

## Chapter 3 **Regulation**

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*A licensed clinic is the term used to describe a place where assisted reproductive procedures are carried out.*

The regulation of assisted reproductive technology (ART) is contentious because it must take account of and respond to a range of issues, including patients' rights, scientific and technological change, professional autonomy, ethical concerns, standards for treatment and community expectations.

The commission has not been asked to review the entire regime for regulation of ART in Victoria. In our review of the *Infertility Treatment Act 1995*, we have been asked to examine the issues of eligibility for treatment and the regulation of altruistic surrogacy. However, in addressing these matters, we have also had to consider the fundamental question of whether the State should play a role in controlling or overseeing the provision of ART.

In this chapter we outline the regulatory framework that governs the provision of ART services in Victoria and other jurisdictions. Regulation of access to treatment, status of children, access to donor information and surrogacy are examined in greater detail in later sections of the report. We also explore some of the debates about the extent to which ART should be subject to regulation by the State, and outline the approach adopted by the commission in this reference.

### REGULATION IN VICTORIA

Victorian legislation dealing with ART was first enacted in 1984. Victoria was the first state in Australia, and the first jurisdiction in the world, to enact legislation regulating assisted reproduction. This legislation was introduced following recommendations made by a committee established in 1982 by the Victorian Government, the Committee to Consider the Social Ethical and Legal Issues arising from IVF, headed by Professor Louis Waller (the Waller Committee). The Waller Committee's terms of reference were:

To consider whether the process of IVF should be conducted in Victoria and, if so, the procedures and guidelines that should be implemented in respect of such processes in legislative form or otherwise.<sup>1</sup>

The Waller Committee concluded that in-vitro fertilisation (IVF) and the use of donated sperm, eggs and embryos were acceptable practices, but that safeguards should be implemented to control their use. In particular, it recommended that IVF should only be conducted in authorised hospitals, and that counselling and information should be provided to people prior to treatment

to ensure free and informed consent. The committee also recommended that participants in the IVF program be married and have attempted alternative means of conception for at least 12 months before joining the program, and that admission to donor treatment programs be based on need.<sup>2</sup> The committee recommended that donors should receive counselling and provide consent prior to donation, and that a registry to enable donors, recipients and donor conceived people to obtain non-identifying information about each other be introduced.<sup>3</sup>

### INFERTILITY (MEDICAL PROCEDURES) ACT

The *Infertility (Medical Procedures) Act 1984* was introduced following recommendations made by the Waller Committee. The Act, which came into effect on 1 July 1988:

- outlined a regime for regulation of IVF procedures, confining the treatment to married couples and establishing an approval process for hospitals
- established a process for people to obtain information about donors or children born as a result of IVF treatment, including the process for a donor to contact a person born with the use of his or her sperm or eggs
- prohibited commercial surrogacy arrangements and made surrogacy agreements void.

The Infertility (Medical Procedures) Act did not contain any direct reference to the best interests or welfare of children born as a result of treatment procedures.

The Act established a Standing Review and Advisory Committee on Infertility (SRACI), which was to 'consider and if appropriate, approve proposals for experiments on embryos, and to advise the Minister for Health in relation to infertility and on procedures for its alleviation'.<sup>4</sup> It was required by the Act to provide an annual report to parliament, 'on all relevant procedures carried out in approved hospitals, and on its own work'.<sup>5</sup>

Between May 1990 and October 1991, SRACI completed a three-volume report on the Infertility (Medical Procedures) Act, which included recommendations for amendment. The Victorian Government, influenced by the impact of technological innovation and the experience of the interpretation and operation of the Act, decided to pass new legislation to regulate ART.<sup>6</sup> The then Minister for Health, Marie Tehan, said the new legislation:

would make clear key aspects of current IVF laws which had been made redundant or uncertain by recent advances in scientific procedures as well as ensuring that IVF techniques are in line with community standards.<sup>7</sup>

## INFERTILITY TREATMENT ACT

The new legislation, the *Infertility Treatment Act 1995*, came into effect on 1 January 1998. The principal differences between the new and old Acts are the abolition of the 12-month waiting period to enter the IVF program, the introduction of the right of people born as a result of donor treatment procedures to obtain identifying information about their donors, and the establishment of a new licensing authority and regulatory body, the Infertility Treatment Authority.

The main purposes of the Act are to regulate:

- fertilisation procedures and donor insemination procedures
- access to information about these procedures
- research using human eggs, sperm and embryos.<sup>8</sup>

The Act sets out broad principles to guide decision making, and establishes an independent regulatory authority and a licensing regime for treatment providers. It also contains provisions about surrogacy arrangements, and aims to promote research into the incidence and causes of infertility.

## Guiding Principles

Guiding principles set out in the Infertility Treatment Act apply when people are undertaking any of the activities regulated by the Act. The principles are:

- The welfare and interests of any person born or to be born as a result of a treatment procedure are paramount.
- Human life should be preserved and protected.
- The interests of the family should be considered.
- Infertile couples should be assisted in fulfilling their desire to have children.<sup>9</sup>

The principles are listed in the order of importance they are to be given when carrying out any of those activities. It follows that the welfare and interests of the child are of paramount importance.

## Treatment Procedures

The Infertility Treatment Act regulates certain activities called ‘treatment procedures’ and ‘donor treatment procedures’. A treatment procedure is any one of the following:

- insemination of a woman with donor sperm
- transfer of an egg, or sperm, or both to the body of a woman
- transfer to the body of a woman of an embryo formed outside the body.

A donor treatment procedure includes any of the above that involve the use of donated gametes (sperm or eggs) or donated embryos.<sup>10</sup>

The Act contains provisions which determine who may undergo infertility treatment procedures, including who may use donated gametes and embryos to become pregnant, and in what circumstances. It also sets out requirements which must be met by people who donate gametes. In the second section of this report we examine these eligibility requirements in detail. In the fourth section, we discuss the regulation of surrogacy arrangements in Victoria.

## Infertility Treatment Authority

The Infertility Treatment Act established the regulatory body to oversee the implementation of the Act in Victoria, the Infertility Treatment Authority (ITA). The ITA’s functions include compiling and providing access to medical records, administering licensing and approvals systems, monitoring compliance, considering requests for extensions to storage periods, and approving the import or export of gametes or embryos.<sup>11</sup>

## Licensing

The Infertility Treatment Act limits the people who can carry out assisted reproduction procedures. Most procedures can only be carried out by an approved doctor at a licensed hospital or day procedure centre, or a licensed research institution. In this report, we will use the term licensed clinic to refer to these centres.

The ITA is responsible for approving clinics and hospitals to carry out treatment procedures and issues the conditions for licence with which licensees must comply in delivering their services.<sup>12</sup> The conditions include matters which are additional to the requirements under the legislation, such as compliance with the National Health and Medical Research Council’s *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research* (the NHMRC guidelines),<sup>13</sup> accreditation by the Fertility Society of Australia’s Reproductive Technology Accreditation Committee (RTAC),

- 1 Committee to Consider the Social, Ethical and Legal Issues Arising from In Vitro Fertilization, Victoria, *Committee to Consider the Social, Ethical and Legal Issues Arising from In Vitro Fertilization Interim Report* (1982) 1.
- 2 Ibid 24–5.
- 3 Committee to Consider the Social, Ethical and Legal Issues Arising from In Vitro Fertilization, Victoria, *Report on Donor Gametes in IVF* (1983) paras [3.14], [3.28].
- 4 Standing Review and Advisory Committee on Infertility, *Annual Report 1996*.
- 5 Ibid.
- 6 See Victoria, *Parliamentary Debates*, Legislative Assembly, 4 May 1995, 1244 (Marie Tehan, Minister for Health).
- 7 Office of the Minister for Health, ‘Minister Details New IVF Legislation’ (Press Release, 4 May 1995).
- 8 *Infertility Treatment Act 1995* s 1.
- 9 *Infertility Treatment Act 1995* s 5.
- 10 *Infertility Treatment Act 1995* s 3.
- 11 *Infertility Treatment Act 1995* s 122.
- 12 Infertility Treatment Authority, *Conditions for Licence: Clinics, Hospitals and Day Procedure Centres* (7th ed, 2006).
- 13 National Health and Medical Research Council, *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research* (2004).

staffing, recordkeeping and notifications. The Conditions also provide guidance to licensees about legislative provisions which have been subject to judicial interpretation.

Donor insemination can be performed outside a licensed clinic by an approved doctor.

In July 2006, the Infertility Treatment Act was amended to allow entities other than hospitals and day procedure centres to be licensed to carry out infertility treatment.<sup>14</sup> In the second reading speech for the amending Bill, the then Minister for Health, Bronwyn Pike, explained that the purpose of the Bill was to enable an infertility treatment provider to apply and be granted a licence to conduct treatment in their own right:

At present section 93 of the act permits the Infertility Treatment Authority to issue a licence only to a public hospital, a denominational hospital, a private hospital or a day procedure centre. There is no capacity to issue a licence for a stand-alone organisation which is a legal entity, such as, for example, Melbourne IVF or Monash IVF ...

The current licensing arrangements are not ideal for the governance of the licence. It means that the licensee may not be the clinic providing treatment, and hence there is a lack of clarity between the licensee and the clinic over legal responsibilities and obligations.

This amendment expands the category of entities that can apply for and be granted a licence to include proprietors of clinics that provide infertility treatment services and are either based within a hospital or day procedure centre or access the clinical services of a hospital or day procedure centre.<sup>15</sup>

The ITA has subsequently amended its conditions of licence to reflect this amendment.<sup>16</sup>

### Donor Registers

The Act requires clinics and doctors carrying out treatment procedures to collect specified information about each treatment procedure and resulting birth, and to provide that information to the ITA. The ITA is required to maintain a register of this information. The Act sets out the rights of donor-conceived people, recipient

parents, donors and their families to access the information about donor treatment procedures recorded in the registers.<sup>17</sup> The parties have different rights to access information according to the date on which the donation in question was made. In Chapter 15 of this report, we discuss the operation of the registers in more detail.

### NHMRC GUIDELINES

The National Health and Medical Research Council (NHMRC), a Commonwealth statutory authority, has, through its Australian Health Ethics Committee (AHEC), issued national guidelines for ethical use of reproductive technology in clinical practice and research. The Infertility Treatment Act remains the primary instrument regulating ART in Victoria, but as noted above, compliance with the NHMRC guidelines is a condition of licence for Victorian treatment providers.<sup>18</sup>

The NHMRC guidelines contain nine ethical principles to guide the clinical practice of ART:

1. *Respect all participants*
2. *Respect human embryos*
3. *Use open and consistent decision making*
4. *Provide information and counselling*
5. *Obtain consent*
6. *Maintain privacy and confidentiality*
7. *Keep detailed records*
8. *Collect and report outcomes data*
9. *Respect conscientious objections.*<sup>19</sup>

The guidelines require that participants in ART be provided with relevant information, receive counselling and give informed consent to treatment. They do not address eligibility for treatment or how the welfare of the child might be taken into account in decisions about treatment outside these requirements. The guidelines do however state that clinics 'should maintain documented practices and procedures, identifying the line of responsibility for each' and should develop specific protocols for access to, and eligibility for, treatment.<sup>20</sup>

The NHMRC guidelines also deal with matters such as storage arrangements for gametes and embryos, record keeping and data reporting, and the introduction of innovative procedures.

## MEDICAL PRACTICE REGULATION

The NHMRC guidelines stipulate that all clinics offering ART must obtain accreditation by a recognised authority. The Reproductive Technology Accreditation Committee (RTAC) of the Fertility Society of Australia (FSA) provides accreditation. RTAC's responsibilities include setting and monitoring standards for ART centres, and publishing a Code of Practice. The ITA requires clinics to be accredited by RTAC, in order to be eligible for a licence under the Infertility Treatment Act. All Victorian clinics are RTAC-accredited and must abide by RTAC requirements in addition to complying with Victorian law.

Medical practitioners providing ART services are also subject to general medical regulation under the *Medical Practice Act 1994*, the *Health Services Act 1988* and the *Health Services (Conciliation and Review) Act 1987*, and are also expected to comply with the Code of Ethics of the Australian Medical Association.<sup>21</sup>

## CLONING AND EMBRYO RESEARCH

As noted above, the Infertility Treatment Act regulates research using human eggs, sperm and embryos. This research is distinct from the use of human gametes and embryos in ART, which is for reproductive purposes. Stem cell research and cloning fall outside our terms of reference, but their regulation is outlined briefly below.

Developments in cloning and embryo research during the 1990s raised new ethical challenges and prompted calls for regulation. In 2002 the Council of Australian Governments agreed that nationally consistent legislation should be implemented to ban certain practices considered unacceptable, and to regulate research using gametes and embryos.

The *Prohibition of Human Cloning Act 2002* (Cth) and the *Research Involving Human Embryos Act 2002* (Cth) prohibited human cloning and several other practices considered unacceptable, including the creation of human embryos for any purpose other than for attempting to achieve a pregnancy in a woman. Certain uses of excess human embryos created through ART were permitted in accordance with licensing conditions. These Acts operated concurrently with state and territory legislation which also came into force in 2002. Accordingly, the Infertility Treatment Act sets out a regime for the ITA to approve permitted research. The Act prohibits cloning of human embryos<sup>22</sup> and the creation of human embryos for research purposes.<sup>23</sup> NHMRC and RTAC guidelines also provide guidance on research practice.

The Prohibition of Human Cloning Act and the Research Involving Human Embryos Act each require that they be reviewed after two years.<sup>24</sup> Accordingly, the Acts were reviewed by the Legislation Review Committee (known as the Lockhart Review) in 2005. The committee reported to federal parliament that 'it is generally accepted that there is an ongoing need for legislation in this area',<sup>25</sup> but that an overly prescriptive approach had disadvantages. The committee recommended changes to the regulatory system to allow strictly controlled research on human embryos. It also recommended that:

- research involving the creation and use of human embryos should be subject to national legislation
- reproductive cloning should continue to be prohibited
- the creation of human embryos by nuclear transfer should be permitted, under licence, according to strict regulatory guidelines, including strong ethical guidelines for egg donation.

In response to the recommendations of the Lockhart Review, new legislation to regulate embryo research and cloning was passed in 2006. The *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006* (Cth) will enable certain types of research involving embryos to be permitted provided the research is approved by the NHMRC licensing committee. From 12 June 2007, the Act will permit the creation of human embryos by nuclear transfer for research purposes. Recently legislation has been introduced into the Victorian parliament to reflect the federal amendments.<sup>26</sup> The federal legislation must be reviewed again in three years.

## STATUS OF CHILDREN LEGISLATION

In addition to regulation of the clinical aspects of ART, Victoria, along with all other Australian jurisdictions, has enacted legislation to deal with the status of children born as a result of donor treatment procedures. The *Status of Children Act 1974* was amended in 1984 to extinguish the parental status of donors and to presume the couple to whom the child is born to be the child's parents, regardless of genetic connection. The extent and consequences of these provisions are examined in detail in Chapter 11-13.

14 *Health Legislation (Infertility Treatment and Medical Treatment) Act 2006*.

15 Victoria, *Parliamentary Debates*, Legislative Assembly, 31 May 2006, 1461 (Bronwyn Pike, Minister for Health).

16 Infertility Treatment Authority (2006), above n 12.

17 *Infertility Treatment Act 1995* Pt 7.

18 For recent judicial consideration of the NHMRC guidelines see *YZ v Infertility Treatment Authority* (2005) VCAT 2655 (Unreported, Justice Morris, 20 December 2005). This decision is further discussed at page 66.

19 National Health and Medical Research Council, above n 13, paras 5.1-5.9.

20 *Ibid* para 5.3.

21 Australian Medical Association, *Code of Ethics* (2004, revised 2006).

22 *Infertility Treatment Act 1995* Part 4A Division 1.

23 *Infertility Treatment Act 1995* Part 4A Division 2.

24 *Prohibition of Human Cloning Act 2002* (Cth) s 25; *Research Involving Human Embryos Act 2002* (Cth) s 47.

25 Legislation Review Committee, Parliament of the Commonwealth, *Legislation Review: Prohibition of Human Cloning Act 2002 and the Research Involving Human Embryos Act 2002* (2005), 158.

26 Infertility Treatment Amendment Bill 2007, introduced by the Hon B Pike, 13 March 2007.

**REGULATION IN OTHER JURISDICTIONS**

The Commonwealth does not have the constitutional power to legislate over ART. This means that there are different approaches to regulation across states and territories. As in Victoria, South Australia and Western Australia have directly regulated the provision of ART services.<sup>27</sup> These states have legislation that sets out criteria for access to treatment and requires doctors providing infertility treatment to be licensed by a specific statutory agency. The legislation also provides for codes of practice that detail clinical practice standards.<sup>28</sup> The remaining states and territories in Australia adhere to national ethical standards for treatment, best practice guidelines and standards developed by national bodies, such as the NHMRC guidelines and the RTAC code of conduct.<sup>29</sup>

JURISDICTION	LEGISLATION	NHMRC & RTAC GUIDELINES
New South Wales	8	4
Victoria	4	4
Western Australia	4	4
South Australia	4	4
Queensland	8	4
ACT	8	4
Tasmania	8	4
Northern Territory	8 (but clinics adhere to SA legislation)	4

The Australian Health Ethics Committee has recommended that because ART entails significant social and political, not just ethical, concerns it should be subject to legislation in all Australian jurisdictions. It also believes that without uniform legislation 'regulation of national data collection, maintenance of a centralised database and monitoring of research could not be achieved'.<sup>30</sup> A number of submissions received by the commission also called for nationally consistent regulation.<sup>31</sup> As discussed in Chapters 2 and 4, another consequence of the absence of uniform ART legislation is that people who are ineligible for treatment in one state often travel to unregulated states to undergo treatment.<sup>32</sup>

International regulatory regimes range from prohibitive or restrictive legislation, to facilitative legislation to no legislation at all.<sup>33</sup> Italy and Germany, for example, have adopted a very restrictive and cautious approach to ART. Controls on the use of ART and access to treatment exist in Canada, the United Kingdom and New Zealand, where legislation contains broad principles to which practitioners must adhere when making decisions about treatment. In the United Kingdom, a code of practice operates in conjunction with a statutory licensing system to regulate the conduct of treatment. There is some control over fertility treatment in most Scandinavian countries, ranging from permissive legislation in Sweden to strict legislative control in Norway.

In the United States, there is no federal regulation of ART. Approximately 30 states have enacted legislation in the area, including one state, New Hampshire, which explicitly regulates access to treatment.<sup>34</sup> Voluntary societies, such as the American Society of Reproductive Medicine and the Society for Assisted Reproductive Technology (SART) develop practice guidelines and minimum standards for member clinics, set reporting requirements and facilitate educational programs. Over 85% of ART clinics in the United States are members of SART.<sup>35</sup>

## SHOULD ART BE REGULATED?

The question of whether, and to what extent, the law should govern the use of ART is controversial.<sup>36</sup> Some people think ART is simply a medical procedure which should not be regulated differently from any other treatment. According to this view, the principles of individual autonomy and reproductive freedom should prevail and decisions should be made by the treating doctor and the patient, subject to the normal requirement for a proper standard of care.<sup>37</sup> Another argument against regulation is that because there is no consensus in the community about what ethical principles should apply to reproductive choices, moral and ethical decisions should be made by the individuals concerned and not imposed by the state. Further, interference by the state may hinder developments in treatment-enhancing technologies. Proponents of this view also argue that clinical issues can be addressed through professional self-regulation in the form of guidelines and codes of practice.

On the other hand, some people argue that ART is different from other forms of medical treatment because the creation of children raises complex moral and social questions. On these grounds, it is argued that ART should be regulated by the state. As one submission commented, ART 'raises profound questions that go to the very core of our understanding of the creation of human life'.<sup>38</sup> In Victoria, one of the reasons for regulating ART has been to limit the types of people who are eligible for treatment. However, regulation can also have a range of purposes directed at achieving other specific objectives, such as:

- protecting patients and children to be born against genuine risk of harm by implementing safeguards and ensuring the quality of services
- establishing procedures to support patients through the process and ensure they are able to make informed decisions about treatment options
- prohibiting particularly harmful or unacceptable activities such as the implantation of multiple embryos, and reproductive cloning

- instilling public trust and confidence in the delivery of services using emerging technologies
- making decision-making processes fair and transparent and the people responsible for those decisions accountable
- clarifying the status of children and parents where donated gametes have been used to conceive a child
- providing access to information about a donor conceived person's genetic origins
- controlling the expenditure of public funds
- providing processes for consultation and review about future changes to legislation, particularly in response to rapidly changing technology.

Although some people argue that regulation of ART is obtrusive and interferes in matters considered to be private,<sup>39</sup> there appears to be agreement in the literature produced by policy makers and academics that a degree of careful and balanced intervention by the state in ART is justified to achieve some or all of the objectives listed above.

Martin Johnson, Professor of Reproductive Services at the University of Cambridge, has concluded that some form of external regulation of ART seems inevitable, although he argues that it is vital to ensure that such regulation 'be driven by clear, outcome-based objectives'.<sup>40</sup> Philosophers Leslie Cannold and Lynn Gillam argue that:

*the state has an obligation to protect the interests of its citizens and regulation is a legitimate method of achieving this. It is possible that ART can be practised in ways that threaten the interests of at least some citizens and so, in principle, it is ethically permissible for the state to regulate in such situations.*<sup>41</sup>

Helen Szoke, Lexi Neame and Louise Johnson, past and present executive officers and research and policy staff at the Infertility Treatment Authority, acknowledge that government intervention in ART is problematic, but suggest there is:

*potential for [governments] to constitute an independent player in this arena, and assist in resolving conflicts and formalising an expression of public interest. Of course, such a resolution will not satisfy all parties, as the conflict is often based on incommensurable moral values and we live in a pluralistic society.*<sup>42</sup>

- 27 *Reproductive Technology (Clinical Practices) Act 1988 (SA), Human Reproductive Technology Act 1991 (WA)*. In 2003 the NSW Government released a draft Assisted Reproductive Technology Bill for the purposes of public consultation. At the time of writing the bill had not been introduced into parliament and no further details about its progress were available.
- 28 *Reproductive Technology (Code of Ethical Clinical Practice) Regulations 1995 (SA)*. In Western Australia, a code of practice has not been drafted, but the Commissioner of Health provides clinics with directions (*Human Reproductive Technology Directions*).
- 29 For a discussion of the law in the Northern Territory, ACT, NSW, Tasmania and Queensland see John Seymour and Sonia Magri, *ART, Surrogacy and Legal Parentage: A Comparative Legislative Review* (2004), 23–6.
- 30 National Health and Medical Research Council (2004), above n 13, para 1.6. See also Don Chalmers, 'Professional Self-regulation and Guidelines in Assisted Reproduction' (2002) 9(4) *Journal of Law and Medicine* 414, 428.
- 31 Submission PP1 322 (Australian Infertility Support Group).
- 32 Note that 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).
- 33 Helen Szoke, Lexi Neame and Louise Johnson, 'Old Technologies and New Challenges: Assisted Reproduction and its Regulation' in Ian Freckleton and Kerry Petersen (eds), *Disputes and Dilemmas in Health Law* (2006) 187, 194–6.
- 34 Seymour and Magri (2004), above n 29, 6.
- 35 Society for Assisted Reproductive Technology, 'What is SART?' available at <[www.sart.org/WhatsSART.html](http://www.sart.org/WhatsSART.html)> at 10 January 2006.
- 36 For a more detailed discussion of the arguments about regulation, see (2002) 9(4) *Journal of Law and Medicine*, Special Issue: Regulating Reproduction, for example, Chalmers (2002), above n 30, 425–8.
- 37 See, eg, submission CP 174 (Professor HWG Baker).
- 38 Submission CP 166 (Christine Campbell).
- 39 See, for example, 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.
- 40 Martin 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, 413.
- 41 Leslie Cannold and Lynn Gillam, 'Regulation, Consultation and Divergent Community Views: The Case of Access to ART by Lesbian and Single Women', *Journal of Law and Medicine* 498, 501–2.
- 42 Szoke, Neame and Johnson (2006) above n 33, 187, 206.

***In all actions concerning children, whether undertaken by public or private social welfare institutions, courts of law, administrative authorities or legislative bodies, the best interests of the child shall be a primary consideration.***

They posit that the government's role in an area of such complexity and technological development is to manage this process of change, in part by engaging the community in ongoing dialogue.<sup>43</sup>

Governments, too, have broadly recognised the need for regulation of ART. As Professor Ken Daniels has observed:

*Most countries seem to have accepted that there is a role for the state and that as a consequence, the implementation of that role will limit or constrain reproductive choice. Most of the debate and conflict in recent years has centred on the nature and extent of that role, rather than its appropriateness.*<sup>44</sup>

In 2005 the United Kingdom House of Commons Science and Technology Committee argued that:

*there should be a balance between the freedom of individuals to make their own reproductive choices and the legitimate interests of the state, but that any intervention into reproductive choice must have a sound ethical basis and also take into account evidence of harm to children or to society.*<sup>45</sup>

In the United Kingdom, the government agreed with the committee that legislation remains necessary and has expressed its commitment 'to the principles of good regulation, which include ensuring that regulation is proportionate and appropriately targeted'.<sup>46</sup> The government agreed that 'the emphasis of regulation should be on improving standards and systems and the development of good practice, with the principal aim of protecting patients'.<sup>47</sup>

The commission has paid particular attention to the ways in which legislation has addressed the objective of protecting the interests of children born as a result of ART, and how it responds to technological change.

### **BEST INTERESTS OF THE CHILD**

The most common justification for regulation of ART is the need to protect children from any harm that may arise as a result of the method or circumstances of their conception. The rationale for this approach is that the state has a responsibility to protect the legitimate interests and needs of children because they are incapable of participating in the decision-making process in relation to their own conception.

The *Convention on the Rights of the Child*, to which Australia is a signatory, directs that:

*In all actions concerning children, whether undertaken by public or private social welfare institutions, courts of law, administrative authorities or legislative bodies, the best interests of the child shall be a primary consideration.*<sup>48</sup>

The principle of best interests of the child is central to ART legislation in Victoria, South Australia, Western Australia, the United Kingdom and Canada, albeit using different terminology. In some cases the legislation refers to the 'welfare' or 'welfare and interests' and in others to the 'best interests' or 'health and wellbeing' of the child or person to be born. The legislation variously requires the welfare or best interests of the child to be the 'paramount' or 'primary' consideration, to take 'priority' or to be 'taken into account'.<sup>49</sup>

In addition, the NHMRC guidelines state that 'clinical decisions must respect, primarily, the interests and welfare of the persons who may be born'.<sup>50</sup> This principle also underpins the *Family Law Act 1975* (Cth),<sup>51</sup> and the Victorian *Adoption Act 1984*<sup>52</sup> and *Children and Young Persons Act 1989*.<sup>53</sup>

The best interests of the child principle has been the subject of considerable debate and controversy over the years, both as it relates to ART but also in its more general application to child protection, social welfare and family law.<sup>54</sup> The arguments made against requiring consideration of the best interests of children in the particular context of ART may be summarised as follows:

- The principle of best interests is contestable, subjective and indeterminate. It is often intended to reflect specific socio-cultural values, generally about 'desirable' family types and can be used to justify discrimination against non-conventional families. For example, in some jurisdictions it has been assumed that limiting access to reproductive services to heterosexual couples will act as sufficient safeguard to protect children from harm.
- It is unfair to subject people using ART to an assessment level that does not apply to people who conceive children without the assistance of reproductive technologies. There is no justification for imposing a higher standard on ART users.
- It is impossible to predict what will be in the best interests of a child who has not yet been conceived, as every person is unique. By contrast, the best interests of a child in the context of a child protection or adoption case or a family law dispute can be ascertained with some degree of certainty, because their individual needs can be identified. It is more appropriate to assess the best interests of a child born through ART, if at all, once the child has been born and some risk of harm has been identified.
- It is also argued that it is problematic, from a philosophical perspective, to suggest that non-existence would be preferable to an existence which is considered to be less than ideal.<sup>55</sup>
- Although the principle is persuasive at a policy or ethical level, it is impossible to apply at a clinical level.<sup>56</sup> It is difficult and time-consuming for clinicians to obtain information from all prospective patients about their background and parenting capacity.

Despite these reservations about the best interests of the child principle, legislatures continue to adhere to it. In December 2006, for example, the United Kingdom government reported that it:

*believes that the presence of a 'welfare of the child' section in the law remains valuable and proposes to retain a duty for treatment centres to consider the welfare of the child who may be born as a result of treatment, or any other child who may be affected.*<sup>57</sup>

Some regimes have attempted to address some of the criticisms and limitations of applying the principle. For example, in Canada the legislation prohibits discrimination against participants on the grounds of marital status or sexual orientation.<sup>58</sup> In the United Kingdom, the Human Fertilisation and Embryology Authority issues a code of practice to guide clinics on how to take the welfare of the child into account when assessing those seeking treatment.<sup>59</sup> The current guidelines contain a presumption to provide treatment to all those who request it, unless there is evidence that the child to be born would face a risk of serious medical, physical or psychological harm. Evidence is drawn from the patient's medical and social history. In South Australia, the Reproductive Technology (Code of Ethical Clinical Practice) Regulations 1995 contain presumptions against treatment of people who potentially pose a risk to children, and in limited circumstances, there is the possibility of recourse to a review panel.

Importantly, our consultations revealed that almost everyone believes the promotion of the best interests of the child should remain the primary concern in the regulation and provision of ART services, even if they differ on precisely how a child's interests should be protected in the context of access to ART.

- 43 Ibid 207.
- 44 Ken Daniels, 'Regulation and Reproductive Choice: The New Zealand Approach' (2005) 8(2) *Human Fertility* 75, 75.
- 45 House of Commons Science and Technologies Committee, *Human Reproductive Technologies and the Law* Fifth Report of Session 2004–05: Volume 1 (2005), 169.
- 46 The Stationery Office, *Government Response to the Report from the House of Commons Science and Technology Committee: Human Reproductive Technologies and the Law* Cm 6641 (2005), 6. See also Foreword by Minister of State for Public Health in Department of Health [United Kingdom], *Review of the Human Fertilisation and Embryology Act: A Public Consultation* (2005), v.
- 47 The Stationery Office (2005) above n 46, 26.
- 48 United Nations, *Convention on the Rights of the Child*, UN GAOR, 44<sup>th</sup> sess, UN Doc A/44/736 (1990) art 3(1). For a discussion of the convention and its application to ART, see John Tobin, *The Convention on the Rights of the Child: The Rights and Best Interests of Children Conceived Through Assisted Reproduction* (2004).
- 49 The Hon. Alistair Nicholson, previously Chief Justice of the Family Court of Australia, has expressed the opinion that he doubts that there is any significant difference between the terms 'welfare and interests' contained in the Infertility Treatment Act and the principle of 'best interests of the child' found in the *Convention on the Rights of the Child* and in the Family Law Act: 'Children's Rights in the Context of Infertility Treatment', paper presented to the Infertility Treatment Authority Symposium, 2 November 2006.
- 50 National Health and Medical Research Council, above n 13, para 5.1.
- 51 *Family Law Act 1975* (Cth) s 60CA.
- 52 *Adoption Act 1984* s 9.
- 53 *Children and Young Persons Act 1989* s 87.
- 54 See Emily Jackson, *Regulating Reproduction: Law, Technology and Autonomy* (2001); Kristen Walker, 'Should There Be Limits on Who May Access Assisted Reproductive Services? A Legal Perspective' in Jennifer Gunning and Helen Szoke (eds), *The Regulation of Assisted Reproductive Technology* (2003) 123, 131–2; Margaret Coady, 'Families and Future Children: The Role of Rights and Interests in Determining Ethical Policy for Regulating Families' (2002) 9(4) *Journal of Law and Medicine* 449.
- 55 Emily Jackson, *Fertility Treatment: Abolish the Welfare Principle* (2003) available from <www.spiked-online.com/Articles> at 11 June 2003.
- 56 Ken Daniels, 'An Examination of the "Best Interests of Children" in the Field of Assisted Human Reproduction' (1998) 8 *Eubios Journal of Asian and International Bioethics* 146.
- 57 Department of Health [United Kingdom], *Review of the Human Fertilisation and Embryology Act: Proposals for Revised Legislation (including Establishment of the Regulatory Authority for Tissue and Embryos)* Cm 6989 (2006)10. It should be noted that in December 2006 the UK government announced its decision to propose that the reference in the Act to the need of the child for a father be removed: Department of Health [United Kingdom], *Review of the Human Fertilisation and Embryology Act: Proposals for Revised Legislation (including Establishment of the Regulatory Authority for Tissue and Embryos)* Cm 6989 (2006) 10.
- 58 *Assisted Human Reproduction Act* (Can) s 2(e).
- 59 Human Fertilisation and Embryology Authority, *Code of Practice* (6th ed, 2003), Part 3.

**TECHNOLOGICAL CHANGE**

Our terms of reference ask us to consider whether changes should be made to the Infertility Treatment Act to reflect rapidly changing technology in the area of assisted reproduction. Developments in assisted reproductive technology present a significant challenge for lawmakers: legislation can quickly become redundant, unworkable or obstructive if the subject matter being regulated changes. These problems generally arise when legislation is prescriptive, that is, when it is specific about what treatments can or cannot be provided and there is no scope for flexibility in the application of the law.

Although the restrictive consequences of legislation are often intentional, because governments have made decisions about where the boundaries should lie in respect of scientific advances, a lack of flexibility can have a range of undesirable effects. In particular, it may result in legal challenges to the validity of the legislation, as in the case of *McBain v State of Victoria*,<sup>60</sup> or people may seek specific redress from the courts, as in the posthumous use of sperm cases of *AB v Attorney-General (Vic)*<sup>61</sup> and *YZ v Infertility Treatment Authority*.<sup>62</sup>

When there is no prospect of treatment being legally provided in Victoria, people may choose to travel to jurisdictions with less restrictive laws, sometimes with the support and encouragement of Victorian clinicians.<sup>63</sup>

Another consequence of prescriptive regulation is that the body charged with administering the Act may encounter problems resolving matters of interpretation where the legislation is detailed and/or definitions of technical terms are ambiguous. In its submission, the ITA stated that during the first five years of its operation, it sought 32 legal opinions to assist it to apply provisions of the Act.<sup>64</sup>

It may also be difficult to apply the Act to new technologies that were not envisaged when it was drafted. For example, a new technology may produce the same outcome as an older technology that is banned, but be permitted because it does not fall within the scope of the legislation.

The parliament may be called on to amend the legislation on an ad hoc basis to respond to the circumstances of particular cases. For example, in 2001 the Infertility Treatment Act was amended to permit a woman to use stored embryos in circumstances where her husband had died after the creation of the embryos.<sup>65</sup>

The Lockhart review grappled with these issues in the context of embryo research and the prohibition of human cloning.<sup>66</sup> The committee reported that it was:

*widely acknowledged that prescriptive legislation has a number of disadvantages, because it is difficult to anticipate advances in knowledge and potential new uses of the technologies. This difficulty, combined with the complexity of the science involved, inevitably leads to ambiguities and difficulties in interpretation.*<sup>67</sup>

The committee therefore advocated a more flexible regulatory approach, involving a combination of legislation, regulations, guidelines and the capacity of the licensing body to issue rulings on interpretation of legislative provisions.<sup>68</sup>

The commission convened a meeting of a group of senior clinicians and scientists who work in the ART field.<sup>69</sup> The group identified a range of problems they experience as a result of restrictive definitions in the legislation governing their activities. They agreed that the legislation should establish a framework for the development of regulation by a body (such as the ITA) in consultation with the community, practitioners and patients. The group also suggested that, in order to ensure the legislation endures advances in technology, it should describe what treatment outcomes are permitted, rather than attempting to define the specific treatment procedures and technologies that are permitted.

Commentators such as Timothy Caulfield, Lori Knowles and Eric Meslin, while acknowledging the difficulty of crafting policy that is 'both comprehensive and responsive to the evolving science and bioethical considerations',<sup>70</sup> are critical of prescriptive approaches to the regulation of ART and reproductive genetics:

*Too often, we believe, the search for a regulatory response to certain scientific developments has led governments to adopt simple bans and prohibitions. We recognise that this approach is often a*

result of political or jurisdictional constraints or the result of a lack of other regulatory options. Using the law in such a manner is, however, frequently an inappropriate means of regulating behaviour in this complex and dynamic area. With rare exception, legal prohibitions are blunt—that is, they tend to be either overly permissive or overly restrictive—inflexible, and incapable of reflecting the depth and diversity of ethical views inextricably linked to the policy debates surrounding reproductive genetics.<sup>71</sup>

Proposals to address the difficulties of regulating an area of rapidly changing technology generally advocate the implementation of framework legislation, elements of which are already a feature of the Victorian Act. This is where legislation sets the framework for governance of the activities in question and articulates the relevant values and guiding principles, but leaves the details of regulation to a regulatory body.<sup>72</sup> Compliance with standards of practice is ensured through a licensing system. Helen Szoke, Lexi Neame and Louise Johnson, for example:

*regard legislation which devolves the proscriptive regulations governing practice and implementing guidelines, directives or codes as a promising model for the regulation of ART in Australia in the future. However, the fact remains that without legislation there exists no watertight enforcement mechanism for such codes.*<sup>73</sup>

One area which is characterised by rapid technological change, and is regulated in a more flexible way, is that of pre-implantation genetic diagnosis (PGD) of embryos. PGD is used to screen embryos where there is a risk that a child may inherit a genetic disorder, and enables selection and implantation of only unaffected embryos. The traits that can be identified and screened out through PGD are expanding rapidly. The way in which the Infertility Treatment Act regulates pre-implantation genetic diagnosis allows new developments in embryo screening to be made available to patients without the need for review or amendment of the law. The legislation does not mention PGD, nor does it list the types of conditions which may be identified through this process. Instead, the ITA approves new applications of PGD as part of its licensing function. This process is discussed in further detail in Chapter 5.

One of the most important features of regulating an area as complex and dynamic as ART is the need for ongoing community consultation and debate. As Caulfield, Knowles and Meslin conclude:

*No law or policy will or should aim to bring closure. We need to develop a regulatory regime that can work within this reality. Steps must be taken now to move towards a flexible regulatory scheme that promotes ongoing public and professional dialogue, sets limits which respect the ethical commitments we hold as a society, and fosters a climate which will promote valid scientific and clinical endeavour.*<sup>74</sup>

## COMMISSION'S APPROACH

The commission has concluded the continued regulation of ART in Victoria is justified. The use of ART raises issues which go beyond the interests of particular individuals and may affect the whole community. Different participants in ART (primarily patients, their partners, donors, and children born as a result) have different interests and needs which must be protected and balanced. The state is able to play an important role in helping to ensure this is done in a fair and transparent way.

People have a range of views about the ethical and social implications of creating children through the use of ART. This makes it particularly important that ART is open to public scrutiny and the public has the opportunity to express their views about the conditions under which it is provided. Regulation can identify the public interests which must be considered when treatment is provided and give democratic legitimacy to decisions about ethical and moral issues.<sup>75</sup>

Self-regulation by scientists and medical practitioners is not transparent and provides limited scope for public debate about issues in which many members of the community feel they have a stake. However, in the commission's view it is appropriate for technical clinical matters to continue to be dealt with in guidelines developed by national expert bodies such as RTAC and the NHMRC.

Techniques of assisted reproduction are evolving rapidly. Many of the medical and social consequences of ART are not yet fully understood.<sup>76</sup> Regulation can deal with this

- 60 (2000) 99 FCR 116.
- 61 (2005) 12 VR 485.
- 62 (2005) VCAT 2655 (Unreported, Justice Morris, 20 December 2005).
- 63 See Kerry Petersen, et al, 'Assisted Reproductive Technologies: Professional and Legal Restrictions in Australian Clinics' (2005) 12 *Journal of Law and Medicine* 373, 383–4.
- 64 Submission CP 24 (Infertility Treatment Authority). This figure does not include opinions sought in relation to particular court cases.
- 65 *Infertility Treatment (Amendment) Act 2001*, s 5. Joanne Bandel-Caccamo lobbied the Victorian government to remove the prohibition on the use of stored embryos after the death of her husband. The couple had been receiving ART treatment and had embryos in storage: Fay Burstin, 'Widow wins right to IVF' *Herald-Sun* (Melbourne) 12 October 2001, 17.
- 66 Legislation Review Committee, Parliament of the Commonwealth, *Legislation Review: Prohibition of Human Cloning Act 2002 and the Research Involving Human Embryos Act 2002* (2005), 153–8.
- 67 *Ibid* 158.
- 68 *Ibid* 158, 182.
- 69 Technological Change Working Group consultation, 21 October 2004.
- 70 Timothy Caulfield, et al, 'Law and Policy in the Era of Reproductive Genetics' (2004) 30(4) *Journal of Medical Ethics* 414, 414.
- 71 *Ibid*.
- 72 *Ibid* 416; see also Sonia Magri, 'Research on Human Embryos and Cloning: Difficulties of Legislating in a Changing Environment and Model Approaches to Regulation' (2005) 12 *Journal of Law and Medicine* 483.
- 73 Szoke, Neame and Johnson (2006) above n 33, 187, 207.
- 74 Caulfield et al (2004) above n 70, 416–7. See also Belinda Bennett, 'Rewriting the Future? Biomedical Advances and Legal Dilemmas' (2006) 13 *Journal of Law and Medicine* 295, 303.
- 75 Helen Szoke, 'The Nanny State or Responsible Government?' (2002) 9(4) *Journal of Law and Medicine* 470, 477.
- 76 We discuss this in Chapter 2.

uncertainty by monitoring practices, controlling use of particular technologies, and implementing protections against identifiable harms and risks. The regulatory scheme must be able to respond to technological change, to address emerging problems and to respond to shifts in social attitudes. As the experience in Victoria has shown, constant changes and discoveries have made the present legislative scheme difficult to apply.

To this end, the commission has recommended changes to the Infertility Treatment Act which would promote a responsive and flexible regulatory regime. The legislation should set down guiding principles which reflect broad community expectations, and should establish processes to facilitate access to ART. There should be sufficient flexibility and scope for discretion built into those processes to ensure the legislative framework can endure developments in the technology and our understanding of the impact of ART on participants, in particular the children who are born as a result. We have proposed that the more difficult decisions to be made about the provision of ART services be devolved to interdisciplinary decision-making bodies that have the necessary expertise and skill to respond to the features of individual cases, and the implications of new developments in treatment. We also believe individuals affected by the decisions made by these bodies should have a right of review.

As to the issue of protecting the interests of the child to be born, the commission believes this aim should remain fundamental to the regulation of ART, but at the same time should be carefully implemented to ensure the principle is applied fairly in each case. In Chapter 5 we discuss the different approaches regulation of this area may adopt, and propose new processes to deal with cases where a potential child may be at risk of harm.