Human Cloning And Other Prohibited Practices Act 2004 Comes Into Law

The Human Cloning And Other Prohibited Practices Act 2004 (‘Act’) was first read in the Singapore Parliament on 20 July 2004. It will come into force on 1 October 2004. The Act deals with the sensitive and morally explosive subject of human cloning and the use of human embryos for research, and seeks to ban practices that would be considered morally repugnant. At the same time, the Act also seeks to allow leeway for scientists working in Singapore to carry out some measure of research, but without allowing them to step outside morally acceptable boundaries. This will allow the development of Singapore as a hub for research and development both in the region and world-wide.

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What Amounts To Human Embryos And Human Embryo Clones

Before looking at the substantive provisions of the Act which contain the critical prohibitions, it is necessary to look at the key definitions in the Act on which these prohibitions are based.

Human Embryo

A ‘human embryo’ is defined to mean any live embryo that has a human genome or an altered human genome and that has been developing for less than eight weeks since the appearance of two pro-nuclei or the initiation of its development by other means. Clearly human embryos created by the fertilisation of a human egg by human sperm would fall in the definition. To ensure that no grey area is inadvertently created, the definition does not rely on defining when fertilisation commences or is complete. Instead, it relies upon the appearance of the pro-nuclei to establish the existence of a human embryo. Scientifically, the appearance of the pro-nuclei indicates that the nuclei from the sperm and the egg are aligning prior to possible fusion, and is the pre-cursor to development of the embryo.

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includes the following types of embryos:

- a human egg that has had its nucleus replaced by the nucleus of a somatic cell (that is, a mature cell from the body) by the process referred to as somatic cell nuclear transfer; and
- a parthenogenetic human embryo (Such an embryo is created by mechanically or chemically stimulating a human egg so that it undergoes spontaneous activation and exhibits some of the characteristics of a fertilised human egg. A parthenogenetic human embryo has the capacity to continue its development in a similar manner to a human embryo created by fertilisation.)

One area that might give rise to difficulties is the inclusion of the term ‘live’ in the definition: to fall under the Act, a human embryo must be ‘live’. The difficulty is that, with a cell or a collection of cells, it can be difficult to determine exactly what ‘live’ constitutes as there are intermediate states of cellular activity between when a cell can be considered clearly alive and when it would clearly be considered dead. This issue is not addressed in the Act, and may well have to be litigated in the courts on a case-by-case basis.

**Human Embryo Clone**

A ‘human embryo clone’ is defined to mean any human embryo that is a genetic copy of another living or dead human. It adopts a wide evidential test, providing that it is sufficient to establish that the set of genes in the nuclei of the cells of the living or dead human has been copied. Further, the Act states that it is not necessary to establish that the copy is an identical genetic copy.

The lack of the need to establish that the copied genes are identical do not merely reflect the evidential difficulty and cost of genetic tests to establish an exact match between two sets of DNA. The effect is also to further expand on what amounts to a ‘human embryo clone’ for the purposes of the Act. This definition would therefore also capture the following:

- the presence of DNA outside the nucleus (ie, mitochondrial DNA) that is not identical to the living or dead human from which the nuclear DNA was taken, as would occur in an embryo created using the somatic cell nuclear transfer technique;
- spontaneous changes to the nuclear DNA that may occur during the development of a human embryo clone; and
- the deliberate alteration of the DNA so that the intention is to produce a clone of another human, but where the nuclear DNA could no longer be considered an identical copy of the original DNA.

As regards the last item, it should be noted that this point is also addressed within the definition of human embryo, which includes one that has an altered human genome. Accordingly, an embryo that is a clone of another human and has had its genome deliberately altered will still be considered a human embryo and therefore, as its original genome was copied, a human embryo clone.

**Human Cloning**

First and foremost, the Act establishes that it is an offence ‘to place any human embryo clone in the body of a human or the body of an animal’ (section 5 of the Act). Notably, the Act does not make it an offence to create a human embryo clone. Effectively, therefore, the Act would allow the creation of human embryo clones which, subject to the restrictions on the use of human embryos set out in the Act (discussed below under ‘Primary Prohibited Uses Of Human Embryos’), could be used for research purposes but would then not be allowed to grow to maturity and birth. This would thus avoid the scandal of the actual live birth of a human clone.

It should be noted that the prohibition is wide insofar as the Act refers to placing the human embryo clone in a human or animal body and not a human or animal reproductive tract. This would cater for advances in technology that might allow the development of a clone outside of a womb and in some other portion of the human body. Insofar as technology might become sufficiently advanced to allow the development of a foetus within a wholly artificial womb, this is dealt with by section 7 of the Act and discussed below under ‘Primary Prohibited Uses Of Human Embryos’.

For purposes of completeness, the Act stipulates that it is not a defence that the human embryo clone did not survive or could not have survived. In other words, that the human embryo clone that was placed in an animal or human body eventually miscarried would not amount to a defence.
Primary Prohibited Uses Of Human Embryos

The Act provides for three main prohibitions on the use of human embryos. There are various other offences which will also be discussed below (see ‘Subsidiary Prohibited Uses Of Embryos’), but these are essentially ancillary to the three main prohibitions which are:

- a prohibition against developing a human embryo for more than 14 days where the embryo was created other than by fertilisatation of a human egg by human sperm;
- a prohibition against developing a human embryo outside the body of a woman for more than 14 days; and
- a prohibition against collecting a viable human embryo from the body of a woman.

Embryo Development And Stem Cell Research

Before looking at the three main prohibitions, it is necessary to set out their scientific context in order to better understand their impact and effect.

Stem cell research has generated more excitement, scrutiny and controversy than any other recent area of scientific study. Stem cells are important both medically and scientifically because they have the ability to develop into all the different cells types found in the body. More mature cells lose this ability to some degree or completely. Due to their Protean nature, stem cells are considered to have a great deal of potential for curing various diseases and for medical research. Accordingly, research using stem cells has been a major issue that governments the world over have had to grapple with, and various countries have responded with varying degrees of prohibitions. The issue of stem cell research is raised here because, as will have been noted, the prohibitions listed above refer to a 14-day limit. This 14-day limit is critical in the issue of stem cell research.

When a sperm fertilises an egg, the resulting single cell begins to divide and multiply at a rate much faster than that observed in somatic (i.e., mature cells). Scientists refer to these cells as totipotent stem cells. These primordial embryonic cells have the potential to grow into a complete mammal. Within days of fertilisation, these new and dividing cells form a hollow sphere, called a blastocyst. Stem cells arising in the inner mass of the blastocyst are called the embryonic stem cells. These embryonic stem cells are considered pluripotent – they can divide indefinitely and blossom into all the various tissue types of the human body, but they have the lost the totipotent ability to grow into a separate being. After roughly 14 days, these embryonic stem cells divide to give rise to what will eventually develop into the spine. At this stage, the stem cells within the embryo are considered multipotent. These stem cells can grow into some tissues, but not all tissues. Those destined to become bone or blood, for example, may not be able to form stomach or skin.

It is the embryonic stem cells with their pluripotent ability that are particularly used and useful for medical and scientific research. It will be noted that these embryonic stem cells lose their pluripotent ability at about 14 days after fertilisation. Essentially, this is the 14-day period that is being referred to in the prohibitions.

Developing Human Embryos Created Other Than By Fertilisation Of A Human Egg By Human Sperm

Section 7 of the Act provides that, 'No person shall develop any human embryo, that is created by a process other than the fertilisation of a human egg by human sperm, for a period of more than 14 days, excluding any period when the development of the embryo is suspended.'

As with the human embryo clones, it is development and not creation that is prohibited. Accordingly, the Act does not prohibit human embryos from being created and developed up till the 14th day of development. The embryo thus created could be used as a reservoir of stem cells. These stem cells can be harvested from the embryo which can then be destroyed prior to the 14th day of development. As the prohibition excludes the period when the development of the embryo is suspended from the 14-day time limit, it would also allow human embryos to be created and put into storage for their subsequent development and harvesting of stem cells.

It should be noted that the prohibition here affects human embryos created by a process other than by the fertilisation of a human egg by human sperm. In other words, it deals with human embryos created by asexual means, such as by parthenogenesis, embryo splitting or somatic cell nuclear transfer. Among other things, such assexual techniques can be used to create human embryo clones. The section essentially would not prohibit the creation of human embryo clones and their development up to the 14th day, and the harvesting of stem cells from such embryos.

This is particularly significant as an important aspect of medical development and research involves the creation of stem cells from an adult’s own genetic material. As these stem cells have the identical genetic make-up of the donor, these stem cells can be used in the donor without fear of rejection by the donor’s immune system. As these stem cells can be grown into
other types of cells (for example, marrow cells) or, hopefully, even organs, research into this area holds out the promise of human transplants of organs with little or no fear of rejection by the donor’s body.

Developing Human Embryos Outside The Body Of A Woman

Section 8 of the Act provides that, ‘No person shall develop any human embryo outside the body of a woman for a period of more than 14 days, excluding any period when the development of the embryo is suspended.’

Again, the 14-day time limit should be noted, and the non-prohibition of the use of human embryos for the harvesting of stem cells has already been discussed above.

Section 8 has a clear bearing on the field of assisted reproduction – an industry which has been very profitable while at the same time helping childless couples have a baby. As the prohibition here deals with human embryos developed with any means, it would cover embryos created by the fertilisation of a human egg by human sperm, and subsequently kept in vitro (ie, outside the body of a woman). Such methods of fertilisation are commonly used in assisted reproductive technology. In practice, what this means is that human embryos created by assisted reproductive technology must be implanted, stored or allowed to die (if unsuitable for implantation or excess to the needs of the couple for whom the embryo was created) before the 14th day of their development. The impact of this should be minimal as it is standard clinical practice when assisted reproductive technology is done for embryos to be implanted when they have reached between three and seven days of development.

It should further be noted that a further impact of the Act with regards to assisted reproductive technology is the definition of sperm used in the Act. ‘Human sperm’ is defined as including human spermatids. Spermatids are one of the precursor cells of sperm and can be used in assisted reproductive treatment to create an embryo through the procedure known as intracytoplasmic sperm injection, where a man may be unable to produce functional sperm cells. Accordingly, as drafted, this clause would not prohibit a human embryo from being created by fertilising a human egg with human spermatids, and for the resulting embryo to be carried to term.

Collecting A Viable Human Embryo From The Body Of A Woman

Section 9 of the Act prohibits the removal of any human embryo from the body of a woman for the purpose of collecting a viable human embryo.

Essentially, this section prevents the removal of viable human embryos from the body of a woman after fertilisation has taken place: a practice sometimes referred to as embryo flushing. Embryo flushing is commonly used in animal husbandry, and while there have been no recent reports of it being used in humans there is a concern that a healthy human embryo could be removed from a woman’s uterus before it implants so that it could be used for research or for transfer to another woman. This clause bans such a practice.

Notably, the prohibition against collection is a blanket prohibition. Accordingly, it should be noted that human embryos created by whatever means cannot be first created, then implanted in a woman’s body, then subsequently removed for the purpose of collecting a viable human embryo. This would essentially mean that medical research and development must confine itself to creating and developing human embryos for research in vitro (ie, outside a woman’s body). In other words, once implanted in a woman’s body, the Act would require the embryo to be carried to term unless this was terminated (whether naturally or artificially).

Subsidiary Prohibited Uses Of Embryos

Supplementing the three main prohibited practices set out above, are the prohibitions of four additional practices.

Placing Of Human And Animal Embryos

The Act prohibits:

- placing a human embryo in the body of an animal (for example, using a chimpanzee to gestate a human foetus);
- placing an animal embryo in the body of a human (for example, using a human to gestate a chimpanzee foetus);
- placing a human embryo in the body of a human other than in a woman’s reproductive tract (for example, allowing a woman who has lost her uterus to gestate a child in another part of her body).

The prohibitions essentially address public concerns about the morality of allowing a human child to be gestated in anything other than a human womb, and for the human womb to be used to carry anything non-human.

Prohibited Embryos

The Act puts in place various prohibitions on the use of prohibited embryos. A prohibited embryo is essentially one that has been developed contrary to the principles of sections 7, 8 and 9 of the Act. In other words, a prohibited embryo is:
any human embryo that has been developing outside the body of a woman for a period of more than 14 days, excluding any period when the development is suspended (essentially mirroring sections 7 and 8); and

• any human embryo that was removed from the body of a woman by a person intending to collect a viable human embryo (essentially mirroring section 9).

For purposes of allowing for flexibility and advances of medical science, a ‘prohibited embryo’ will also include such other thing as may be prescribed to be a prohibited embryo for the purposes of the Act.

The Act therefore prohibits:

• placing a prohibited embryo in the body of a woman knowing that, or reckless as to whether, the embryo is a prohibited embryo;

• importing any prohibited embryo into Singapore; and

• exporting any prohibited embryo out of Singapore.

These prohibitions are essentially to prevent persons from using these methods to get around sections 7, 8 and 9 of the Act.

Trade In Eggs, Sperm And Embryos

Finally, also prohibited is the trade in human eggs, sperm and embryos which the public would generally regard as repugnant, and akin to the commercial sale of persons and babies (for example, slavery). Under the Act, both parties that are involved in commercial trading of such material would be committing an offence (for example, the person who sells the egg, sperm or embryo and the person who purchases the egg, sperm or embryo).

Accordingly, the effect of this provision on research and development based on human eggs, sperm and embryos is that companies and researchers carrying out such work would not be able to pay people in order to get them to sell their eggs or sperm for research, but would have to rely on donations. A further effect is that companies engaging in such research may have to link up with or ally with clinics that provide assisted reproduction treatment, as a by-product of such treatment is often an excess supply of eggs, sperm or embryos.

The Act does provide for some reasonable carve-outs from this prohibition:

• It would allow the reimbursement of reasonable expenses related to the supply of human eggs, sperm and embryos, including expenses incurred for the collection, storage and transport where relevant. Accordingly, if, for example, semen is transferred from one clinic to another, the second clinic could reimburse the first clinic for the costs of storage and transport of the semen.

• In further support of the industry of assisted reproduction, the Act provides that the prohibition does not cover the provision of any service for facilitating the donation and receipt of any human egg, human sperm or human embryo by receiving, storing, processing and subsequently implanting the donated human egg, human sperm or human embryo in the body of another human, whether or not for consideration.

Finally, it should be noted that this prohibition would not seem to cover the commercial sale of stem cells. Accordingly, it would seem to allow for stem cells to be created and harvested in Singapore, and then sold to laboratories both within this country, and possibly outside of Singapore as well.
Prohibitions Not Included

For a fuller picture, it is perhaps useful to consider various matters dealt with in the legislation of other countries that the Act is silent about and which are therefore not prohibited in Singapore. In this regard, we have already dealt with the fact that the creation of human embryos for research by various methods is not prohibited (as opposed to their development beyond 14 days). This is, of course, part of the government’s already stated initiative to allow stem cell research in Singapore.

In addition to the prohibitions currently contained in the Act, the Australian Act also prohibits various other practices, which prohibitions have not been carried over into our Act.

Creating A Human Embryo With The Genetic Material Of More Than Two Persons

Under the Australian Act, a person commits an offence if the person intentionally creates or develops a human embryo containing genetic material provided by more than 2 persons. This section strikes at, among other things, a fairly experimental procedure of assisted reproduction known as cytoplasmic transfer.

Cytoplasmic transfer involves the injection of some of the cytoplasm (the part of the cell outside the nucleus) from a healthy, donor egg into a recipient patient’s egg, with the aim of overcoming certain problems that the patient has with regards to achieving pregnancy. In particular, various scientists consider this procedure as being particularly valuable to older women to assist them to become pregnant. Both safety and ethical concerns have been raised regarding cytoplasmic transfer. Additionally, any live child born may have DNA from three separate people, posing ethical concerns. The DNA from the third party (the donor of the healthy egg) would be mitochondrial DNA, which is thought not to have an impact on the physical characteristics of the child. However, the impact (if any) of the third party mitochondrial DNA on normal development is currently not totally clear.

As cytoplasmic transfer would still involve the fertilisation of the egg with human sperm, the development of the foetus to full term within the body of a woman would be permitted under the Act.

Use Of Precursor Cells Taken From A Human Embryo Or Foetus

The Australian Act also prohibits taking precursor cells from a human embryo or a human foetus, intending to create a human embryo. It also prohibits intentionally developing an embryo so created.

Precursor cells are cells taken from another human embryo or foetus that have the potential to develop into egg or sperm cells. In Australia, the purpose of this prohibition was to prevent individuals from obtaining precursor cells and using these cells in an attempt to develop a human embryo whether for reproductive or any other purposes. The reason for this practice being prohibited in Australia was the fear that if precursor cells were to be used in such an attempt, then children could potentially be born (using ova and / or sperm derived from a foetus or embryo) never having had a living genetic parent.

Insofar as this technique would involve taking precursor cells to develop ova and sperm, which would then be used to fertilise each other and create an embryo, it would be permitted under the Act. In addition, as noted above under ‘Developing Human Embryos Outside The Body Of A Woman’, the definition of ‘sperm’ under the Act includes spermatids, which are the precursor cells of sperm. Hence, the use of such precursor cells to fertilise a human egg and to thus create a human embryo which could then be carried to term would not be prohibited.

Alteration Of The Human Genome

It is also an offence under the Australian Act for a person:

• to alter the genome of a human cell in such a way that the alteration is heritable by descendants of the human whose cell was altered; and

• in altering the genome, the person intended the alteration to be heritable by descendants of the human whose cell was altered.

This prohibition outlaws any manipulation of a human genome that is intended to be heritable, that is, able to be passed on to subsequent generations of humans. It essentially bans what is commonly referred to as germ line gene therapy. In germ line gene therapy, changes would be made to the genome of egg or sperm cells, or even to the cells of the early embryo. The genetic modification would then be passed on to any offspring born to the person whose cell was genetically modified and also to subsequent generations. Such therapy is considered to have potential use in assisting couples who have potential genetic diseases to conceive a healthy child free from such a disease. Of course, it also carries with it the spectre of eugenics.

Creation Of Chimeric Embryos

Finally, the Australian Act also bans the intentional creation of a chimeric embryo. In brief, the Australian Act essentially disallows the creation of an embryo which mixes human and animal genetic
material or components. This creation would not be prohibited under our Act. However, its omission from our legalisation is likely not very far-reaching, as, insofar as any such creation would not likely involve the fertilisation of a human egg by human sperm (hence, not falling under the carve-out to section 7 of the Act), any chimeric embryo created would not be allowed to develop beyond the 14-day time limit imposed under section 7 of the Act.

Penalties And Enforcement

Enforcement of the Act will come under the purview of the Director of Medical Services (‘Director’). In allowing the Director to enforce the Act, he has been given extensive investigative powers, and an enforcement officer appointed by the Director may at any time and without warrant, enter, inspect and search any premises and the facilities therein that are being used, or that he has reasonable cause to believe are being used, for any prohibited practice.

These investigatory powers are backed by a statutory bite as any person who:

- refuses or fails, without reasonable excuse, to comply with any requirement of an enforcement officer;
- gives any false or misleading information when required to furnish any information to an enforcement officer; or
- obstructs, or impedes an enforcement officer in the performance or execution of his duty,

is guilty of an offence and is liable on conviction to a fine not exceeding S$5,000 or to imprisonment for a term not exceeding 12 months or to both.

Finally, a contravention of the various prohibitions contained in the Act as discussed above carry heavy penalties. An offender can be jailed for up to 10 years, fined up to S$100,000, or face both a prison sentence and a fine.

Conclusion

It will be seen that the Act seeks to strike a fine balance between what the public finds morally acceptable and the countervailing needs of advancing medical science and treatment, and developing Singapore’s position as a hub of medical research and development, as well as a centre for assisted reproductive therapy. In its approach, the Act has adopted a more liberal attitude than that shown in some other countries (notably the United States).