In recent years, there have been many advances in assisted reproductive technology, in terms of both technological advances and changes in social attitudes. The system of regulation in Queensland is in need of review since it was last considered nearly 25 years ago. The need for review is demonstrated by examining the regulation in Australia as a whole and the impact this has on regulation in Queensland. The paper considers two specific issues. The general access criteria are examined in order to determine who is able to gain access to treatment services, together with how this impacts on gaining access to, and the regulation of, in vitro fertilisation (IVF) and pre-implantation genetic diagnosis (PGD). These issues are discussed mainly in the context of creating tissue-matched children that could act as a cure for an existing ill sibling. The recent review of assisted reproductive technologies (ART) regulation conducted by the Victorian Law Reform Commission is also considered in context of how this may impact on the future regulation of other jurisdictions. The main focus however, is on future options available for Queensland should regulation be reviewed in the future.

I  INTRODUCTION

The use of ART in new and controversial ways raises a range of moral concerns and arguably an element of caution on the way that future regulation of such practices should progress. It has been nearly 25 years since regulation was first considered in Queensland, and no legislation on the regulation of ART has been passed to date. The

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1 Legislation has been passed recently in Queensland on the subject of human embryo research and cloning in response to consideration of those topics at a national level by the Council of Australian Governments (COAG): Research Involving Human Embryos and Prohibition of Human Cloning for
current system in Queensland relies on professional accreditation and guidelines. There are several problems with such an approach which will be demonstrated in this article. In particular, the lack of legislation potentially enables inconsistencies between clinics operating within Queensland in relation to some issues that are not comprehensively addressed by national guidelines.

There is no regulatory body overseeing developments in ART in Queensland and this means that new uses of the technology are not monitored. An example of this is the use of PGD.2 PGD has developed the use of IVF and involves carrying out an embryo cell biopsy on a number of fertilised embryos in order to genetically analyse them. This enables a fertility 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. Previously, abnormalities could only be discovered during pregnancy. Such advance 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.

The use of PGD in IVF treatments to prevent transmitting a genetic disease is not radically new. However, PGD has also been utilised to determine the tissue type of an embryo which can be implanted in order to try and achieve a pregnancy that will result in the birth of a child who is a tissue type match to an existing ill-sibling. Such children have been referred to as ‘saviour siblings’.3 Once the child is born, blood stem cells from the umbilical cord (and sometimes even bone marrow from the child) will offer the prospect of a cure for the ill-sibling who may be, for example, suffering from a rare blood disorder and require a blood stem cell transplant.

The need for Queensland to review the current regulatory approach will be demonstrated by examining two specific issues that impact on both the availability and regulation of PGD for the purposes of establishing the tissue type of an embryo. Limits on access to treatments will be considered generally and then discussed in context of those seeking access to treatments to create a tissue-matched child. The way in which PGD is monitored will also be considered. The regulation of ART is addressed in different ways throughout Australia, and drawing comparisons to other jurisdictions enables establishing the potential options available to Queensland should regulation be reconsidered. Therefore, an analysis of the broad regulatory structure that exists in

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2 For the purposes of this discussion, the use of PGD is not discussed in the context of human embryo research which is subject to statutory regulation under Commonwealth legislation: Research Involving Human Embryos Act 2002 (Cth) as amended by the Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006 (Cth), and also relevant complimentary State or Territory legislation, ibid.

3 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’, MACMILLAN English Dictionary <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 in any case. 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.
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Australia is first needed to demonstrate the complexity of the current approach and how this impacts on regulation in Queensland.

II REGULATION OF ART IN AUSTRALIA

The regulatory regime of ART in Australia varies significantly. 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 the RTAC, requires adherence to the National Health and Medical Research Council (NHMRC) Guidelines.4 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 comprehensive. This is reflective of the recognition that some of the issues, such as eligibility for treatment, the posthumous use of gametes and embryos, and the use of PGD were originally considered as issues to be left to each State and Territory to decide. The Australian Health Ethics Committee (AHEC), the major committee of the NHMRC responsible for developing the guidelines, considered that these issues were beyond their remit.5 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 procedures are directly addressed.6 There has been some national consideration in response to issues surrounding ART, resulting in several recommendations for a national approach to regulation in Australia.7 Commonwealth legislation has been formulated in order to regulate human cloning and the practice of medical research involving human embryos and the use of excess embryos from ART procedures that are no longer needed by the participants.8 Many jurisdictions, including Queensland, have also passed legislation on

5 See National Health and Medical Research Council, Ethical Guidelines on Assisted Reproductive Technology (1996) v.
6 National Health and Medical Research Council, above n 4, 2.
7 The Family Law Council of Australia Report on reproductive technology recommended that a multidisciplinary body oversee matters relating to reproductive technology at a national level (Family Law Council of Australia, Creating Children: A Uniform Approach to the Law and Practice of Reproductive Technology in Australia (Australian Government Publishing Service, 1985). The functions of the body were suggested to include: advising federal and state governments; monitoring medical research; analyse the implications of ART for society; provide information for the community; develop clear guidelines for ethics, practice records, access to information and counselling; recommending research on the ongoing effects of reproductive technology, and; present an annual report. The plans to implement such a body were not followed through fully, but the National Bioethics Consultative Committee (NBCC) was created, which, according to Chalmers, had success in focusing debate and preparing reports, but not in changing public policy. For a detailed review of the development of such issues, see D Chalmers, 'Professional Self-regulation and Guidelines in Assisted Reproduction' (2002) 9(4) Journal of Law and Medicine 414.
Despite such legislative development, there has been no consistent legislation on those issues that were considered beyond the remit of the AHEC and when the NHMRC re-issued its guidelines in 2004 they specifically dealt with some of these issues. 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.’

Only three States have legislated directly on the subject. In such jurisdictions, legislation prevails over both the RTAC Code of Practice and NHMRC guidelines, 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.’ Furthermore, Bennett comments that the: ‘regulatory framework for assisted conception is complicated by Australia’s federal legal structure.’

Despite the lack of consistent legislation between Australian jurisdictions, nearly all have considered the subject of ART and have at some point, appointed specialist committees to review the issues raised by the technologies and make recommendations for how regulation should progress. Comprehensive legislation was passed in Victoria, South Australia and Western Australia to regulate ART. These jurisdictions opted to operate on a license-based system with statutory bodies appointed to oversee the regulation in those jurisdictions.

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9 Surrogacy Parenthood Act 1988 (Qld); Infertility Treatment Act 1995 (Vic); Family Relationships Act 1975 (SA); Surrogacy Contracts Act 1993 (Tas); Parentage Act 2004 (ACT).
12 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. Clinics, Hospitals and Day Procedure Centres, (7th ed, 2006) 9.
13 Helen Szoke, ‘Australia – A Federated Structure of Statutory Regulation of ART’ in Jennifer Gunning and Helen Szoke (eds), The Regulation of Assisted Reproductive Technology (2003) 75, 75.
16 Infertility Treatment Act 1995 (Vic).
18 Human Reproductive Technology Act 1991 (WA).
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III REGULATION OF ART IN QUEENSLAND

The failure of the Queensland Government to implement ART legislation means that Queensland relies primarily on professional guidelines. Furthermore, many clinics in Queensland rely on recommendations made in a report issued in 1984 by a specialist committee appointed by the Queensland Cabinet.\(^19\) Importantly, the lack of legislative action in Queensland has resulted in a system of regulation enabling the NHMRC to ‘fill the gaps’ originally intended to be dealt with by the legislature of each State or Territory. It is submitted that in light of developments in reproductive technologies, the regulatory regime is again in need of review. Not only has the practice of ART rapidly advanced, but so too have social attitudes towards assisted conception and alternative family structures, requiring the issues to be re-examined. This paper does not seek to establish exactly how Queensland should regulate the practice of ART, but will demonstrate why the current system needs to be reconsidered. After considering the current approach in Queensland, two specific issues will be considered to demonstrate the need for reconsidering regulation. First, limits to accessing ART services in Queensland will be discussed, and second, the use of PGD for the creation of a child with matching tissue to an existing ill sibling will be considered.

A The Demack Report

The Queensland Cabinet appointed a Committee in 1983 to consider issues surrounding ART. The report was delivered in 1984 and considered whether legislative action was required in relation to a number of issues. The Committee made several recommendations.

At the time the report was delivered, control of medical research and treatment was exercised on the basis of acceptance of ethical standards and the NHMRC had recommended to the Ministers of Health of the States and Territories that it should be mandatory that each institution undertaking research, maintain an institutional ethics committee. However, in light of the rapid development of medical technology, the Committee appointed in Queensland considered that entrusting issues to ethics committees alone was insufficient.\(^20\) The Committee commented:

> that the range and complexity of the issues of an ethical character which have been or are likely to be thrown up by changes in medical technology, and the public policy implications of these issues, are such that it would be insufficient to entrust their resolution to the ethics committees of particular organisations or institutions.\(^21\)

The Committee therefore recommended that the Queensland Bioethics Advisory Committee (QBAC) be established. The function of the QBAC would include an advisory role in relation to bioethical issues to both the Government and medical organisations and institutions, a responsibility to monitor advances in ART, as well as acting as an educational resource for the community.\(^22\)

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\(^{19}\) Demack, above n 15.  
\(^{20}\) Ibid 46.  
\(^{21}\) Ibid.  
\(^{22}\) Ibid 46-8.
The Committee also considered that ethical guidelines alone were not a sufficient form of regulation, and that medical practice on the topic should be controlled through guidelines issued by professional institutions, including the proposed QBAC.  

Furthermore, it was considered that legislation may be necessary in order to enforce penalties should such guidelines be breached.  

Proposed legislation would also address the issue of the status of children born as a result of ART procedures and the legal liability of those involved in delivering them.

The Committee also advised that treatments should only be available to couples where there is a known risk of a ‘severe genetic disease or an obvious and otherwise irremediable bar to fertility.’ 

Furthermore, although the Committee felt that there should be no legislative ban on granting access to heterosexual de facto couples in a stable relationship, priority was to be given to married couples. 

The Committee also advised that before any person is admitted on to a treatment programme, appropriate counselling should be received, informed consent should be obtained, and anyone involved in an IVF programme must have the right to withdraw.

Despite the recommendations of the Committee to establish statutory regulation of ART in Queensland, no specific legislation dealing with ART has been passed. Therefore, regulation of ART in Queensland relies primarily on the guidelines issued by the NHMRC.

### B NHMRC Guidelines

The guidelines issued by the NHMRC have been described as national standards of acceptable practice. Accreditation under the FSA’s RTAC is mandatory for ART units and requires adherence to both the RTAC Code of Practice (mainly addressing standards of clinical practice, based on a ‘quality management system model of risk-benefit’) and the NHMRC guidelines. However, there is some concern expressed with the enforcement of these provisions. The fact that infringement of the guidelines is not a legal offence, like similar provisions existing in the statutory jurisdictions is one concern. Thus, infringement will normally lead to a loss of funds from the NHMRC for the purpose of research or publication of infringement in Parliament. Some commentators have stated that therefore, the guidelines are only strictly enforceable against institutions receiving NHMRC funding and it is possible that private institutions not relying on NHMRC funding for research may not adhere to the guidelines.

However, the FSA considers the meaning of s 11 of the Research Involving Human Embryos Act 2002 (Cth), to encompass the use of human embryos in any way without

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23 Ibid 49.
24 Ibid.
25 Ibid 50.
26 Ibid 81.
27 Ibid 82.
28 Ibid.
29 Chalmers, above n 7, 418.
31 Chalmers, above n 7, 418.
32 Ibid.
RTAC accreditation to amount to a criminal offence under Commonwealth law.\textsuperscript{33} That section states that a person who ‘intentionally uses, outside the body of a woman, a human embryo that is not an excess ART embryo; and the use is not for a purpose relating to the assisted reproductive technology treatment of a woman carried out by an accredited ART centre’, commits an offence.\textsuperscript{34} Therefore, all clinics must be accredited and adherence to the NHMRC guidelines is required as part of that accreditation agreement.

The Demack Report suggested establishing a statutory framework for the regulation of ART in Queensland, requiring the creation of an independent body such as the QBAC to oversee regulation. A statutory footing for ART regulation implementing an overseeing regulatory body working on the basis of a licensing system, may address some of the concerns relating to the enforcement of current standards and guidelines. Furthermore, such a body, as was suggested, could play a part in advising the Government of advances in the field, as well as providing an educational resource for members of the community.

Alternatively, Queensland may consider that a lighter form of regulation is more justified in light of the fact that the NHMRC guidelines do address a number of significant issues, such as: consent to treatment, storage of gametes and embryos, counselling services for participants, posthumous conception and the use of PGD. An example of a lighter form of regulation has been put forward in New South Wales.\textsuperscript{35} The proposed legislation does not seek to implement a full licensing system similar to that in other statutory jurisdictions. The New South Wales Department of Health comments that a system of ‘registration’ is more appropriate because of the fact that many issues under the ART scope are sufficiently regulated by national guidelines.\textsuperscript{36} The proposed system of registration does not require compliance with a list of conditions, but is instead concerned with identifying ‘the providers of ART services in order to facilitate appropriate compliance and enforcement activity in respect of the provisions of the Bill.’\textsuperscript{37} The main purpose of the proposed legislation in NSW is therefore to focus on aspects of ART which are currently unregulated or where there is ‘real potential for individual or social harm.’\textsuperscript{38} This lighter form of regulation may carry some advantages. In particular, the regulatory framework may be able to respond to advances in technology more effectively, unlike a system of prescriptive legislation which requires statutory amendment and modification.\textsuperscript{39}

\textsuperscript{33} Reproductive Technology Accreditation Committee, above n 30, 8.
\textsuperscript{34} Section 8 of the Research Involving Human Embryos Act 2002 (Cth) defines an ‘accredited ART Centre’ as a: ‘person or body accredited to carry out assisted reproductive technology by the Reproductive Technology Accreditation Committee of the Fertility Society of Australia’.
\textsuperscript{35} The Assisted Reproductive Technology Bill 2007 (NSW) has recently been re-introduced to Parliament and replaces the proposals put forward in the Assisted Reproductive Technology Bill 2003 (NSW). New South Wales, Parliamentary Debates, Legislative Assembly, 7 November 2007, 1 (Reba Meagher, Minister for Health).
\textsuperscript{37} Ibid 3.2.
\textsuperscript{38} Ibid 3.1.
commentators have noted that the system of accreditation and compliance with national guidelines in conjunction with legislation ‘provides an important model for how self-regulatory mechanisms can be combined with laws to achieve best practice in an area.’

If Queensland followed a similar approach to the proposed NSW legislation, then it would first be necessary to identify which elements are currently unregulated as well as considering aspects of ART which involve ‘real potential for individual or social harm’. It is suggested that Queensland might implement a public consultation process to address the latter concerns, as social attitudes have significantly changed since the subject was first considered in the early 1980s.

Other commentators have also identified the need for Queensland to consider the regulation of ART focusing on, as they were then considered, some of the more controversial aspects of ART. These included, who should be granted access to treatment services, and establishing a method of ensuring that donor-conceived children have a right to access information about their genetic origins. It is not suggested that such issues are not still fundamental considerations in the scope of ART. In fact, the former of these issues is also the subject of discussion in this paper. There is however, a need to reconsider the regulatory approach in light of other emerging dilemmas.

IV DEMONSTRATING THE NEED TO RECONSIDER REGULATION

A Eligibility Criteria

The NHMRC guidelines do not impose eligibility criteria determining who may access treatment services and even though there are no statutory provisions addressing the issue, there has been some judicial consideration of access to ART in Queensland. A lesbian woman, JM, who had been in a 4-year same-sex relationship, was denied access to treatment by a fertility clinic in Queensland. JM took action against the clinic, asserting that the clinic was in breach of the Anti-Discrimination Act 1991 (Qld) for discriminating against her on the basis of her sexual orientation. The case was originally heard before the Anti-Discrimination Tribunal, which found that there had been both direct and indirect discrimination by the clinician. It was held that direct discrimination had occurred because she was denied treatment on the basis of her

Szoke, Neame and Johnson, above n 10, 199.

See New South Wales Department of Health above n 36, 3.1.


Ibid.

Section 10 of the Anti-Discrimination Act 1991 (Qld) states: ‘(1) Direct discrimination on the basis of an attribute happens if a person treats, or proposes to treat, a person with an attribute less favourably than another person without the attribute is or would be treated in circumstances that are the same or not materially different. (2) It is not necessary that the person who discriminates considers the treatment is less favourable. (3) The person’s motive for discriminating is irrelevant. (4) If there are 2 or more reasons why a person treats, or proposes to treat, another person with an attribute less favourably, the person treats the other person less favourably on the basis of the attribute if the attribute is a substantial reason for the treatment. (5) In determining whether a person treats, or proposes to treat a person with an impairment less favourably than another person is or would be
same-sex relationship, and indirect discrimination had occurred because the clinic had demanded that consent was required by her male partner. The latter was apparently an unreasonable request.

The Queensland Supreme Court overturned both findings of discrimination holding that the clinician had not discriminated directly against JM on the basis of her relationship, but on the basis that she was not medically infertile. The determination of infertility was to be on the basis of the inability to conceive after engaging in heterosexual intercourse over a period of 12 months. The Court also held that there was no indirect discrimination in requiring JM to provide the name and signature of her male partner on the consent form. According to Ambrose J, 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”’. Essentially, the question was whether the practice adopted in general (and not specifically to JM), was reasonable for the clinician to adopt in the circumstances.

On this basis, requiring the consent form to be filled out by the male partner did not constitute indirect discrimination. The issue was also appealed to the Queensland Court of Appeal, who agreed that there had been no direct discrimination. Whether there had been indirect discrimination was a question of ‘reasonableness’ and the issue was remitted to the Anti-Discrimination Tribunal to decide.

When the case was remitted, the Anti-Discrimination Tribunal considered whether the conduct of the clinician was reasonable and concluded that it was for a number of reasons. The policy of the clinic was to follow the guidelines issued by the NHMRC and the Queensland Health Department. The latter included recommendations to follow the proposals made in the Demack Report which therefore focused the delivery of treatments to those who are at risk of passing on a genetic disease or disorder, or clinically infertile. Furthermore, the fact that the clinic had publicised to sperm donors that their gametes would be used to assist infertile heterosexual couples was also a significant factor in determining the reasonableness of the clinician’s conduct:

> treated in circumstances that are the same or not materially different, the fact that the person with the impairment may require special services or facilities is irrelevant.'

Section 11 of the Anti-Discrimination Act 1991 (Qld) states: '11(1) Indirect discrimination on the basis of an attribute happens if a person imposes, or proposes to impose, a term — (a) with which a person with an attribute does not or is not able to comply; and (b) with which a higher proportion of people without the attribute comply or are able to comply; and (c) that is not reasonable. (2) Whether a term is reasonable depends on all the relevant circumstances of the case, including, for example: (a) the consequences of failure to comply with the term; and (b) the cost of alternative terms; and (c) the financial circumstances of the person who imposes, or proposes to impose, the term. (3) It is not necessary that the person imposing, or proposing to impose, the term is aware of the indirect discrimination. (4) In this section — “term” includes condition, requirement or practice, whether or not written.'

JM v QFG, GK and State of Queensland [1996] Queensland Anti-Discrimination Board, No H38 of 1996 (Unreported, President Atkinson, 31 January 1997). According to that decision, the fact that the clinician demanded consent from the applicant’s male partner was an unreasonable request.

Ibid.


Ibid.

Given that the respondent was clearly conducting his practice in accordance with established medical and ethical guidelines (whether out-dated, soundly based, or whether legally binding upon him or not), and was requesting sperm donations as part of that practice, the use to which he was obliged to put the donated sperm cannot be overlooked. It would not be unreasonable to confine the use of the sperm to “infertile couples” in accordance with his representations to the potential donors … the donated sperm had been collected by reference to representations that it would be used for infertile heterosexual couples, and it is at that time and in those circumstances that the issue of reasonableness arises.  

Clinics in Queensland following the Demack Report will therefore require participants to be at risk of passing on a genetic disease through natural conception, or be clinically infertile. The latter requires an inability to become pregnant after a 12-month period of unprotected heterosexual sex. According to Stuhmcke, this ‘reflects a mainstream heterosexual narrative as to the ‘appropriate or normal’ manner in which to conceive a child.’ Furthermore, Stuhmcke comments that: ‘it is not heterosexuality alone which qualifies a woman for ART treatment, the pre-requisite of complying with the medical definition of infertility is heterosexual intercourse as part of a longer term heterosexual couple’.  

Despite the fact that there are no eligibility criteria imposed within Queensland by legislation or guidelines, the judicial decision involving JM has declared that clinics imposing restrictions which can only be met by heterosexual couples are justified in doing so, if they are relying on outdated recommendations. Although it was beyond the scope of the Anti Discrimination Tribunal to examine the validity of guidelines issued by the Queensland Health Department, these guidelines require clinics to deliver cutting edge 21st century technology on the basis of a report founded upon social attitudes which are nearly 25 years in the past.  

There is need for Queensland to reconsider the question of eligibility for treatment and whether the restrictive definition of infertility should continue to remain as a justified criterion for clinics to impose on those seeking treatments. It is submitted that the recommendations made by the Demack Report are outdated. Legislation preventing access to ART on the basis of marital status or sexual orientation has been prohibited in Australia, but the narrow definition of infertility remains to act as an obstacle for single and lesbian women seeking access to ART. It remains to be seen whether the access requirements will be the subject of further challenge. A wider consideration of the question of access is now required to be undertaken.  

The issue of eligibility for treatment has been considered in detail by other jurisdictions and may be of assistance for reconsidering future regulation in Queensland. Much could be learnt from the difficulties faced in those other jurisdictions. An example of this is the Victorian Law Reform Commission’s (VLRC) extensive review of the law relating

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to ART in Australia, which has recently published a Final Report on the subject.\textsuperscript{57} The report concluded: ‘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’.\textsuperscript{58}

Furthermore, the VLRC has also proposed a broader definition of the 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).\textsuperscript{59}

If the subject of access to treatment is re-examined in Queensland, a wider consideration of the meaning of ‘infertility’ will need to be considered in context of further potential discrimination challenges and whether there should be more recognition given to alternative family structures.

The approach taken on the issue of access to treatment in Queensland, if reconsidered, will be largely dependant upon the underlying approach taken to justifying the use of ART generally. The main justification for making treatment services available in Australia has been to alleviate the harshness of infertility, as well as providing treatment to those who are at risk of passing on genetic disease or abnormality through natural conception. This was the justification for a restrictive meaning of the term ‘infertility’ in Victoria and was the reasoning put forward in the \textit{Demack Report} for making treatment services available in Queensland. This justification has also been expressed in legislation passed in other Australian jurisdictions.\textsuperscript{60} However, in light of changing social attitudes, a different approach may also be considered. Queensland may prefer a more liberal approach. In New South Wales, following a review of the regulation in that State, proposed legislation followed such an approach. The main purpose of the NSW Bill is to prevent the commercialisation of human reproduction and protect the interests of those involved in the provision of ART treatments.\textsuperscript{61} This can be contrasted with the approach in other statutory jurisdictions and the recommendations made in the \textit{Demack Report}, primarily concerned with alleviating clinical infertility and preventing transmission of genetic disease.\textsuperscript{62}

\textsuperscript{58} Ibid.
\textsuperscript{59} Ibid 68.
\textsuperscript{60} For example in Western Australia, the preamble of the \textit{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.’
\textsuperscript{61} Clause 3 of the Assisted Reproductive Technology Bill 2007 (NSW).
\textsuperscript{62} Demack, above n 15.
Furthermore, in line with the purpose of the proposed legislation, the NSW 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.  

If the subject of access to ART is reconsidered in Queensland, then many of these factors will need to be balanced in order to determine who may be granted access to services in the future. There is much to be learnt from some of the problems experienced in defining the limits and boundaries of access when examining the regulation in other jurisdictions. A narrow approach to the meaning of infertility is likely to lead to further challenges of that definition in the future. However, at the other end of the spectrum, failing to define in any terms the issue of who may access treatment may allow different clinics operating in the same jurisdiction to place different barriers on access. 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. However, if a narrow construction of eligibility is adopted for future regulation, then it is also necessary to consider the impact a narrow definition will have on the second limb of the eligibility criteria. Namely, that it can be justified where the participants are at risk of passing on a genetic disease or disorder if they were to conceive naturally. This will be considered in context of the use of PGD for the creation of tissue-matched children.

B PGD and the Creation of Tissue-Matched Children

Whilst the focus of this paper is to draw attention to controversial developments in the field of ART and the impact these have on future regulation, it does not seek to aim to address exactly how such technologies should be regulated. The remaining part of this paper will consider the current regulatory approach in light of developing technologies, focusing on the creation of tissue-matched children. As already discussed, IVF procedures for this purpose require the use of PGD. It should be noted that whilst PGD is not radically new, its use has increased in recent years and this may provide some justification for a more comprehensive system of regulation. PGD has also been

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63 New South Wales Department of Health, above n 36, 4.3.
64 For example, in 2005, 69 women in Victoria underwent IVF with PGD in order to ensure that the embryo was free from a known genetic disease, and in that same year, 131 women in Victoria also used PGD for recurrent pregnancy failure (see below n 65). The total number of women who underwent IVF in Victoria in 2005 in licensed clinics was 4869. Infertility Treatment Authority, Annual Report (2006) 26. On this basis it could be argued that the proportion of those patients who actually use PGD is relatively small in comparison to the number of women who undergo IVF. This can be compared to data from five years previously, which shows that 3449 women underwent IVF, and only 75 of those also underwent PGD: Infertility Treatment Authority, Annual Report (2000) 22-8.
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utilised by some couples to ensure that their future children will be of the same tissue type to an existing ill child. The new child will offer the chance of a cure for the existing ill child. Thus, not only is the use of the technology becoming more popular, it is also being used in new ways, which perhaps also justify a more comprehensive system of regulation.

As has been established, Queensland relies directly on the NHMRC guidelines and it is therefore necessary to examine how they address the issue of PGD. The current NHMRC guidelines note that PGD can be used to detect serious genetic conditions in order to improve ART outcomes, and in rare circumstances, to select an embryo with compatible tissue for a sibling. The guidelines also go on to state that pending further community discussion, PGD must not be used to detect conditions that are not of serious harm to the person to be born; social sex selection; or selection in favour of a defect or disability. The guidelines do not require clinics to seek permission prior to the use of PGD, except in the case of selection of an embryo with compatible tissue for a sibling. Selection of embryos for the purpose of tissue compatibility is only permitted in the case of siblings, and clinics must seek advice from a clinical ethics committee (or relevant state or territory regulatory agency) prior to using PGD for such purpose, who should ascertain that:

- the use of PGD will not adversely affect the welfare and interests of the child who may be born;
- the medical condition of the sibling to be treated is life-threatening;
- other means to manage the medical condition are not available; and
- the wish of the parents is to have another child as an addition to their family and not merely as a source of tissue.

The guidelines also require that those seeking PGD must be given access to both a clinical geneticist and a genetic counsellor in order that they understand how the technology works and how it is applied to their embryos.

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65 Many women suffer from recurrent pregnancy loss (RPL) which can happen for a number of reasons, but one cause is a result of chromosome abnormalities (aneuploidy) in embryos. PGD can be used to genetically analyze the embryos of women who suffer from RPL and those embryos that do not show abnormalities can be implanted in order to try and achieve a higher pregnancy rate. See Patrizio et al, ‘High Rate of Biological Loss in Assisted Reproduction: It is in the Seed, Not in the Soil’ (2007) 14(1) Reproductive BioMedicine Online 92-5.
66 National Health and Medical Research Council, above n 4, 12.1.
67 Ibid 12.2.
68 Ibid 12.
69 Ibid 12.3.
70 Ibid.
71 Ibid.
72 Ibid 12.4-12.5. Clinics are also required to give up-to-date, objective, and accurate information in line with the ‘information giving’ section of the guidelines (9.1 and 9.2), and that those seeking the treatment should be encouraged to consider the following factors when deciding the appropriateness of PGD: information regarding the reliability of results; genetic and clinical information about the condition; the clinic’s previous reproductive experience; information regarding the condition being tested for including the range of effects of the disease or abnormality; the experience of families living with the condition and how it can be managed; and also the extent of social support available: 12.5.1.
Therefore, in Queensland, the use of PGD generally for reproductive purposes is not monitored, and the only use of the technology which requires approval is when using it to select embryos on the basis of tissue compatibility. One further issue that also needs future consideration is interpretation of the NHMRC guidelines for the use of PGD and particularly, the creation of tissue-matched children. The NHMRC guidelines state that pending further community discussion, PGD must not be used to detect conditions that are not of serious harm to the person to be born.\textsuperscript{73} Although the guidelines do state that ‘what counts as a serious genetic condition is controversial’,\textsuperscript{74} there is no further clarification on interpretation of these terms. Arguably, the fundamental aim of prohibiting the use of PGD for conditions that are not of serious harm to the person to be born is to prevent ethical criticism of the use of PGD for the screening out of non-serious disease and avoid the practice of the selection of embryos on the basis of what some may argue as eugenics.\textsuperscript{75} Clarification of the term ‘condition’ is needed. Critics may argue that the use of PGD to establish tissue type is a use of the technology for detection of a ‘condition’ that does not seriously harm the child to be born. Thus, would a more narrow reading of the terms contained in the NHMRC guidelines also prevent the use of PGD where the sole purpose is to establish tissue type? These are further issues that will be relevant for consideration should the regulation of ART be reconsidered in Queensland.

The lack of eligibility criteria under the NHMRC guidelines also impacts significantly on the use of PGD for the creation of tissue-matched children. This can be demonstrated by examining the statutory jurisdictions where eligibility criteria are prescribed in legislation. In those jurisdictions, PGD will only be available where the primary purpose is to ensure that the embryo is free from genetic disease.\textsuperscript{76} If tissue typing is also conducted, it will be ancillary to the main purpose of PGD. Furthermore, in Victoria, when using PGD for establishing tissue type not only must the legal requirements under the legislation be met (the eligibility criteria), but a number of further conditions and ethical considerations are imposed on clinics as a condition of licence.\textsuperscript{77} Furthermore, for the purpose of creating tissue-matched children, clinics must gain approval by the Victorian regulatory body, the Infertility Treatment Authority.

\textsuperscript{73} National Health and Medical Research Council, above n 4, 12.2.
\textsuperscript{74} Ibid 12.1.
\textsuperscript{76} Section 8(3) of the \textit{Infertility Treatment Act 1995} (Vic) 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.’ Section 23(a) of the \textit{Human Reproductive Technology Act 1991} (WA) 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’. Section 13(3) of the \textit{Reproductive Technology (Clinical Practices) Act 1988} (SA) 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.
Thus, the use of PGD in Victoria is monitored by the statutory body which oversees the regulatory regime in that State. Similarly, in Western Australia and South Australia, PGD is only permitted where the primary purpose is to prevent transmission of a genetic disease. In Western Australia, all uses of PGD must be authorised by the statutory body, the Reproductive Technology Council (RTC) and although the issue of using the procedure for creating tissue-matched children is not addressed, if it was to occur it would be monitored by the RTC which is required to approve all uses of PGD. Despite the imposition of eligibility criteria in South Australia, the South Australian Council on Reproductive Technology (SACRT) does not monitor the use of PGD in a similar way to the other statutory jurisdictions. Therefore, in South Australia, the use of PGD will be monitored only so far as the NHMRC guidelines require, and this is applicable to all the remaining jurisdictions which do not directly address the issue.

Should the matter be considered in Queensland, there are a number of options available. Again, these are demonstrated by examining other Australian jurisdictions. Between the statutory jurisdictions alone there is a vast difference in approach, with Western Australia requiring all uses of the technology to be approved, Victoria requiring only some uses to be approved (but monitoring all uses thoroughly), and South Australia requiring no system of approval or notification. The latter approach is how the regulation also operates in the remaining jurisdictions, including Queensland, where the only check on the use of PGD is when it is used for the selection of an embryo with compatible tissue for an ill sibling. Even then, the only requirement is that the matter is referred to an institutional ethics committee.

There are a number of problems that arise under the current context of regulation in Queensland. First, the reliance on the NHMRC guidelines means that there are no mandatory eligibility criteria imposed. This issue has already been examined in the context of the narrow definition given to infertility, but it is also significant in relation to the use of PGD for creation of tissue-matched children.

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

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78 Infertility Treatment Authority, *Tissue Typing in Conjunction with Preimplantation Genetic Diagnosis*, above n 77.
79 National Health and Medical Research Council, above n 4, 12.3.
80 Ibid.
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. 82

Even if Queensland opted for a more narrow definition of who is able to access treatments, then there is still the option to make exception for the purpose of creating a tissue-matched child. This is demonstrated by the Victorian Law Reform Commission’s Final Report, 83 which notes that the current system of regulation in Victoria 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 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. If Queensland reviews the regulation and opts to define who should be eligible for treatments, similar to the suggestions by the VLRC, there is the potential to allow exceptions to those criteria in certain cases.

V RECONSIDERING REGULATION

A Time for Queensland to Legisllate?

In a recent lecture addressing the ability of the law to keep pace with technology, Justice Michael Kirby commented on the topic of regulation, noting that quite often there is either too much or too little law on a particular topic. 84 Examining the comparison between the statutory and non-statutory jurisdictions within Australia provides an example of this, with some states regulating the topic in a prescriptive manner, 85 and others relying on professional and ethical guidelines. Furthermore, Kirby J went on to comment that it is very important to realise that if nothing is done in the face of science, a decision is made; to do nothing is to make a decision. 86 The inaction of the Queensland legislature could be viewed as an endorsement of the current regulatory approach. With the exception of the issue of eligibility for treatment, some may argue that the current state of regulation of ART is satisfactory. 87 Thus, there is a high standard of professional regulation and overlap between the accreditation process administered by the FSA and the RTAC, and the guidelines issued by the NHMRC.

83 Victorian Law Reform Commission, above n 57.
86 Kirby, above n 84.
87 See Chalmers, above n 7.
However, using Kirby J’s analogy, inaction potentially signifies the endorsement of an approach that in many respects falls short of even some of the recommendations put forward in the Demack Report in 1984.\textsuperscript{88} This is particularly so in relation to the use of PGD for the creation of tissue-matched children. The use of PGD is not monitored by an independent body in Queensland, such as that existing in Victoria. The only form of PGD that is required to be monitored in Queensland is to put the issue of selecting embryos on the basis of tissue type before an institutional ethics committee under the NHMRC guidelines.\textsuperscript{89} As already stated, the Demack Report concluded that entrusting issues to ethics committees alone was not a sufficient form of monitoring advances in such technologies.\textsuperscript{90} In addition to the problems outlined in relation to eligibility criteria, this example raises another need for reconsidering the current approach in Queensland.

B Significance of the VLRC’s Report

Throughout this article reference has been made to the VLRC’s final report on the topic of ART. 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 alone. Therefore, the recommendations made will be particularly significant to the other statutory jurisdictions in Australia when reviewing legislation in the future. Furthermore, the issues arising from the report are also of importance for other jurisdictions that do not currently have a statutory system of regulation but may consider legislating on the topic in the future.

In Queensland, if the issue of regulation is reconsidered there are several options open to the legislature in limiting who may gain access to fertility treatments. One option is to limit treatments strictly, similar to the approach adopted currently in Victoria. This would allow access only to those who are clinically infertile or at risk of passing on a genetic disease when conceiving naturally. The focus of this paper has been to demonstrate that it is now appropriate to reconsider whether this narrow approach traditionally adopted is still justified. Whilst it is acknowledged that the suggestions proposed by the VLRC are aimed at amending some of the difficulties of the prescriptive nature of the Victorian legislation, the proposals may also provide a suitable option for other jurisdictions wishing to define who should be able to seek access to treatments without seeking to limit treatments to a narrow class of people. If eligibility criteria were to be imposed under a statutory system of regulation in Queensland, then the VLRC’s suggestions could be implemented to enable a broader meaning to be given to the access criteria.

As already discussed, the VLRC has noted that there is the potential for an ART regulatory body to consider whether clinics can allow for exceptions to the eligibility criteria in certain cases, such as the creation of tissue-matched children. This is also a significant point to be considered should the topic of legislation be addressed in Queensland in the future.

\textsuperscript{88} Demack, above n 15.
\textsuperscript{89} National Health and Medical Research Council, above n 4, 12.3.
\textsuperscript{90} Demack, above n 15, 46.
If the issue of regulation is reconsidered, Queensland may choose not to address the issue of eligibility as is now the case under the NHMRC guidelines. Again, as already discussed, this approach has the potential to result in different clinics imposing different access criteria and is a further point of significance for any future consideration of regulation. Therefore, the importance of the review of the VLRC cannot be underestimated and the suggestions made provide a suitable mid-point for the spectrum of regulating access to treatments.

VI CONCLUSION

This paper has examined the nature of the regulation existing in Australia on the topic of ART. It has been established that there are a broad range of regulatory approaches varying from legislation, to professional standards and guidelines. The particular issue of eligibility for treatment has been examined in detail and the difficulties faced by other Australian jurisdictions have provided examples of the problems faced in limiting access to treatments. The original consideration of the issues in Queensland resulted in no legislative action and since the original review in the early 1980s no further consideration or consultation has been undertaken. Not only does this mean that the proposals made in the Demack Report are not in line with current social attitudes, but also that there are many practices and emerging technologies under the ART scope that were not even contemplated by the Committee. The definition of the term infertility has been problematic for other jurisdictions in Australia, and the VLRC has recently proposed a wider definition of the term. Similarly, the remaining statutory eligibility criteria also pose a problem when viewed in the context of selecting embryos in order to create a tissue-matched child. Similarly, the VLRC has also proposed that there should be circumstances other than the traditional strict eligibility criteria where access to treatments should be granted, giving the example of creation of a tissue-matched child as one of those exceptions. Whilst in Queensland, there are no eligibility criteria imposed by legislation or the NHMRC guidelines, each clinic may still choose to limit access to treatment on the basis of its own policy. This may lead to the result that there is a difference in approach between clinics operating within Queensland (or other non-statutory jurisdictions). The failure to specifically address the issue will continue to lead to a divergence of approach as to who may access treatments. Furthermore, the report recommended that an overseeing regulatory body also be established to keep track of such advances, as well as play an educational role for members of the community. The importance of keeping track of developments in ART was stressed in the Demack Report and in Queensland, this has not been done. This body would have also had the function of approving some controversial uses of ART, as it was not considered sufficient to entrust such issues to institutional ethics committees alone. The lack of action in Queensland has endorsed an approach that only recommends the use of ethics committees in exceptional instances (such as the creation of a tissue-matched child). These examples only relate to a limited number of issues under the scope of ART, and even then, it is easily demonstrated that reconsideration of the regulation of ART in Queensland is long overdue.

Queensland could benefit vastly from some of the material produced by other Australian jurisdictions (particularly the work of the VLRC), also faced with difficulties in relation to regulating ART. With recognition of some of the extremely sensitive issues involved under the scope of this topic, perhaps now is one of the best times to move forward with a national approach to regulating ART. Such approach would be in
line with recent developments for the national regulation of human embryo research and cloning, as well as proposals to consider uniform laws for surrogacy. Whichever way Queensland chooses to act, overdue consideration of these issues (at the very least), will be extremely welcomed.

91 The Standing Committee of Attorneys General (SCAG) has agreed to consider drafting uniform laws for surrogacy across all states and territories: Attorney-General Phillip Ruddock, ‘Nationally Consistent Surrogacy Laws a Step Closer’ (Media Release 210/2006, 10 November 2006).