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No. 17 2002–03

Research Involving Embryos and Prohibition of Human Cloning Bill 2002

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I N F O R M A T I O N A N D R E S E A R C H S E R V I C E S

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No. 17 2002–03

Research Involving Embryos and Prohibition of Human
Cloning Bill 2002

Jennifer Norberry
Law and Bills Digest Group
14 August 2002

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Research Involving Embryos and Prohibition of Human Cloning Bill 2002

Date Introduced: 27 June 2002

House: House of Representatives

Portfolio: Prime Minister

Commencement: Formal provisions commence on Royal Assent. The commencement dates of the Bill's substantive provisions are detailed in the Main Provisions section of the Digest.

Purpose

To ban human cloning and other 'unacceptable practices' and to regulate the use of excess human embryos created by assisted reproductive technology (ART). The Bill is designed to be part of a national scheme which will include complementary State and Territory laws.

Background

Human cloning¹

Introduction

As early as 1983 a legal commentator, Professor George Smith II, predicted 'It is expected that within the not too distant future a human will be cloned'.² This was at a time when tadpoles were the only animals to have been cloned by nuclear transfer by scientists.³ Professor Smith foreshadowed the potential advantages of cloning in terms of a solution to infertility and a method of reproduction which would avoid the transmission of genetic abnormalities, as well as the potential to research the aetiology of various diseases. He went on to consider whether the law should regulate who may be cloned and in what circumstances, or whether legislative regulation would stifle continued scientific experimentation.

In the intervening two decades, although scientists have succeeded in cloning a number of other animals, including sheep⁴, cows and rhesus monkeys⁵, little else has changed. The

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legal issue of whether, and if so in what form, cloning technologies should be regulated or prohibited has not been resolved.

It seems important to make the distinction between cloning for reproductive purposes and use of cloning and other technology such as embryonic stem cell research for research and therapeutic purposes.

One academic commentator has noted that ‘The development of somatic cell nuclear transfer [see below] has certainly created a legal vacuum in many countries, which governments are struggling to fill.’⁶

Types of cloning technology

Basically, cloning is a type of asexual reproduction that results in the production of an organism which is a genetic copy of another organism. Cloning occurs in nature, including certain plants and other organisms which reproduce asexually. Identical twins are also naturally occurring ‘clones’.⁷

However, it is not these natural processes which people generally have in mind when speaking about cloning. They are referring to processes of manipulating nature to produce identical organisms. There are presently two basic methods of cloning—nucleus substitution and embryo splitting.

Nucleus substitution (also known as somatic cell nuclear transfer)

This is the method which was used to produce Dolly the sheep, and which is anticipated to be attempted by the scientists who have announced their intention to clone human beings.

Basically, it involves taking an egg cell, removing the cell’s nucleus (which contains almost all of the genetic material), and replacing it with another cell nucleus. This other nucleus may be taken from any somatic cell, such as a skin cell or liver cell. (In the case of Dolly the sheep, the cell was taken from the sheep’s mammary gland.) Scientists then apply an electric current, which causes the enucleated egg and its new nucleus to fuse and develop into an embryo. At this stage the embryo can be transplanted into the gestational mother, who may or may not be the source of the original egg cell or the somatic cell.

Because the nucleus contains most of the DNA of an organism, the cloned embryo and any resulting baby would be substantially genetically identical to the person from whom the somatic cell was taken. However, it would also have a very small amount of DNA attributable to the mitochondria in the egg cell, as mitochondria occur outside the cell nucleus and would not be removed when the nucleus is substituted.

What is unique about cloning by nucleus substitution is that there is no need for fertilisation of the egg, as this occurs in the process of sexual reproduction. Most human cells contain 46 chromosomes, made up of two strands each consisting of 23 chromosomes. However, sex cells are different. A female egg cell contains only 23 chromosomes, as does a male sperm cell. When an egg is fertilised by sperm, the female

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chromosomes pair up with the corresponding male chromosomes, giving the resulting baby a unique genetic identity. With human cloning by nucleus substitution, this combination does not occur, because a cell nucleus already containing the full complement of 46 chromosomes is inserted. Thus, there is no need for fertilisation of the egg.

This method is also known as fusion.

Embryo splitting

This technique involves fertilising an egg with sperm, and dividing the newly formed embryo to form two or more individuals. This is the mechanism that occurs naturally in the case of identical twins. It can also be performed in the laboratory. The resulting individuals will be genetically identical to each other, but not a clone of either parent. This method is also known as fission.

Uses of cloning techniques

Cloning may result in the production of an individual with the same nuclear genome (reproductive cloning or whole-body cloning) or the production of a cell, tissue or organ with an identical nuclear genome to an individual (sometimes called ‘therapeutic cloning’).⁸

Reproductive cloning

In reproductive cloning, a cloned embryo—whether produced by somatic cell nuclear transfer or by embryo splitting—would be implanted in a woman to develop until birth. This technique, as applied in animals, has already produced cloned whole sheep, rats, cows, and rhesus monkeys.

Reproductive cloning has not yet been attempted in humans. However, there are reports that scientists in South Korea cloned a human embryo to the four cell stage, using an egg and somatic cell from the same woman, although this has not been reported in any refereed scientific journal. In 1999, there were reports that scientists at the Massachusetts laboratory of Advanced Cell Technology cloned a male human embryo from a skin cell taken from a leg, and that this embryo developed to nearly 400 cells before being destroyed. It seems this experiment was repeated successfully a number of times, and all embryos were destroyed prior to 14 days development.⁹

So-called ‘therapeutic cloning’

This technique involves cloning human embryos not for the purpose of allowing them to develop until birth, but to extract certain cells—the so-called ‘embryonic stem cells’—from them and grow them into tissues for the development of therapies for adults suffering from certain diseases. The embryos are created by nucleus substitution using nuclei from an adult patient. Thus the stem cells are clones of the patient, and have the potential to

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grow into any type of tissue for disease treatment. The removal of stem cells results in the destruction of the embryos.

Related development – embryonic stem cell lines

A second scientific breakthrough, conceptually distinct from cloning technology, is the isolation of human embryonic stem cells, which first occurred in 1998. Embryonic stem cells are pluripotent cells, which means they have the capacity to turn into any cell type in the adult body. They are extracted from an early human embryo at the blastocyst stage of development (approximately 5-7 days after fertilisation). The removal of cells destroys the capacity of the embryo to continue to grow and develop. Embryonic stem cells, once extracted, can be grown in culture and can replicate seemingly indefinitely. Thus, the isolation and extraction of stem cells from a single embryo can lead to the creation of thousands of identical stem cells, known as an ‘embryonic stem cell line’.

Embryonic stem cells are currently used for research. Because they have the ability to develop into a diverse range of specialised tissues and organs, the hope is eventually to be able to use embryonic stem cells to grow human tissues and organs which can be transplanted into humans for the treatment of disease.

The use of embryonic stem cells involves cloning only in the sense of the multiplication of cells, a process which occurs naturally in the human body. Embryonic stem cells could, however, have their nuclei removed and replaced with the nuclei from human somatic cells. This combination of technologies has potential benefits as it would enable cells to be grown which are genetically identical to the patient, which would dramatically reduce the risk of tissue or organ rejection, and remove the need for powerful immuno-suppressant medication. There is some scientific speculation that this therapeutic cloning technique may be superseded in the future by other methods which avoid cloning and the destruction of embryos.¹⁰

Arguments for and against reproductive cloning and human embryonic stem cell research¹¹

Reproductive cloning

Much of the debate on human cloning has centred around the prospect of cloning adult human beings for reproductive purposes. This possibility has fascinated some and caused revulsion in others.

The arguments have relevance mainly to cloning by somatic cell nuclear transfer, that is, asexual reproduction of the genome of an existing human being. However, they also have relevance to embryo splitting or twinning if the resulting embryos are not all implanted at the same time. This is because embryo splitting if all are implanted does not involve replicating an existing known genome, merely replicating an entirely new genome

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produced by sexual reproduction. It is thus similar to having 'natural' monozygotic twins. However, if some embryos were stored and later implanted, arguments about uniqueness and identity etc would have the same force as they have in arguments about somatic cell nuclear transfer.

Arguments for reproductive cloning

The main arguments in favour of reproductive cloning are:

The fundamental human right to procreate

Some, particularly American, commentators assert that the denial of access to cloning technology may infringe the right to procreate of those individuals who are unable to reproduce in the normal manner.¹² It would thus provide an alternative to using donor gametes where either partner is infertile or lacking in gametes. It is argued that prohibiting reproductive cloning may deny some infertile couples the opportunity to have a child who is genetically related to them.¹³

Cloning could also be used to provide genetically related children to gay men and lesbians.¹⁴

Avoidance of transmission of genetic disabilities

A second argument is that cloning technology has the potential to eliminate some genetic diseases or disabilities (such as cystic fibrosis or spina bifida), as it would enable couples at high risk of having children with a genetic disease to clone one of themselves, another family member or an existing child who is free of the disease. Thus, cloning may provide an alternative to current techniques of prenatal and pre-implantation diagnosis, which can screen fetuses and embryos for genetic diseases.

Cloning would also be a way of avoiding mitochondrial disease.

Cloning a dead or dying child

It is sometimes suggested that cloning should be permitted on compassionate grounds to replace a dead or dying child.

Arguments against reproductive cloning

The main arguments against reproductive cloning are:

The potential physical dangers of using a still experimental science

It is undeniable that the science of cloning is still in its infancy. It has been reported that cloning so far carries a high rate of miscarriages and abnormalities. Insufficient is also known about the development of cloned animals to ascertain whether they develop normally or are at increased risk of deformities. Some of the developmental

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risks whose probability is as yet unknown include premature ageing, somatic mutation, telomere shortening, cancer and dedifferentiation.¹⁵

In view of the current state of scientific knowledge, many scientists argue that it would be irresponsible or at least premature to create a cloned child, thus exposing him or her to potentially unknown and unacceptable risks as he or she develops.

Fear of eugenics

Another common argument is that selecting children on the basis of certain genetic characteristics may lead to a revival of enthusiasm for eugenics, the breeding out of certain genetically inherited characteristics. A related concern is that selecting children on the basis of some qualities (such as absence of a particular disability) may be interpreted as a subtle form of rejection of those people already in existence who have those 'undesirable' characteristics. There is popular fear, fuelled by films such as Ira Levin's *The Boys from Brazil* and novels such as Aldous Huxley's *Brave New World*, that cloning may be used to produce either a master race or a slave race.

However, we may need to address the argument that our society already practices certain forms of eugenics, such as pre-conception and pre-natal screening and the abortion of foetuses with genetic disabilities or diseases.

Possible psychological harm to children – autonomy, identity and kinship issues

There is concern that a clone, as a later-born identical twin to an already existing person, will be confused as to their relationship with the person from whom they are cloned. Cloning will lead to the creation of new biological relationships, as a woman may bear a child who is the clone of herself (is the clone thus properly to be understood as her child or twin sister?), or the clone of her husband or other relative of the same generation. Difficult questions may be raised as to whether the genetic relationship or the emotional or social one is to be given preeminence.

There is also a fear that having the same genome will lead to a lack of individual identity. Clones may be confused or be subject to strong parental expectations to behave in a manner similar to the person from whom they are cloned, rather than given sufficient autonomy and individuality to develop their own identity. It is inescapable that a person is chosen to be cloned because of some quality or qualities which he or she possesses, which it is hoped the clone will also possess. This arguably leads to a certain loss of uniqueness of the clone as an individual, or, as Hans Jonas put it, deprives the clone of the 'right to ignorance' of facts about his or her origin that are likely to be 'paralyzing for the spontaneity of becoming himself' or herself.¹⁶

Against this, others have emphasised that human individuality is not reducible to genetic factors, that people are a product both of their biology and their family, cultural and social environment. Hence, human dignity is not affected by the mere sharing of genetic inheritance with another person.¹⁷

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Commodification of children

A commonly-expressed objection to cloning for reproductive purposes is that it leads to (or reflects) a view that children are commodities, or objects which exist to satisfy adult desires, rather than ends in themselves. Thus, it is argued, even cloning to replace a dead child devalues the child by seeing him or her not as irreplaceable and unique, but as interchangeable with another child.¹⁸

Resource allocation issues

The science of cloning is, to date, inexact and experimental. This is well illustrated by the arduous process followed by the team at the Roslin Institute in the creation of 'Dolly' the sheep. Four hundred and thirty eggs were extracted from 40 donor sheep, 277 reconstructed eggs were developed, but only 29 embryos resulted. Thirteen surrogate mothers were used, and all of this resulted in the birth of only one clone, Dolly.¹⁹ A question may be raised whether it is an efficient use of finite resources to devote so much in terms of time, money, labour and gametes, to such an uncertain end.

A further question is the social justice implications of permitting human cloning, which one might foresee would be available only at a prohibitively high cost, thereby restricting it to the very rich, and exacerbating the already unfair advantages of wealth.

Religious reasons

Cloning has been unequivocally condemned by religious leaders of major Western faiths, including Protestant, Catholic, Jewish and Muslim clerics.²⁰ A major theme is that human beings are endowed with an inherent dignity, being created in God's image. Religious leaders believe that cloning abuses this dignity, jeopardising each person's unique identity as well as treating human beings as means to an end. Some faiths also object to interference in the natural, divinely ordained order of human sexual reproduction. There is also a theme of reluctance to (indeed sometimes a revulsion of) interference in the natural order, or 'playing God'.

Implications for genetic diversity

Some argue that 'natural selection allows for the emergence of unanticipated variants with survival capacity, whereas controlled evolution allows for the development of only that which humankind can envision.'²¹ Variety may be an aesthetic value, providing 'novelty, originality and fascination'²² in the world, or it may be an environmental necessity. It may be that eventually, if too many cloned people are selected and certain traits are bred out, significant inbreeding may result in substantial risks to the gene pool.

Public policy reasons

Cloning may cause difficult policy issues relating to family structure, which may interfere with rights of inheritance and other legal rights.

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Embryonic stem cell research

Opinion is divided in Australia on this, whether it uses surplus IVF embryos or purpose-created embryos made using nucleus substitution. The key issue is that it involves the destruction of embryos. It thus involves very similar ethical questions to the destruction of 'surplus' IVF embryos pre-implantation.

Arguments for embryonic stem cell research

Researchers argue that embryonic stem cell research has the following beneficial applications²³:

Basic research

Cloning techniques would greatly facilitate basic research aimed at understanding matters such as cell division and early human development. This research may provide important clues into things such as the origin of birth defects, and the way alterations in cell division are involved in producing cancer and the ageing process. Research on embryonic stem cells is much more attractive than the current research on animals, because sometimes animal models have differences which make transferring results into humans difficult or speculative.

Discovering new growth and differentiation factors, as these proteins can be difficult to identify in animals. This may help to identify proteins which can be given to people as treatment to regenerate damaged tissues.

Developing new medicines and treatments

For example, genetic modifications made to diseased cells may lead to treatments or cures for diseases such as Alzheimer's or Parkinson's. Using embryonic stem cells promises a higher accuracy rate, reduces the number of animals required in research and testing, and may lead to the faster development of pharmaceutical treatments.

Developing cell-based spare parts for transplantation

Some degenerative diseases cannot be treated pharmaceutically, but require replacement of damaged cells. Embryonic stem cell lines could eventually be used to develop cells, tissues or even organs for transplantation, although the research is currently not this far advanced. This type of treatment has potential to provide, for example, skin grafts for burns victims or bone marrow for cancer patients.

Embryonic stem cell technology may even be combined with somatic cell nuclear transfer, by extracting the stem cells from an embryo created by the fusion of the patient's own somatic cell (such as a skin cell) with an enucleated egg. The stem cells thus derived could then be grown into specific tissues or organs which could be transplanted back into the patient without fear of rejection and without the need for immuno-suppressant drugs. It would also provide a way around the serious shortage of

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organs and tissues for transplantation. It may be possible to extract cells from a person's healthy kidney and fuse them with embryonic stem cells to then grow a second kidney for transplantation.

Associate Professor Julian Savulescu, currently at Oxford University, is of the view that there is no relevant difference between research and experimentation on early embryos and later embryos and early foetuses. Indeed, he considers 'producing embryos and early foetuses as a source of tissue for transplantation may be morally obligatory', although he acknowledges that producing a live cloned child for the same purpose may be more problematic.²⁴

Arguments against embryonic stem cell research

The main concern over embryonic stem cell research involves the use and destruction of human embryos in the process of extracting the stem cells. Although the embryos are at a very early stage of development, some argue that the early embryo has the equivalent legal and moral status of a baby or an adult. The key to this argument is thus the time at which 'personhood' or a 'soul' is acquired. These notions are strongly contested ethically.

In response, scientists argue that this is not so, because cells within an embryo may form the baby or the supporting tissue such as the placenta or the amniotic sac. Further, a large number of early embryos will fail to develop for natural causes even if implanted. Finally, scientists argue that the embryos from which stem cells are extracted are embryos which are going to be discarded or destroyed in any event, because they are surplus to the IVF program.²⁵

Different considerations are raised where an embryo is created specifically to extract stem cells, as is contemplated by the last scenario involving cloning an embryo for autologous transplantation.²⁶ This is particularly so given the present inexactitude of the science and the possibility that many, perhaps hundreds, of embryos may need to be cloned before one survives to the stage where embryonic stem cells can be extracted and used for treatment purposes.

Another concern is that an embryo might be created, whether by cloning or by artificial fertilisation method of sexual reproduction, and then split. One embryo might be implanted and left to develop to birth, whereas the other could be frozen to be used as spare organs or tissues should its twin ever need them.²⁷ This again raises questions about using human life as a means to an end, and issues of human dignity.

The Australian Academy of Science supports permission to continue using cloning technology so long as it does not result in the production of babies.²⁸

It has also been argued that adult stem cells can be used successfully in research rather than embryonic stem cells. This remains a contested issue.²⁹

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Existing Commonwealth, State and Territory legislation dealing with human cloning and research involving human embryos³⁰

Three States—Victoria, Western Australia and South Australia—have laws which attempt to ban human reproductive cloning. They also regulate, to differing extents, research on human embryos. This legislation was passed prior to the landmark cloning of Dolly the sheep by somatic cell nuclear transfer. Thus, because it had not conceived of the possibility of such technology being possible, the definitions and prohibitions contained in existing State legislation may not be effective to deal with the possibility of cloning.

In summary:

- the definitions of ‘cloning’ in the Victorian, Western Australian and South Australian statutes are not consistent and each statute prohibits slightly different conduct
- legislation in the three States does not completely prohibit embryo research. For example, the Victorian Act bans destructive research on embryos but does not forbid research on human embryonic stem cells (so long as an embryo was not destroyed in Victoria in order to obtain those cells).³¹

Further details can be found in the [Human Cloning](#) report of the House of Representatives Standing Committee on Legal and Constitutional Affairs.

At present there is no cloning legislation in New South Wales³², Tasmania, the ACT or the Northern Territory. Cloning for reproductive or research purposes in these jurisdictions would therefore be subject to relevant NHMRC guidelines.³³ However, it should be noted that these do not have legal force and are not legally binding. Nor is cloning legislation in effect in Queensland³⁴, although that State has adopted a Code of Ethical Practice for Biotechnology in Queensland.³⁵

At Commonwealth level, human cloning and certain experiments involving combinations of human cells and animal cells are banned by the *Gene Technology Act 2000* as amended.³⁶ Section 192B prohibits the ‘cloning of a whole human being’, a term which is defined to mean ‘the use of technology for the purpose of producing, from one original, a duplicate or descendant that is, or duplicates or descendants that are, genetically identical to the original’. The maximum penalty is 2000 penalty units or 10 years imprisonment. The Act also prohibits placing human cells into animal eggs or placing a combination of human and animal cells into a human uterus.³⁷

Constitutional issues

The Research Involving Embryos and Prohibition of Human Cloning Bill 2002 prohibits human cloning and certain uses of human embryos, regulates other practices and establishes an Embryo Research Licensing Committee. A valid Commonwealth law needs

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to be grounded in a head or heads of constitutional power and not offend any express or implied constitutional prohibitions.

Among the heads of Commonwealth constitutional power that might support such laws are³⁸:

- the corporations power [section 51(xx)]. This power enables the Commonwealth Parliament to pass laws with respect to ‘foreign corporations, and trading or financial corporations formed within the limits of the Commonwealth’. The Commonwealth’s power to make laws about corporations is not unlimited. For instance, the corporations in question must be ‘constitutional corporations’. In other words they must be foreign or trading or financial corporations.

A foreign corporation is a corporation incorporated in a foreign jurisdiction. Whether a corporation is a trading or financial corporation will generally depend on what activities it engages in. Thus, if a corporation engages in significant or substantial trading activities or significant or substantial financial activities it will be a trading or financial corporation, respectively.

Assuming that a corporation is a foreign, trading or financial corporation, the next question to be asked is which of its activities can the Commonwealth regulate. While it is not clear that all activities of a constitutional corporation can be regulated, the corporations power will support a broad range of laws—for example, laws regulating the trading activities of a corporation and acts done by the corporation for the purposes of trade.³⁹

The corporations power could be used to regulate the activities of private sector constitutional corporations. However, research might also be carried out by universities which are typically incorporated by statute. If a university is involved in trading activities or if it runs a significant treasury operation, then the Commonwealth is likely to have extensive powers to regulate that university’s cloning technology activities. In the recent case of *Quickenden v. O’Connor*⁴⁰, the Full Federal Court held that the University of Western Australia was both a trading corporation (on the strength of its buying, selling and rental of property, sales of publications and services, parking operations etc) and a financial corporation (noting an administrative structure using financial skills assisted by sound financial advice to place substantial funds on the short term money market).

- the trade and commerce power [section 51(i)]. The corporations power will not extend to non-constitutional corporations, to non-corporations eg partnerships or sole traders or to small businesses that are not incorporated. Section 51(i) of the Constitution gives the Commonwealth power to make laws in respect to ‘trade and commerce with other countries, and among the States’ and has the potential to cover some commercial activities not within the scope of the corporations power.

Using the ‘international’ aspect of the trade and commerce power, the Commonwealth could enact legislation prohibiting the import or export of human embryos or other

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material. Additionally, section 51(i) is likely to support a law prohibiting trade between the States in human embryos—so long as such a law does not offend section 96 of the Constitution which guarantees freedom of interstate trade.

Section 51(i) may also enable the Commonwealth to pass laws about intrastate trade and commerce if this is the only practical way to regulate interstate trade. However, it might be expected that the High Court would closely scrutinise such laws.

- territories power (section 122). The nature of the power in section 122 has been described by the High Court on many occasions as ‘plenary’.⁴¹ A plenary power is one that is full, complete or unqualified. Legislation enacted in reliance on section 122 does not need to fall within any other head of constitutional power.
- power over Commonwealth authorities, agencies and places (sections 51, 52, 61, 64 etc⁴²). The Commonwealth has constitutional power over its own departments, agencies, employees and places. Using these powers, it could comprehensively regulate or prohibit the use of cloning technologies in those departments, agencies and places and by its own employees.
- census and statistics power [section 51(xi)]. The Commonwealth’s power over census and statistics has been used to enact laws which enable data to be collected and analysed on a vast range of topics. Laws have also been passed under the census and statistics power to create offences of non-compliance with the *Census and Statistics Act 1905*.⁴³ According to Professor John McMillan, the power could be used to direct health workers (and presumably others, such as medical researchers or institutes) to ‘maintain records and to periodically provide statistics to a Commonwealth agency. The same obligation could be imposed upon State agencies ...’.⁴⁴
- external affairs power [section 51(xxix)]. The external affairs power will support legislation which implements treaties to which Australia is a party. It also supports laws about matters physically external to Australia and may support laws about subjects of international concern. The Attorney-General’s Department recently gave evidence to a Parliamentary Committee that Australia is under no obligation under treaty or customary international law to ban medical research involving human embryonic stem cells.⁴⁵ The Department also took the view that human embryonic stem cell research is not a matter of constitutional ‘international concern’.⁴⁶ However, in relation to human cloning, evidence was given to the Parliamentary Committee that Article 11 of the Universal Declaration on the Human Genome and Human Rights could ground constitutional ‘international concern’.⁴⁷ Article 11 says ‘Practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted’.
- quarantine power [section 51(ix)]. The scope of this power is uncertain and it has rarely been considered by the High Court.⁴⁸ A narrow reading of the power would confine it to ‘isolation at the border of a country of people, plants and animals to

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prevent the spread of disease.⁴⁹ However, Professor John McMillan suggests that an expansive interpretation of the power would ‘extend to measures of a preventive or protective nature to halt the spread of disease within a country’ and might also be used to pass national laws about biotechnology and genetic engineering.⁵⁰

- copyrights, patents & trade marks power [section 51(xviii)]. If the Commonwealth wished to create disincentives for particular cloning technology research, then it might use the intellectual property power found in section 51(xviii) of the Constitution to deny intellectual property rights, such as patents, to the fruits of that research.
- taxation power [section 51(ii)]. A further way in which disincentives could be provided would be through a targeted taxation regime.
- Commonwealth funding & grants powers (sections 81 and 96). Funding and grants powers could be used to impose practical restrictions on medical research involving cloning technologies. Using section 96 of the Constitution the Commonwealth Parliament can make grants to any State subject to terms and conditions. Section 81 of the Constitution enables the Commonwealth Parliament to appropriate money for Commonwealth purposes. These, and other powers, could be used to restrict or prevent funding of facilities, health service providers etc involved with particular medical research. However, they would only have a limited effect on medical research carried out entirely in and funded by the private sector.
- incidental power (found in each head of legislative power and expressly provided for in section 51(xxxix)).
- implied nationhood power. This power is said to derive from the ‘existence and character of the Commonwealth as a national government ... to engage in enterprises and activities particularly adapted to the government of a nation and which cannot be otherwise carried on for the benefit of the nation’.⁵¹ The implied nationhood power has been identified as a source of power for Commonwealth legislation such as the *Science and Industry Research Act 1949* which established the CSIRO.⁵² However, the scope of the power remains very uncertain.

In its recent report, *Human Cloning: Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem Cell Research*, the House of Representatives Standing Committee on Legal and Constitutional Affairs concluded that:

... the Commonwealth has the constitutional power to enact legislation regulating most aspects of research involving the use of cloning technologies. The legislation could be enacted relying on the Commonwealth’s constitutional power over areas such as corporations, trade and commerce, quarantine, territories, import and export, patents, statistics, external affairs, actions by the Commonwealth or Commonwealth authorities as well as its power to attach conditions to its funding of projects and institutions.

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However, the Committee did not think that the Commonwealth's power was sufficient to cover all aspects of cloning technology research, a view also taken by the Commonwealth Attorney-General's Department submission to the Committee which said:

... [while] it may be possible to legislate in a piecemeal fashion using a number of Commonwealth heads of power ... ultimately it is probably the case that the Commonwealth Parliament does not have the power to enact legislation that would provide a comprehensive basis for prohibiting scientific research aimed at achieving reproductive human cloning or cloning research that involves the use of embryonic tissue.⁵³

The Attorney-General's Department also took this view in relation to:

... the conduct of research using embryonic stem cells, the creation of embryos for research; or for the purposes of obtaining compatible tissue for transplantation (stem cells, tissues or organs).⁵⁴

The Bill does not attempt to establish a comprehensive legislative framework relating to human cloning and stem cell research by relying solely on Commonwealth legislative power. Instead, it contemplates a cooperative legislative scheme where the States and Territories also pass legislation dealing with human cloning and stem cell research and conferring power on a Commonwealth licensing authority. The Bill has been introduced following a Council of Australian Governments (COAG) meeting which reached agreement on nationally consistent legislation on human cloning (see below). It recognises State and Territory interests and legislative capacity in these matters and attempts to ensure that there are no gaps in the legislative scheme.

This raises the subject of Commonwealth-State cooperative legislative schemes.

Commonwealth-State cooperative schemes

The division of constitutional power between the Commonwealth and the States creates gaps in the legislative power of each Australian jurisdiction and has prompted the use of different techniques to achieve national uniformity in the law and/or its administration.⁵⁵ These techniques have been categorised by Professor Cheryl Saunders as:

- template schemes. A template scheme is one where the one jurisdiction enacts a law and that law, as amended from time to time, is adopted and applied by each other jurisdiction. Sometimes the enacting jurisdiction is the Commonwealth, using its constitutional, plenary power over Territories.
- bucket schemes. A bucket scheme involves the establishment of an administering agency by one jurisdiction eg the Commonwealth. Other jurisdictions then legislate to confer power on that agency.

Co-operative legislative schemes often use both template and bucket arrangements. An example is the former corporations scheme where the Commonwealth used its territories

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power to enact a Corporations Law (template) and also established the regulatory body, the Australian Securities Commission, on which the other jurisdictions conferred power (bucket).⁵⁶

Commonwealth-State cooperative schemes have a long history. One of the earliest joint bodies was the River Murray Commission⁵⁷ established by the *River Murray Waters Act 1915* (Cwlth) and by complementary State legislation (*River Murray Waters Act 1915* (NSW), *River Murray Waters Act 1915* (Vic) and *River Murray Waters Act 1915* (SA)).

Until recently, such schemes were thought to be relatively secure in a constitutional sense. For instance, in 1983 in *R v. Duncan; Ex parte Australian Iron and Steel Pty Ltd*, the High Court had held that the Commonwealth and the States could jointly establish and empower a Coal Industry Tribunal to determine industrial disputes. Gibbs CJ said:

The Constitution effects a division of powers between the Commonwealth and the States but it nowhere forbids the Commonwealth and the States to exercise their respective powers in such a way that each is complementary to the other. There is no express provision in the Constitution, and no principle of constitutional law, that would prevent the Commonwealth and the States from acting in cooperation, so that each, acting in its own field, supplies the deficiencies in the power of the other so that they may achieve, subject to such limitations as those provided by s 92 of the Constitution, a uniform and complete legislative scheme ...⁵⁸

In the same case Deane J said that Commonwealth-State cooperation was 'a positive objective of the Commonwealth'.⁵⁹

However, co-operative legislative schemes are not without constitutional limits. Recent High Court decisions, like that in *R v. Hughes*⁶⁰, raised a number of questions, some as yet unanswered, about cooperative schemes.

The decision in *Hughes* tells us that where a State law confers functions on a Commonwealth entity, the Commonwealth can use the incidental power found in the Constitution to pass a law permitting those functions to be exercised by the Commonwealth entity. The situation becomes more complex where the Commonwealth law expressly or impliedly imposes a duty on the Commonwealth entity to exercise the power or function so conferred. In such a case, or where the function is a coercive one, it may be necessary for a Commonwealth head of power to be found which supports the law. Another question left unresolved by the High Court in *Hughes* is whether a duty imposed on a Commonwealth entity under a cooperative legislative scheme can only be imposed by a Commonwealth law and cannot be imposed by a State law.

Since the decision in *R v. Hughes* the Government has introduced a number of Bills designed to secure the constitutional validity of various Commonwealth-State cooperative schemes.⁶¹ Among these are the *Agricultural and Veterinary Chemicals Legislation Amendment Act 2001* which aims to shore up the cooperative national scheme for the evaluation, regulation and control of agricultural and veterinary chemicals, and the *Therapeutic Goods and Other Legislation Amendment Bill 2002* which relates to the cooperative scheme for therapeutic goods. Both the 2001 Act and the 2002 Bill allow for the possibility that State laws can

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impose duties on Commonwealth entities but provide a fall-back position in case it transpires that only a Commonwealth law can impose such a duty. The Research Involving Embryos and Prohibition of Human Cloning Bill 2002 also takes this approach (see below).

Recent Commonwealth responses to human cloning and stem cell research

In August 1999, then Health Minister, Dr Michael Wooldridge MP, asked the House of Representatives Standing Committee on Legal and Constitutional Affairs to review the report of the Australian Health Ethics Committee on *Scientific, Ethical and Regulatory Considerations Relevant to Cloning of Human Beings*.

In June 2001, the Council of Australian Governments (COAG) discussed assisted reproductive technology including human cloning. A communique issued on 8 June 2001 stated:

The Council committed itself to achieving nationally consistent provisions in legislation to prohibit human cloning .

It also agreed that jurisdictions work towards nationally consistent approaches to regulate assisted reproductive technology and related emerging human technologies.

In reaching agreement on this latter issue Heads of Government were acutely aware of the need to engage the community on the matter and to ensure that all sectors of the community benefit fully from advances in medical science while prohibiting unacceptable practices. The Council has sought a report from Health Ministers by the end of the year on technical issues with the aim of a nationally consistent approach being in place in all jurisdictions by June 2002.

In July 2001, Australian Health Ministers agreed to work cooperatively to ensure consistency in laws banning the cloning of humans.⁶²

In August 2001, the House of Representatives Committee presented its report, *Human Cloning: Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem Cell Research*. The Committee's recommendations included:

- the enactment of legislation to regulate human cloning and stem cell research
- that such legislation should include a ban on cloning for reproductive purposes combined with criminal penalties and loss of an individual's research licence
- the establishment of a national licensing body empowered to issue licences for research involving the isolation, creation and use of embryonic stem cells.⁶³

A minority of Committee members opposed any research which involved the destruction of human embryos and expressed concerns 'about the continued use of embryonic stem cells that have been derived from embryos, whether in Australia or overseas'.⁶⁴ In February 2002 there were media reports that, following a submission from Minister for

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Ageing, Mr Kevin Andrews MP, Cabinet had taken an in-principle decision to ban certain forms embryonic stem cell research.⁶⁵ The Prime Minister was reported as giving qualified support for such a ban but saying he would canvass opinion before coming to a conclusion. In March 2002, it was reported that Opposition Leader, Mr Simon Crean MP, proposed a conscience vote for party members on stem cell research.⁶⁶

On 4 April 2002 the Prime Minister announced that he had written to each of the Premiers and Chief Ministers about stem cell research. He said:

I think it is desirable that we have a uniform position throughout Australia. ... In the course of formulating my own views and contributing to the formulation of the Government's views I have consulted quite widely with scientists and with a number of church leaders. ...

I'll be proposing a total ban on human cloning and other unacceptable practices ... I am proposing [on] behalf of the Commonwealth that the Commonwealth and the States and Territories should allow the use of surplus ART embryos for research purposes. ... Our proposal at this stage is that only existing embryos should be available for that research. ...

It is our proposal and our intention to legislate both the ban on human cloning, and also the conditions attaching and governing the use of embryos for research purposes ... We will ask the states and territories to mirror that legislation at a State and Territory level so that we have a comprehensive national legislative framework governing aspects of this.

Members of Government parties will be allowed a free vote on this issue.⁶⁷

At its meeting on 5 April 2002, COAG considered a Report on *Human Cloning, Assisted Reproductive Technology and Related Matters* which outlined two options for action. The first was for voluntary compliance with revised NHMRC/AHEC Guidelines combined with legislative repeal in the three States with cloning legislation. The second was for nationally consistent bans on 'unacceptable practices'.⁶⁸

Immediately after the COAG meeting, a joint press conference was held by the Prime Minister, the Premiers and Chief Ministers where it was announced that agreement had been reached on proposals for nationally consistent legislation that had been put to the Premiers and Chief Ministers, with two changes. The first was for a general consent to research by donors. The second was for a sunset provisions in the legislation that would mean that the research ban on embryos created after 5 April 2002 would expire in not more than three years.⁶⁹ The States and Territories agreed to introduce mirror legislation, generally with a conscience vote being allowed for both Ministers and backbenchers.⁷⁰

The terms of the agreement reached at the COAG meeting can be found in a Communique and Attachment issued on 5 April 2002.⁷¹ Among the matters detailed in the Communique were:

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- a nationally consistent ban on the cloning of a human being
- nationally consistent regulation of certain ‘unacceptable practices’. ‘Unacceptable practices’ include creating an embryo outside a woman’s body other than for assisted reproduction, creating an embryo for assisted reproduction that contains genetic material from two or more people or conducting embryo flushing.⁷²
- appropriate ethical oversight of research involving embryos based on nationally consistent standards, monitoring of compliance with these standards and penalties for non-compliance
- a nationally consistent approach to the development or use of embryos for the derivation of stem cells including a ‘strict regulatory regime under nationally-consistent legislation ... administered by the National Health and Medical Research Council (NHMRC) as the national regulatory and licensing body’
- a review of the ban on the development of embryos for purposes other than assisted reproduction within three years.⁷³

Following the COAG meeting, the Government engaged in consultations on an exposure draft Bill ‘with a range of people in the fields of ART, medical research, consumer issues, ethics and law, in each capital city between 24 May and 6 June 2002’.⁷⁴ A summary of some of the opinions expressed during the consultative process is found in Attachment 1 of the Explanatory Memorandum.

On 30 May 2002, the Prime Minister announced that the successful applicant to establish and operate Australia’s Biotechnology Centre of Excellence was the Centre for Stem Cells and Tissue Research. The Prime Minister said that the Centre would receive \$43.5 million over four years and that the centre would be required to comply with statutory requirements, including ‘regulations arising from recent decisions taken by COAG on the 4th of April 2002’.⁷⁵

On 27 June 2002, the present Bill was introduced into the House of Representatives.

Main Provisions

General

Clause 4 recites constitutional underpinnings for the proposed legislation including the corporations power, the interstate and overseas trade and commerce power, the external affairs power, the census and statistics power and the express incidental power. While not uncommon, such recitations are not conclusive because it is the function of the High Court to decide whether a law is wholly or partly valid in a constitutional sense.

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The Act will bind the Crown but does not make the Crown liable for criminal offences (**clause 5**).

The proposed legislation extends to the Commonwealth's external territories (**clause 6**). Inhabited external territories are Norfolk Island, Christmas Island, Cocos (Keeling) Island.⁷⁶

In **clause 7**, 'State' is defined to include the Australian Capital Territory and the Northern Territory.

Prohibited practices including human cloning

Offences relating to human cloning and other practices

Part 2 of the Bill contains offence provisions relating to human cloning and the creation and use of human embryos. These provisions commence 28 days after Royal Assent (**clause 2**).

It will be an offence to:

- intentionally create a 'human embryo clone' (**clause 8**). A 'human embryo clone' is defined in **subclause 7(1)** as a human embryo that is a genetic copy of a living or dead human being. It is not necessary to establish that the copy is an 'identical genetic copy' [**subclause 7(2)**]. This provision is intended to overcome the sort of problems encountered in existing State legislation where the expression 'genetically identical' is used. The definition expressly excludes an embryo created by fertilisation and so is not intended to capture assisted reproductive technology (ART). However, an embryo that is created by embryo splitting is included in the definition of 'human embryo clone' and it is thus an offence split an embryo [**subclause 7(4) and clause 8**].
- intentionally place a human embryo clone in a human or animal body (**clause 9**)
- intentionally import or export a human embryo clone (**clause 10**).

In each case the maximum penalty is imprisonment for 15 years. It is not a defence that the clone did not or could not have survived (**clause 11**).

Other offences contained in Part 2 are:

- intentionally creating a human embryo other than by fertilisation or intentionally developing such an embryo (**clause 12**). Thus, it will be an offence to create a human embryo by techniques like embryo splitting which do not involve the fertilisation of a human egg by sperm.⁷⁷
- intentionally creating a human embryo outside a woman's body other than to achieve a pregnancy in a particular woman (**clause 13**). ART procedures may result in the

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creation of multiple embryos in an attempt to bring about a pregnancy in a particular woman. In an attempt to ensure that such practices are not criminalised, the Explanatory Memorandum states that **clause 13** is not intended to restrict the number of embryos that may be created to bring about a pregnancy in a particular woman or to prohibit the creation of embryos that may, eventually, be found to be unsuitable for or otherwise unused by a particular woman.⁷⁸

- intentionally creating or developing a human embryo containing genetic material provided by more than 2 persons (**clause 14**). This clause is intended to prevent the use of certain new ART techniques such as cytoplasmic transfer.⁷⁹
- intentionally developing a human embryo outside a woman's body for a period of more than 14 days (**clause 15**). This will not prevent embryos being stored before the 14th day of their development because any period during which development is 'suspended' is excluded from the calculation of the 14 day period [**subclause 7(3)**].
- using human precursor cells intending to create or develop a human embryo (**clause 16**). A precursor cell is defined as 'a cell that has the potential to develop into a human egg or human sperm' [**subclause 7(1)**].
- altering a human genome intending the alteration to be inherited by the donor's descendants (**clause 17**). This clause is intended to ban germ line gene therapy.⁸⁰
- removing a human embryo from a woman's body intending to collect a viable human embryo (**clause 18**). This clause is intended to criminalise embryo flushing.⁸¹
- intentionally creating a chimeric embryo or hybrid embryo (**clause 19**). These terms are defined in **subclause 7(1)**. The object of **clause 19** is to criminalise the creation or development of transgenic human embryos.⁸²
- intentionally placing a human embryo in an animal or an animal embryo in a human (**clause 20**).
- intentionally importing or exporting a human embryo, knowing or being reckless about whether the embryo is a 'prohibited embryo' (**clause 21**). The expression 'prohibited embryo' is defined in **subclause 21(4)**. In general terms it is an embryo obtained in contravention of the prohibitions specified in **clauses 12-19**. It includes a human embryo created by a process other than the fertilisation of a human egg by a human sperm. Under **clause 21** it is also an offence to place a 'prohibited embryo' in the body of a woman.
- intentionally trading (offering or obtaining 'valuable consideration') in human eggs, human sperm or human embryos (**clause 22**). The expression 'valuable consideration' is defined in **subclause 22(3)** to include inducements and to exclude a person's reasonable expenses when supplying an egg, sperm or embryo. 'Reasonable expenses' is also defined in **subclause 22(3)**.

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Regulating the use of excess ART embryos and other matters

Definitions

The definitions provisions (**clauses 23 and 24**) commence 28 days after Royal Assent (**clause 2**).

Offences

Clauses 25-27 create offences relating to the unlicensed use of excess ART embryos, the use of embryos that are not excess ART embryos, and breaches of licence conditions. The penalty for these offences is a maximum of 5 years imprisonment. **Clauses 25-27** commence six months after Royal Assent (**clause 2**). The Explanatory Memorandum states that the delay in commencement will enable a new NHRMC licensing committee to be established (see below), allow time for licence applications to be made to that committee and ‘allow the States and Territories to introduce complementary legislation and, where necessary, repeal existing provisions of State legislation that ban the use of excess ART embryos’.⁸³

It will be an offence to intentionally use an ‘excess ART embryo’ unless the use is licensed or is an ‘exempt use’ (in which case a licence is unnecessary) (**clause 25**). An ‘excess ART embryo’ is one created for use in ART treatment of a woman which is excess to her needs and the needs of her spouse (if any) at the time the embryo was created, as evidenced by their written authority (**clause 24**). ‘Exempt use’ includes storage, removal from storage or transportation of the embryo, observing the embryo, allowing it to succumb, certain uses in accredited ART centres, and uses prescribed by regulation [**subclause 25(2)**]. Permissible uses in accredited ART centres include use where the excess ART embryo is unsuitable for use in the woman for whom it was created, use to achieve a pregnancy in another woman, use in diagnostic investigations associated with ART treatment of the woman for whom the embryo was created and uses prescribed by regulation.

It will also be an offence to intentionally use a non-excess ART embryo outside a woman’s body where the use is not part of an ART program conducted by an accredited ART centre [**subclause 26(1)**]. An ‘ART program’ is a program carried out in accordance with a code of practice issued by the Reproductive Technology Accreditation Committee of the Fertility Society of Australia or a code prescribed by the regulations [**subclause 26(2)**].

Finally, it will be an offence to knowingly or recklessly breach a licence condition (**clause 27**).

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Licensing and monitoring

Provisions relating to the NHMRC Embryo Research Licensing Committee (Licensing Committee) commence 28 days after Royal Assent (**clause 2**), as do the remaining provisions of the Bill.

The Licensing Committee is established by **clause 28**. It consists of nine members appointed by the Minister (**clause 31**) following nominations from the States, the ACT and the Northern Territory and any prescribed bodies. One member must come from Australian Health Ethics Committee. The other 8 members are persons with specified expertise including research ethics, ART, its regulation, a relevant area of law, consumer health issues and embryology. While the Minister is, in general, only obliged to consult with States about appointments to the Licensing Committee, neither the Chairperson nor the member appointed for their expertise in ART regulation can be appointed without the agreement of a majority of jurisdictions. Appointments are for a period of not more than 3 years. Re-appointment is possible (**clause 32**).

The Licensing Committee must provide information to the NHMRC for inclusion in its annual report to Parliament (**clause 33**) and can also report directly to Parliament on 'matters relating to the Committee's functions' (**clause 34**).

The functions of the NHMRC Licensing Committee include licensing the use of excess ART embryos [**clauses 29(a) and 35**]. The Committee cannot issue a licence unless it is satisfied that:

- protocols exist for consent to be obtained from each 'responsible person' (defined in **clause 23**: see below) in relation to the embryo
- if using the embryo may damage or destroy it, only an embryo created before 5 April 2002 will be used
- the project proposed by the applicant has been assessed and approved by a properly constituted Human Research Ethics Committee (HREC) [**subclause 36(3)**].

In making licensing decisions, the Licensing Committee must also consider matters such as the number of excess ART embryos likely to be used, whether the use of excess ART embryos will advance knowledge or treatment in a way that 'could not reasonably be achieved by other means', relevant NHMRC guidelines and any matters prescribed by regulation [**subclause 36(4)**]. After making a decision about a licence application the Licensing Committee must notify the applicant, the relevant HREC and State body⁸⁴ (**clause 37**).

Where a licence is issued, a copy must be provided to the relevant HREC and State body [**subclause 37(2)**]. Licences are subject to conditions contained in the licence and to statutory conditions including consent and reporting requirements (**clause 39**). For instance, each 'responsible person' must have given their consent to the use of the excess ART embryo. 'Responsible person' is defined as each person who created the egg or

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sperm and their spouse (at the time) and the woman for whom the embryo was created and her spouse (at the time) (**clause 23**).

The Licensing Committee is empowered to vary, suspend or revoke a licence (**clauses 40 and 41**). Where a licence is varied, suspended or revoked the Licensing Committee must notify the licence holder, the HREC and the relevant State bodies (**clause 43**).

The Licensing Committee also has record-keeping functions. These involve the maintenance of a database containing the names of licensees and details of licences including authorised uses of excess ART embryos, licence conditions and duration. The database is to be publicly available but cannot contain 'confidential commercial information' (**clause 44**). The expression 'confidential commercial information' is defined in **clause 23** as information which has a commercial or other value that could be reasonably expected to be destroyed or diminished on disclosure.

The Licensing Committee Chairperson can appoint Commonwealth, State or Territory officers as inspectors (**clause 48**). These inspectors can enter premises with the consent of the occupier or, if the premises are used for licensed activities, at reasonable times (**clauses 50 and 54**). Inspectors are also empowered to search premises, inspect and sample human embryos on those premises, and inspect and copy records (**clauses 50 and 51**). If an inspector believes on reasonable grounds that there is evidence on the premises of an offence against the Act, then the inspector can secure the premises until a seizure warrant can be obtained (**clause 52**).

Inspectors will be issued with identity cards that must be carried when they are acting in an official capacity (**clause 49**). An inspector's powers cannot be exercised lawfully if he or she has been 'required' to produce an identity card by the occupier of premises and fails to do so (**clause 53**).

Compensation for damage caused by an inspector's failure to exercise care when operating equipment or other facilities is provided in **clause 55**.

Disclosing 'confidential commercial information'

In general, a person who performs functions under the Act or a corresponding State law commits an offence if they knowingly disclose 'confidential commercial information' (**clause 45**). The maximum penalty for this offence is two years imprisonment. It is not an offence to disclose confidential commercial information to the Commonwealth, a State or Territory when carrying out statutory duties, or when ordered to do so by a court or with the consent of the person for whom the information has a commercial or other value.

Administrative review of Licensing Committee decisions

Licence applicants and licence holders may apply to the Administrative Appeals Tribunal (AAT) for a review of certain Licensing Committee decisions including a decision not to

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issue a licence, decisions about licence conditions and decisions about varying, revoking or suspending a licence (**clauses 46 and 47**).

Clause 59 provides that if the Licensing Committee makes a decision using powers conferred by corresponding State or Territory laws then that decision can be reviewed by the (Commonwealth) Administrative Appeals Tribunal (AAT) if two conditions are met. First, if the relevant State or Territory law provides that the decision can be reviewed by the AAT. And, second, if Commonwealth regulations provide that the decision can be reviewed by the AAT.

Commonwealth/State arrangements

The Bill provides that it is not intended to exclude the operation of any State or Territory laws capable of operating consistently with it [**clause 56 and subclause 57(4)**]. This provision will have two effects. First, to override any inconsistent State or Territory laws. For example, the Explanatory Memorandum says:

One of the intended effects of this clause is that if a State has existing legislation that, for example, bans the use of excess ART embryos, such a law would not be capable of operating concurrently with the Act and as such it is intended that the Act override the State law to the extent that it is inconsistent.⁸⁵

Second, it will preserve consistent State or Territory laws. On this account, it is designed to counter any argument that the Commonwealth law is designed to displace State laws by operation of section 109 of the Constitution⁸⁶ or Territory laws by operation of the paramount legislature principle.

Subclause 57(1) is a consent provision. It says that a corresponding State or Territory law can confer functions, powers and duties on the Licensing Committee, a Commonwealth authority or a Commonwealth officer. A ‘corresponding State law’ is defined as a State or Territory law gazetted by the Commonwealth Minister as a corresponding State or Territory law (**clause 7**). Functions, powers and duties conferred by State or Territory corresponding laws on the Licensing Committee or a Commonwealth authority or officer are conferred with the consent of the Commonwealth. The reference to ‘duties’ in clause 57 contemplates the possibility that a State law can impose a duty on a Commonwealth authority. It also takes account of the possibility that the High Court may find that duties exist in a cooperative scheme even in the absence of the word ‘duty’. In either event, the Commonwealth will need to consent to the conferral of duties as well as powers and functions by State laws. **Subclause 57(3)** aims to restrict the conferral of functions, powers or duties within constitutional confines.

Clause 58 deals with duties imposed on Commonwealth entities and officers by corresponding State or Territory laws. It provides for two possibilities:

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1. if the imposition of the duty is within State or Territory legislative powers and constitutionally permissible—then the duty is taken to be imposed by the relevant State or Territory law [**subclause 58(2)**]. This allows for the possibility that the High Court will find that a State law can impose a duty on a Commonwealth entity.
2. if (1) is not constitutionally permissible then **subclause 58(3)** provides that the duty is taken to be imposed by Commonwealth law. This is a fall-back position and allows for the fact that the High Court could decide that a State law cannot impose a duty on a Commonwealth entity. In such a case, **subclauses 58(4)-(6)** state that the Commonwealth relies on all legislative powers available to it to support the imposition of duties by Commonwealth law.

Sunset clause

As a result of **clause 60**, prohibitions on research which damages or destroys excess ART embryos created on or after 5 April 2002 will be lifted either on 5 April 2005 or earlier (if the Council of Australian Governments declares an earlier date by notice in the *Gazette*).

Review of the Act

An independent review of the legislation's operation must be commissioned by the NHMRC as soon as possible after the second anniversary of Royal Assent. The review report must be submitted to COAG before the third anniversary of Royal Assent (**clause 61**).

Regulation making powers

As is usual in Commonwealth statutes, the Governor-General is empowered to make regulations under the Act [**subclause 62(1)**]. However, before such regulations are made, the Commonwealth Minister must be satisfied that the States and Territories have been consulted and that the proposed regulations have been prepared having regard to State and Territory views [**subclause 62(2)**].

Amendments to the *Gene Technology Act 2000* (Cwlth)

Item 1 of Schedule 1 repeals sections 192B, 192C and 192D of the Gene Technology Act. These provisions currently ban human cloning and certain experiments involving combinations of human and animal cells. They will be unnecessary once the Research Involving Human Embryos and Prohibition of Human Cloning Act comes into effect.

As stated above, **item 1** commences 28 days after Royal Assent (**clause 2**).

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Concluding Comments

It is beyond the scope of this Digest to comment about the ‘science’ contained in the Bill and the likely reach and impact of the provisions dealing with human cloning and embryo research. There will clearly be debate about the Bill’s intentions and effects. For instance, in a paper presented in July 2002, Professor Loane Skene and Mr Brendan Gogarty ask whether the Bill is intended to ban embryo splitting and, if so, whether ‘couples should be banned from having twins by IVF’.⁸⁷ The Bill’s prohibitions extend to embryo splitting (see **subclauses 7(1), 7(4)** and relevant offence provisions such as **clause 8**) but may, in any case, attract comment from both proponents and opponents of the ban.

The wording of other provisions in the Bill may be facially ambiguous. For instance, **clause 13** bans the creation of an embryo outside the body of a woman unless the intention is to attempt to achieve a pregnancy ‘in a particular woman’. Because of the potential reach of this clause, the Explanatory Memorandum then states that it is not intended to ban Pre-Implantation Genetic Diagnosis, prevent therapeutic procedures being carried out on an embryo, restrict the number of embryos that ‘may be created for the purposes of achieving pregnancy in a particular woman’ or prevent the creation of embryos that could become excess ART embryos.⁸⁸

Other questions that might be raised relate to the fault elements in some of the offence provisions. Chapter 2 of the Commonwealth Criminal Code applies principles of criminal responsibility to all Commonwealth offences. It says that offences are made up of physical elements (which may be conduct, the circumstances of conduct or the results of conduct) and fault elements (such as intention, knowledge, recklessness or negligence).

Chapter 2 specifies default fault elements that apply to physical elements in Commonwealth offences. These default fault elements, which are ‘read into’ offence provisions unless they are expressly ousted, are ‘intention’ in the case of conduct and ‘recklessness’ in the case of the circumstances or results of conduct. Many of the offence provisions contained in the Bill expressly mention ‘intention’. The reason for this may be to provide an unambiguous template for the States and Territories to reproduce in their own legislation—given that they have not, as yet, adopted the principles of criminal responsibility contained in Chapter 2.⁸⁹ But are all the offence provisions unambiguous? For instance, **clause 14** creates an offence where a person ‘intentionally creates or develops a human embryo containing genetic material provided by more than 2 persons’. Is this offence constituted by conduct which encapsulates the creation or development of a human embryo containing genetic material provided by more than 2 persons? Or, does the offence consist of conduct (creating or developing a human embryo) and circumstance (the embryo contains genetic material provided by more than 2 persons). In the latter case, does the wording of the provision indicate that ‘intention’ applies to both the physical elements of conduct and circumstance or only to the conduct, with ‘recklessness’ applying to circumstance by default operation of Chapter 2 of the Criminal Code.

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Endnotes

- 1 This material was originally provided by Katrine del Villar, Law & Bills Digest Group, Parliamentary Library.
- 2 George P Smith II, 'Intimations of Immortality: Clones, Cryons and the Law' (1983) 6(1) *University of New South Wales Law Journal* 119 at 119.
- 3 For example, see JB Gurdon, RA Laskey and OR Reeves 'The developmental capacity of nuclei transplanted from keratinised skin cells of adult frogs' (1975) 34 *Journal of Embryology and Experimental Morphology* 93-112. See also Ian Wilmut, Keith Campbell and Colin Tudge, *The Second Creation: The age of biological control by the scientists who cloned Dolly* (2000) at 90-97.
- 4 Dolly the sheep, cloned from a cell taken from a sheep's udder, was the most famous, and is reported in I Wilmut, A E Schnieke, J McWhir, A J Kind and K H S Campbell 'Viable offspring derived from fetal and adult mammalian cells' (1997) 385 *Nature* 812-13. The team at the Roslin Institute had previously cloned two sheep (Megan and Morag) from cells taken from a 9 day old embryo: K H S Campbell, J McWhir, W A Ritchie and I Wilmut, 'Sheep cloned by nuclear transfer from a cultured cell line' (1996) 380 *Nature* 64-66. After Dolly, the team produced a further three cloned sheep from cells taken from an aborted sheep fetus, as well as four more sheep cloned from cells from a nine-day old embryo. The South Australian Research and Development Institute has also produced Matilda the cloned sheep.
- 5 For reports of the cloning of cows in Denmark, Australia, France and the USA, and rhesus monkeys at the Oregon Regional Primate Research Centre, USA, see Alex Sleator, *Cloning*, House of Commons Library Research Paper No 97/43 (27 March 1997) at 11-12; and Judith Thomson, 'Legal and Ethical Problems of Human Cloning' (2000) 8(1) *Journal of Law and Medicine*, 31 at 32.
- 6 Dean Bell, 'Human Cloning and International Human Rights Law' (1999) 21(2) *Sydney Law Review* 202 at 209.
- 7 See Martin Pera, 'Cloning and embryonic stem cells' (June 1999) 50 *Australian Rationalist* 5 at 5.
- 8 See Australian Academy of Science statement on *Human Stem Cell Research*, April 2001.
- 9 See Thomson, op.cit. 31 at 32. See also, reports of reproductive cloning in Italy and Russia—'Human clones by year's end spawn "freak" fears', *The Australian*, 28 May 2002.
- 10 See, for example, 'Researchers find way to improve body's tolerance of stem cells', *Age*, 31 July 2002.
- 11 This material was originally provided by Katrine del Villar, Law & Bills Digest Group, Parliamentary Library and updated as appropriate.
- 12 Smith, op.cit. at 123-124.
- 13 John A Robertson, 'Human cloning and the challenge of regulation' (1998) 339(2) *New England Journal of Medicine* 119 at 119.
- 14 See Gregory Pence, *Who's Afraid of Human Cloning?* (1998) pp. 114-115.

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- 15 See Dana Wensley 'Being human: science and philosophy of cloning' (May 1999) 148 *Bulletin of Medical Ethics* 13 at 14; Thomson, op.cit. 31 at 33.
- 16 Hans Jonas, 'Philosophical essays: From ancient creed to technological man' (1974) at 162-163; quoted in George J Annas, 'Why we should ban human cloning' (1998) 339(2) *New England Journal of Medicine* 122 at 124.
- 17 See for example, Michael Lupton, 'Human cloning—The law's response' (1997) 9 *Bond Law Review* 123 at 131.
- 18 Annas, op.cit, 122 at 123.
- 19 See Dana Wensley 'Being human: science and philosophy of cloning' (May 1999) 148 *Bulletin of Medical Ethics* 13 at 14.
- 20 See Dennis Shanahan, 'Faiths unite to put cloning on poll agenda', *The Australian*, 29 October 2001.
- 21 Miles Little, 'Animal cloning and the possibility of cloning humans – Science, law and ethics' (1998) *Judicial Review* 57 at 61.
- 22 Ronald Dworkin, 'Playing God' (May 1999) 41 *Prospect* 37 at 39.
- 23 See generally Martin Pera, 'Cloning and embryonic stem cells' (June 1999) 50 *Australian Rationalist* 5 at 7-8; Alex Sleator, *Cloning*, House of Commons Library Research Paper No 97/43 (27 March 1997) at 13-15; Lupton, op.cit., 123 at 130.
- 24 Julian Savulescu, 'Should we clone human beings?' (June 1999) 50 *Australian Rationalist* 10 at 16.
- 25 See Pera, op.cit. 5 at 8.
- 26 The transplantation of an organism's own cells or tissues.
- 27 Lupton, op.cit., 123 at 131.
- 28 Australian Academy of Science, *On Human Cloning: A Position Statement* (4 February 1999).
- 29 See, for example, Dianne Nicol, Donald Chalmers & Brendan Gogarty, 'Regulating biomedical advances: embryonic stem cell research', (2002) 2 *Macquarie Law Journal* 31; House of Representatives Committee, op.cit. 'Stick to adult cells: Anderson', *Canberra Times*, 6 August 2002; 'Researchers find a way to improve body's tolerance of stem cells', *The Age*, 31 July 2002; 'Found in bone marrow: the Mr Fixit of stem cells', *Sydney Morning Herald*, 21 June 2002; 'Embryonic stem cells: the debate we shouldn't have', *The Age*, 27 March 2002; 'The technology', *The Australian*, 1 April 2002.
- 30 This material is based on information provided by Katrine del Villar, Law & Bills Digest Group, Parliamentary Library.
- 31 House of Representatives Standing Committee on Legal and Constitutional Affairs, *Human Cloning: Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem Cell Research* (August 2001).

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- 32 In September 2001, the Human Reproductive Cloning and Trans-Species Fertilisation Bill 2001 was introduced into the NSW Parliament. It lapsed on prorogation at the second reading stage in the Legislative Assembly.
- 33 Particularly, the *National Statement on Ethical Conduct in Research Involving Humans* (1999) and the *Ethical Guidelines on Assisted Reproductive Technology* (1996).
- 34 The Cloning of Humans (Prohibition) Bill 2001 was introduced in the Queensland Parliament in November 2001 but has not been passed.
- 35 The Code is not legally binding.
36. See sections 192B, 192C and 192D of the *Gene Technology Act 2000*.
- 37 Sections 192C and 192D respectively.
- 38 Some of this material was supplied by Natasha Cica and Sean Brennan, Law & Bills Digest Group, Parliamentary Library.
- 39 See John McMillan, ‘The constitutional power of the Commonwealth in public health’, in Australian Institute of Health Law & Ethics, *Public Health Law in Australia. New Perspectives*, 1998.
- 40 (2001) 184 ALR 260 at 276-7, 288-9.
- 41 *Lamshed v. Lake* (1958) 99 CLR 132 at 153 per Kitto J; *Spratt v. Hermes* (1965) 114 CLR 226 at 242 per Barwick CJ; *Teori Tau v. Commonwealth* (1969) 119 CLR 564 at 570—unanimous High Court; *Berwick Ltd v. Gray* (1976) 133 CLR 603 at 607 per Mason J; *Northern Land Council v Commonwealth* (1986) 161 CLR 1 at 6—unanimous High Court.
- 42 See *Re Residential Tenancies Tribunal (NSW); ex parte Defence Housing Authority* (1997) 190 CLR 410.
- 43 McMillan, op.cit.
- 44 *ibid*, p. 113.
- 45 See submission of the Attorney-General’s Department to the House of Representatives Standing Committee on Legal and Constitutional Affairs, pp. S 530-537, S 874.
- 46 *ibid*, p. S 874.
- 47 Associate Professor Loane Skene, University of Melbourne, Evidence to the House of Representatives Standing Committee on Legal and Constitutional Affairs, Reference: Scientific, ethical and regulatory aspects relevant to human cloning, 1 March 2000, LCA 45.
- 48 *ibid*.
- 49 *ibid*, p.108.
- 50 *ibid*.
- 51 *Victoria v. Commonwealth* [AAP Case] 134 CLR 338 at 397 per Mason J.
- 52 *Victoria v. Commonwealth* (AAP Case) (1975) 134 CLR 338 per Mason J at 397.
- 53 House of Representatives Committee, op.cit., para. 11.42.

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- 54 Submission of the Attorney-General's Department to the House of Representatives Legal and Constitutional Affairs Committee, p. S537.
- 55 Cheryl Saunders, 'A new direction for intergovernmental arrangements', (2001) 12 *Public Law Review* 274.
- 56 *ibid.*
- 57 Gary A Rumble, 'The Commonwealth/State co-operative basis for the Australian Wheat Board and the National Companies and Securities Commission: Some constitutional issues', (1980) 7 *Adelaide Law Review* 348.
- 58 *R v. Duncan, Ex parte Australian Iron and Steel Pty Ltd* (1983) 158 CLR 535 at 552.
- 59 *R v. Duncan, Ex parte Australian Iron and Steel Pty Ltd* (1983) 158 CLR 535 at 589 quoted in Tony Blackshield & George Williams, *Australian Constitutional Law & Theory. Commentary and Materials*, 3rd ed, Federation Press, Sydney, 2002.
- 60 (2000) 171 ALR 155.
- 61 For a comprehensive description of the decision in *Hughes* see Sean Brennan, Agriculture and Veterinary Chemicals Legislation Amendment Bill 2002, *Bills Digest No. 133 2000-01*. Other Bills introduced by the Commonwealth Government partly or wholly in response to *Hughes* and the High Court's decision in *Re Wakim; ex parte McNally* (1999) 198 CLR 511 are: Corporations Bill 2001; Australian Securities and Investments Commission Bill 2001; Corporations (Securities Exchanges Levies) Bill 2001; Corporations (Futures Organisations Levies) Bill 2001; Corporations (National Guarantee Fund Levies) Bill 2001 and Corporations (Fees) Bill 2001, Crimes Amendment (Forensic Procedures) Bill 2000, National Crime Authority Amendment Bill (No.2) 2000, Gene Technology Bill 2000.
- 62 Dr Michael Wooldridge MP, Minister for Health and Aged Care, Media Release, '[National Framework Agreed to Prevent the Exploitation of Human Cloning](#)', 31 July 2001.
- 63 The full text of the Committee's report can be found via:
<http://www.aph.gov.au/house/committee/laca/humancloning/contents.htm> (accessed 31 July 2002).
- 64 Committee members Mr Kevin Andrews MP, Mr Alan Cadman MP, Mr John Murphy MP and Mrs Danna Vale MP considered that 'research and therapy involving the destruction of human embryos should be prohibited'. House of Representatives, *op.cit.*, p. 120. These Committee members also expressed concerns about the continued use of embryonic stem cells in research (*ibid.*, see pp. 123-4). The majority of Committee members (Ms Nicola Roxon MP, Mr Bruce Billson MP, Ms Julie Bishop MP, Mr Alan Griffin MP, Mr Duncan Kerr MP and Mr Stuart St Clair MP) would 'accept non-reproductive cloning research involving embryonic stem cells because of its potential for the treatment of serious disease'. *ibid.*, p. 118.
- 65 Initially, it was reported that the Federal Government planned to ban embryonic stem cell research. Mr Andrews then told reporters that there was 'no proposition to prohibit continued research on existing stem cell lines and there is no proposition that I am aware of to prohibit research involving adult stem cells', 'Stem-cell research row looms', *Financial Review*, 27 February 2002. See also 'Embryo ban shocks premiers', *The Age*, 27 February 2002; 'Government yet to decide on cloning ban', *The Canberra Times*, 27 February 2002, 'Howard

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to study stem cell research before ban', *Sydney Morning Herald*, 27 February 2002; 'Andrews sells qualified stem cell ban', *Financial Review*, 1 March 2002.

- 66 'Crean calls for a conscience vote on stem cell research', *Sydney Morning Herald*, 13 March 2002.
- 67 Prime Minister, *Transcript of Press Conference*, Parliament House, 4 April 2002.
- 68 See Research Involving Embryos and Prohibition of Human Cloning Bill 2002, Explanatory Memorandum, pp. 36-9.
- 69 Prime Minister, *Transcript of the Prime Minister, the Hon. John Howard MP, Joint Press Conference with Premiers and Chief Ministers*, Parliament House, Canberra, 5 April 2002.
- 70 See for example, Premiers Rann, Gallop and Bracks at the Joint Press Conference the Prime Minister, Premiers and Chief Ministers held at Parliament House in Canberra on 5 April 2002 following the COAG meeting.
- 71 Council of Australian Governments, [Communique](#), 5 April 2002 (accessed 13 August 2002).
- 72 'Embryo flushing involves the obtaining of an embryo from the body of a woman after fertilisation has taken place in vivo. During the time the pre-implantational embryo is floating free in the uterus it is flushed out and transferred to a recipient's uterus where implantation takes place. It therefore involves the displacement of a healthy embryo which is about to implant in the woman's uterus'. New South Wales Health, *Review of the Human Tissue Act 1983. Discussion Paper: Assisted Reproductive Technologies*, 1997.
- 73 Council of Australian Governments, [Communique](#), 5 April 2002 (accessed 13 August 2002).
- 74 Explanatory Memorandum, p. 39.
- 75 See Prime Minister, *Transcript of the Prime Minister the Hon John Howard MP, Announcement of the successful applicant for the Biotechnology Centre of Excellence*, 30 May 2002. See also 'Stem cell research wins \$44m funding', *The Courier-Mail*, 31 May 2002; Senator Brian Harradine, 'Harradine questions Department of Industry about \$46 million gift to Trounson stem cell centre', *Press Release*, 30 May 2002.
- 76 The Commonwealth has plenary power under section 122 of the Constitution to legislate for the territories, including external self-governing and non-self-governing territories.
- 77 Explanatory Memorandum, pp. 8-9.
- 78 *ibid*, pp. 9-10.
- 79 *ibid*, pp. 10-11.
- 80 *ibid*, p. 12.
- 81 *ibid*, p. 12.
- 82 *ibid*, p. 13.
- 83 Explanatory Memorandum, p. 3.
- 84 A 'State body' is a body notified to the Licensing Committee by a State (or Territory) (**clause 23**).

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- 85 Explanatory Memorandum, p. 30.
- 86 Section 109 of the Constitution says that ‘When a law of a State is inconsistent with a law of the Commonwealth, the latter shall prevail, and the former shall, to the extent of the inconsistency, be invalid.’
- 87 Loane Skene & Brendan Gogarty, ‘A legal perspective on stem cell research and cloning’, paper presented at the Dean’s Lecture Series, University of Melbourne, 26 July 2002.
- 88 Explanatory Memorandum. pp. 9–10.
- 89 The Model Criminal Code, which includes Chapter 2, is designed to be adopted by each State and Territory. Constitutionally relevant chapters are also being progressively enacted by the Commonwealth.

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