending mother, because both entities would share the same nuclear DNA. This definition has now been replaced.

\textsuperscript{163} For this approach to having two distinct meanings of clone in a scientific sense, see National Health and Medical Research Council, SCIENTIFIC, ETHICAL AND REGULATORY ASPECTS OF HUMAN CLONING (1998). Gogarty notes that the Australian Academy of Science statement Human Stem Cell Research (2001) concentrates on the outcome rather than the method but with a lower threshold for similarity than that required by the NHMRC. B. Gogarty, Cloning Around with Words (Regulating the New Frontiers: Legal Issues in Biotechnology, Hobart 2002) at 146. Although both reasons were advanced to the Andrews Committee as reasons why reproductive cloning should be prohibited, the Andrews Report favored the latter definition (Andrews Report, supra note 104, at paras 2.36 and 6.37).

\textsuperscript{164} Smajdor and Cutas, supra note 45, at 4.
offend the first-generation state ART regulations and NHMRC Guidelines around genetic identity because the genetic contributors will be identifiable. Further, it is unlikely that using a gamete produced by one member of a same sex couple and a counter-gender gamete produced by the other partner offends the prohibition on mixing gametes from two people of the same sex, because these provisions expressly refer to the germ cell produced by that sex rather than using the term gamete. That is, they prohibit, for example, the mixing of ‘sperm’ (rather than gametes) from different men.

It is possible such use is also not prohibited by the second-generation regulations. The Heerey Review considered whether an express prohibition on the clinical use of SCD gametes was needed. It recommended that the reproductive use of human SCD gametes should not be permitted because the Australian community had not had sufficient opportunity to consider that use. Nevertheless, it decided that a legislative ban was not needed because use of the technology was not a real possibility at that time. The Review also pointed to the prohibition on placing in a woman embryos created by a process other than fertilization of a human egg by a human sperm. It is submitted here that this is not sufficient to prevent the clinical use of SCD gametes. SCD gametes are likely to be ‘human gametes’ for the purposes of the national scheme, because the relevant definitions are inclusive rather than prescriptive, leaving open the possibility that other forms of gametes can be included. Further, SCD gametes will contain the human genome, and the analogous definition of human embryo includes embryos created through ‘artificial’ processes such as cloning. This interpretation means resulting embryos would be created by fertilization and the prohibition on implantation would not apply.

A final development in SCD gametes further challenges the regulation of the minimum number of genetic contributors. As the Heerey Review explained, ‘this technology might also enable one person to have their own child without another parent through the fertilization of his or her natural gamete with an opposite-sex [SCD] gamete derived from the same person.’ The Heerey Review recommended that creation of embryos for research using SCD gametes be permitted but added that this

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165 Lockhart Review, supra note 134, at 35, briefly noted that at that time, ‘[t]his technique [development of gametes from ESC] and other novel methods of producing gametes are being developed overseas (see Section 4.2) but cannot be developed for human use in Australia under current legislation.’ See also ISSCR, Guidelines for Stem Cell Research and Clinical Translation (2016) guideline 2.1.

166 Heerey Review, supra note 1146, at 65.

167 It concluded: ‘This recommendation should not be read as implying that the Review Committee thinks that the reproductive use of human [SCD] gametes should ultimately be permitted. Instead, it simply seeks an increase of scientific knowledge about human [SCD] gametes.’ Id. at 66.

168 Id. at 65. That provision is Prohibition of Human Cloning for Reproduction Act 2002 (Cth) s 20(3)(a).

169 Prohibition of Human Cloning for Reproduction Act 2002 (Cth) s 8(1) definition ‘human sperm. The definition is ‘human sperm’ includes human spermatids.’ With respect to eggs, s 8(7) provides that ‘A reference in this Act to a human egg is a reference to a human oocyte.’ The Heerey Review expressly recommended that human egg and human sperm should not be defined in the legislation. Heerey Review, supra note 146, at rec 16. However, it also recommended that a legislative definition of ‘IVD gametes’ be included and this has not been done. Id. at rec. 12.

170 Id. at 65. See U.S. Ethics Committee of the American Society for Reproductive Medicine, Using family members as gamete donors or gestational carriers, 107 FERTILITY AND STERILITY 1136 (2017).
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was ‘provided that the sperm and egg are not derived from the same person.’\textsuperscript{171} This change was not made to the legislation. The prohibition on reproductive cloning would not prevent such embryos. An embryo created from SCD gametes derived from the somatic cells of one person would not be a clone of that person because the embryo would be created by fertilization of an egg by a sperm, allowing recombination of genetic material (albeit from the same individual). The embryo’s nuclear DNA would not be identical to that of the ‘parent’ whose cells were used to create the gametes.\textsuperscript{172} The only state ART legislation which addresses this issue (that of WA) would be ineffective here because it refers to the counter-gender gamete coming from another member of the family rather than from the one intending parent.\textsuperscript{173} However, it is likely that such use is prohibited by the NHMRC Guidelines. Pursuant to those Guidelines, clinics are prohibited from creating embryos from gametes derived from close genetic relatives.\textsuperscript{174} It is submitted this should apply to self-fertilization although further clarity in the guideline (by expressly referring to self-fertilization) would be beneficial.

C. Heritability

That is not the end of the legislative difficulties for reconstructed reproductive embryos. It is arguable that mitochondrial replacement and other cell reconstruction techniques are prohibited by a further provision in the national scheme. This prohibits the alteration of the genome of human cells in such a way that the alteration is heritable by the descendants of the human whose cell was altered, if that alteration is intended to be heritable.\textsuperscript{175} The definition of human cell for these purposes means the prohibition applies to eggs, fertilized eggs or embryos involved in mitochondrial replacement, and also SCD gametes (assuming the argument below that SCD gametes are human sperm and eggs is correct).\textsuperscript{176}

It is unclear what genome or heritable means in this context.\textsuperscript{177} Like with the prohibition around the maximum number of genetic contributors, it is arguable that genome for these purposes should not include mtDNA. The Explanatory Memorandum on the original provision says it is intended to prohibit:

\begin{itemize}
  \item \textsuperscript{171} Heerey Review, supra note 146, at rec. 11.
  \item \textsuperscript{172} Nevertheless, the risk of genetic anomalies is thought to be greater for such children. See, for example, Peter Whittaker, Stem Cells to Gametes: How Far Should We Go?, 10 Human Fertility 1 (2007).
  \item \textsuperscript{173} Human Reproductive Technology Act Directions 2004 (WA), Directions 7.3 and 7.4, made under the Human Reproductive Technology Act 1991 (WA) Part 3.
  \item \textsuperscript{174} NHMRC Guidelines, supra note 67, at guideline 5.2.2.
  \item \textsuperscript{175} Prohibition of Human Cloning for Reproduction Act 2002 (Cth) s 15(1). Placing an embryo with such a cell into a woman is also prohibited. Prohibition of Human Cloning for Reproduction Act 2002 (Cth) ss 20(3) and (4)(f). The Lockhart Review had recommended that the creation of ‘traditional’ embryos carrying heritable changes to their genomes for research be allowed, provided that such creation was licensed. Lockhart Review, supra note 134, 164. However, this recommendation was not adopted, and the Government’s Legislative Response to the recommendations does not explain the reason for this. Australian Senate Standing Committee on Community Affairs, Legislative responses to recommendations of the Lockhart Review (Cth 2006).
  \item \textsuperscript{176} Human cells for these purposes are defined to include human embryonal cells, human fetal cells, human sperm, or human eggs. Prohibition of Human Cloning for Reproduction Act 2002 (Cth) s 15(2).
  \item \textsuperscript{177} This has been identified as a common problem in a review of international approaches. See Rosario Isasi et al., Editing Policy to Fit the Genome? Framing Genome Editing Policy Requires Setting Thresholds of Acceptability, 351 Science 337, 337 (2016).
\end{itemize}
any manipulation of a human genome that is intended to be heritable, that is, able to be passed on to subsequent generations of humans. This clause bans what is commonly referred to as germ line gene therapy. In germ line gene therapy, changes would be made to the genome of egg or sperm cells, or even to the cells of the early embryo. The genetic modification would then be passed on to any offspring born to the person whose cell was genetically modified and also to subsequent generations. Ambiguity arises because it is unclear if a change to mtDNA is a germline change. Heritable changes for the purposes of the equivalent UK offense (which prohibits clinical applications of germline modification) are limited to changes to nuclear DNA. Nevertheless, the United Kingdom took the step of excluding mitochondrial replacement from the operation of this provision by expressly allowing mitochondrial replacement for particular specified purposes. Similarly, Singapore’s Bioethics Advisory Committee has suggested distinctions be made on the basis of whether nuclear or mitochondrial DNA is the subject of change. The Netherlands has also moved to legalize mitochondrial replacement but has taken a more liberal approach to heritable changes. Its legislation (2002 Dutch Embryo Act) limits the ban on reproductive germline modification to the intentional modification of the nuclear DNA. This approach arguably allows genome editing of the mtDNA to ‘repair’ existing mtDNA rather than replace it. It is submitted that the Australian prohibition on heritable changes to the human genome was not intended to prevent changes to mtDNA. The prohibition on embryos containing genetic material from more than two people would not have been needed if mtDNA was included in genome for the purposes of the prohibition on making heritable changes to the genome.

VI. DISCUSSION
This paper’s examination of Australia’s reproductive technology regulations demonstrates the intentional protection of only some of the matters included in the concept of genetic identity. First-generation regulatory responses to concerns about the genetic identity of children conceived with ART were intended to ensure that the identity of the child’s genetic contributors was known and that legal parentage was certain. These matters are central to children’s genetic identity. But using the interpretation of genetic identity adopted by this paper, children’s genetic traits are another important part of a child’s genetic identity. The maximum and minimum numbers on genetic contributors and prohibition of heritable changes to the genome, imposed by second-generation regulation (the national scheme), could be seen as addressing this aspect of genetic identity. However, this was not the objective of the regulations. As explained above, the national scheme’s constraints on genetic contribution to reproductive embryos

178 Commonwealth, House of Representatives, EXPLANATORY MEMORANDUM supra note 159, at 12.
179 Singapore, Bioethics Advisory Committee, supra note 6, at para 76. Note though that Singapore does not have an equivalent prohibition in its legislation. The Committee also noted that selecting male embryos could avoid intergenerational impacts although it has not yet decided whether to take that approach. The Singaporean Committee seems to have accepted the view that mitochondrial replacement is not genetic modification because whole intact mitochondria are replaced by the technique rather than existing mitochondrial DNA being modified.
180 Guido De Wert et al., Responsible Innovation in Human Germline Gene Editing: Background Document to the Recommendations of ESHG and ESHRE, 26 European Journal of Human Genetics 450, 456 (2018).
are an artifact of regulatory evolution rather than a deliberate step to protect resulting children's genetic identity. These past responses to genetic contribution and impacts on children's genetic identity should inform the third-generation regulatory responses in preparation for emerging reproductive technologies. Reform is urgently needed to update the regulations around reproductive embryos while being mindful of the repercussions for genetic identity. In particular, decisions must be made about the significance (or not) of the kind (nuclear or mitochondrial) and amount of genetic contribution to human embryos.

The emerging technology closest to clinical use in Australia is mitochondrial replacement. While such use is currently prohibited, legalization could be achieved by clarifying that mtDNA is excluded from the meaning of human genome for the purposes of the national scheme. There is currently no definition of genome in the national scheme. This straightforward approach would mean mitochondrial replacement would not contravene the two prohibitions in the national scheme preventing clinical use: the prohibitions against reproductive embryos containing genetic material from more than two persons and against making heritable changes to the human genome. Treating mtDNA as separate from the human genome would not jeopardize existing regulations protecting children's genetic identity, namely, the state ART regulations and NHMRC Guidelines. As explained in Section 4, the kind and amount of DNA contributed to a human embryo is not relevant to these protections. Unlike the United Kingdom's approach whereby mtDNA donors are not treated as gamete providers, the state ART regulations and NHMRC Guidelines do not distinguish between the contribution of nuclear and mitochondrial DNA. The contribution of either kind of DNA is therefore sufficient to attract the protections provided by these regulations. An alternative to excluding mtDNA from the meaning of human genome is to exclude it only in relation to particular therapies, such as mitochondrial replacement. The difficulty here is that the purpose and consequences of therapies and the techniques used in those therapies change over time. A committee could be authorized to make decisions on what these therapies are into the future, to future proof this aspect of the regulations, but independent policy guidance around the significance of the kind and amount of genetic contribution would be sensible.

The justifications for taking the step set out above are arguably as important as the step itself. As discussed in Section 4, both the Australian Senate inquiry into mitochondrial replacement and the UK Government rejected the conclusion that mtDNA affects a child's personal characteristics and traits. Justifying legalization of mitochondrial replacement on the basis of the lack of impact on the resulting child's traits is neither necessary nor the best approach for Australia. Such justification is not necessary because as the analysis in Section 5 demonstrates, the prohibition on reproductive embryos containing genetic material from more than two people was driven by concerns around safety and efficacy. The Australian Government has recently proposed that the safety and efficacy of mitochondrial replacement be addressed by an Australian scientific panel and/or studies by Australian experts.181 If mitochondrial replacement is found to be sufficiently safe and effective, legalization would be

181 Australian Government response, supra note 39, at 4. See also Australian Senate Standing Committee on Community Affairs, supra note 12, at paras 3.97–3.106.
consistent with the objectives of the national scheme. As to the second objection, that it is not the best approach in the context of Australian law, justification on the basis that there is no impact on children’s genetic identity invokes broader protections of that identity than Australian law has previously provided. Existing protections of children’s genetic identity is limited to certainty around contributors’ identity and parentage. Broadening of protection may be acceptable given that attitudes of Australian society have probably moved on since the creation of the national scheme, but unnecessary difficulties are created. For example, excluding mtDNA from the national scheme’s understanding of the genome on the basis that mtDNA is not relevant to genetic traits inevitably strengthens calls to allow corrective genome editing of mtDNA. Further, there could be calls to allow genome editing of nuclear DNA involved in the operation of genes on mtDNA on the basis that they similarly are not relevant to genetic identity. As the NHMRC advised in its submission to the Senate inquiry into mitochondrial replacement, ‘there is considerable research overseas into editing specific genes in the nuclear DNA of human embryos,’ particularly to correct mutations leading to disease or disability, and there may be calls to allow this in Australia. Instead, if mitochondrial replacement is to be legalized, justification should be framed in terms of the significance (or not) of the therapeutic purpose of the technology.

Moving from mitochondrial replacement to genome editing and SCD gametes, the analysis above shows that regulations imposing a minimum number on genetic contributors need urgent amendment. The minimum boundary is intended to prevent reproductive cloning but should also ensure that consanguinity does not occur. It must be clarified that SCD gametes used in the creation of reproductive embryos cannot be sourced from the one person. Further, if clinical mitochondrial replacement is legalized and the mtDNA donor is, as submitted in this paper, treated as a genetic contributor, regulations should ensure that a donor’s contribution of mtDNA is not sufficient to cause reproductive embryos to comply with the minimum boundary. Without such clarification and assuming mtDNA is excluded from the meaning of genome, it could be argued that reconstructed embryos conceived with nuclear DNA from SCD gametes derived from the same individual have two genetic contributors when nuclear DNA is moved into a donor’s enucleated egg through mitochondrial replacement. State ART regulations and NHMRC Guidelines should also be amended to use the neutral term of gamete and not sperm or egg as is currently used to ensure that children conceived using emerging technologies receive the same protections of their genetic identity as other children.

Finally, difficult decisions need to be made about whether and why genome editing of the mitochondrial and/or nuclear DNA of embryos should continue to be prohibited. Public consultation is urgently needed on the significance of these technologies and concerns about the resulting child’s genetic identity resulting from the crossing of the maximum boundary, to inform policy decisions on this matter.

182 Australian Senate Standing Committee on Community Affairs, supra note 12, NHMRC submission at 8. See also David Baltimore et al., Biotechnology: A Prudent Path Forward for Genomic Engineering and Germline Gene Modification, 348 SCIENCE 36 (2015). Hong Ma et al., Correction of a Pathogenic Gene Mutation in Human Embryos, 548 NATURE 413 (2017).
VII. CONCLUSION

Knowing what science is capable of is not the best way to answer questions about whether and how to protect genetic identity, but it is fundamental to deciding how to regulate it. As Price says ‘[w]hen faced with hard social questions in areas of changing science, the law should look to that science for input, not answer.’\(^{183}\)

In the reproductive space, Australian law responds to concerns around the impact on the resulting children’s genetic identity. Making the limited changes suggested above to allow clinical use of mitochondrial replacement in Australia will legalize the technology while ensuring resulting children receive the same protection of their genetic identity as other children. However, those changes will not be sufficient for long—other technologies are quickly developing which also challenge current regulations. A broader overhaul of the national scheme is required, to make it more responsive to scientific and societal changes. As a European expert body has said, ‘[i]t should be considered to structure a legal framework that could be more flexible and promptly reactive to the evolution of the technologies and possibilities, under an appropriate societal oversight.’\(^{184}\) What protections should be given to children’s genetic identity should be part of policymakers’ considerations when updating Australia’s reproductive technology reproductive framework. But responding to this requires an understanding of genetic identity itself. It was suggested in Section 1 that this should be understood to include the narratives around a technology. Regulatory responses form part of this narrative, and justifications for and language in regulations matter for this reason.\(^{185}\)

The approach taken in the United Kingdom is instructive here. The UK regulations focus on the purpose of a technology, in particular what therapeutic purpose it serves, rather than the technology itself. Such an approach means decisions must be made by policymakers as to the uses of a technology, something on which public consultation is needed. Further, this approach is more straightforward in the United Kingdom than in Australia because the United Kingdom does not have the splintered regulatory framework that Australia does. The changes suggested above will require both federal and state government approval and changes to national and state legislation. But a third-generation approach to regulation is urgently needed, and policymakers need to begin now.\(^{186}\)

\(^{183}\) W. Nicholson Price, *Am I My Son? Human Clones and the Modern Family*, 11 *The Columbia Science and Technology Law Review* 119, 121 (2010).

\(^{184}\) G. De Wert et al., *supra* note 189, at 456.

\(^{185}\) Natacha Salomé Lima, *Narrative Identity in Third Party Reproduction: Normative Aspects and Ethical Challenges*, 15 *J. of Bioethical Inquiry* 57 (2018).

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