Human embryo cloning prohibited in Hong Kong

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Since the birth of Dolly (the cloned sheep) in 1997, debates have arisen on the ethical and legal questions of cloning-for-biomedical-research (more commonly termed “therapeutic cloning”) and of reproductive cloning using human gametes. Hong Kong enacted the Human Reproductive Technology Ordinance (Cap 561) in 2000. Section 15(1)(e) of this Ordinance prohibits the “replacing of the nucleus of a cell of an embryo with a nucleus taken from any other cell,” i.e., nucleus substitution. Section 15(1)(f) prohibits the cloning of any embryo. The scope of the latter, therefore, is arguably the widest, prohibiting all cloning techniques such as cell nucleus replacement, embryo splitting, parthenogenesis, and cloning using stem cell lines. Although the Human Reproductive Technology Ordinance is not yet fully operative, this article examines how these prohibitions may adversely impact on basic research and the vision of the Hong Kong scientific community. It concludes that in light of recent scientific developments, it is time to review if the law offers a coherent set of policies in this area.

KEY WORDS: Cloning; CNR; Dolly; embryos; fertilization; Hong Kong; parthenogenesis; *quintavalle*.

INTRODUCTION

The idea of Hong Kong as the biotechnological center of the region has been much discussed. The Medical Faculty of the University of Hong Kong aspires to build “world medicine” and to develop Hong Kong as the “biomedical capital” of Asia (1). The appointment of the University of Hong Kong’s Vice-Chancellor, Professor Tsui Lap-chee, an internationally renowned geneticist, and the establishment of the Genome Research Centre (1), the Biomedical Engineering Center, and the Centre of Human Reproduction all point to the same vision.

Cloning, an important activity in the life sciences and biotechnology, is not a recent endeavor. Cloning (and genetic engineering) has long been part of the agricultural and food industry, for crops and animal improvement, pest control, and the conservation of rare species. It has also been part of the biopharmaceutical industry (2,3). Recent interest (4) in cloning began when Ian Wilmut, an English embryologist,

successfully cloned Dolly the sheep (5).² The technique used to create Dolly is a form of asexual reproduction (or cloning) and it is very different from human sexual reproduction. As can be seen in Fig. 1 (below), it involves the removal of the nucleus of an egg and its replacement with the nucleus of a somatic (body) cell. Using an electric current, the somatic cell and the nucleus are fused and this “reconstructed” egg commences cell division. The product, Dolly, is almost genetically identical to that of the nucleus donor. Today, this cloning technique is variously referred to as somatic cell nucleus transfer (SCNT), cell nucleus replacement (CNR), the Dolly technique, or nucleus substitution into an egg. In this paper, I shall refer to this technique as cloning or CNR. In cloning Dolly, Ian Wilmut’s aim was to produce genetically altered animals for the “pharming” industry rather than to clone human beings (6,7). Nevertheless, the creation of Dolly has triggered much debate about cloning humans and the use of cloned human embryos in biomedical research.

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² Since Dolly, other cloned animals include cow (Ming Pao, Feb 28, 2003) and cat (Ming Pao, Jan 23, 2003).

Fig. 1. Stages of human fertilization and cloning. Reproduced from Human Cloning and Human Dignity, the Report of the President's Council on Bioethics, PublicAffairs, USA, 2002, p 68.

Today, many are familiar with two types of cloning (classifications based on the motives for cloning): reproductive cloning and cloning-for-biomedical-research (or "therapeutic cloning") (8,9). Reproductive cloning refers to the use of cloning technology with a view to producing a child, and this necessarily involves the implantation of a cloned embryo into a woman's womb.

Cloning-for-biomedical-research refers to the use of cloning techniques to create embryos, not with a view to creating a child, but for purposes of extracting³ embryonic stem cells for research. The aim is to understand the causes of disease, and ultimately, to develop cell-based therapy. To that extent, stem cell research holds promises for the future of medicine and as such cloned human embryos may become invaluable research tools (10,11). However, as it has been rightly pointed out, there is nothing "therapeutic" about this type of cloning, either to the entity created or any existing individual. The therapeutic aspect of this type of cloning refers to the potential

it holds for future medical treatment, but not the research itself. To avoid any possible confusion, this paper will adopt the terminology used by the President's Council on Bioethics and describe this type of cloning as cloning-for-biomedical-research (4,12).

The reasons for, and the arguments both for and against, reproductive cloning have been debated at length elsewhere and will not be repeated at length here (4,8,13,14). In brief, it has been said that reproductive cloning may be used to produce biologically-related offspring, to avoid genetic diseases, to obtain compatible tissue for transplant, to reproduce a duplicate copy of a descendent, loved one or an individual with desirable traits. The arguments for reproductive cloning are that individuals ought to be free to fulfill their desire to have biologically-related or healthy offspring so long as there is no harm to others. The arguments against reproductive cloning are that the right to have children does not extend to the right to have children by whatever means, and this right is limited by the need to protect the interests of the cloned child, family, and society. As reproductive cloning carries the risk of deformity to the cloned child and birth mother, it amounts to

³ The embryos die as a result.

an unethical experiment. Dolly was a good example showing the concomitant risks in cloning: she was produced after 277 embryos were used, of these 29 were implanted into recipient ewes and only one developed into a live lamb. Similar experiments in humans would be totally unacceptable (4). Other arguments against reproductive cloning are that it would amount to an experiment in:

- human reproduction (it treats a child not as a gift but as a design product);
- human identity (it involves creating an individual to inherit a genetic identity lived in advance by another);
- genetic choice and design (it involves producing a child whose genetic make-up has been preselected); and
- family and social life (it alters relations within the family and between generations, thus, a mother is also a twin sister and a grandparent is also a parent to an offspring, and that child may be biologically linked to only one parent).

Opponents of reproductive cloning argue that all these experiments are unacceptable and a ban on reproductive cloning needs to be absolute and permanent in nature. From a legal point of view, there is now a general consensus that reproductive cloning is unacceptable (11,15). At the international level, Article 11 of the Universal Declaration on the Human Genome and Human Rights stipulates that:

Practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted.

At the regional level, Article 1(1) of the European Convention on Human Rights and Biomedicine (16,17), Additional Protocol on the Prohibition of Cloning Human Beings stipulates that:

Any intervention seeking to create a human being genetically identical⁴ to another human being, whether living or dead, is prohibited.

The United Kingdom, as well as other jurisdictions,⁵ has enacted the Human Reproductive Cloning Act

2001 (9) which makes it a criminal offence for a person to “place in a woman a human embryo which has been created otherwise than by fertilization.”

Although there is a general consensus against reproductive cloning, debates concerning cloning-for-biomedical-research continue. This article examines the prohibited activities related to human embryos, especially cloning, by the Hong Kong Human Reproductive Technology Ordinance (HRTTO). Although the HRTTO is not yet in force, it is important to anticipate what the various prohibitions mean. The HRTTO shares some important features with the United Kingdom Human Fertilization and Embryology Act 1990 (HFE Act); and the HFE Act will be discussed, where relevant, to assist in interpreting the HRTTO. More importantly, the English House of Lords’ decision in *R v Secretary of State for Health ex parte Quintavalle* (hereafter referred to as *Quintavalle*)⁶ has held that “embryo” in the HFE Act covers the product of CNR. The impact of *Quintavalle* on interpreting the HRTTO will be considered. This article concludes that many of the restrictions in HRTTO are falling behind rapid scientific developments. They no longer form a coherent set of policies. If Hong Kong is serious about becoming the biotechnological or biomedical center of Asia, the law needs to be reviewed.

HUMAN REPRODUCTIVE TECHNOLOGY ORDINANCE (Cap 561)

Back in 1987, the Hong Kong government set up a committee on Scientifically Assisted Human Reproduction. The committee examined the social, moral, ethical, and legal implications of human reproductive technology. Its final report, containing 22 recommendations, was presented to the Executive Council in October 1992 (18). In 1995, a Provisional Council on Reproductive Technology was set up to advise on the regulatory framework for reproductive technology. A Working Group on Reproductive Technology Bill was tasked with scrutinizing the proposed legislation. The Human Reproductive Technology Bill was gazetted on Jan 3, 1997 (18) and enacted in June 2000.

Like the HFE Act, the Human Reproductive Technology Ordinance (HRTTO) represents a comprehensive piece of legislation regulating

⁴ Article 1(2) goes on to define genetically identical to mean “sharing with another the same nuclear gene set.”

⁵ Similar legislation includes the Human Cloning and Other Prohibited Practices Act (2004) Singapore; s21 of the Prohibition of Human Cloning Act 2002, Commonwealth of Australia, makes it an offence to place a human embryo into other than in a woman’s reproductive tract.

⁶ [2003] UKHL 13.

reproductive technology procedures, the use for research and other purposes, of embryos and gametes.⁷ However, as various subsidiary legislation supporting the HRTTO is still being drafted, the bulk of the HRTTO (including the prohibited activities regarding embryos to be discussed below) is likely to become operational only in 2006.⁸ In this paper, I shall, however, examine the law as if the whole of the HRTTO is in force now.

Prohibited Activities Regarding Embryos and Gametes

Section 15(1) of the HRTTO contains a number of prohibitions regarding embryos. It provides that

No person shall –

- (a) for the purposes of embryo research –
 - (i) bring about the creation of an embryo; or
 - (ii) combine human and nonhuman gametes or embryo or any part thereof such as to give rise to a 2-cell zygote;
- (b) keep or use an embryo after the appearance of the primitive streak;⁹
- (c) place any nonhuman gametes or embryo or any party thereof in any human;
- (d) place any human gametes or embryo or any party thereof in any animal;
- (e) replace the nucleus of a cell of an embryo with a nucleus taken from any other cell; or
- (f) clone any embryo.¹⁰

The prohibition in section 15(1)(a) relates to embryo research only, whereas all the other prohibitions in

(b)–(f) are general in nature. Section 15(1)(a)(i) prohibits the creation of embryos for research, and section 15(1)(a)(ii) prohibits, for the purposes of embryo research, the mixing of human and nonhuman gametes or embryos such as to give rise to a 2-cell zygote. This prohibits cross-fertilization and the creation of hybrid or chimeric embryos. Although the HRTTO does not use the terms hybrid or chimeric embryos, a hybrid embryo refers to an embryo created as a result of fertilization of a human egg by animal sperm or animal egg by human sperm.¹¹ A chimeric embryo refers to a human embryo into which a cell, or any part of a cell, of an animal has been introduced.¹² The prohibition to cross-fertilization is limited to the creation of a 2-cell zygote. Thus, the mixing or combining of gametes from different species per se is not prohibited if it does not involve the creation of a 2-cell zygote. The “hamster egg penetration test” used in infertility treatments is an example. This is a functional test on human sperm by mixing it with the eggs of a hamster for testing the fertility or normality of the sperm. This is not prohibited so long as it is done pursuant of a license and anything which is formed must be destroyed not later than the 2-cell stage.¹³ Section 15(1)(b) prohibits the development of an embryo outside the human body for more than 14 days. Thus, embryos created for assisted reproduction must be implanted, stored,¹⁴ or allowed to die before the 14th day of their development. Section 15(1)(c) and (d) prohibit the placing of any nonhuman gametes or embryos into any human, or vice versa (that is, the placing of any human gametes or embryo into any animal). This will be discussed again later. Section 15(1)(e) prohibits the “replacing of the nucleus of a cell of an embryo with a nucleus taken from any other cell,” that is, nucleus substitution into an embryo. Section 15(1)(f) prohibits the cloning of any embryo.

Amongst all these prohibitions, sections 15(1)(a)(i), 15(1)(e), and 15(1)(f) are directly relevant to cloning and will be discussed in detail below.

⁷ See the Hong Kong Legislative Council Brief on the Human Reproductive Technology Bill, HWB/M/39/1 pt.9 96. One of the legislative proposals was that “embryo research should be subjected to control. Creation of embryos for the purposes of research, embryo research after the fourteenth day of fertilization, cross-species fertilization, and cloning of embryo should be prohibited.”

⁸ As of today, only Parts I and II and Schedule 1 of the HRTTO are in force.

⁹ That is, beyond 14 days.

¹⁰ HFEA, S3 provides:

(1) “No person shall –
 (a) bring about the creation of an embryo, or
 (b) keep or use an embryo, except in pursuance of a licence.
 (2) No person shall place in a woman –
 (a) a live embryo other than a human embryo, or
 (b) any live gametes other than human gametes. (3) A licence cannot authorize –
 (a) keeping or using an embryo after the appearance of the primitive streak,
 (b) placing an embryo in any animal,
 (c) keeping or using an embryo in any circumstances in which regulations prohibit its keeping or using, or
 (d) replacing a nucleus of a cell of an embryo with a nucleus taken from a cell of any person’s embryo or subsequent development of an embryo.”

¹¹ This has happened in animals, e.g., a mule is a cross fertilization between a female horse and a male donkey.

¹² This has happened in animals, e.g., a geep which is a sheep–goat chimera. For a similar reference to hybrid and chimeric embryo, see s20 of the Prohibition of Human Cloning Act 2002, Commonwealth of Australia.

¹³ This test is also allowed in the UK by virtue of Schedule 2 para (1)(f) and Schedule 2 para (3)(5) of the HFEA 1990, provided that it is done pursuant of a license and anything, which forms, must be destroyed not later than the 2-cell stage.

¹⁴ Time in storage is not counted, see s15(4) of the HRTTO.

Meaning of an Embryo

The HRTTO and the HFE Act share a common definition on embryos. Section 2(7) of the HRTTO defines an embryo as follows:

In this Ordinance, except where otherwise stated –

- (a) embryo means a live human embryo where fertilization is complete; and
- (b) references to an embryo include an egg in the process of fertilization, and, for this purpose, fertilization is not complete until the appearance of a 2-cell zygote.

At first glance, this definition coincides with our traditional understanding of human biology, that is, an embryo is a product of fertilization, and fertilization is a process covering a span of time beginning with the sperm meeting an egg and ending with the fusion of the sperm and egg. A careful reading reveals that the definition is not useful; it defines an embryo as “embryo.” This tautology is coupled with a contradiction—in that an embryo is an entity where “fertilization is complete” as well as an egg “in the process of fertilization.”¹⁵

Quintavalle: CNR Creates an Embryo At the heart of the debate in *Quintavalle* is whether the product of CNR is an embryo and comes within the regulatory regime of the HFE Act. For some, the reference to fertilization in this definition clearly rules this out. As Margaret Brazier said:

Consider the analogy of plant production. You can reproduce your favorite rose in two ways. Ensure pollination and the creation of seeds resulting in a new rose, and you have a rose resulting from fertilization. Take a cutting of that rose, root it in compost, and once again you have a new rose. But your second rose is genetically identical to its original and created by propagation not fertilization (19).

The applicant in *Quintavalle*, a Pro-life Alliance, argued that the HFE Authority, a statutory authority tasked, inter alia, with granting licenses for embryo research, did not have the power to grant a license for CNR. Furthermore, even if it had the power, it was prohibited by section 3(3)(d)¹⁶ which manifested the HFE Act's policy against cloning.

The House of Lords held against the applicant on both arguments.¹⁷ Noting that CNR was not contemplated by Parliament at the time of the passage of the HFE Act, and taking a purposive approach to interpretation, the House of Lords held that the product of CNR is an embryo within the ambit of the HFE Act. On the scientific process involved in fertilization and CNR, Lord Bingham summarized as follows:

In the ovary the egg is a diploid germ (or reproductive) cell. It is described as “diploid” because its nucleus contains a full set of 46 chromosomes. By the process of meiotic division the nucleus divides into two parts. Only one of these, a pronucleus containing only 23 chromosomes (described as “haploid”) plays any further part in the process. Fertilization begins with the male germ cell, the sperm, whose pronucleus contains 23 chromosomes, meets the haploid female germ cell and is a continuous process taking up to 24 hours. As part of the process the male and female pronuclei fuse to form one nucleus with a full complement of 46 chromosomes, a process known as syngamy. The one-cell structure that exists following syngamy is the zygote. After several hours the cell divides to create a 2 cell zygote. At this stage it is generally referred to as an embryo ... CNR is a process by which the nucleus, which is a diploid, from one cell is transplanted into an unfertilized egg, from which ... the nucleus has been removed. The [replacement] nucleus is derived from either an embryonic or a foetal or an adult cell. The cell is then treated to encourage it to grow and divide, forming first a two-cell structure and then developing in a similar way to an ordinary embryo ... The famous Dolly the sheep was produced by CNR. Live young have since been produced by CNR in some other mammals. It has not yet been attempted in humans. ... CNR of the kind under consideration does not involve fertilization.¹⁸

As Lord Bingham put it, the only relevant difference between a fertilized and a cloned embryo is that:

... the CNR embryo, if allowed to develop, will grow into a clone of the donor of the replacement nucleus which the embryo produced by fertilization will not.¹⁹

Lord Bingham was sympathetic to the difficulty of legislating against a background of fast-moving medical and scientific development. He

¹⁵ Lord Millett said that the “vagaries of the Parliamentary process” partly explains the seemingly contradictory provisions, [2003] UKHL 13, para 48.

¹⁶ See Footnote 10.

¹⁷ For an analysis of both the High Court and the Court of Appeal ruling, see (20)

¹⁸ [2003] UKHL 13, para 2.

¹⁹ [2003] UKHL 13, para 15.

said:

It is not often that Parliament has to frame legislation apt to apply to developments at the advanced cutting edge of science.²⁰

He concluded that the words, “where fertilization is complete” are not intended to form an integral part of the definition of embryo. What qualifies an embryo for protection within the HFE Act is “live” and “human” with the potential to develop into a human being. Lord Steyn, having examined the purpose of the HFE Act, concluded that the words “where fertilization is complete” is merely illustrative of the legislative purpose. Alternatively, he was willing to read into the definition a phrase, that is, embryo as “a live human embryo where [if it is produced by fertilization] fertilization is complete.”²¹ For Lord Millet, the phrase “where fertilization is complete” does not form part of the definition of the word embryo. It merely indicates the stage of development that an embryo must reach before it qualifies for protection. Once the organism produced by CNR has reached the 2-cell stage, it is an embryo “in every sense of that term.”²²

Quintavalle: Nucleus Substitution into an Embryo, CNR, Embryo Splitting, Parthenogenesis, and Cloning Using Stem Cell Lines *Quintavalle* held that a product of CNR is an embryo. It also held that CNR is not prohibited by section 3(3)(d) of the HFE Act and that section 3(3)(d) prohibits only nucleus substitution into an embryo. The applicant argued that, if the HFEA prohibited one form of cloning, namely, nucleus substitution into an embryo, it had manifested its intention to ban all other forms of cloning, including CNR.²³ This argument, however, was not accepted. The House of Lords held that the HFE Act bans only one form of cloning and that embryo splitting—by a microsurgical method which produces an exact copy of an embryo (hence identical twins)—a known technique at the time of the passage of the HFE Act, is not prohibited.

Today the HFE Act does not prohibit the creation of embryo for research. Consequently, it is permissible to create an embryo either by way of fertilization, CNR, or embryo splitting for research, although both the creation and research require a license.

Indeed, a license has been granted for using CNR in research.²⁴ Although it was not stated explicitly, the *Quintavalle* decision means that parthenogenesis (or “virgin birth,” see Fig. 2) is also not prohibited. Parthenogenesis is where an egg is triggered to commence differentiation by means of a variety of stimuli but in the absence of sperm (23). According to *Quintavalle*, a parthenogenetic oocyte, with the potential to develop into a 2-cell stage, is an embryo.²⁵ Furthermore, CNR could, in theory, also be applied to any cell nucleus including those of stem cells (16), and effectively, stem cell lines could potentially be used to generate embryos for research.

Back to Embryo in HERTO

Section 2(7) of the HERTO raises exactly the same question as that in *Quintavalle*. Section 2(7) clearly contemplates an embryo being a product of fertilization only. So construed, the HERTO becomes ineffective in regulating embryo research. Thus, embryos created by fertilization for research would be prohibited by section 15(a)(i), but cloned embryos would not come within the same provision (although it may be caught by section 15(1)(f), see the discussion below). More importantly, the mixing of human and nonhuman gametes or embryos, for the purposes of embryo research, such as to give rise to a 2-cell zygote would be prohibited by section 15(1)(a)(ii) only if the 2-cell zygote results from fertilization, but not if there is no fertilization. Another example would be that CNR products could be kept for more than 14 days, as they would be outside the prohibition in 15(1)(b). Further section 2(7) and section 15(1)(f) cannot be reconciled; the former talks about fertilization, whereas the latter envisages embryos created

²⁴ The HFE Authority has granted the first cloning-for-biomedical-research license in 2004, see www.hfea.gov.uk/PressOffice/Archive/1092233888.

²⁵ The Infertility Treatment Act 1995 (Victoria, Australia) expressly prohibits this procedure. S48 of this Act bans certain experimental procedures. One such prohibited experimental procedure is “the transfer of a parthenogenetic oocyte or parthenogene to the body of a person or an animal.” “Parthenogenetic oocyte” is defined to mean “an oocyte in which parthenogenesis has occurred or is occurring” and, in turn, “parthenogenesis” is defined to mean “cell division in an oocyte which only involves the chromosomes of an oocyte,” and, in turn, “oocyte” is defined to mean “an ovum from a woman but does not include a parthenogenetic oocyte.” Although parthenogenesis was mentioned in the UK “Report of the Committee of Inquiry into Fertilization and Embryology,” Cm 9314, HMSO, 1984 (the Warnock Report), it is not prohibited by HFEA.

²⁰ [2003] UKHL 13, para 12.

²¹ [2003] UKHL 13, para 26, see also (21,22)

²² [2003] UKHL 13, paras 43–46.

²³ [2003] UKHL 13, Lord Bingham, para 18.

Fig. 2. Stages of parthenogenesis. Reproduced from the President's Council on Bioethics, p 68.

via cloning, although the latter arguably could be accommodated by "except where otherwise stated"²⁶ in which case the protection to be offered to such an embryo needs to be addressed.

Assuming that the HRTTO did not prohibit embryo cloning—that is, if section 15(1)(f) is omitted—the meaning of an "embryo" still needs to be addressed in light of CNR. Arguably, a contemporary meaning is now provided by the *Quintavalle* decision. Following the *Quintavalle* decision means that all embryos, fertilized or cloned, are within section 2(7). Consequently, all forms of cloning techniques for creating embryos, even unknown at the time of the passage of the HRTTO, are prohibited by section 15(1)(a)(i). This would render section 15(1)(f) almost obsolete.

The *Quintavalle* decision, however, does not address the question that arises in the context of the HRTTO; that is, whether the word "embryo," in section 15(1)(f), should be read as "clone" or "the cloned." The ordinary and literal meaning of the word "clone," used as a verb in section 15(1)(f), refers to "propagate as a clone" or "to reproduce asexually. (4)" Section 15(1)(f) does not limit cloning to any specific technique. "Cloned," as a noun, refers to the original from which an identical copy is made, whereas a "clone," as a noun, refers to the duplicate of the original. Depending on the meaning adopted, the prohibition in section 15(1)(f) may read either: no person shall propagate an existing embryo (the cloned); or no person shall propagate such as to create an embryo (the clone).

Embryo as "the Cloned"

If "embryo" in section 15(1)(f) is read as "the cloned," it prohibits embryo splitting only. This reading is consistent with the historical background of the HRTTO. Although the Human Reproductive Technology Bill was first gazetted in 1997, the draft of that bill, with the same provision (as section 15(1)(f)), was examined by the Working Group on Reproductive Technology in late 1995. Cloning as a technique then known to the general scientific community as well as to the popular press was embryo splitting, not CNR. Consequently, CNR could not have been contemplated.

Other legislation sharing a similar legislative timeframe as the HRTTO also prohibits cloning, and cloning is defined to mean, inter alia, embryo splitting. For instance, section 3 of the Infertility Treatment Act 1995 (Victoria, Australia) states that:

clone means to form, outside the human body, a human embryo that is *genetically identical to another human embryo* or person.²⁷

More clearly expressed is the Reproductive Technology (Code of Ethical Research Practice) Regulations 1995 (South Australia),²⁸ in which rule 2 states that cloning means:

any procedure directed at producing two or more *genetically identical embryos from the division of one embryo*.

²⁶ s2(7) of the HRTTO.

²⁷ s47 of the Infertility Treatment Act 1995 (Victoria, Australia) provides that, "A person must not carry out or attempt to carry out cloning."

²⁸ s6 of the Reproductive Technology (Code of Ethical Research Practice) Regulations 1995 (South Australia) also prohibits cloning.

Rule 2 specifically identifies the cloned as an embryo and the clone as another embryo, and hence is restricted to embryo splitting.

A search of the *Hong Kong Hansard* shows that there was no discussion concerning section 15(1)(f).²⁹ It could be argued that section 15(1)(e) prohibits nucleus substitution into an embryo (which is a form of cloning), section 15(1)(f) merely prohibits another form, that is, embryo splitting.³⁰

Embryo as "the Clone"

If, however, the word embryo refers to "the clone," it means that the precise nature of the original copy is irrelevant. The prohibited activity, in section 15(1)(f), is focused on what is being produced. As it was said in *Quintavalle*, embryo means "live" and "human" with the potential to develop into a human. Once the organism produced by CNR has reached the 2-cell stage, it is an embryo "in every sense of that term."³¹ Construing embryo as the end product is consistent with the purpose of the legislation in protecting and regulating the use of an embryo. The prohibition on cloning, consequently, transcends the techniques to be developed from time to time. This outcome, however, put strain on the definition of embryos in section 2(7), which was passed in 2000 when CNR was a well-known technique. It is difficult to argue that a definition that clearly excludes it will now be interpreted to cover it.

CONCLUSIONS

This paper has highlighted the internal inconsistencies and contradictions in section 2(7) and section 15(1) of the HRTTO. Although most of the HRTTO is not yet in force, it is important that legislative prohibitions are clear.

What is necessary by way of reviewing the law is that, first, the definition of "embryo" in

section 2(7) needs to be updated in light of CNR. Second, although the word "embryo" in section 15(1)(f) could be read either as "the cloned" or "clone," it could be read as both, giving section 15(1)(f) the widest possible scope, transcending any particular cloning technique. This, together with an updating of the definition of embryo, resolves any apparent conflict between sections 2(7) and 15(1)(f). However, it will render the six words in section 15(1)(f) virtually redundant; hence, what is prohibited by section 15(1)(f) overlaps with that in section 15(1)(a)(i). Section 15(1)(f) remains useful only to catch embryo creation for purposes other than embryo research.

Third, whether the prohibition of all forms of cloning for research is a policy which should be adhered to today is a matter requiring further discussion in light of (a) scientific developments over the last decade and (b) the vision of Hong Kong being the biotechnological center of Asia. As it has been discussed at the beginning of this article, there is a consensus that reproductive cloning should not be permitted. Section 15, despite its extensive prohibition relating to embryos, however, has yet to address this issue. Thus, the *placing* of a cloned embryo, using a woman's egg and the cell nucleus of the cloned individual, created probably in breach of s15(1)(f), into a woman is not prohibited. Further, one may recall that section 15(1)(a)(ii) prohibits cross-fertilization (and possibly cloning) between human and nonhuman gametes. But what is interesting is that section 15(1)(c) prohibits the *placing* of "any nonhuman gametes or embryo or any party thereof in any human" and the *placing* of "any human gametes or embryo or any party thereof in any animal." It remains to be seen whether such a cloned embryo, e.g., using the nucleus from a human cell and an animal oocyte, is deemed to be a "human" or "nonhuman" embryo. If it is deemed to be human, it could be placed in a human, but not in any animal. If it is deemed to be nonhuman, it could be placed in an animal, but not in any human. Surely such a cloned embryo should not be placed in either a human or an animal!

Fourth, despite section 15(1) prohibiting the creation of an embryo for embryo research, the HRTTO defines "embryo research" to include the very activity it prohibits; section 2 provides that "embryo research" "means any research involving the creation, use or manipulation of any embryo." A reconciliation of this major inconsistency is needed.

²⁹ See the discussions in the Bills Committee on the Human Reproductive Technology Bill (www.legco.gov.hk); see also the second reading at the Legislative Council, www.info.gov.hk/gia/general/199809/09/0909174.htm.

³⁰ The prohibitions of embryo splitting may sound curious as there may be medical reasons why it may be considered appropriate as part of infertility treatment. For instance, a wife undergoing IVF may avoid undergoing several attempts at egg retrieval. Additionally, artificial production of identical twins does not necessarily raise any of the objections associated with reproductive cloning.

³¹ [2003] UKHL 13, para 43.

Finally, although the creation of an embryo for research is prohibited, embryo research may continue on unused embryos (left behind by couples receiving infertility treatment). Such research falls within the regulatory framework of the HRTTO, and consequently a license is required. The HRTTO regulates the use of embryos, including the extraction of stem cells from an embryo.³² However, once the stem cells have been extracted, any research done on those stem cells are no longer regulated because such research is not "embryo research." Similarly, there is no law governing embryonic stem cell research if the stem cells are imported (24). To complicate the issue further, if importation is to be regulated, the question is whether such regulation should affirm the current HRTTO's policy which prohibits embryo creation for research; thus requiring the prohibition of importation except those extracted from unused embryos only (25).

This is where the law falls behind much of the debates engendered by rapid scientific development (26). In the 13 years between the work of the committee on Scientifically Assisted Human Reproduction in 1987 and the enactment of the HRTTO in 2000, reproductive cloning and cloning-for-biomedical-research was not formally discussed. Consequently, there appears to be no clear policy in the HRTTO for these subjects. Section 5(1) of the HRTTO provides that the Council on Human Reproductive Technology shall, *inter alia*, keep under review information about embryo research and advise the Secretary for Health and Welfare. It is time that cloning and stem cell research be reviewed in Hong Kong. Such a review should not be limited to the use of embryos; it should also be broadened to cover the use of fetal or other bodily tissues or materials.³³ If Hong Kong is to become the biotechnological center of the region, a clear set of rules needs to be in place guiding the conduct of proper scientific research in this fast advancing field. Further, the rationale behind

the current cloning prohibition needs to be reviewed well before the long awaited HRTTO comes into force.

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³² See s2 of the HRTTO: extracting stem cells from an embryo involves "use or manipulation of" an embryo.

³³ Under the HRTTO, there is a prohibition relating to using of fetal tissues for infertility treatment, but not for research. S15(2) of the HRTTO provides that "no person shall, for the purposes of a reproductive technology procedure, keep or use any fetal ovarian, or fetal testicular, tissue." Thus, the use of fetal tissues for embryo germ cells or the use of adult stem cells for research is not regulated. See "Stem-cell Research Team Shows World the Way" *South China Morning Post*, May 22, 2005; "Stem-cell Transplants Bring Hope to Patients" *South China Morning Post*, Dec 13, 2004; "How Pioneering Stem Cell Therapy Changed the Lives of Grateful Patients" *South China Morning Post*, Jan 4, 2003.

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