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Smith, Malcolm K. (2007) Reviewing Access to Assisted Reproductive Tecnology for the Creation of 'Saviour Siblings': Limits on the Basis of Genetic Disposition?. In *Proceedings The Australasian Bioethics Association and The Australian and New Zealand Institute of Health, Law and Ethics Joint Conference 2007. Health, Bioethics and the Law: Inclusions and Exclusions*, Melbourne, Australia.

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REVIEWING ACCESS TO ASSISTED REPRODUCTIVE TECHNOLOGY FOR THE CREATION OF 'SAVIOUR SIBLINGS': LIMITS ON THE BASIS OF GENETIC DISPOSITION?

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The regulation of assisted reproductive technology (ART) in Australia is a complicated mix of legislation, professional standards and guidelines. The legislation in Victoria, South Australia, and Western Australia, place limits on access to fertility services that do not exist in the non-statutory jurisdictions. Those who are clinically infertile or at risk of passing on a genetic disease or disorder if they were to naturally conceive are able to access services. However, it is arguable that the statutory eligibility criteria remain discriminatory in two ways despite the impact of previous court challenges. Firstly, it remains discriminatory to deny access to single and lesbian women unless they have been unable to conceive after having heterosexual intercourse over a required time frame.

The main focus of the paper however, relates to the second aspect of the statutory eligibility criteria, particularly in relation to the creation of 'saviour siblings'. Some couples seek access to IVF services on the basis that they wish to have another child who would also be a tissue type match for an existing ill child. The use of pre-implantation genetic diagnosis offers assistance in establishing tissue type prior to implantation of an embryo in the IVF cycle. However, under the current statutory eligibility criteria, a couple will only be granted access if they are themselves at risk of passing on a genetic disease or disorder. This means a couple who wish to use PGD *solely* to detect tissue type would not fall within the eligibility criteria. The lack of eligibility criteria in the non-statutory jurisdictions means that the technology is potentially available for detecting tissue compatibility regardless of whether the parents are themselves at risk of passing on a genetic disease. A distinction that is arguably irrelevant.

INTRODUCTION

The regulatory regime of assisted reproductive technology (ART) in Australia is extremely varied. The Fertility Society of Australia (FSA) requires clinics and practitioners to be accredited by the Reproductive Technology Accreditation Committee (RTAC), and the *Code of Practice for Assisted Reproductive Technology Units 2005* issued by such, requires adherence to the National Health and Medical Research Council (NHMRC) Guidelines.¹ The majority of Australian States and Territories have relied on this form of regulation alone and have not passed legislation dealing directly with the issues surrounding ART. The NHMRC guidelines are not as detailed as statutory regimes. This is reflective of the recognition that some of the issues should be left to each State or Territory to decide and are beyond the remit of the Australian Health Ethics Committee (AHEC), the major committee of the NHMRC responsible for developing the guidelines.² Furthermore, there was a call for a uniform and comprehensive framework of legislation issued to all States and Territories by the NHMRC in hope that the social and ethical issues that arise with such

¹ NHMRC, *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research*, September 2004.

² NHMRC, *Ethical Guidelines on Assisted Reproductive Technology*, AGPS, Canberra, 1996, p v.

procedures are directly addressed.³ Only three States have legislated directly on the subject.⁴ In such jurisdictions, legislation prevails over both the RTAC Code of Practice and NHMRC guidelines,⁵ although for the most part legislation on the topic is consistent with them. The structure of regulation in Australia is far from straightforward. Szoke comments that '[a]rguably, Australia may be described variously as a rich tapestry of diversity in terms of the regulatory structure, or a patchwork of regulatory stitching lacking cohesion and order.'⁶ Furthermore, Bennett comments that the 'regulatory framework for assisted conception is complicated by Australia's federal legal structure'.⁷

In Victoria, Western Australia and South Australia, legislation has addressed many of the issues surrounding ART, including: eligibility for treatment services, consent provisions, counselling services to be provided by clinics,⁸ limits on gamete and embryo storage, posthumous conception, the use of pre-implantation genetic diagnosis (PGD), and the status of donors of gametes and the requirements for clinics to maintain a record of such information. Furthermore, the legislative provisions in those jurisdictions create statutory bodies to oversee the statutory framework, all three operating on the basis of a licensing system requiring clinics and clinicians to gain approval from the State prior to delivering treatment services.

In the remaining jurisdictions, despite the lack of legislation clinics are still subject to regulation. As already mentioned, adherence to the RTAC Code of Practice and the NHMRC guidelines is a requirement under the accreditation process administered by the FSA. Furthermore, State or Territory Health Departments may also require fertility clinics to adhere to certain protocols or guidelines. Whilst the NHMRC guidelines alone do address many of the issues covered by State legislation mentioned above, the development of the guidelines has been on the basis of an incremental approach. When issuing the guidelines in 1996, the NHMRC noted that there are certain complex 'social and political' issues involved in regulating ART services, including eligibility criteria, posthumous use of gametes and embryos, and PGD, all considered 'beyond the remit of AHEC in relation to medical research'.⁹ With the exception of eligibility criteria, these issues were subsequently addressed in the 2004 guidelines. Szoke *et al.* comment that these 'changes may well be because the NHMRC's advice in the 1996 guidelines that reproductive technologies should be regulated by statute in each State went unheeded'.¹⁰

There is substantial overlap between the statutory provisions and national guidelines but one fundamental aspect the AHEC has not addressed is that of eligibility for treatment services. This paper will examine the limits placed upon individuals seeking access to fertility treatments. This will involve an analysis of the criteria imposed within the statutory jurisdictions and the significance of such criteria in comparison to the non-statutory jurisdictions, particularly in relation to the creation of 'saviour siblings'.

³ NHMRC, above n 1, 2.

⁴ *Infertility Treatment Act 1995* (Vic); *Human Reproductive Technology Act 1991* (WA); *Reproductive Technology (Clinical Practices) Act 1988* (SA).

⁵ In Victoria for example, 'where the requirements of the Act are different to those of the RTAC *Code of Practice for Assisted Reproductive Technology Units* (2005), then the requirements of the Act take precedence and will be enforced' and similarly, 'where NHMRC Guidelines are inconsistent with the Victorian legislation, the Act takes precedence and over-rides the NHMRC Guidelines.' Infertility Treatment Authority, *Conditions for Licence* (August 2006), 9.

⁶ Helen Szoke, 'Australia - A Federated Structure of Statutory Regulation of ART' in Jennifer Gunning and Helen Szoke (ed), *The Regulation of Assisted Reproductive Technology* (2003) 75, 75.

⁷ Belinda Bennett, 'Symbiotic relationships: Saviour siblings, family rights and biomedicine' (2005) 19(3) *Australian Journal of Family Law* 195.

⁸ In Victoria and South Australia, counselling is *required to be undertaken* by all participants. *Infertility Treatment Act 1995* (Vic) s 11; Regulation 11(4), *Reproductive Technology (Code of Ethical Clinical Practice) Regulations 1995* (SA). In Western Australia and the non-statutory jurisdictions, counselling is not a mandatory requirement – clinics are simply required to make it available to participants: *Human Reproductive Technology Act 1991*, section 22(7); NHMRC, above n 1, 9.3

⁹ NHMRC, above n 2, p v.

¹⁰ Helen Szoke, Lexi Neame, and Louise Johnson, 'Old technologies and new challenges: Assisted reproduction and its regulation' in Ian Freckelton and Kerry Petersen (eds), *Disputes & Dilemmas in Health Law* (Federation Press, Sydney, 2006) 187

The term saviour sibling is relatively new and has been defined as 'a child who is born with genetic characteristics specifically designed to treat the illness of an existing brother or sister'.¹¹ Couples who naturally conceive have a low chance of creating a child that will be a suitable tissue type match for an existing ill-sibling and this has led to families requesting assistance from fertility clinics in order to gain access to *in vitro* fertilisation (IVF) techniques.¹² Pre-implantation Genetic Diagnosis (PGD) has developed the principle of IVF to enable the screening through embryo cell biopsy, of fertilised embryos. The procedure has been typically used by couples at risk of passing on a genetic disease or disorder through natural conception. PGD involves removing one of the cells from the embryo and enables a clinic to determine whether certain genetic characteristics are present in the embryo, or more commonly, to ensure that the embryo intended to be implanted is free from genetically inherited disease. The process enables determination of whether a child is going to be healthy (at least from a genetic point of view) before the embryo is even implanted into the womb.

When the embryo cell is examined for hereditary disease, human leukocyte antigens (HLA) can also be examined to determine whether the embryo will develop into a child with matching tissue type to an existing ill sibling. For some diseases, using blood stem cells harvested from the umbilical cord of the 'saviour sibling' can provide greater prospects of a cure compared with treatment procedures such as bone marrow transplants.¹³

The creation of 'saviour siblings' is permitted in Australia in some circumstances, but in the statutory jurisdictions is dependant upon whether the couple are using PGD primarily for the purpose of preventing the transmission of a genetic disease or disorder. In those jurisdictions, creation of a 'saviour sibling' is therefore subject to the parents being at risk of transmitting genetic disease when conceiving naturally. Enactment of legislation in those jurisdictions was focused on the primary purpose of enabling access to ART for those who were unable to conceive naturally, or at risk of passing on disease through natural conception.¹⁴ It is arguable that this original narrow view of who should be able to access treatment services needs reconsideration. Not only have the current statutory eligibility criteria been subject to legal challenge but also the need for review is further demonstrated by the distinction drawn between the statutory and non-statutory jurisdictions in relation to the creation of 'saviour siblings'.

STATUTORY ELIGIBILITY CRITERIA

Treatments in the statutory jurisdictions are only offered to infertile couples or infertile single women, or those who are at risk of passing on a genetic disorder or disease if they were to naturally conceive.¹⁵ Access was originally limited to married or heterosexual de facto couples, but

¹¹ Definition found at <www.macmillandictionary.com/new-words/030627-saviour-sibling.htm> at 17 July 2007. The term can be criticised on the basis of the implication that parents wishing to create such children are doing so *only* for the purpose of a potential cure for their existing child. Many parents however may wish to have another child to add to their family. The ability to determine the tissue type of that child to potentially cure an existing sibling should not therefore be the only consideration when examining the motives of the parents. For ease of reference, the term will be used throughout the discussion.

¹² See Stephen Bellamy, 'Lives to save lives - the ethics of tissue typing' (2005) 8(1) *Human Fertility* 5

¹³ Lisa Belikin, "The Made to Order Saviour." *The New York Times Magazine*, 1 July 2001.

¹⁴ For example in Western Australia, the preamble of the *Human Reproductive Technology Act 1991* (WA) states: "Parliament considers that the primary purpose and only justification for the creation of a human embryo in vitro is to assist persons who are unable to conceive children naturally due to medical reasons or whose children are otherwise likely to be affected by genetic abnormality or disease, to have children, and this legislation should respect the life created by this process."

¹⁵ In Victoria, the *Infertility Treatment Act 1995* (Vic) s 8 (3) states: In the opinion of a doctor, she must be unlikely to become pregnant with her own egg and her husband's sperm other than by a treatment procedure, or; In the opinion of a doctor with specialist qualifications in human genetics, she must be likely, if she became pregnant with her own egg and her husband's sperm, to give birth to a child with a genetic abnormality or risk communicating a disease to a child unless she undergoes a treatment procedure. In Western Australia, the *Human Reproductive Technology Act 1991* (WA) s 23(a) enables access to ART services where it 'would be likely to benefit' a woman or a couple who are unable to conceive 'due to medical reasons', or 'whose child would be likely to be affected by a genetic abnormality or disease'.

this was challenged in both Victoria and South Australia. The *Sex Discrimination Act 1984* (Cth) prohibits discrimination on the basis of marital status and in *McBain v The State of Victoria & Ors*¹⁶ the marital requirement under the *Infertility Treatment Act 1995* (Vic) was challenged on the basis that a doctor could not comply with both the Commonwealth legislation and the legislation in Victoria when approached by a single woman seeking access to fertility treatment. The Federal Court of Australia held that the Victorian legislation is discriminatory and that it is invalid on the basis that it is inconsistent with the Commonwealth legislation under section 109 of the Constitution.¹⁷ As a result of the *McBain* decision, a woman is not denied access to treatment simply because she is not married or in a heterosexual de facto relationship. Furthermore, in *YZ v Infertility Treatment Authority*, Justice Morris stated that as a result of *McBain*, the Act ‘must be read on the basis that certain of its provisions are inoperative, or, at least, must be understood as being subject to some modification’.¹⁸ A similar ruling was made by the Supreme Court of South Australia in *Pearce v South Australian Health Commission and Others*¹⁹ declaring the marriage requirement under section 13(3) of the *Reproductive Technology (Clinical Practices) Act 1988* (SA) inconsistent with the *Sex Discrimination Act 1984* (Cth).²⁰ In Western Australia, the *Human Reproductive Technology Act 1991* (WA) has been modified and the definition of de facto relationships and partner includes same sex relationships as well as heterosexual relationships.²¹

The Victorian Law Reform Commission (VLRC) has recently published its Final Report on the issue of Assisted Reproductive Technology & Adoption, and has commented on the issue of eligibility for treatment procedures, stating ‘that the marital status requirement is not only inconsistent with the principle of non-discrimination, but it also bears no relationship to the health and wellbeing of children, which must be the paramount concern of the law governing ART.’²²

Marriage has been removed as a requirement for couples seeking access to ART in the statutory jurisdictions. Infertility and the risk of passing on genetic disease remain as the primary factors in establishing access. Infertility has been given a narrow meaning,²³ and access will only be granted

In South Australia, the *Reproductive Technology (Clinical Practices) Act 1988* (SA) Section 13(3) allows treatment where the licensee has been given a letter by a medical practitioner stating either; (i) that the male or female (or both) are infertile, or; (ii) there is a risk that a genetic disease or abnormality would be transmitted to a child conceived naturally.

¹⁶ [2000] 99 FCR 116

¹⁷ Section 109 of Australian Constitution states that ‘when a law of a State is inconsistent with a law of the Commonwealth, the latter shall prevail, and the former shall, to the extent of the inconsistency, be invalid.’

¹⁸ [2005] VCAT 2655 (Unreported, Morris P, 20 December 2005)

¹⁹ (1996) 66 SASR 486.

²⁰ See above n 17.

²¹ *Acts Amendment (Lesbian and Gay Law Reform) Act 2002* (WA), and see Reproductive Technology Council, ‘*Acts Amendment (Lesbian and Gay Law Reform) Act 2002 – Amendment of the Human Reproductive Technology Act 1991 and the Artificial Conception Act 1985*’ (2002), available at <http://www.rtc.org.au/clinics/docs/Info-Gay_and_Lesbian.pdf> at 17 July 2007.

²² Victorian Law Reform Commission, *Assisted Reproductive Technology & Adoption Final Report*, Report No. 10 2006-2007, 67.

²³ In Victoria, the ITA sought guidance on the interpretation of the statutory term ‘unlikely to become pregnant’, as the Federal court in *McBain* was not required to, and did not rule on further eligibility criteria under the legislation. The advice received by the ITA stated that a woman must be *clinically* infertile to gain access to treatment (Legal opinion of Gavan Griffith QC, available from the ITA: www.ita.org.au). Contradicting advice was also given to the ITA by Peter Hanks QC who advised that Griffith’s interpretation reinforces the discriminatory nature of the legislation which was ruled unlawful in *McBain* – as women in a married or de facto relationship do not have to be clinically infertile to gain access to treatment procedures whereas a single woman does have to be clinically infertile to meet the access requirements. In response, Griffith confirmed his original interpretation of the term. The ITA implemented such advice, advising licensed clinics that all women, including those who are not married or in a de facto relationship can only be treated after a medical assessment confirming clinical infertility. The treating clinician has a duty to document clearly the reasons that access to treatment has been granted and, if there is any doubt, the case may be referred to the ITA for advice as to eligibility. ITA, *Conditions for Licence*, above, n 23, 15-16. The ITA goes on to comment that it ‘should be noted that senior counsel’s advice to the Authority states that “The Victorian Act is not transformed by the decision into a law generally regulating alternative methods for conception free of any confining limitation to defined clinical infertility”. Justice Sundberg’s judgment also emphasises this characteristic.’ ITA, *Conditions for Licence*, above n 5, 16.

to those who are unable to conceive due to medical reasons. This narrow definition of infertility still acts as a barrier to single and lesbian women seeking to access treatment services as women are required to show that they are unable to become pregnant after a 12 month period of heterosexual intercourse.

The VLRC has proposed a broader definition of the clinical infertility requirement, recommending that a 'woman be eligible for treatment if she is unlikely to become pregnant and that her inability to become pregnant (or to carry a pregnancy or give birth to a child, or likelihood of transmitting a genetic abnormality or disease) be assessed on the basis of the circumstances in which she finds herself (whether single, married, in a same-sex relationship, psychologically averse to having sexual intercourse with a man, or otherwise).'²⁴

This wider definition proposed by the VLRC would widen the availability of ART in Victoria. It also demonstrates that legislation enacted on the topic of ART needs to evolve in accordance with social attitudes and this is evident from the legal challenges made to the legislation in Victoria requiring broader subsequent interpretation of the statutory terms.

The second limb of the eligibility criteria in the statutory jurisdictions requires there to be a risk of passing on a genetic disease to a child conceived naturally.²⁵ A couple seeking access to treatment to create a 'saviour sibling' will only be able to utilise PGD if they are themselves at risk of passing on a genetic disease or disorder. This means that the primary purpose for using PGD must be for the detection of a genetic abnormality in the embryo. If tissue typing is conducted, it is considered as ancillary to the main purpose of the use of PGD. In Victoria, this is emphasised by the guidelines issued by the Infertility Treatment Authority on the subject of PGD and the selection of embryos based on tissue compatibility.²⁶ Furthermore, when seeking to use the procedure for the creation of a child with compatible tissue for an existing ill child, a number of further factors and ethical considerations are required to be considered by the treating institution.²⁷ Even though the specific issue of selecting embryos on the basis of tissue compatibility is not addressed in Western Australia and South Australia, the statutory eligibility criteria restrict the use of PGD in the same way, limiting its availability to those at risk of passing on genetic disease when conceiving naturally.

WIDENING THE SCOPE FOR THE CREATION OF 'SAVIOUR SIBLINGS'

In the remaining Australian jurisdictions, regulation occurs primarily through the accreditation process administered by the FSA, requiring adherence to the RTAC Code of Practice and the NHMRC guidelines. These national guidelines address a number of significant issues under the ART scope but do not impose eligibility criteria limiting who may access treatments. Taylor-Sands notes that the lack of access criteria in the non-statutory jurisdictions 'leave open the possibility that PGD can be used solely for tissue typing'.²⁸

²⁴ Victorian Law Reform Commission, above n 22, 68.

²⁵ In Victoria, the *Infertility Treatment Act 1995* (Vic) s 8 (3) states: In the opinion of a doctor, she must be unlikely to become pregnant with her own egg and her husband's sperm other than by a treatment procedure, or; In the opinion of a doctor with specialist qualifications in human genetics, she must be likely, if she became pregnant with her own egg and her husband's sperm, to give birth to a child with a genetic abnormality or risk communicating a disease to a child unless she undergoes a treatment procedure. In Western Australia, the *Human Reproductive Technology Act 1991* (WA) s 23(a) enables access to ART services where it 'would be likely to benefit' a woman or a couple who are unable to conceive 'due to medical reasons', or 'whose child would be likely to be affected by a genetic abnormality or disease'. In South Australia, the *Reproductive Technology (Clinical Practices) Act 1988* (SA) Section 13(3) allows treatment where the licensee has been given a letter by a medical practitioner stating either; (i) that the male or female (or both) are infertile, or; (ii) there is a risk that a genetic disease or abnormality would be transmitted to a child conceived naturally.

²⁶ Infertility Treatment Authority, 'Genetic Testing and the Requirements of the *Infertility Treatment Act 1995*: Policy in Relation to the Use of Pre-implantation Genetic Diagnosis (PGD)', (April 2006) and ITA, 'Tissue Typing in Conjunction with Preimplantation Genetic Diagnosis', (January 2004).

²⁷ See ITA, *Ibid*.

²⁸ Michelle Taylor-Sands, 'Selecting "saviour siblings": Reconsidering the regulation in Australia of pre-implantation genetic diagnosis in conjunction with tissue typing' (2007) 14 *Journal of Law and Medicine* 551, at page 560.

The difference in approach between the statutory and non-statutory jurisdictions has significant implications. If the parents of an ill child have explored potential avenues for treatment with no success, and the most probable chance of curing that child is to perform a blood stem cell transplant (or in some cases a bone marrow transplant) from a sibling with compatible tissue, then the parents may wish to use PGD to ensure that their next child is a compatible tissue match. In some instances, the existing ill child may be suffering from a condition that is not genetically inherited, but has onset after birth. The parents may therefore be at no risk of passing on a genetic disease if they were to conceive naturally. Thus, as the existing ill child did not genetically inherit the condition, the parents are at no greater risk of passing on the condition when conceiving in the future. The lack of eligibility criteria in the non-statutory jurisdictions opens the possibility for accessing the use of PGD for such a purpose. Fundamentally, access will not be immediately denied despite the fact that the primary purpose for seeking the use of IVF is to establish the tissue type of an embryo to be implanted, and not for the purpose of preventing transmission of a genetic disease.

Even if a clinic is not required to impose limitations under State or Territory legislation, limits similar to those imposed under ART statutes may still be imposed by the actual clinic. Clinics may therefore require those seeking services to be medically infertile or at risk of passing on a genetic disease through natural conception as part of their own policy. This is demonstrated in the Queensland decision of *JM v QFG* in which a lesbian woman was denied access to treatment by a fertility clinic in Queensland on the basis that the doctor was carrying out his normal procedure in assisting women 'to which he had decided to confine his attention, being women with a problem of "medical infertility"'.²⁹ If the clinic chooses to limit treatment in such a way, those seeking to use PGD *solely* for the purpose of establishing tissue type will not meet the imposed criteria and therefore be denied access to treatment. Not only does this potentially result in different approaches between the statutory and non-statutory jurisdictions based on the imposition of statutory eligibility criteria, but also between clinics operating in the same jurisdiction where eligibility is determined on the basis of a particular clinic's policy.

Whilst the purpose of this paper is to establish the possible distinctions drawn between the statutory and non-statutory jurisdictions on the basis of the eligibility criteria imposed, it does not seek to justify an ethical basis as to which option should be preferred.³⁰ Instead, it seeks to demonstrate the problems that may arise in any future reform or legislative action on the topic of ART when drafting specific provisions outlining who should be eligible for treatment.

One of the clearest examples of the difficulties faced in relation to prescriptive legislation can be demonstrated by examining the legislation in Victoria, which has been subject to a number of subsequent legal challenges and extensive review by the VLRC. Changes to legislation require amendment by Parliament and this has happened 4 times since the Act came into force in 1998.³¹ Furthermore, because of the nature of the regulation, the ITA has had to seek 32 legal opinions during five years of the Authority's operation in an attempt to clarify issues of interpretation.³² Not only has the review process by the VLRC resulted in suggested reform of the definition of infertility, but also a suggested exception to the second limb of the eligibility criteria for the specific issue of using IVF for the creation of 'saviour siblings'. The Victorian Law Reform Commission's *Final Report*,³³ notes that the current system of regulation is too inflexible and does not allow clinics to treat those who may wish to access treatment for reasons other than infertility or risk of passing on genetic disease or disorder. On this basis, the VLRC has recommended that clinics should allow

²⁹ [1998] QCA 228

³⁰ For an ethical discussion on the distinction, see Sally Sheldon and Stephen Wilkinson, 'Hashmi And Whitaker: An Unjustifiable and Misguided Distinction?' (2004) 12(2) *Medical Law Review* 137; Stephen Bellamy, above n 12; Michelle Taylor-Sands, above n 28.

³¹ *Infertility Treatment (Amendment) Act 1997* (Vic), *Infertility Treatment (Amendment) Act 2001* (Vic), *Health Legislation (Research Involving Human Embryos and Prohibition of Human Cloning) Act 2003* (Vic), and *Infertility Treatment Amendment Act 2007* (Vic). See also, Helen Szoke *et al.* (2006) above n 10, 202

³² *Ibid*, 202

³³ Victorian Law Reform Commission, above n 22.

access to participants on grounds other than those currently outlined under the legislation, giving the example of the creation of a 'saviour sibling' as one of those grounds. If such recommendations were implemented, there is the potential to allow access to IVF to use PGD *solely* for the purpose of detecting the tissue compatibility of an embryo in Victoria.

The VLRC has set a benchmark for review of current ART statutes in Australia. Of fundamental importance is the fact that the issues arising in relation to the Victorian legislation are not exclusive to that jurisdiction. As has been established, similar provisions exist under the legislation in Western Australia and South Australia and it is therefore important for both of those jurisdictions to also consider the implication of the detailed review conducted by the VLRC. Furthermore, the issues arising in the statutory jurisdictions are of equal importance for other Australian jurisdictions that may consider the issue or regulation of ART in the future.

ART REGULATORY APPROACHES

The prescriptive nature of the Victorian approach can be compared to the legislation in the United Kingdom, which delegates far more discretion to the statutory body overseeing the regulation.³⁴ This enables the UK's statutory body to change policy on a particular issue (within its jurisdiction) without the need for legislative reform. The UK's Human Fertilisation and Embryology Authority (HFEA) initially restricted the use of PGD for the purpose of selecting an embryo with compatible tissue for an existing ill sibling to cases where the child to be born was itself at risk of being born with a serious genetic disease.³⁵ However, the HFEA later amended its policy stating that PGD can be used for tissue typing even where the primary purpose is not for the detection of a genetic disorder or disease.³⁶

The ability to change policy is due to the fact that there are no specific access criteria imposed by the legislation in the UK. Treatment is not limited to married couples, nor is there a requirement that those seeking treatment are clinically infertile or at risk of passing on a genetic disease or disorder, such as the criteria imposed in the Australian statutory states. The main assessment that is to be made by any clinic providing treatment services in the UK relates to the welfare of the child.³⁷ The decision to grant access to treatment is largely dependant upon an assessment made by the professional involved in delivering the treatment. Johnson comments:

"The Act thus gives discretion to both the regulatory authority (the HFEA) and through it to the practitioners in many areas of ART practice. This is regulation with a light touch. It combines an educational and standard-raising role with the flexibility to respond to changing circumstances and attitudes."³⁸

³⁴ For a discussion of the prescriptive nature of the Victorian legislation in comparison to other jurisdictions, see: Kerry Petersen, 'The Regulation of Assisted Reproductive Technology: A comparative Study of Permissive and Prescriptive Laws and Policies' (2002) 9(4) *Journal of Law and Medicine* 483; H W Gordon Baker, 'Problems with the Regulation of Assisted Reproductive Technology: A Clinician's Perspective' (2002) 9(4) *Journal of Law and Medicine* 457, and; Helen Szoke, 'The Nanny State or Responsible Government?' (2002) 9(4) *Journal of Law and Medicine* 470.

³⁵ Human Fertilisation and Embryology Authority. Press Release HFEA to allow tissue typing in conjunction with preimplantation genetic diagnosis, 13th December 2001 accessed at <<http://www.hfea.gov.uk/cps/rde/xchg/SID-3F57D79B-F8819974/hfea/hs.xsl/960.html>> at 17 July 2007, and Human Fertilisation and Embryology Authority. Press Release, HFEA confirms that HLA tissue typing may only take place when preimplantation genetic diagnosis is required to avoid a serious genetic disease, 1st August 2002 accessed at <<http://www.hfea.gov.uk/cps/rde/xchg/SID-3F57D79B-F8819974/hfea/hs.xsl/967.html>> at 17 July 2007.

³⁶ Human Fertilisation and Embryology Authority. Press Release, HFEA agrees to extend policy on tissue typing, 21st July 2004 accessed at <<http://www.hfea.gov.uk/cps/rde/xchg/SID-3F57D79B-F8819974/hfea/hs.xsl/1046.html>> at 17 July 2007.

³⁷ *Human Fertilisation and Embryology Act 1990* (UK) section 13(5) states: "A woman shall not be provided with treatment services unless account has been taken of the welfare of any child who may be born as a result of the treatment (including the need of that child for a father) and of any other children who may be affected by the birth."

³⁸ Martin H Johnson, 'The Art of Regulation and the Regulation of ART: The Impact of Regulation on Research and Clinical Practice' (2002) 9(4) *Journal of Law and Medicine* 399.

A similar approach has been proposed in New South Wales,³⁹ a jurisdiction that has not previously legislated on the subject of ART. Interestingly, the main purpose of the proposed Bill is to prevent the commercialisation of human reproduction and protect the interests of those involved in the provision of ART treatments.⁴⁰ In line with the purpose of the proposed legislation, the Bill does not require participants to meet eligibility criteria similar to those in the statutory jurisdictions. The New South Wales Department of Health comments:

“The decision not to include eligibility criteria is based on the notion that it is not the role of legislation to screen out “good” prospective parents from “bad” prospective parents. The law does not impose any restrictions upon individuals in the general community who wish to become parents. Indeed, it is generally considered a fundamental right of individuals to be able to have children and form families as they choose.

... The role of the legislature has not been to make rules regarding classes of persons who may or may not become parents (as this is not necessarily a predictor of harm) but to make rules to safeguard the rights of individual children whose welfare has been compromised.”⁴¹

This more liberal approach may be appropriate for future reform in dealing with some of the difficulties faced by the current statutory jurisdictions in ascertaining who may be granted access to treatments. According to Stuhmcke, the requirement of clinical infertility ‘reflects a mainstream heterosexual narrative as to the ‘appropriate or normal’ manner in which to conceive a child’,⁴² and such approach is not necessarily of fundamental importance in considering the primary factor of the outcome of fertility treatments, that being the welfare of the child to be born. Similarly, parents seeking access to ART for the purposes of creating a ‘saviour sibling’ may be denied access to treatments if they are not themselves at risk of passing on a genetic disease and the imposition of such a requirement is not necessarily of fundamental importance in protecting the welfare of the child to be born.⁴³

The complicated structure of ART regulation in Australia has led to a significant difference in approach between jurisdictions, particularly the statutory and non-statutory jurisdictions.⁴⁴ Future consideration for reform of current ART statutes has many possible options. Continued narrow definitions of accessibility of services may be preferred in order to limit the class of persons who may seek access to ART. Such approach however, is likely to continue to receive heavy criticism in light of changing social attitudes to such technologies, such as those discussed in the VLRC’s *Final Report*.⁴⁵ Furthermore, jurisdictions that have not previously regulated ART by statute should also be cautious of the problems faced by implementing restrictive access criteria should they choose to consider legislative action in the future. Failing to address the issue of who may access

³⁹ In 1997, the New South Wales Department of Health conducted a review of the human tissue legislation, which addressed the issue as to whether legislation was needed in New South Wales. The outcome of the process resulted in the production of a consultation draft bill, the *Assisted Reproductive Technology Bill 2003* which has been the subject of constant review, and has recently been reintroduced to Parliament in the form of the *Assisted Reproductive Technology Bill 2007*, New South Wales, *Parliamentary Debates*, Legislative Assembly, 07 November 2007, 01, Reba Meagher, Minister for Health.

⁴⁰ Clause 3 of the *Assisted Reproductive Technology Bill 2007* (NSW).

⁴¹ New South Wales Law Reform Commission, *Artificial Conception – Human Artificial Insemination*, Report No 49 (1986); New South Wales Law Reform Commission, *Artificial Conception – In Vitro Fertilisation* Report No 58 (1988); New South Wales Law Reform Commission, *Artificial Conception – Surrogate Motherhood* Report No 60 (1988).

⁴² Anita Stuhmcke ‘Limiting Access to Assisted Reproduction: *JM v QFG*’ (2002) 16 *Australian Journal of Family Law* 1, 5-6.

⁴³ For an analysis of the risks involved in the use of PGD and the distinction between using the process primarily for detection of genetic disease, and using it solely for the purpose of establishing tissue type see Sally Sheldon and Stephen Wilkinson, above n 30, and Stephen Bellamy, above n 12.

⁴⁴ For a discussion of the effect of different regulatory approaches on clinical practice, see Kerry Petersen *et al*, ‘Assisted reproductive technologies: Professional and legal restrictions in Australian clinics’ (2005) 12(3) *Journal of Law and Medicine* 373.

⁴⁵ Victorian Law Reform Commission, above n 22.

treatment services not only has the potential to lead to inconsistencies between jurisdictions, but also inconsistencies between clinics operating in the same jurisdiction.

CONCLUSION

This paper has examined the current approach in Australia on the issue of eligibility for ART procedures. The complicated regulatory structure provides an understanding of how the approach varies between jurisdictions and has also revealed the similar approach in the statutory jurisdictions on the issue of eligibility for treatment. The failure of the remaining jurisdictions to legislate directly on the topic of ART has also demonstrated how the lack of eligibility criteria leads to a difference in approach, particularly in relation to the creation of 'saviour siblings'. Furthermore, the failure to address the issue of eligibility for treatment services also has the potential to lead to differences in approach between clinics operating in the same jurisdiction.

The issue of eligibility for treatment under the scope of ART has been subject to constant discussion, review and legal challenge in Australia. The VLRC has carried out an extensive review of the law in this area and has made several recommendations for changing the regulation in Victoria. Whilst Victoria's statutory regime is prescriptive in nature, giving little discretion to the regulatory body to amend policy, it should be noted that the problems faced in relation to eligibility for treatment are just as relevant in Western Australia and South Australia. The extensive review conducted by the VLRC will be of significant value to those jurisdictions should they choose to reconsider the issue of eligibility for treatment in the future. Furthermore, the review will also be important to the remaining States and Territories that have not yet regulated eligibility for treatment services in those jurisdictions. Whilst the restrictive approach discussed in this paper has resulted in a number of problems of interpretation, the more liberal approach of not implementing access criteria may also lead to problems, in that clinics operating within the same jurisdiction may restrict access in different ways. Somewhere in the middle, lies the option for the legislature to define in broad terms, exactly who may access treatments. The broad definition of infertility suggested by the VLRC may prevent discrimination in the future. Similarly, regulatory approaches that give parents access to IVF services to create a 'saviour sibling' whether or not they are at risk of passing on a genetic disease may also prevent challenges in the future for what has been described as an unjustifiable and misguided distinction.⁴⁶

⁴⁶ Sheldon and Wilkinson, above n 30.