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Assisted Reproductive Technology Bill 2007

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ASSISTED REPRODUCTIVE TECHNOLOGY BILL 2007

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Second Reading

The Hon. TONY KELLY (Minister for Lands, Minister for Rural Affairs, Minister for Regional Development, and Vice-President of the Executive Council) [5.04 p.m.], on behalf of the Hon. John Hatzistergos: I move:

That this bill be now read a second time.

I am pleased to bring before the House the Assisted Reproductive Technology Bill 2007. Extensive consultation has been undertaken regarding the practice of assisted reproductive technology [ART] in New South Wales. This process commenced with the release of a discussion paper by the Department of Health in 1997. Prior to finalising its recommendations to government following this extensive consultation process, the department convened a reference group to provide expert advice on the medical, scientific, social and ethical issues involved. Public consultation has continued with an exposure draft bill and accompanying information guide, which were tabled in Parliament in December 2003. Stakeholders responded very positively to the draft bill. More than 60 submissions were received. All the issues raised were carefully considered and, where appropriate, have been incorporated into this bill. I express the Government's appreciation to the many people and organisations who contributed to the development of this important legislation. The extent and quality of the submissions that were made during the development of this legislation reflect the degree of community interest in the regulation of reproductive technology. I seek leave to have the balance of my speech incorporated in *Hansard*.

Leave granted.

The legislation has benefited greatly from the valuable contributions made by organisations, members of the community and health professionals.

The bill aims to address a range of issues relating to the social and ethical aspects of ART which were identified during the consultation process as warranting a legislative response.

It provides a broad framework for the practice and conduct of ART services.

The development of this legislation has been guided by three important principles.

The first is to recognise obligations already imposed on ART providers by the existing laws, such as the Medical Practice Act 1992.

The second is to recognise the rights of individuals to have control over the use of their genetic material.

The final principle is "the best interests of the child" and a recognition of the paramount importance of this principle.

The bill does not duplicate the existing regulatory framework that applies to the clinical aspects of ART practice.

Rather it complements and enhances the current system to clarify and protect the rights and obligations of people involved in ART treatment and it must be recognised that this includes the rights of children born as a result of that treatment.

I wish to clarify that the definition of "embryo" in the bill is different to the definition of "human embryo" in the Human Cloning for Reproduction and Other Prohibited Practices Act.

The reason for that difference is that the bill is designed to regulate the social aspects relating to the provision of ART treatment while the Human Cloning for Reproduction and Other Prohibited Practices Act is designed to prohibit certain ethically unacceptable practices and to regulate a further range of ethically contentious

practices.

Given the focus of the bill is on regulating the social aspects of assisted reproductive technologies and on protecting the interests of the people involved in the relevant procedures, it is vital that the provisions of the bill dealing with embryos apply as soon as the gametes are joined to form an embryo.

The legislation is consistent with and complements the National Health and Medical Research Council's Ethical Guidelines on the use of Assisted Reproductive Technology in Clinical Practice and Research. The definition of "embryo" in the bill is entirely consistent with the use of that term in the guidelines.

Part 2 of the bill regulates providers of assisted reproductive technology.

It establishes a system of registration and a public register of ART providers and permits only registered providers to provide ART services in New South Wales.

ART services are any medical treatment or procedure that procures or attempts to procure pregnancy other than by sexual intercourse and includes artificial insemination in-vitro fertilisation and gamete intrafallopian transfer.

The collection and storage of gametes is also an ART service for the purpose of the bill.

The bill sets minimum standards about the provision of ART services including that;

all treatment is to be provided by registered medical practitioners;

providers must make counselling available to individuals spouses and donors involved in such treatment; and

providers must comply with any infection control standards prescribed by regulation.

The second underlying principle in the bill is recognition of the rights of individuals involved in ART treatment either directly or as donors to have control over the use of their genetic material.

The bill requires providers to use gametes in accordance with the consent provided by the person from whom they were obtained.

Donors will be able to withdraw or modify their consent to the use of their gametes at any time before the gamete is implanted in a woman or until an embryo is created using those gametes.

In the case of an embryo created using sperm created by a woman's spouse the spouse is to be able to withdraw his consent at any point up until the embryo is implanted.

These provisions ensure that a person's gametes can only be used in accordance with their own explicit instructions and consent. For example if a person dies their gametes can only be used if that person consented to the posthumous use whilst they were alive.

Similarly gametes may only be collected from a person who is in a persistent vegetative state or otherwise unable to consent if that person gave consent to collection and use of their gametes before losing the ability to consent.

Clause 17 of the bill allows a gamete donor to place conditions on their consent, including a condition that directs that their gametes can only be used by a particular person or a particular classification of people.

For example, people of a particular cultural or ethnic background may only consent to the use of their gametes by people from a similar background.

The ability for donors to place conditions on the use of their gametes is especially important because any child born as a result of that donation will be able to identify their genetic parents and may wish to contact or meet them.

It is believed to be in the best interests of the child for the genetic parent to have given consent to the circumstances surrounding the child's birth and upbringing.

To put this in another way, it will not be in the child's best interests to discover later in life that their genetic parent has a fundamental objection to their existence or the social and cultural circumstances in which they were raised.

Clause 27 of the bill recognises the interests of people involved in treatment by limiting the number of women who can be provided with gametes from the same donor to five.

This allows families to have several genetically related children whilst reducing the risk of donor offspring unknowingly entering a relationship with a blood relative.

Children are protected from exploitative or inappropriate involvement in ART procedures by clause 29 of the bill.

That clause provides that with the exception of the collection and storage of gametes for the child's future use no ART treatment may be provided to a child.

The only circumstances in which a child's gametes may be collected and stored are if a medical practitioner certifies that there is a reasonable risk of the child becoming infertile before becoming an adult.

The gametes obtained cannot be used until the child becomes an adult and consents to their use.

The third and most important underlying principle in the bill is the recognition of the rights of the children born as a result of ART procedures and the importance of acting in their best interests.

A fundamental aspect of this right is the availability of and access to information about their biological parents and siblings.

Part 3 of the bill constitutes the central ART donor register so that children born from ART procedures using donor gametes or in some circumstances their parents or other persons with parental responsibility may access identifying and non-identifying information about their biological parent.

Providing information to the register will be mandatory and anonymous donations will be outlawed.

Children born following the use of donated gametes will also be able to place information on the register to be accessed by the donor.

Access to this information will only be allowed in accordance with the child's consent and that consent can only be given once the child becomes an adult.

The placing of information on the register will be entirely voluntary, although the bill does make provision for the regulations to prescribe non-identifying information that can be released to the donor without consent.

I emphasise that the mandatory donor register will not operate retrospectively.

While this is a matter of some concern to groups representing donor-conceived children, it is important that the guarantees of anonymity that many donors were given in the past are respected.

However, I am pleased to advise that the bill will facilitate the creation of a voluntary retrospective register.

This allows donor-conceived children born prior to the commencement of this legislation to access information about their biological parent and have contact with that parent if the donor agrees to provide information to the voluntary register.

Similarly, donor-conceived children will be able to place information on the register and consent to that information being made available to their donor.

The ability of donor-conceived children to obtain information about their genetic background is a matter that is of vital importance to those children and in many cases their parents.

The registers both mandatory and voluntary will help those children to fill what many consider to be a major gap in their lives.

Part 4 of the bill concerns surrogacy arrangements.

This part of the bill prevents the commercialisation of human reproduction by unequivocally prohibiting commercial surrogacy.

Consistent with existing law it makes all surrogacy arrangements, whether commercial or altruistic, void and therefore unenforceable.

This includes those agreements made before the legislation commences.

Part 5 of the bill provides powers for the inspection of premises where ART services are provided and

enforcement of the Act including the power to:
enter and inspect premises
request information and records
remove items for analysis or testing
obtain and execute a search warrant

Part 6 of the bill provides for powers of enforcement in respect of ART providers.

This includes the power to prevent an ART provider who has contravened relevant legislation, including the Human Cloning for Reproduction and Other Prohibited Practices Act 2003 and the Research Involving Human Embryos (New South Wales) Act 2003, from providing services.

Such a prohibition may be made for an unlimited time or for a specified period for breaching the requirements of the Act or regulations.

Part 6 also recognises the existing regulatory role of the Fertility Society of Australia by providing that an ART provider who has been refused accreditation or had accreditation suspended by that society's Reproductive Technology Accreditation Committee may be prohibited from providing ART services. It is proposed to commence the Act by proclamation. There will be a lengthy and detailed implementation period during which the Department of Health will consult extensively with stakeholders on regulations under the bill, including regulations concerning the donor register and infection control standards.

It is essential that stakeholders be involved in the development of the donor register and be provided with clear information on their rights and obligations before the Act commences.

Furthermore, it is my intention that the donor register be established and operational when the legislation commences.

Whilst a substantial amount of planning has already been undertaken, the practical steps involved in creating the registers cannot be undertaken until the details of the relevant regulations have been settled.

This bill clarifies and protects the rights and obligations of people involved in ART treatment.

It provides a strong regulatory framework for the ethical and social issues raised by these technologies in a manner that is sensitive to and achieves an appropriate balance between the diverse needs of donor-conceived children, parents, donors and providers.

Most importantly, the bill recognises the primacy of the best interests of the children conceived using the technology whilst providing clear directions about the rights and obligations of donors, parents and providers.

As such, the bill represents a major advancement in the appropriate regulation of a medical technology that raises far-reaching and complex social and ethical issues.

I commend the bill to the House.

The Hon. JENNIFER GARDINER [5.05 p.m.]: The Opposition does not oppose the Assisted Reproductive Technology Bill, but we wish to refer to a number of issues during this important debate. The bill prevents the commercialisation of human reproduction. Its aim is to protect the interests of certain persons who are affected by assisted reproductive technology, commonly known as ART treatment. It sets out requirements so that assisted reproductive technology providers will, in future, need to be registered by the Director General of the Department of Health. It also sets out requirements about the provision of assisted reproductive technology services, including that assisted reproductive technology services must be undertaken by or under the supervision of a registered medical practitioner and that counselling services are made available.

It also places a number of restrictions on the use of gametes and embryos. Pursuant to this bill, providers of assisted reproductive technology will have to collect certain information from persons involved in the treatment and donors. Further, the director general will establish a central assisted reproductive technology donor register that permits persons involved in this treatment and donors to obtain information about other persons. It also permits a person who was born as a result of this treatment using a donated gamete to obtain information from the donor. The bill prohibits commercial surrogacy and will make surrogacy agreements from the past void. It also sets up a regime for the enforcement of this legislation.

The Opposition acknowledges that families affected by assisted reproductive technology, particularly children

born from anonymous sperm donation, have been active in promoting the need for this bill. We note that similar legislation is in place in other jurisdictions. For example, similar legislation has been in place in Victoria since 1995. So New South Wales is dragging the chain. Back in 1997 the New South Wales Department of Health released a discussion paper and a draft exposure bill was tabled in 2003. The shadow Minister for Health, Jillian Skinner, has met with the main lobby group, the Donor Conception Support Group, on a number of occasions. In 2005 Mrs Skinner asked questions on notice relating to the failure of the New South Wales Government to act on this matter, with a view to prompting the Government to get its act together.

In November 2005 Mrs Skinner asked: Why has legislation on assisted reproductive technology not been tabled in Parliament when the draft exposure bill was presented back in 2003? She asked: When will legislation be put before the Parliament? She asked: What steps is the Government taking to secure the records of donor offspring already conceived in New South Wales? She also asked: Will the Government put in place a voluntary register to enable donor offspring and past donors to lodge their details so that identification may take place if desired by both parties? In February 2006 the then Minister for Health replied that the Government was currently considering the submissions made in response to the draft exposure bill and was developing legislation for introduction into Parliament. It has been slow to surface but it is good that it has appeared at this point. The current Minister for Health flagged her intention to introduce the bill on 4 November.

The Opposition believes that the bill largely reflects the current practice in relation to assisted reproductive technology. The bill will allow people born as a result of assisted reproductive technology treatment in the future to obtain information about their donor. A central register will be set up to help address concerns about the potential of such people unknowingly entering into a relationship with a biological sibling. That matter is debated increasingly in the public arena. The Opposition does not oppose the bill.

The Hon. KAYEE GRIFFIN [5.11 p.m.]: I support the Assisted Reproductive Technology Bill 2007. Protection for people who are unable to give consent to donate their gametes may arise where a person is not conscious, not legally competent or is dead. Part 2 of the bill prevents the use of a gamete or the export of a gamete from New South Wales without the prior consent of the gamete provider. Furthermore, clause 23 of the bill prevents a gamete being used after the gamete provider's death, unless the provider of the gamete has consented during his or her lifetime. This will allow gametes in storage to be used where the gamete provider has died but only where consent has been obtained from the gamete provider for his or her gamete's use in posthumous conception. The recipient must also be notified about the donor's death and agree to receive those gametes. This approach is consistent with parts 6.15 and 8.4 of the National Health and Medical Research Council's ethical guidelines on the use of assisted reproductive technology in clinical practice and research.

Gamete donors may limit the number of times their gametes can be used. In the absence of any limit imposed by the donor, the bill specifies that only five women can have children using the same donor's gametes. The limit of five will apply also if the donor seeks to specify a number greater than five. The bill does not limit the number of children the five women may each have. This allows parents to freely choose the size of their family and to have genetically related children. It is not appropriate to legislate family size or to limit the number of genetically related siblings born to couples solely on the basis that the children were conceived using assisted reproductive technology. This maintains consistency with part 6.3 of the National Health and Medical Research Council's ethical guidelines on the use of assisted reproductive technology in clinical practice and research, which provides that the number of children born from a single donor should be limited.

Careful consideration has been given, and will continue to be given, to the kind of information, in addition to the identity of the donor-offspring, that should be recorded on the central assisted reproductive technology donor register. In respect of the donor, it is proposed that the following minimum information be collected at the time of donation: name, date of birth and other information required to establish identity; basic physical description—height, hair colour, eye colour, build; place of birth; country of parents' birth; language spoken at home; marital status; occupation; and number of children. In respect of children, the provision of information to the register will be voluntary. However, the register will be developed with the capacity for the following information to be recorded: name, date of birth and other information which may be required to establish identity; place of birth; country of parents' birth; language spoken at home; marital status of parents; occupation of parents; and number of siblings at time of birth.

Also, there will be a voluntary register for children born using assisted reproductive technology procedures before the commencement of the legislation. In line with the National Health and Medical Research Council's ethical guidelines on the use of assisted reproductive technology in clinical practice and research, most assisted reproductive technology clinics do not accept anonymous donations. This has been the case since 1996. However, before that time many donors were guaranteed anonymity. The voluntary register will enable consenting donors and donor-conceived children to access any information that is voluntarily provided. Development of the voluntary register will be undertaken in consultation with stakeholders, and those consultations will inform the type of information that can be included on the register.

The Hon. MARIE FICARRA [5.15 p.m.]: The Coalition supports the Assisted Reproductive Technology Bill 2007. The bill recognises that the paramount responsibility we have as legislators is to protect the interests of children

conceived using assisted reproductive technology, such as artificial insemination, in-vitro fertilisation and gamete intra-fallopian transfer. Assisted reproductive technology is a great gift of life given to men, women, parents and families. It is an area where scientific developments have brought so much joy into individual and family lives.

This bill will recognise the rights of individuals involved in assisted reproductive technology to have control over their genetic material. Currently, public assisted reproductive technology clinics are obliged to keep all patient records relating to the assisted reproductive technology in accordance with the Medical Practice Act 1992 and State Records Authority Regulations 2004. In order to attain accreditation from the Reproductive Technology Accreditation Committee, private clinics need to comply with the guidelines endorsed by the National Health and Medical Research Council. However, after so many years of successful operation of assisted reproductive technology, additional necessary checks and balances should be put in place. We recognise the need to put regulations in place to ensure that we continue to improve the ethical and social outcomes from such technological advances.

This bill addresses the concerns that have been expressed with regard to donors, parents and offspring. In this regard I acknowledge the worthwhile contribution over many years of the Donor Conception Support Group, whose representatives have met with many members to better inform them of the background of this legislation and related assisted reproductive technology issues. Victoria introduced similar laws in 1995—12 years ago. I cannot ignore the undue lengthy process that the New South Wales Government has engaged in to arrive at this point, and it deserves comment. New South Wales Health released a discussion paper on the subject back in 1997 and positive input with more than 60 submissions provided by the Australian Medical Association, individuals and other relevant medical bodies, donor and patient support groups.

Legislation was introduced in this Parliament in 2004 and it has been shelved ever since. Why? We have lagged behind Victoria and Queensland for some time and this unnecessary delay has caused more anxiety and problematic social issues for many Australians. Children have the right to know their identity and, importantly, their genetic heritage. Thankfully, this will be the end of anonymous gametes—predominantly sperm donations in New South Wales. We have come a long way from the previous concepts of wanting to protect chiefly adult rights, prospective parents' rights and donors' rights to privacy. There is now a better understanding of the importance of sharing genetic knowledge. With so many births from assisted reproductive technology such situations are becoming better accepted and understood in our community.

Children conceived in the early years of assisted reproductive technology are now adults and have wanted to know their genetic parentage. Advances in genetic science and the linkage to certain diseases and medical conditions have meant that the knowledge of genetic parentage is useful for persons born as a result of assisted reproductive technology. This bill will allow such persons if they so desire to find out more information about their genetic parents, siblings and half siblings where they exist and consent. Naturally, such information on siblings will be made available only with the sibling's consent.

Providing information to the register will be mandatory for this legislation to work. However, consent to release such information will always be required, especially in cases of conception prior to this legislation coming into force. In such cases this retrospective register will be voluntary for donors and offspring. The mandatory register for new cases will exist at the same time as a voluntary register. My questions to the Minister are: What resources will be provided to ensure public awareness of this retrospective information gathering? What form of and how much advertising or notification to previous gamete donors and their offspring will occur and who will undertake it? Are there any time frames in place for such an exercise?

Part 3 of the bill, dealing with the central assisted reproductive technology register, will allow offspring, and in some cases parents or other persons with parental responsibility, to access identifying and non-identifying information about their biological parent. Offspring will be able to place information on this register to be accessed by relevant donors. Access to this information can be given only with the offspring's consent and only when they become an adult. It should be stressed that the mandatory donor register will not operate retrospectively, respecting the original undertaking of anonymity given by authorities in the past.

I wish to express a concern on behalf of the Donor Conception Support Group about the time limits on the keeping of assisted reproductive technology birth information on the central register. The bill provides for 50 years and the Coalition asks that the Government consider making this limitless as is the case for normal births. Moreover, how often will registered assisted reproductive technology clinics be obliged to provide necessary information to the central register? I would have thought this should be regular—for example, quarterly—and included in this legislation. Victoria has mandated every six months for the transfer of such information.

This bill recognises the rights of gamete donors to have their gametes used in accordance with their expressed consent, especially in future given the greater likelihood of contact between donors and offspring. Clause 17 of the bill allows for the placement of consent conditions by donors that their gametes can be used only by a certain person or a particular classification of person, including racial and cultural distinctions. Donors will be able to withdraw or modify their consent for the use of their gametes—either egg or sperm—at any time before the gamete is implanted in a woman or until an embryo is created using that gamete. This will apply even when that

donor is a woman's spouse and in posthumous circumstances to ensure that a person's gametes will always be used in accordance with their current and explicit instructions and consent. Gametes can be harvested only from a person who is in a persistent vegetative state or otherwise incapable of giving consent if that person gave clear consent to such collection prior to their losing their ability to consent.

Because a sperm donor must undergo a number of medical and other checks, the cost to the sperm bank is not inconsiderable. This normally means that some clinics until now may have used the same donor to produce pregnancies in a number of different women. The number of pregnancies permitted varies according to law and practice. I am delighted that clause 27 of the bill will limit to five the number of women who can be provided with gametes from the same donor. This restriction will reduce the risk of donor offspring unknowingly entering into a relationship with a blood relative.

Victoria limits donations to 10, Western Australia to five, New Zealand to 10, Denmark to 25 and Sweden to 12. Most European countries are steadily amending their legislation, as we are doing in New South Wales. In the United Kingdom there is a limit of 10 families that can use the gametes of one donor. However, there is no limit to the number of children that may be born to each such family from the same donor. A donor may set a lower limit and may impose conditions on the use of his sperm. In addition, there is no prohibition on the export of sperm from the United Kingdom provided that the number of families created in there does not exceed 10 at the time of the export. This means that in practice some donors may produce substantial numbers of children, particularly where sperm samples are exported within the European Union to countries such as Belgium or Spain.

The United States limits a donor to 25 live births per population area of 850,000. However, there is no central tracking and it has been estimated that only about 40 per cent of births are reported. It is likely that some donors have more than 100 genetic children. That is clearly unsatisfactory. Some sperm banks impose lower limits—for example, the Sperm Bank of California has a limit of 10 families per donor—and it is recognised that State legislatures will have to amend their laws as assisted reproductive technology-related social and genetic issues gain prominence.

It is worth noting that the United Kingdom has a similar central register to that we are currently debating. It has a register of people conceived using gamete donation after 1 August 1991. People conceived using donations made after 1 April 2005 have the right to know who their donor was when they turn 18. UK DonorLink is a voluntary register for people conceived before 1 August 1991 and for their donors. There also exists a very successful international web-based registry called the Donor Sibling Registry, which has helped to facilitate more than 3,900 matches between people who share genetic ties—that is, donor offspring, half siblings and donors—through the unique donor identity numbers assigned by the sperm banks to the donors. Meetings between donors and their offspring and between half siblings have in general been extremely successful and are becoming increasingly common.

Clause 29 protects children against any possible exploitative or inappropriate involvement in assisted reproductive technology procedures. The only circumstance in which a child's gametes can be collected and stored is if a medical practitioner certifies that there is a risk of the child becoming infertile before becoming an adult, usually in the case of oncology treatment or serious endocrinological, gynaecological or urological conditions. Then gametes cannot be used until the child becomes a consenting adult. The bill prevents surrogacy whether for altruistic or commercial reasons, and this will include any agreements made before this legislation commences. Assisted reproductive technology providers will have to be registered and treatment provided by appropriately specialised doctors. Part 5 of the bill will allow the entry and inspection of assisted reproductive technology premises, the ability to request information and records, to remove items for analysis and testing, and to obtain and execute a search warrant. Hopefully these powers will be used sparingly, but they are necessary. Interestingly, a search of the Internet established that in Victoria a donor must be:

Aged between 21- 45 years

Not in a high risk AIDS group

Prepared to consent to the release of identifying information to offspring - donor treatment can only be facilitated under circumstances where the child can know their genetic parents

Compliant with all relevant legislation and regulation relating to donation of gametes. (RTAC Code of Practice; NHMRC Ethical guidelines on the use of assisted reproductive technology in clinical practice and research September 2004, Vic. Human Tissue Act 1982)

Prepared to provide information on previous donations and agree to limit births to no more than 10 families, if relevant

Prepared to undertake screening tests for infectious and genetic diseases

Prepared to have all frozen semen quarantined for 6 months and undertake repeat screening tests prior to release of semen

Prepared to undergo counselling (this includes with partner if relevant)

Able to provide a genetic family medical history

Prepared to release medical information to the recipients to enable informed consent

Preferably less than 40 years of age

They are all sensible recommendations. It is pleasing to see that this bill will mandate counselling to be provided to individuals, spouses and donors involved in the assisted reproductive technology process where they so desire at the point of information release from the register and naturally during the assisted reproductive technology procedure itself. Personal, ethical, familial and social issues undoubtedly arise both during treatment and later in life for offspring, donors, spouses and families, especially regarding their genetic background. For these reasons counselling will provide accurate, impartial, sensitive and up-to-date information and support. Gamete donor registers, both mandatory and voluntary retrospective registers, will assist many Australians to fill important emotional, physical and social gaps in their lives. This bill recognises the importance of assisted reproductive technology children's and offspring's interests and rights to their genetic heritage as uppermost while ensuring the rights and obligations of donors, parents and providers in this ever-widening field of necessary medical science. The Coalition does not oppose the bill.

Debate adjourned on motion by Reverend the Hon. Fred Nile and set down as an order of the day for a future day.

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