



# Human Cloning and Other Prohibited Practices Amendment Bill 2007

## Human Cloning and Other Prohibited Practices Amendment Bill 2007

Extract from NSW Legislative Assembly Hansard and Papers Wednesday 30 May 2007.

### Agreement in Principle

**Ms VERITY FIRTH** (Balmain—Minister for Women, Minister for Science and Medical Research, Minister Assisting the Minister for Health (Cancer), Minister Assisting the Minister for Climate Change, Environment and Water (Environment)) [10.55 a.m.]: I move:

That this bill be now agreed to in principle.

It is my strong view that, wherever possible, governments have a responsibility to act to alleviate human suffering and preserve human dignity. It is for this reason that I am committed to ensuring that constructive and responsible research can be carried out in New South Wales. The Human Cloning and Other Prohibited Practices Amendment Bill allows new research activities to be undertaken within the strict regulatory framework that was enacted in 2003. It allows important and potentially beneficial research that may have a profound effect on major human diseases such as diabetes, Parkinson's disease, spinal cord injury, and heart and eye disease. Importantly, the bill also allows for research that has the potential to lead to improvement in fertility treatments.

The bill is the New South Wales component of the nationally consistent scheme that prohibits human reproductive cloning and provides for certain types of research to occur. The New South Wales commitment to the nationally consistent scheme goes back to 5 April 2002, when the Council of Australian Governments [COAG], after much discussion, agreed to a national scheme to prohibit human cloning and regulate research involving human embryos. The Commonwealth introduced legislation consistent with this agreement in May 2002. Although the Commonwealth's constitutional powers enabled its legislation to cover the majority of the field, complementary legislation was required by States and Territories to ensure a uniform framework and to avoid uncertainty about the application of the law.

In 2004 the Council of Australian Governments signed an inter-governmental agreement committing all States and Territories to introducing and maintaining nationally consistent legislation to ban human cloning and establish a national regulatory regime for the use of excess assisted reproductive technology embryos in research. All jurisdictions except the Northern Territory introduced and passed complementary legislation. The New South Wales Human Cloning and Other Prohibited Practices Act 2003 and the Research Involving Human Embryos Act 2003 were assented to on 7 July 2003. When the 2002 Council of Australian Governments agreement was struck the possible introduction of today's bill was already envisaged, with the need to review the proposed legislative scheme being a key facet of the agreement.

The Commonwealth passed its legislation in December 2002 and was required to

complete and table a review of the legislation within three years of assent—that is, by 12 December 2005. New South Wales was also required to conduct a review but could do this either independently or as part of the Commonwealth process. The New South Wales Government chose the latter course, and the review report on the New South Wales legislation will be tabled in the House today. The Commonwealth review was conducted by an independent committee comprising experts in law, ethics, medical practice and science. The committee was chaired by Justice Lockhart. I The Commonwealth passed its legislation in December 2002 and was required to complete and table a review of the legislation within three years of assent—that is, by 12 December 2005. New South Wales was also required to conduct a review but could do this either independently or as part of the Commonwealth process. The New South Wales Government chose the latter course, and the review report on the New South Wales legislation will be tabled in the House today. The Commonwealth review was conducted by an independent committee comprising experts in law, ethics, medical practice and science. The committee was chaired by Justice Lockhart. I would like to acknowledge the significant work of Justice Lockhart and the members of his committee in conducting a comprehensive and sensitive review. Justice Lockhart's passing is a great loss to Australia.

The Lockhart review was tabled in Federal Parliament on 19 December 2005. Subsequently in October 2006 Senator Kaye Patterson introduced a bill that sought to give effect to some of the most important Lockhart recommendations. This bill was assented to on 12 December 2006. On 3 May 2007 the Victorian Parliament passed legislation to correspond with the Commonwealth amending Act. When the Commonwealth legislation comes into effect on 12 June 2007, there will no longer be a nationally consistent legislative framework in this area. Accordingly, at the 13 April 2007 Council of Australian Governments meeting, State and Territory leaders signed a notice of variation to the original intergovernmental agreement, renewing their commitment to nationally consistent arrangements for the prohibition of human cloning for reproduction and the regulation of human embryo research. This means that all States and the Australian Capital Territory will use their best endeavours to introduce corresponding legislation into their legislatures by 12 June 2008 and to maintain nationally consistent arrangements over time.

The New South Wales amending Act that I introduce today mirrors the Commonwealth legislation. The New South Wales Act is structured in two sections: The first sets out the practices that remain prohibited outright; and the second sets out those practices that are prohibited unless authorised under licence. In order to understand the new bill it is important to note that the original New South Wales research Act incorporated the Commonwealth research Act by reference, making it the law of this State. It primarily sets out a licensing and monitoring scheme that is administered and enforced by the Commonwealth. Therefore, the original New South Wales research Act did not repeat in detail the provisions of the Commonwealth Act. Consequently, little detail is required in the New South Wales bill to give effect to the Commonwealth amendments. Conversely, the original New South Wales prohibited practices Act did not incorporate the equivalent Commonwealth Act by reference because it contained a large number of serious offences and it was considered preferable to spell out the offences and the penalties.

In introducing the bill today I want to stress that prohibition on human cloning for

reproduction remains, as do the heavy penalties for this offence. As well as the prohibition, other practices will remain prohibited and attract heavy penalties. The practices that remain completely prohibited can be found in schedule 1, item [8], part 2, division 1. They include collecting a viable human embryo from the body of a woman; the sale or trade of sperm, eggs and embryos; creating a human embryo by fertilisation of a human egg by a human sperm other than to achieve pregnancy in a particular woman; creating a chimeric embryo; developing a human embryo outside the body of a woman for more than 14 days; and creating or developing a human embryo by fertilisation that contains the genetic material provided by more than two persons. The bill also provides that some practices that are currently prohibited will be allowed under licence to support Assisted Reproductive Technology [ART] research and clinical practice or the study and treatment of disease. The maximum penalty for undertaking practices that are completely prohibited is 15 years imprisonment and for undertaking research without a licence is 10 years imprisonment. The enabling provisions are subject to restriction on the length of time the embryo is allowed to develop and a prohibition against implantation.

In order to appropriately oversight the scheme, the powers of the Commonwealth licensing committee have been strengthened and extended. Practices that are prohibited unless authorised by licence are set out in schedule 1, item [8], part 2, division 2. Somatic Cell Nuclear Transfer— In order to appropriately oversight the scheme, the powers of the Commonwealth licensing committee have been strengthened and extended. Practices that are prohibited unless authorised by licence are set out in schedule 1, item [8], part 2, division 2. Somatic Cell Nuclear Transfer—or therapeutic cloning, as it is commonly known—will be allowed should this bill be passed. Somatic Cell Nuclear Transfer refers to the creation of an embryo using a somatic cell and an ovum. A somatic cell is any cell in the human body apart from sperm or eggs: a skin cell is an example of a somatic cell. The Somatic Cell Nuclear Transfer process involves removing the nucleus from the ovum and replacing it with the nucleus from the somatic cell. The resulting entity is then stimulated to cause it to divide. This division is allowed to occur until there are about 100 cells—that is, to the blastocyst stage—and then the stem cells are extracted.

The important point to note about Somatic Cell Nuclear Transfer is that the process aims to reproduce cells, not to create a person. The embryos produced by Somatic Cell Nuclear Transfer do not involve an egg and a sperm. They are never intended for reproduction or for implantation into a woman; indeed, implantation is prohibited. Somatic Cell Nuclear Transfer is about creating stem cells. These stem cells are genetically almost identical to the person from whom the somatic cell was taken. This genetic similarity is significant as it vastly reduces the likelihood of rejection should the stem cells be transplanted back into the individual. The genetic similarity is also significant because it allows the scientist to study a patient's disease at the cellular level. At this point Somatic Cell Nuclear Transfer is regarded as particularly important for understanding normal and abnormal cell development and for models to study disease processes and genetic disorders.

Proposed section 17, which is inserted by schedule 1 [8] of the bill, permits Somatic Cell Nuclear Transfer by allowing an embryo to be created by means other than fertilisation but only under licence. The practice is subject to prohibitions contained in the New South Wales bill and through the interaction of this bill with the

Commonwealth legislation, which prohibits development beyond 14 days or implantation. The practice is strictly for research and development of treatments and not for reproduction. As indicated, the legislation prohibits the embryo developing beyond 14 days or being implanted.

That same provision will also allow for the creation of a human embryo by parthenogenesis for research purposes. Parthenogenesis refers to a process by which the ovum itself is caused to divide and develop to form an embryo-like entity. No sperm or other living cells are involved in this process. Parthenogenesis may provide an alternative source of stem cells. Importantly, it may also assist in the study of ovarian tumours or mitochondrial disease. In item [8] of schedule 1, clause 18 of the bill allows the creation of a human embryo for research purposes using the genetic material from more than two people, so long as the embryo is not created by the fertilisation of a human egg and sperm. This will allow research into problems such as mitochondrial disease. The mitochondria are the engines or powerhouses of the ovum and are contained in the watery substance surrounding its nucleus. Diseases that are caused by defects in the mitochondria affect all children born to a woman with this condition. Mitochondrial diseases are complex, severely debilitating and often fatal. Research into this condition, therefore, has the potential to alleviate the major physical and emotional burden that is placed on women who have this condition and their families.

The creation of a hybrid embryo, using an animal egg and human sperm, will also be allowed solely for the purposes of testing sperm quality and for a period up to but not including the first cell division. That is less than 48 hours development. This research is important in understanding and treating infertility. It should be noted that this practice was allowed in New South Wales prior to the introduction of the national legislation in 2002. It is also important to note that the creation of a hybrid embryo for any other purpose or for a longer period is strictly prohibited. The limitations on the creation and development of hybrid embryos are given effect by the interaction of the New South Wales bill and the new Commonwealth legislation. A further Assisted Reproductive Technology practice that will be allowed should the bill be passed is research on embryos found to be unsuitable for implantation. This will allow for the study of disease processes and embryo development. This change is underpinned by requirements to strengthen existing National Health and Medical Research Council guidelines.

I draw the Parliament's attention to the new definition of "human embryo" that is contained in the bill. It is based on the definition developed by the National Health and Medical Research Council. The original definition referred to very early stage activity, that is, just after the moment of fertilisation, which is almost impossible to visualise in practice. Accordingly, it was agreed that a new definition should be inserted in the bill. It is worth commenting that in developing the new definition, the National Health and Medical Research Council and, indeed, the Lockhart Committee, noted that the matter of defining an embryo was extremely complex and that there was no consistent or widely used definition. The new definition in the bill is intended to provide practicality, simplicity and certainty. It defines an entity as an embryo from the first cellular division that occurs after fertilisation is complete—a moment that can be visualised and defined in practice. The new definition will ensure that Assisted Reproductive Technology research to improve the treatment of

infertility is able to be undertaken, but will prohibit any research on egg and sperm embryos, which is consistent with community attitudes. There are a range of other machinery and administrative amendments contained in the bill, but I believe those I have outlined represent the major changes that need to be drawn to the attention of the House.

The issues that we are here to debate cross party political lines; they even cross religious, ethnic and community lines. I have carefully considered the debates that took place when the original legislation was brought to the House. I acknowledge that there are some people in the community and members of the House who do not accept the rationale behind the 2003 Act and will not accept the rationale behind the introduction of this amending legislation. I respect but cannot agree with their perspectives. I support the bill and urge others to do so because the research that will be allowed is being undertaken to improve fertility treatment and practice and to provide insights, therapies and cures for a variety of diseases, including diabetes, cardiovascular conditions, cancer, Parkinson's disease, spinal cord injury and motor neurone disease.

All of these diseases carry a huge emotional burden and significant socioeconomic impacts for individuals, their families and the broader community. Throughout history, medical breakthroughs, especially significant ones, are often initially viewed with concern. That is fair enough; these breakthroughs do push the boundaries of what society is used to, and it is proper that we ask questions. Objections were raised to both heart and kidney transplant technology when it first began. However, I ask members to think of the wives and husbands, the children and the grandchildren who have been given the gift of many extra years with the people they love because of the success of heart transplants. Breakthroughs in medical research deliver outcomes not only for the individuals afflicted but also for their family and friends. Who are we not to allow the research that could provide similar breakthroughs for people suffering from diabetes or motor neurone disease? Who are we to deny a family the hope of a cure for the person they love?

I will never forget the analogy used by the Reverend Ivan Head when we were discussing the ethics of pursuing stem cell research. Reverend Head referred to the chocolate wheel of life; that is, the lottery that we all face when it comes to our health and the conditions or accidents that can befall any of us. If the technology exists which can relieve this human suffering and which can provide hope to those of us whom fate has delivered a particularly cruel blow then surely it is our moral duty to act on that knowledge, to do everything in our power to alleviate human suffering where we find it and to preserve human dignity.

The New South Wales bill re-establishes national consistency and enables research to be undertaken under licence and in an ethically appropriate way that includes appropriate safeguards, provides public good and has benefit or potential for which there is support from the broad scientific and general community, notwithstanding variations in community opinion on some issues. I have established two major information sessions for members of Parliament and other interested parties who may wish to understand the proposed bill and the thinking and processes that led to its development. I encourage all members to attend these sessions and look forward to an informed and compassionate debate on these issues. In so doing, I commend the bill to the House.