What exactly is an exact copy? And why it matters when trying to ban human reproductive cloning in Australia

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This paper examines the current Australian regulatory response to human reproductive cloning. The central consideration is the capacity of the current regulatory regime to effectively deter human cloning efforts. A legislative prohibition on human cloning must be both effective and clear enough to allow researchers to know what practices are acceptable.

This paper asks whether the current Australian regime evinces these qualities and suggests that Australia should follow the example set in the UK by the enactment of the Human Reproductive Cloning Act 2001.

Cloning is a subject which both fascinates and frightens. The prospect of cloning humans, however, has created most controversy and debate in recent years. The idea that humans can exercise such precise control over their own reproductive processes evokes, in many, notions such as genetic determinism or the commodification of life. Unlike many other areas of reproductive technology and indeed biotechnology, the practice has been near unanimously condemned by the scientific, medical, ethical, and general communities.

Yet, in many cases, such public sentiment has yet to translate into comprehensive regulatory outcomes. One of the primary reasons for this is the practical difficulty regulators have in designing laws capable of the requisite flexibility to control advancing technology. The momentum and pace at which biotechnology has moved over the last decade have left many legislators unprepared, off guard, and vulnerable.

This paper examines the current Australian regulatory response to human reproductive cloning. The central consideration is the capacity of the current regulatory regime to effectively deter human cloning efforts. A legislative prohibition on human cloning must be both effective and clear enough to allow researchers to know what practices are acceptable. This paper asks whether the current Australian regime evinces these qualities and suggests that Australia should follow the example set in the UK by the enactment of the Human Reproductive Cloning Act 2001.

HUMAN CLONING: AUSTRALIAN AND INTERNATIONAL REACTIONS

The idea of producing children who are exact replicas of living (or deceased) people has received near unanimous condemnation by the world community. The UNESCO Declaration on the Human Genome and Human Rights 1997 states that “practices such as reproductive cloning of human beings shall not be permitted.” The document has been signed by 186 nations, reflecting international consensus on many ethical issues in the application of biotechnology to humans. Human cloning remains the only technology which the document expressly prohibits outright and without reservation. The world’s major religions have also voiced their objection to the practice.

The Australian position reflects the international stance. At the Council of Australian Governments’ meeting in June 2001, all heads of government agreed that cloning should be prohibited. The House Standing Committee on Legal and Constitutional Affairs, headed by the Hon Kevin Andrews MP, produced a comprehensive report, tabled in September 2001 entitled, Human Cloning: Scientific, Ethical And Regulatory Aspects Of Human Cloning And Stem Cell Research (the Andrews Report). It cited “overwhelmingly strong opposition to cloning... expressed by nearly all who provided submissions or gave evidence to the inquiry.”

OBJECTIONS TO HUMAN CLONING

There are diverse objections to cloning, some clearly defined, others more obscure and inherently tied into notions of humanity, morality, and ethics. It is not within the scope of this paper to examine the validity of the opposition to human cloning but merely to recognise that there is a widespread community consensus that the activity should be prohibited.

Risk

The most common objection to cloning humans is that the current technology is unsafe. Official statistics indicate that only a very small percentage of non-human clones are ever born, with many embryos not implanting or being lost during pregnancy. Of the small proportion of live births around half of all clones have suffered a condition known as large offspring syndrome which can cause terminal problems including enlarged placetas and fatty livers, or underdeveloped vital organs. Those that survive have a high chance of dying from heart and blood vessel problems, malformed arteries, diabetes, immune system deficiencies, and physical deformities.

Diversity

Cloning presents, albeit if taken to the extreme, a departure from human diversity. By undertaking asexual reproduction, the gene pool will be narrowed and humanity’s ability to overcome disease will be constrained. Cloning represents what
some see as a “slippery slope” towards unwarranted and unmanaged interference with evolutionary development.

**Lack of need**

An objection commonly raised by scientists, but which also verges on the ethical, is that there is little or no scientific or medical justification for cloning. Both the Australian Society for Reproductive Biology and the Fertility of Society of Australia have criticised the practice as inappropriate, both scientifically and medically. As such, it is argued, motives for human cloning are based on increasing personal notoriety rather than the greater good.6

**Human dignity**

One of the most common ethical objections to cloning is reflected in the UNESCO declaration and Council of Europe 1998 Convention on Human Rights and Biomedicine, which declares the practice “contrary to human dignity”. Just what constitutes “human dignity” is hard to qualify, primarily because any attempt to reach such a definition will be inherently subjective, tending to encapsulate what it is to be “human”.

The Anglican diocese of Melbourne submitted to the Andrews committee that cloning was instrumental in nature because it:

- bring[s] a person into existence for reasons outside the person themselves...to clone is to exercise unprecedented control over the genetic dimension of another individual...

Indeed, this element of control over the genetic make up of successive generations is evocative of concepts of eugenics which were rejected by the world community after the second world war.

**Autonomy**

Opponents of cloning claim that the free will and autonomy of a clone would be severely impacted upon either intentionally or by virtue of continuing comparisons with their genetic parent. The instinct to direct that child's development, they argue, would be strong. Even where there was no substantial pressure to mirror the achievements of the clonal parent, the clone would live in the shadow of its predecessor.

**Individuality**

Cloning is said to breach a fundamental right to individuality. By allowing cloning, humanity would be forgoing the intrinsic knowledge that each person is new and unique, not predetermined, prejudged, or prejudiced by what or who has gone before or after each person. Uniqueness of identity and individuality are some of the most deep felt and inherent signifiers of self. Just as a great artwork would lose its value in identical reproductions, so human beings can be said to lose their intrinsic inimitability in reproductions of themselves.

As noted above, this is a far from comprehensive list of objections to human cloning. It is, however, sufficient to note that these reflect a variety of views held by various sectors of the community. In a world divided by ethical, political, and social differences such a near universal consensus is rare.

**THE CLONERS**

Despite the apparent consensus that human cloning should be prohibited, some still seek to clone a human being. Whilst no mainstream clinician has publicly announced an intention to clone, two notable claims have been made by groups with relevant expertise in reproductive technologies.

Brigitte Bosselier is a Raeliean, a member of a sect that believes cloning will perpetuate a life cycle predating man. She has degrees in biological, physical, and analytical chemistry. She claims to have cloned human embryos and to have funding from parents interested in “resurrecting” their dead child. Bosselier argues that “we have enough information to proceed with human cloning”.7

Dr Panos Zavos has also announced his intention to dedicate himself solely to cloning. Like Bosselier, Zavos has no specific qualifications in fertility therapies.8 It is not so much Zavos, however, but his Italian collaborator, Professor Servino Antinori, who has caused anxiety among observers. Antinori is seen by many as a cavalier scientist and has on several occasions broken convention and the dictates of the Catholic church (of which he is a member) to undertake reproductive techniques, such as allowing postmenopausal women to conceive, in the various private clinics that he runs.

Both groups have expressed their intention to clone a human, despite widespread condemnation. Crucially, both groups have stated they will seek out and utilise any legal system which does not specifically ban the practice.9

**THE NEED FOR LEGISLATION**

Clones cannot be “undone”. We cannot destroy our mistakes, or purge the world of any baby born via means we disagree with. Political and academic shaming and even expelling of one of the would be cloners from the International Infertility Association has done little to deter them from their objective. What is needed, therefore, is legislation which is sufficiently proscriptive and sufficiently proactive, a regime with adequate power and jurisdictional reach, to ensure that it cannot be circumvented or undermined. Legislation can also be problematic, however, inasmuch as it is constrained by the document and the words chosen by parliament and any subsequent interpretation placed upon those words by a court.

In the common law tradition, the legislature and the judiciary each act as a check and balance upon the other. A primary function of the courts is to interpret legislation to ensure that parliament has not overstepped its powers. Legislatures have traditionally valued specific and succinct legislation which constrains judges to a narrow ambit of discretion when making decisions. So prescriptive legislation is favoured.

This promotes clarity in the law, allowing a clear demarcation between what is legal and illegal, and clearly delineating the extent of civil rights and obligations. Scientists and researchers should not be encumbered by uncertainty regarding what research they can validly undertake. Community concerns are assuaged by clear laws. Conversely comprehensiveness and precision can lead to convoluted and confusing language, narrow the ambit of the law, and render it rigid and inflexible. Nowhere is this linguistic fragility more acute than in the regulation of advanced technologies. The rapid advancement, improvement, and creation of new techniques can result in statutory descriptions of that technology becoming redundant.

The UK case of Quintavalle, which provides an apt example of how new aspects of technology can create uncertainties as to the applicability of existing legislation. In the first instance, the Pro Life Alliance (who oppose any form of embryo destruction) sought a declaration that the Human Fertilisation and Embryology Act 1990, which regulates the use and creation of embryos throughout the UK, did not cover cloned embryos. The Pro Life Alliance mounted the case in response to a government paper which declared somatic cell nuclear transfer (SCNT) embryos subject to the act.

The process of SCNT, which is central to cloning, involves removing the nucleus of an egg, which contains the mother’s DNA, and replacing it with a donor cell. The two are then fused, creating an embryonic form substantially genetically identical to the donor. The Pro Life Alliance, the plaintiff, argued that the Human Fertilisation and Embryology Act did not cover a SCNT embryo, because the definition of “embryo” in the act only includes a “live human embryo where fertilisation

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is complete’, which occurs with the appearance of a two cell zygote. The Plaintiff submitted that although an embryo created by SCNT resembles a zygote, it does not have the same properties, namely the combination of haploid cells, and does not go through the process of ‘fertilisation’.

The defendant (the UK government) argued that the definition of embryo was formulated before SCNT techniques were known to be applicable to humans, and that such techniques have been known parliament would have definitely included them. Justice Crane found, however, that he was bound to consider only the intention of the 1990 government rather than modern day government. As such his honour declined “any invitation to attempt to rewrite any sections of the 1990 act to make them apply by analogy to organisms produced by [SCNT]”. He pointed out that, should the act not have been overly prescriptive this outcome may have not eventuated. The result was that cloning was unregulated in the UK. The UK government then took this decision to the Court of Appeal which unanimously overturned Justice Crane’s decision on 18 January 2002.

The Court of Appeal found that although the original drafters of the legislation did not intend to include SCNT embryos, it did not “strain the language [of the statute] to breaking point” to include them. The requirement that an embryo come into being only with the appearance of a zygote had “no practical significance to the working of the Act”. Lord Phillips MR, noted that parliament had intended to regulate the creation of all embryos and that unforeseen technical developments should not be allowed to defeat the purpose of the act. It was of some concern that the original finding not only allowed cloning but also other activities, such as hybridisation or gestating human embryos in animals, or vice versa, which was “wholly at odds” with the policy of the act. It was therefore “essential” that they were controlled by statute.

The two courts in Quintavalle returned fundamentally different decisions. The Court of Appeal showed itself willing to adopt an extremely liberal interpretation of the legislation. It is arguable that it interpreted the act too broadly and outside the negative language within the act. The Pro Life Alliance has claimed it will appeal the decision. Regardless of whether this happens, the two decisions serve to show the legal standpoints.

FORMULATING LEGISLATION

The definition of cloning will be at the forefront of any consideration of the success of legislation. In other words, what is a clone and what is not? The question is complex, not only from a scientific perspective, but also from ethical and legal standpoint.

The term “clone” was imported into the modern language in the early twentieth century to describe grafting techniques in plants. By the late twentieth century, however, the word had become part of common language, and is used technically, figuratively, and sometimes even pejoratively to describe reproductions or carbon copies.

The word has also a variety of meanings in the scientific sense. The Australian Health Ethics Committee (AHEC) described two distinct meanings of “clone” in the scientific sense. The first was “asexual reproduction as distinct from its generation by the combination of two gametes”. The second was any technique producing an organism “genetically identical with at least one other entity”. The Australian Academy of Science (AAS) provided a less strict definition of cloning, a clone being only “an organism with the same nuclear genome as another cell or organism”. Although the Andrews Report favoured the latter definition, it stated: “[t]here are many definitions of cloning” and the “existing definitions are confusing”.

The phrase is also used to describe various types of scientific and medical techniques. The two most common “cloning” techniques are relatively simple medical research processes. These are molecular, and cellular, cloning, both staple scientific techniques which have been in existence since the 1970s. Embryonic cloning has existed since at least the 1950s. As the name suggests it produces clones via embryonic cells, by a variety of methods, such as embryo splitting or “nuclear transfer”. Unlike the techniques mentioned above, this type of cloning allows for the creation of a whole living animal. Finally, somatic cell cloning (referred to above as SCNT), allows for differentiations of an adult to be reverted to an embryonic state. They may then be placed into an enucleated egg by nuclear transfer to create a new embryo which is a replica of the donor adult. This means that, unlike embryonic cloning the “clone” will be substantially identical to the parent rather than its siblings.

Embryonic and somatic cell cloning could indeed produce replica offspring but they are of greater relevance in the field of medical research. They enable scientists to investigate early stage life, and most importantly provide tractable cells whose development may be directed along specific lineages. It is hoped that these “stem cells” will provide a source of histocompatible tissue and organs for use in therapies and thus this form of SCNT cloning is generally referred to as therapeutic cloning. This technique destroys the potential of the embryo to be reimplanted into a woman.

The importance of drawing out these various techniques is to highlight that the term “cloning” is a misnomer, in that it covers a variety of methods, outcomes, and purposes. The Andrews report reinforced this proposition stating: “it is important to note that cloning does not necessarily mean the replication of an entire individual [which] is often the public perception”. Indeed, the committee in that case emphasised that “reproductive cloning” itself did not adequately differentiate between whether the “clone” is a few cells or a whole liveborn individual. It is the latter, denoted by the intention to produce a whole human being, which has drawn widespread condemnation. Conversely, the former remains contentious and the debate over the use of the embryo for therapeutic uses rages on. The greatest impediment to the immediate prohibition of reproductive cloning has been the uncertainty over how to regulate therapeutic cloning. This emphasises the importance of segregating the two techniques.

What is different between the two processes? They both rely on the same technique of SCNT to create an embryo with the nuclear DNA of only one parent. As such, they both “reproduce” the DNA of another person and produce an entity capable of forming into a human being. Religious leaders particularly, see little difference between the two, on the basis that the stage to which that embryo is developed is irrelevant. Indeed, a clone is not an actual reproduction in the literal sense. The being is not the same age and does not share the same experiences or memories. So the word “reproductive” is in this sense figurative and really depends on subjective assessments of what is being copied.

The term “therapeutic” may be equally liable to misinterpretation. Proponents of producing a human being by cloning have declared their efforts therapeutic because, they argue, cloning is a reproductive therapy for couples unable to conceive by conventional methods. Finally, the term “therapeutic” will inevitably cause problems to any ethical position that assumes an embryo is a human life with equivalent or substantial rights. In that sense, the technique can hardly be said to be therapeutic to the embryo because it results in its destruction.

The word “cloning” then describes many practices and a simple prohibition on “cloning” would potentially impact on activities outside the intended ambit of the law. The meaning
of cloning must therefore be limited to the class of practice to be targeted. In the absence of a more appropriate word to deal with the technique, this paper will continue to refer to reproductive cloning. For the purposes of this paper, the term is taken to mean any embryo produced by a process other than fertilisation, which is implanted into a human body, with the intention of replicating an existing individual, alive or dead.2 Where referred to, “therapeutic cloning” will be taken to be the creation of an embryo like entity for the purpose of extracting stem cells.

REPRODUCTIVE CLONING: AUSTRALIAN STATUTORY DEFINITIONS

Three Australian states, Victoria, South Australia, and Western Australia have banned “cloning”. In the Australian states without specific legislation, publicly funded institutions are required to comply with NHMRC guidelines for all research involving humans.3 The guidelines also apply to private institutions registered under the Fertility Society of Australia.4

Reproductive cloning is further regulated at the federal level by the Gene Technology Act 2000 (GTA) and states are passing mirror legislation in similar terms. In each jurisdiction the definition of cloning is slightly different:

• GTA: “cloning a whole human being”, further defined as “the production of duplicates or descendants genetically identical to the original”5;6
• Victoria: “form[ing], outside the human body, a human embryo that is genetically identical to another human embryo or person”7;8
• Western Australia: “producing, from one original, a duplicate or descendant that is, or duplicates or descendants that are, genetically identical, live born and viable”9;10
• South Australia: “producing[ing] two or more genetically identical embryos from the division of one embryo”11;12
• NHMRC: producing “two or more genetically identical individuals, including development of human embryonal stem cell lines with the aim of producing a clone of individuals”.13

There are a number of problems with each of these definitions.

In the NHMRC, GTA, and Western Australian acts there is an emphasis on a clone being a complete child. The GTA uses the phrase “whole human being” to connote this. The NHMRC guidelines use the phrase “individual”. But what is a whole human being or individual? Is it a human born live and viable, or does it include a fetus or an embryo? Neither law provides an answer to this contentious question. In Western Australia the issue is clearer, requiring a live born and viable individual, but it would seem to allow the cloning of a fetus (see below).

Another question is whether a human born without a complete brain satisfies any of these tests. Scientists have been able to modify the genes of embryos to produce live tadpoles and mice, without heads or complete brains since the early 1990s.14 Although a disturbing and seemingly implausible idea, it is possible that similar experiments could be replicated on humans, so as to create genetically compatible organs for transplant. Would the legislation cover such an activity?

All jurisdictions define a clone as “genetically identical” to its parent. This is not, however, strictly speaking true, at least where SCNT technology is utilised. A portion of DNA is contained in small organelles known as mitochondria. In SCNT only the nucleus is replaced, not the mitochondria, and so the new organ will retain that small percentage of the mother’s DNA. Furthermore, the multitude of cell divisions in embryonic development can cause mutations in the genetic code of that life form and so genetic differences arise as the life form develops.15

Would this defeat the act? With the exception of purposeful interference with the nuclear DNA, which is a long way off, naturally occurring differences between a clone and its clonal parent may not be enough. The Court of Appeal in Quintavalle reflected a general progress both in the UK and Australia away from literalism towards a purposive reading of the law. In relation to the GTA parliament was clear that it meant “genetically identical” in the sense of SCNT.16 In those states where legislation was created before the invention of SCNT it is arguable that the definition forms part of accepted terminology in the medicolegal world to describe a clone.17 In other words “genetically identical” has been accepted into the general cloning lexicon.18 Nevertheless, the phrase does cause uncertainty and there is always a remote chance that someone may undertake cloning claiming that they are not producing a genetically identical offspring.

Both Victoria and South Australia define embryos or clones in terms which reflect an emphasis on the techniques in existence at the creation of the act. The creation of an “embryo” in Victoria requires the alignment of male and female pronuclei on the mitotic spindle. As SCNT does not require male gametes this definition is problematic. In South Australia, cloning only occurs when a single embryo is split, which describes embryo cloning but would seem to exclude SCNT cloning.

All three state jurisdictions and the NHMRC guidelines, require that interference with an embryo does not diminish the potential of that embryo to be reimplanted into a woman. This means that creating stem cells from embryos is banned because extracting stem cells destroys the embryo’s ability to be reimplanted. Thus researchers must import stem cell lines from overseas.19 Furthermore when that requirement is read in context of the Western Australian and South Australian acts the outcome seems rather strange. In Western Australia the requirement that a clone be “born live and viable” seems to allow for the creation of a cloned embryo or fetus. Providing that the resulting fetus is terminated before birth it would not be a clone in terms of the legislation. In South Australia the lack of a ban on SCNT cloning would seem to allow reproductive cloning but ban therapeutic cloning, because it would destroy the embryo’s ability to be reimplanted.

UNITED KINGDOM

The decision of Justice Crane in Quintavalle caused an immediate and widespread outcry by the UK media, public, and Government over the resulting legislative vacuum with respect to cloning.20 Newspapers claimed that would beclones would immediately exploit the loophole to grow babies in Britain.21

The government responded with sui generis legislation on 4 December 2001. The Human Reproductive Cloning Act 2001 has only two sections. Section 1(1) provides:

A person who places in a woman a human embryo which has been created otherwise than by fertilisation is guilty of an offence.

The act simply prohibits any embryo created by a process other than fertilisation to be implanted into the body of a woman and thus makes it illegal to gestate a cloned embryo. It avoids altogether use of the terms “genetically identical”, “cloning”, and “reproductive cloning”. Instead, it focuses on outcomes.

The act has already received some criticism for not defining “key” terms such as “fertilisation” and “embryo”.22 Yet the attempt to define such terms is precisely the reason that the original act suffered such ambiguity and was subject to legal and judicial debate. Flexibility is beneficial because it means the legislation is not encumbered by reliance on technical definitions. Instead it targets a class of practice. Certainly, the UK Court of Appeal clearly indicated that it was more interested in the policy behind the law rather than exact technical or scientific definitions.
As a consequence of the finding of the Court of Appeal, the UK now has a regime which regulates therapeutic cloning and prohibits reproductive cloning. Hence the traditional legal paradigm of criminalising misconduct which is unilaterally condemned and regulating conduct which is morally ambiguous is maintained. There are calls for the Human Fertilisation and Embryology Act, which regulates the creation of embryos by SCNT and thus therapeutic cloning, to be overhauled.31 Should this happen, the UK government has afforded itself ample time to consider the issues in greater depth.

CONCLUSION
It can be seen from this discussion that the Australian attempts to ascribe features to cloning have arguably led to legislation that is overly prescriptive. In many cases it is unclear whether definitions under the current system are legally sufficient or even if they apply to reproductive cloning at all. At the heart of the problem in determining a successful legal definition of a clone has been the reliance on current methods, or understanding, of technology.

Certainly, South Australia provides the most acute example by focusing on a procedure which is now largely redundant (embryo cloning). Other jurisdictions are, however, similarly limited by relying on descriptions of the physiological features of the “components” of the procedure (sperm, ova, embryo), or the physiological features of the result of that procedure (genetically identical). The definition of all “components” of the cloning process are equally limited by their contemporaneity to the enactment of the legislation and are susceptible to redundancy as new technologies are invented.

Instead of legislators asking “what is the exact technique we wish to control”, they should ask “where do the differences lie between what we will allow to occur and what we will not”. The UK legislators asked themselves the latter question. The answer was that techniques such as IVF and therapeutic cloning were to be accepted while gestating cloned embryos was not. Thus, the core differences between those outcomes were highlighted; IVF utilises conventional fertilisation and therapeutic cloning results in an unimplantable embryo. So to be a “clone” under that legislation the embryo must be created by a process other than fertilisation and then reimplanted into the body.

It was noted above that prescriptive laws are designed to create clarity and assuage public concerns. Yet laws which are overly prescriptive and hence prove too rigid to operate effectively will do exactly the opposite because even if they do not fail outright there will be uncertainty regarding their validity or application. Advanced technologies such as cloning do not warrant the traditional legal paradigm of prescriptive legislation because they evolve too quickly for such legislation to respond. In such cases the emphasis should be on the separation between acceptable or unacceptable rather than on the form of procedure itself. This will assist in constructing clear boundaries between ethical and unethical research and hence create clarity in the law and assuage public distrust in reproductive medicine and science.

AUTHOR’S NOTE
The author notes that part of this article was presented at the Centre for Law & Genetics Symposium, Regulating the New Frontiers: Legal Issues in Biotechnology, under the title, What exactly is an exact clone?, in November 2001 (http://lawgenecentre.org/symposium2001), and which will form part of the centre’s occasional paper series.

ACKNOWLEDGEMENT
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REFERENCES AND NOTES
1 UNESCO. Declaration on the human genome and human rights. UNESCO, 1997; article 11.
5 See reference 4: footnote 22.
7 Yet experts suggest that the figure is much higher due to a lack of reporting of failures: see reference 6.
10 See reference 4: 6.29.
15 Collins V. Simpson C. Italian doctor plans to clone baby in Britain. The Herald 2001 Nov 16; see: http://www.thetheherald.co.uk/news/archive/11-11-19101-1-0-56.html
22 Cloning has more than a biological meaning. It is also used to describe items such as compatible computer platforms, mobile phone hacking or Elvis impersonators. See Fowler’s Modern English Usage [3rd ed]. Oxford: Clarendon Press; 1996; see also reference 21.
25 See reference 4: 2.36.
29 See reference 4: 2.33–2.35
32 Note, however, that even this definition may one day prove inadequate if any form of artificial womb technique allows for the formation of a fetus outside the human body. In that case it may be advisable to add, “which is implanted into the body of a woman, or any device capable of gestating a human being”.
38 Reproductive Technology (Code Of Ethical Research Practice) Regulations 1993 (SA) s2.
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