EMBRYONIC STEM CELL RESEARCH AND CLONING: A PROPOSED LEGISLATIVE FRAMEWORK IN CONTEXT OF LEGAL STATUS AND PERSONHOOD

by

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SUMMARY

The aim of this dissertation is to examine and analyse the judicial framework with regard to embryonic stem cell research and cloning in South Africa. The examination is conducted within the framework of the South African and United Kingdom's legal systems. Focus is placed on aspects of medical law, human rights law as envisaged in the Constitution of the Republic of South Africa, and the law of persons. The specific focus of this dissertation is to examine the intense debate on the moral and legal status of the embryo and fetus in South Africa. A comparative study is undertaken, with the United Kingdom as a background against which recommendations for the South African framework are made. The study firstly provides a clinical overview of stem cell research and cloning. Secondly, the concept of life, in particular human life; the protection of the embryo and fetus under the constitutional guarantee of the right to life, among other constitutionally protected rights, are examined. In this context, the most important finding is that although the fetus is not a bearer of constitutional rights the state has a constitutional duty to protect fetal life in terms of an objective value system. Thereby, the state is permitted to regulate abortion, fetal tissue research, and embryo research to protect fetal life. In particular, the aim of this dissertation is to present a critical summary of the major debates and policy responses relating to embryonic stem cell research and cloning techniques, drawing attention to some of the challenges posed by conflicting moral values in an era of global scientific endeavour, and to provide an analysis of the key ethical and regulatory implications for stem cell therapy. The most important findings are that current South African legislation remains fragmented and ineffective in the manner in which embryonic stem cell research and cloning are regulated. This finding leads to a summary of recommendations, which attempts to provide specific remedies in order to adapt the current regulatory framework in South Africa.

Key terms: Legal status; embryo; fetus; abortion; fetal tissue; assisted reproduction; reproductive rights; human life; dignity; embryonic stem cell research; therapeutic cloning; human reproductive cloning; medical or scientific research; biomedicine.

OPSOMMING

Die doel van hierdie verhandeling is om die juridiese raamwerk met betrekking tot embrioniese stamselnavorsing en kloning in Suid-Afrika te ondersoek en te ontleed. Hierdie ondersoek is binne die raamwerk van die Suid-Afrikaanse en Verenigde Koningkryke se regstelsels onderneem. Daar word gefokus op aspekte van geneeskundige reg, menseregte, soos verskans in die Grondwet van die Republiek van Suid-Afrika, en die personereg. In besonder is die fokus van hierdie verhandeling 'n ondersoek na die intense debat met betrekking tot die morele en regstatus van die embrio en fetus in Suid-Afrika. 'n Vergelykende studie is onderneem, met die Verenigde Koningkryk as agtergrond waarteen voorstelle vir die Suid-Afrikaanse raamwerk gemaak word. Die studie bied eerstens 'n kliniese oorsig van stamselnavorsing en kloning. Tweedens word die konsep van lewe, in besonder menslike lewe; die beskerming van die fetus se grondwetlike reg op lewe, tesame met ander grondwetlike regte, ondersoek. In hierdie konteks is die belangrikste bevinding dat, alhoewel die fetus nie 'n grondwetlike reg op lewe het nie, die staat wel 'n plig het om die lewe van die fetus te beskerm ooreenkomstig 'n objektiewe waardestelsel. Dit laat die staat toe om aborsie, navorsing op fetale weefsel en embrioniese stamselnavorsing te reguleer. In besonder is die doel van die studie om 'n kritiese opsomming te voorsien van die belangrikste debatte rakende beleidsbeginsels in verband met stamselnavorsing en kloning. Aandag word gevestig op die uitdagings voortspruitend uit konflikte oor morele waardes in 'n era van wêreldwye wetenskaplike ontwikkeling, en om die belanghebbende etiese en regsimplikasies van stamselnavorsing te analiseer. Die belangrikste bevinding is dat Suid-Afrikaanse wetgewing steeds onvolledig en ondoeltreffend is in die regulering van embrioniese stamselnavorsing en kloning. Hierdie bevindinge lei tot 'n opsomming van voorstelle in 'n poging om die huidige regsraamwerk in Suid-Afrika te remedieer en sodoende aan te pas.

Sleutelterme: Regstatus; embrio; fetus; aborsie; fetale weefsel; gesteunde bevrugting; reproduktiewe regte; menslike lewe; menswaardigheid; embrioniese stamselnavorsing; terapeutiese kloning; menslike reproduktiewe kloning; mediese of wetenskaplike navorsing; biomedisyne.

"All truth passes through three stages: First, it is ridiculed. Second, it is violently opposed. Third, it is accepted as being self-evident".[1]

[1] The words of Arthur Schopenhauer, 1788-1860, as quoted in Gusman, A (2005) "An appropriate legislative response to cloning for biomedical research: The case against a criminal ban" *Annals Health L* 14(2):361. Arthur Schopenhauer was a well-known German philosopher. His ideas profoundly influenced the fields of philosophy, psychology, and literature.

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CHAPTER 1 INTRODUCTION

1 1 BACKGROUND

1 1 1 Introductory remarks: The rise of reproductive genetics

In recent decades a new branch of law, namely reproductive law, has come into being. It has grown and developed as part of medical law. It consists of different kinds of legal regulations directly concerning human reproduction, and in particular assisted reproduction, the diagnosis and treatment of embryos, fetuses,[2] and embryo research.[3]

The 25-year period since the birth in Britain of Louise Brown, the first "test-tube baby", has resulted in the remarkable development of a range of techniques associated with the manipulation of reproductive processes and an improvement in the effectiveness of methods of medically assisted procreation in humans. These techniques include in vitro fertilisation, embryo transfer, gamete intra-fallopian transfer, intra-cytoplasmic sperm injection, the cryopreservation of embryos and nuclear transfer. Practices such as sperm or egg donation, surrogate motherhood and the selection of embryos before implantation through pre-implantation genetic diagnosis, were made possible.[4] These techniques and practices correspond with unprecedented articulations of genetic knowledge and practices of cell and tissue manipulations that allow women or men diagnosed with different forms of sterility to conceive children. In addition, they carry promises of a growing capacity for the early detection of potentially fatal or severely impairing conditions in embryos, therefore allowing a selection of viable embryos among those generated by some of the above techniques.

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2 The word "fetus" is derived from the Latin meaning "little one", originally a term of endearment and affection. Some writers prefer to use the spelling "foetus". According to the Concise Oxford Dictionary, the preferred spelling is "fetus", but "foetus" can also be used (especially in a non-technical sense). See Concise Oxford Dictionary (1999) "Fetus" 524. According to Williams, "fetus" is etymologically correct and has become the preferred term in medical writing. See Williams, G (1994) "The fetus and the right to life" *Cam LJ* 53(1):71, as quoted in Slabbert, MN (1997) "The fetus and embryo: legal status and personhood" *TSAR* 2:234. In addition, where reference is made to a "fetus" it also includes the embryo.

3 Lang, P (1992) "The legal status of the human foetus" *Crim L Forum Int'l J* 3(3):419, as quoted in Evans, D (1996) *Conceiving the embryo: Ethics, law and practice in human embryology*.

4 Rosamund, S (2005) "The uncertain scope of reproductive autonomy in pre-implantation genetic diagnosis and selective abortion" *Med'l L Rev* 13(3):291. See in general Laing, JA & Oderberg, DS (2005) "Artificial reproduction, the 'welfare principle', and the common good" *Med'l L Rev* 13(1):328-356.

More recently, the new field of reproductive genetics; the coupling of somatic cell nuclear transfer and stem cell technologies which will potentially provide powerful tools for pre-implantation genetic profiling; human embryonic stem cell alteration; and germ-line therapy, has been hailed by some as promising future inroads into a medicine that would become not merely curative or predictive, but regenerative. But others denounce it as bringing with it a dangerous potential for all kinds of ethical abuses in the manipulation of human life and for new forms of eugenics.[5]

It is clear from the above that reproductive technologies and biomedical sciences are progressing at a staggering rate. This fact is currently no more evident than in the burgeoning field of stem cell research, where therapeutic applications such as tissue and organ transplantation are being developed. These therapies have the potential to save millions of lives and greatly reduce human suffering.[6] When James Thomson, a scientist at the University of Wisconsin in Madison, reported in November 1998 that he had succeeded in removing cells from spare embryos at fertility clinics and established the world's first human embryonic stem cell line, he and other scientists got a lot more than they bargained for. It was the kind of discovery that under most circumstances would have blossomed into a major federal research enterprise. Instead, the discovery was quickly engulfed in the turbulent water of religion and politics.[7] Before long, countries around the world were embroiled in the debate.

The scientific, legal, and ethical issues related to embryonic stem cell research and cloning technologies have generated considerable media and public attention over the last few years. Advances in biotechnology have created difficult ethical and moral questions

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5 For useful accounts of these developments and debates see Holland, S *et al* (2002) *The human embryonic stem cell debate: Science, ethics and public policy*. For a general discussion of surrogate motherhood see Pretorius, D (1991) *Surrogate motherhood: Legal issues* (Thesis – LLD.) University of South Africa. (Unpublished). See also Halliday, S & Steinberg, DL (2004) "The regulated gene: New legal dilemmas" *Med'l L Rev* 12(1):2-13.

6 Daley, R (2001) "The ethics of embryonic stem cell research: Finding common ground" [Web:] www.law.mq.edu.au/ANZIHLE/daley%20cp%2001.pdf [Date of access: 21 January 2006].

7 Weiss, R (2005) "The power to divide" *Nat Geogr Mag* 208(1):3 *at* 6.

which cannot be avoided. Governments around the world are grappling with the most appropriate means by which to regulate these technologies. However, advances in science tend to be much faster than advances in the understanding and comprehension of the issue by the general public and governments alike. There have been two major scientific breakthroughs that have shaped the recent development of cloning technologies. The first is somatic cell nuclear transfer, and the second is the isolation of human embryonic stem cells. Related practices such as the use of embryonic stem cells, the prospect of the creation of embryos by somatic cell nuclear transfer for research or therapy, and the use of surplus embryos from assisted reproductive technologies for research purposes, have also created much concern and interest. It is widely argued that, because of the great potential of therapeutic cloning and related research to improve health, it would be unethical to prohibit or restrict the research.[8]

However, the reasons for opposing embryonic research have also been expressed as follows: The human embryo is a distinct, living human being and as such is entitled to all the rights and protections afforded to any other human being; that human life begins at conception; and that fertilisation is not merely an opinion, but a scientific fact. Therefore, the human embryo, regardless by what means it is created, should not be treated as a means to an end. It is entitled to life, liberty and respect. The truth is that the human embryo contains the exact same amount of genetic information as adults do. The embryo differs from an adult not in kind, but only in degree. Once embryonic development commences, a separate and distinct human being comes into being. As such, the embryo should not be used in a purely instrumental fashion. Another argument implies that it is never ethical to sacrifice one human being for the real or perceived benefits of another human being.[9] The question that now comes forward is whether these considerations can be justified.

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8 Brazier, M (2005) "Times of change?" *Med'l L Rev* 13(1):1. See in general Halliday & Steinberg (2004) *Med'l L Rev* 2-13; Halliday, S (2004) "A comparative approach to the regulation of human embryonic stem cell research in Europe" *Med'l L Rev* 12(1):40-69.

9 This reflects the view of the Roman Catholic Church.

In the continuous debate about medical experiments on human beings and embryos, 1984 was a landmark year. Public controversy on the issue literally spanned the continuum of human life, from conception to natural death. In England, a government commission concluded a two-year study by suggesting that experimentation should be allowed on newly fertilised human embryos. The study was prompted in 1982, when in vitro fertilisation pioneer, Robert Edwards, announced that he had observed some newly conceived embryos for two weeks before allowing them to expire in a Petri dish.[10] Experimental medical treatment for humans already born became a topic of nationwide discussion with the first clinical use of new organ transplant techniques. In the celebrated case of Baby Fae and Barney Clark[11] Americans contemplated the use of animal and mechanical organs in human beings and discussed the fine line between exotic treatment for an individual and medical research to benefit future generation.[12] These incidents involved different specialties within medicine and different classes of human subjects, but they all raised the same basic questions about the morality of human experimentation. Those questions are perhaps best illustrated by a more detailed account of the controversy with the longest continuous history, namely research on the human embryo.

A significant consequence of the developments in this field is the production of human embryos in excess of those implanted in women who desire a pregnancy. These "excess

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[10] At the urging of the Roman Catholic bishops of Great Britain and many others, British Parliament began consideration of a bill to prohibit such experiments. The legal position with regard to medical research in the United Kingdom is discussed in chapter 5.

[11] The world only knew her as Baby Fae. The true identity of the two-week-old infant who made medical history on 26 October 1984 was kept strictly confidential by officials at California's Loma Linda University Medical Center, where the successful transplant of a young baboon's heart was performed to keep the baby alive. Run by the Seventh Day Adventist Church, Loma Linda was renowned for its paediatric surgery, and one of its most talented surgeons was Dr Leonard Bailey. While working at a children's hospital in Toronto, Dr Bailey proposed xenografts (cross-species heart transplants) as a possible way to save victims of hypo-plastic heart, a fatal condition in which the left side of the heart is underdeveloped at birth. Infant hearts were rarely available for transplant, so Bailey searched for a viable alternative. However, he met with resistance from many in the health-care field. In 1982, a 62-year-old Seattle dentist named Barney Clark made medical history as the first permanent artificial heart recipient. See Manning, J (2000) "Baby Fae" [Web:] http://eightiesclub.tripod.com/id302.htm [Date of access: 12 April 2006].

[12] A legislative debate also gathered momentum in the United States over federal standards on fetal experimentation that allowed unethical experiments in certain circumstances. Tighter standards were approved by Congress after long debate, and then invalidated when President Reagan vetoed the bill, which included these standards as amendments.

or surplus" embryos are cryopreserved and either implanted at a later stage in the same women in further pregnancy attempts, donated or stored up to about five years, after which they would no longer be viable and would somehow have to be disposed of. Proposals were put forward for a number of the latter embryos to be used, under certain conditions and subject to strict ethical and legal standards, for research on the embryo itself and on its development; on the reproductive process in order to improve medically assisted procreation; or for research related to severe diseases. The growing number of scientific studies pointing towards the role of embryonic stem cells in understanding both cell differentiation and proliferation and possible conditions for the regeneration of damaged tissues or organs turned these excess embryos into a scarce and coveted resource for biomedical and biological research. It is hardly surprising, then, that the debates on how to regulate medically assisted procreation often ended up confronting head-on the issue of the status and potential uses of the human embryos, which were one of the outcomes of medical assisted procreation. And it should be added that this debate encouraged a search for ways of producing human stem cells for research and therapy that would not involve the creation of entities with the potential to become human beings, for instance through harvesting and culturing adult stem cells, of cells from umbilical cord, or through the creation of "quasi-embryos" using somatic cell nuclear transfer.[13]

Stem cells with embryonic characteristics have also been isolated from the primordial germ cells of a 5- to 10-week fetus. It is from these embryonic germ cells that the gametes, ova or sperm normally develop. Research has shown that germ cell-derived stem cells have the ability to differentiate into various cell types, although they are more limited in this respect than embryonic stem cells. It should be noted that these research results have yet to be confirmed by other scientists and the stability of these cell's genetic material is still under discussion. This process is known as fetal tissue research, where fetal tissue or organs obtained after a termination of pregnancy[14] can be used to derive

[13] See in general Lupton, ML (1992) "The legal position of cryopreserved human embryos" *TSAR* 3:466-474. See also Enmon, JL (2002) "Stem cell research: Is the law preventing progress?" *Utah L Rev* 3:621 *at* 637.

[14] Despite the difference between the technical interpretation of "termination of pregnancy" and "abortion", both terms are used interchangeably throughout the dissertation.

stem cells, for example neural stem cells which can be isolated from fetal neural tissue and multiplied in culture.[15]

The debates and controversies on the threats and benefits associated with developments in this field, and in particular the ethical and legal issues raised by them, mobilised a number of people in countries where the capacity for developing this area of research and the will to do so was present. This was the case in most European countries and in the United States and Canada, among others. The issues were also brought to international forums, such as the United Nations and its organisations (for example UNESCO)[16], the Council of Europe and the European Parliament. These institutions produced several documents that aimed at providing a common framework for the regulation of practices involving the manipulation of human life, such as the Universal Declaration on the Human Genome and the Rights of the Human Person proposed by UNESCO in 1996; or the Convention for the Protection of Human Rights and Dignity of Human Beings of 1996, subscribed to by 21 countries in Oviedo, Spain, in 1997.

These debates and controversies frame a discussion that is exemplary of the intermingling of the scientific, political, social, economic, cultural, legal and ethical – which is a defining feature of the objects and practices of the life sciences as we know them today. The recent development of stem cell research, specifically embryo research and cloning raises specific problems with considerable ethical implications such as –

(a) the status of the embryo as a moral entity;
(b) the use of fetal tissue for research and therapeutic purposes; and
(c) the legitimacy of creating hybrids of human/non-human cell lines.

To these, one may add questions on the very definition of the need, desirability or priority of these directions of research when placed alongside pressing needs for health care;

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15 Van Wyk, C (2004) "Clinical trials, medical research and cloning in South Africa" *THRHR* 67(1):1 *at* 17. See also Planned Parenthood Federation of America (2001) "Donating fetal tissue for medical treatment and research" [Web:] www.ppatp.org/FetalTissue.htm [Date of access: 17 January 2006].

16 The United Nations Educational, Scientific and Cultural Organization.

reproductive rights of women; reproductive rights in general and access to reproductive technologies; and public health campaigns, particularly for the poor, marginalised and excluded and disable people. The problems with the distribution of benefits and hazards associated with new technologies (and new forms of inequality that may arise from them in terms of access or new forms of discrimination based on biological "fitness") require that issues of justice be brought into the discussion as well. Besides the question of who is to be included in the definition of the issues in hand, and to debate and deliberation, there has been a criticism of the focus on the moral status of the embryo, as well as the relative neglect of discussing it in relation to the status of women. Different countries have taken different approaches in dealing with these controversies, and many have created legal frameworks, advisory boards and public forums for debate and deliberation.

The fundamental ethical principles applicable to stem cell research are respect for human dignity; the principle of individual autonomy entailing informed consent and respect for the privacy and confidentiality of personal data; the principle of justice and of beneficence with regard to the improvement and protection of health; the principle of freedom of research, which is to be balanced against other fundamental principles; and the principle of proportionality, including that research methods are necessary to the aims pursued and that no alternative, more acceptable methods are available. In addition, it is important to take into account, based on a precautionary approach, the potential long-term consequences of stem cell research and its uses for individuals and society.[17]

1 1 2 The development of biotechnology in South Africa

1 1 2 1 Introductory remarks

South Africa has a solid history of involvement with traditional biotechnology. It has produced one of the largest brewing companies in the world; it makes wines that compare with the best; it has created many new animal breeds and plant varieties, some of which are used commercially all over the world; and it has competitive industries in the manufacturing of dairy products such as cheese and yoghurt. However, South Africa has

[17] European Group on Ethics in Science and New Technologies (2000) "Ethical aspects of human stem cell research and use: Opinion 15" [Web:] www.europa.eu.int/comm/european_ group_ethics/docs/ avis15_en.pdf [Date of access: 24 May 2006].

failed to extract value from the more recent advances in biotechnology, particularly over the last 25 years with the emergence of genetics and genomic sciences, the so-called 3rd generation biotechnology. Many companies and public institutions elsewhere in the world are already offering products and services that have arisen from this new technology. In the United States of America alone, there are 300 public biotechnology companies with a market capitalisation of $353 billion and an annual turnover of $22 billion per year. Moreover, the growth of biotechnology industries is not restricted to developed countries. Developing countries such as Cuba, Brazil and China have been quick to identify the potential benefits of the technology and have established measures both to develop such industries and to extract value where possible and relevant.[18]

The "new" biotechnology that has emerged is built on new knowledge areas such as stem cell research and cloning. This knowledge enables a far greater understanding of the role of genes in biological systems. In particular, it has allowed geneticists to move genetic material from one life form to another in a way that was not previously possible, and more recently, to change even the function of a single cell in an organism (for example, a stem cell to a kidney cell). However, new biotechnology has multiplied the range of biotechnology products and the speed with which it is possible to obtain such products many times. New biotechnology has also increased our understanding of living systems in a way that was previously inconceivable. We can now identify the genetic basis of many diseases and develop drugs to counteract the action of many pathogens. Some of the components of a successful biotechnology sector are already in place in South Africa.

1 1 2 2 The regulation of embryonic stem cell research and cloning in South Africa

Against the background of the above developments in biotechnology, three aspects of South African law need to be considered: In the field of embryonic stem cell research and cloning, a number of private law rules dealing with consent, parentage, succession, contracts, property and delictual liability, which fall outside the scope of this dissertation,

[18] Parker, I *et al* (2001) "A national biotechnology strategy for South Africa" [Web:] http://www.pub.ac.za/resources/docs/biotechstrategy_2002.pdf [Date of access: 15 March 2006].

may find application. A second area is constitutional law and more specifically the Bill of Rights. The right to life and to human dignity, the right to reproduce, and the right to privacy, among other rights, feature prominently as basic concepts in the ongoing development of protective measures. These concepts are dealt with under the provisions of the South African Constitution.[19] These rights envisaged in the Constitution are, however, not absolute and may be limited in terms of section 36. The Constitution does not refer directly to embryos or fetuses and does not define these terms. The question then arises whether the embryo and fetus are constitutionally protected.

A third aspect concerns legislation in the field of health. The first is the Human Tissue Act,[20] which was last amended in 1989. The Human Tissue Act regulates organ and tissue transplantation, and has its origin in the first successful heart transplant operation performed by Professor Christiaan Barnard and his team in December 1967.[21] The Human Tissue Act makes provision for the use of tissue and gametes[22] which are removed from a living donor for medical and dental purposes. The Act also prohibits the use of placentas, fetal tissue and umbilical cords for medical or dental purposes, their transplantation into the body of another living person or their use for the production of a therapeutic, diagnostic or prophylactic substance, except with the consent of the Minister or his nominee[23]. The Human Tissue Act also prohibits the genetic manipulation of gametes or zygotes outside the human body.

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19 The Constitution of the Republic of South Africa, 1996 (hereafter referred to as the Constitution). According to section 1 and 2 of the Citation of Constitutional Laws Act, 2005 (Act 5 of 2005), no Act number is to be associated with the Constitution of the Republic of South Africa. Any reference to the Constitution of the Republic of South Africa, contained in any law in force immediately prior to the commencement of this Act, must be construed as a reference to the Constitution of the Republic of South Africa, 1996.

20 The Human Tissue Act, 1983 (Act 65 of 1983) (hereafter referred to as the Human Tissue Act).

21 Strauss, SA (1991) *Doctor, patient and the law: A selection of practical issues* 147.

22 The specific sections in both the Human Tissue Act and the National Health Act, 2003 (Act 61 of 2003) (hereafter referred to as the National Health Act), dealing with tissue and gametes also make reference to blood and blood products. The regulation of blood and blood products fall outside the scope of this dissertation; therefore throughout this dissertation reference is made to tissue and gametes only.

23 "Minister" is defined in section 1 of the National Health Act as the Cabinet member responsible for health, and in section 1 of the Human Tissue Act as the Minister of National Health and Population Development. Wherever reference to "Minister" is made, one of the above applies.

The second health legislation is the National Health Act,[24] which when enacted into law, will repeal the Human Tissue Act.[25] Therefore, the Human Tissue Act and the regulations issued in terms of section 37 of this Act are still applicable. Control over the use of tissue and organs in humans is regulated in chapter 8 of the National Health Act, which was largely taken over from the provisions of the Human Tissue Act and consolidated them in this regard. Unlike the Human Tissue Act, the National Health Act purports to also address the issue of human cloning by including a definition thereof. However, the National Health Act currently has no substantive provision dealing with human cloning, and it seems that the further regulation thereof will be left to the regulatory powers of the Minister. This is cause for concern. The National Health Act in its current form provides only a rudimentary framework within which South African law can further develop ways of complying with the principles that the international standard-setting process has introduced for further realisation in domestic legal systems.[26] At the time of writing, there are no published regulations to the Act either.

In context of legal status and personhood, the Choice of Termination of Pregnancy Act[27] is of utmost importance. Before 1975 abortion was a common-law crime with only one recognised ground of justification, namely necessity. The Abortion and Sterilisation Act[28] criminalised abortion that did not fall within certain defined circumstances. South Africa made history when the Choice on Termination of Pregnancy Act was promulgated on 1 February 1997. The most important aspect of this Act is that it now generally provides for the legal termination of a pregnancy on request of a pregnant woman.[29] However, the Act does not make provision for the donation of aborted fetal tissue for research purposes. In

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24 The Act was assented to and published in *GG* 26595 of 23 July 2004.

25 Section 93(1) of the National Health Act repeals the Human Tissue Act, which will come into operation on a date fixed by the President in the *Government Gazette*.

26 Strydom, H (2003) "The human rights side of the human genome" *TSAR* 1:37 *at* 53, 54, 55.

27 The Choice on Termination of Pregnancy Act, 1996 (Act 92 of 1996) (hereafter referred to as the Choice on Termination of Pregnancy Act). The Choice on Termination of Pregnancy Act was recently amended by the Choice on Termination of Pregnancy Amendment Act, 2004 (Act 38 of 2004) (hereafter referred to as the Choice on Termination of Pregnancy Amendment Act).

28 The Abortion and Sterilisation Act, 1975 (Act 2 of 1975) (hereafter referred to as the Abortion and Sterilisation Act).

29 Slabbert, MN (2000) *The human embryo and foetus: Constitutional and other legal issues* (Thesis – LLD.) University of South Africa. (Unpublished). 136, 137.

this regard, reference can be made to the Department of Health's guidelines for good practice in the conduct of clinical trials in human participants in South Africa.[30]

The Medical Research Council of South Africa has 33 years experience and background in the ethics of health sciences research. The entrenchment of the culture of human rights as core value in health research and as one of the four strategic goals of the Medical Research Council has elevated the critical role ethics play in the conduct of research and in society, particularly in a developing country undergoing major changes. The first (1977) and second (1987) editions of the Medical Research Council's guidelines on ethics outlined general philosophical approaches to research ethics based on the Declaration of Helsinki and the Nuremburg Code which, while brief, had to be read. The third edition (of 1993) differs considerably from the first two by presenting information in a codified form with more detailed, specific recommendations. It is more of a handbook than the first two editions and could be used as a ready reference. Although these guidelines do not constitute law, they are still legally relevant. These guidelines subscribe to the values enshrined in the Constitution, namely human dignity, the achievement of equality, and the advancement of human rights and freedoms. All research sponsored by the Council must be of the highest ethical standard.

1 2 PURPOSE AND PROBLEM STATEMENT

The legal and ethical issues related to the manipulation of human life, in particular those connected to health and reproduction, set the framework for this dissertation. Focus is placed on current debates on embryo research and its links to the regulation of medically assisted procreation in South Africa. This framework, which at the time of writing is still an "unsolved" case, is particularly interesting from the following points of view: First, it offers an entry point into one of the most controversial issues of "policy for science",

[30] The Medical Research Council's Ethics Committee produced ethics guidelines in the form of a series of five separate booklets in the style of the Australian National Health and Medical Research Council. These booklets were published between 2000 and 2005. These books include: (1) Guidelines on ethics in medical research: General principles. (2) Guidelines on ethics in reproductive biology and genetic research. (3) Guidelines on ethics in the use of animals in research. (4) Guidelines on ethics in the use of biohazards and radiation. (5) Guidelines on ethics in HIV vaccine trials. See Du Toit, D *et al* (1999) Ethics in health research: Book 2: Reproductive biology and genetic research. [Available on internet:] www.sahealthinfo.org/ethics/ book2.htm [Date of access: 10 March 2006.].

together with the people and dynamics involved. Secondly, the explicit links of this debate to international and global attempts at defining common frameworks for the governance of the manipulation of life, and of human life in particular, makes it an interesting instance of the articulation of scales, national and international, in the governance of science and technology. The framework allows a more complete discussion of conducting research in the South African context, and of its links to health and medicine, to ethical debates, to the legal field and to policy making. It also presents a critical summary of the major debates and policy responses relating to embryonic stem cell research and cloning, drawing attention to some of the challenges posed by conflicting moral values in an era of global scientific endeavour.

The discussion also focuses on an examination of the current legislative framework in the United Kingdom. A further aim of this dissertation is to identify certain shortcomings within the South African legal context, and to propose some recommendations to facilitate a beneficial framework for the regulation of embryonic stem cell research and cloning.

1 3 CHOICE OF LEGAL SYSTEMS

The focus point of this dissertation is an examination of the South African legislative framework with regard to embryonic stem cell research and cloning. However, a number of considerations have led to an examination of the current legislative framework in the United Kingdom. According to section 39(1) of the Constitution, international law must be considered, and foreign law may be considered in the interpretation of the Bill of Rights. On 25 July 1978, Louise Joy Brown, the world's first successful "test-tube baby" was born in the United Kingdom. The technology that made her conception possible was heralded as a triumph in medicine and science. The United Kingdom already took a pioneering role in the area of new reproductive technologies in the 1980's. Significant strides were made, not only in terms of scientific and clinical development, but also in relation to relevant legal and ethical issues. In the latter category, attempts were made to address the debate concerning the moral status of human embryos by advocating a "14-day limit" for research. The Warnock Report, published in 1985, stipulated that research

on human embryos only be allowed up to 14 days after fertilisation. The proposed moral dividing line was purely arbitrary to many opponents of the research, yet somehow a quasi break in the ontogeny of a human being came to be used as a legitimate demarcation point. In 1990, the United Kingdom entrenched the 14-day limit in the Human Fertilisation and Embryology Act,[31] and since then most other industrialised nations that permit embryonic research have followed suit. It is interesting to speculate about whether the United Kingdom will set the standard for future embryonic stem cell research.

In January 2001, after lengthy debates, the United Kingdom Parliament passed the Human Fertilisation and Embryology (Research Purposes) Regulations 2001, permitting embryonic stem cell research using either in vitro fertilisation or somatic cell nuclear transfer technology, and thereby condoning therapeutic cloning. The United Kingdom's position is by far the most progressive in the scope of scientific and therapeutic inquiry regarding embryonic stem cell research and cloning. The United Kingdom has sought to licence endeavours with research embryos, whether created by in vitro fertilisation or somatic cell nuclear transfer. For the time being, this position is unique to the United Kingdom. Ultimately then, it is setting the standard for the regulation of this research.[32]

In addition, the need for a public stem cell bank including human embryonic stem cells has been recognised in the United Kingdom. The British Medical Research Council, in collaboration with the Biotechnology and Biological Science Research Council, and with the full backing of the United Kingdom Government, took the initiative in 2002 to establish the first large-scale publicly funded worldwide stem cell bank. The National Institute for Biological Standards and Control is hosting the United Kingdom Stem Cell Bank, which was officially opened on 1 January 2003. Therefore, the manner in which the United Kingdom regulates embryonic stem cell research and cloning sets a well-balanced example for South Africa.

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[31] The Human Fertilisation and Embryology Act, 1990 (hereafter referred to as the Human Fertilisation and Embryology Act).

[32] Herder, M (2002) "The UK model: Setting the standard for embryonic stem cell research?" [Web:] www.law.ualberta.ca/centres/hli/pdfs/hlr/v10_2/10.2herderfrm.pdf [Date of access: 24 March 2006].

Reference is also made to a few international documents to provide insight into international views on this research. Although the main focus is placed on the United Kingdom regulatory framework, the nature and wide scope of embryonic stem cell research and cloning justify – and compel – an analysis of the regulatory framework in a global context. Where applicable, and especially in chapter 6, reference is also made to the regulation of this research, and to applicable case law in the United States of America's legislative regime.

1 4 RESEARCH METHODOLOGY

The following research methodologies are employed: A literature study of the Constitution, statutes, and case law as primary sources of law is followed. In addition, textbooks and writings of authors as secondary sources of law are utilised. Other sources include the internet and electronic databases.

1 5 OVERVIEW OF CHAPTERS

A legal study of embryonic stem cell research and cloning requires an analysis of the ethical and legal issues associated with it, which are examined in subsequent chapters. To understand the legal and ethical issues associated with this research, an understanding of what the research entails is of utmost importance. Therefore, chapter 2 provides a clinical overview of embryonic stem cell research and cloning. An explanation of what stem cell research and cloning are canvasses the ethical issues associated with such work, and outlines the regulatory framework in which it operates. Medical interventions, for example in vitro fertilisation, fetal tissue research, and therapeutic and reproductive cloning are explained. The acquisition, benefits and application of embryonic stem cell research are also discussed. Medical terms are defined in this chapter, therefore a glossary is not provided at the end of the dissertation.

Chapter 3 examines the constitutional framework. The promotion of the constitutional values of human life and dignity is discussed. In addition, and with reference to the South African common law, the question of whether the embryo and fetus are bearers of constitutional rights is answered. For the purposes of this discussion it is not necessary to establish whether the embryo and fetus are human beings, because it would demand a

deeper philosophical analysis beyond the scope of this dissertation. The question is rather whether they deserve the same protection as born human beings. The right to privacy; freedom and security of the person; reproductive equality; freedom of thought, conscience, and religion; as well as the right of access to health care services, among other constitutionally protected rights and, in the context of embryonic stem cell research, abortion and cloning are also examined.

In chapter 4, domestic legislation in the field of health is discussed and examined. The discussion focuses on the Choice on Termination of Pregnancy Act, the Human Tissue Act and the National Health Act. Health legislation can encompass almost any legal instrument that has a bearing on the health of an individual or community. To comprehensively cover all possible aspects is therefore beyond the scope of a dissertation of this nature. The role of the Medical Research Council and the Medical Research Council's guidelines are also explained. Further reference is made to a few international instruments, for example the Declaration of Helsinki and the Nuremberg Code.

Chapter 5 outlines the legal position in the United Kingdom. A description of the English common law is provided with reference to the legal status of the unborn child. The Human Fertilisation and Embryology Act is discussed, as well as the Human Tissue Act of 2004.

The substantive provisions of the Human Tissue Act of 2004 would have come into full force in April 2006. This will allow the Human Tissue Authority, established under the Act, to draw up codes of practice and consult them. Reference is also made to the United Kingdom Stem Cell Bank and the regulation thereof.

The regulation of embryonic stem cell research and cloning is complex and confronting. In chapter 6, some shortcomings in current South African legislation are pointed out and recommendations are made to address these shortcomings. For example, in the context of the debates, controversies and initiatives to create regulatory frameworks at national and international levels, South Africa displays a number of singularities. We still lack a legal and regulatory framework in areas such as the creation and use of and access to human

genetic information for medical or other purposes, medically assisted reproduction, and research on human embryos. In this chapter a few submissions are made to establish the well-balanced regulation of the research.

Chapter 7 concludes the research with a summary and submission of recommendations in light of gaps identified in the current legal system.

1 6 HYPOTHESIS

Strides have undoubtedly been made regarding South Africa's dedication to health care. For example, government has included clauses in the Constitution protecting access to health care services, as well as reproductive freedom and freedom of scientific research, and has also promulgated extensive domestic legislation. However, regardless of these developments, it is proposed that current legislation remains fragmented and ineffective. It is put forward that the inadequate legal framework is directly responsible for the improper management and provision of health care services at present, including reproductive health care services, as well as the regulation of research on embryos and fetuses in South Africa. The proposition advanced by this research is that the absence of a centrally co-coordinated health care structure has attributed to confusion and overlaps. In essence, this research investigates where accountability should lie, and attempts to establish the reasons for this unfocussed approach.

1 7 VALUE CONTRIBUTION

This research exposes the ineffective way in which embryonic stem cell research and cloning is regulated in South Africa. It also points out the shortcomings in current legislation. It is trusted that the research will assist in addressing some of the legal and ethical issues with reference to embryonic stem cell research and cloning in South Africa.

1 8 MOTIVATION

The challenge facing this dissertation is to ensure a comprehensive and detailed study of embryonic stem cell research and cloning in South Africa whilst providing a proposed legislative framework in context of legal status and personhood. Although embryo

research and cloning are written about extensively in the international context, the area is still in its infancy in South Africa. As a result it is imperative to undertake a broad-ranging analysis of not only the legal issues involved, but an in-depth study of the clinical aspects of embryonic stem cell research and cloning is also required to ensure clarification and exposition of the issues surrounding the complex nature of this topic.

Further, as a result of the multifaceted focus of this work, it is necessary to consult numerous legislative texts. For example, a detailed analysis of interrelated constitutional provisions such as the right to life, the right to dignity, the right to reproduce, the right to privacy, and the right to freedom of scientific research and experimentation needs to be undertaken together with a study of the common law, various acts, regulations, guidelines, and policy documents. A scrutiny of conflicting scholarly viewpoints of renowned authors embodying moral, ethical, scientific, and legal issues is also carried out. Finally, it is necessary to undertake a comparative study of the United Kingdom's legal regime, as it has emerged as the leader in the field of embryonic research and cloning, in particular therapeutic cloning. Taking the above into consideration, the length of this dissertation is necessitated by the fact that it covers a wide range of disciplines to ensure that the study is current, inclusive, and complete.

1 9 CONCLUSION

Human embryonic stem cell research raises complex legal and ethical issues. The question of whether it is ethically defensible to do research on embryonic stem cells can be described as a conflict between different values, between different people's rights and obligations, or between the short- and long-term interests of different groups. On the one hand, there is interest in new knowledge that can lead to the treatment of incurable diseases. On the other hand, when this research involves the use of human embryos, it raises the question of ethical values at stake and of the limits and conditions for such research. Opinions on the legitimacy of experiments using human embryos are divided according to the different ethical, philosophical and religious traditions in which they are rooted. However, it is no exaggeration to say that the outcomes of this research may

potentially affect the everyday lives of hundreds, indeed thousands, of ordinary men and women in this country.

In providing a comprehensive legislative framework for stem cell research and cloning in South Africa, the relevant provisions of the Constitution must be observed. Legislation will also have to provide clear guidance for the development of the future use of embryos in research. It is submitted that at present the Human Tissue Act together with its regulations, as well as the Medical Research Council's guidelines, does not keep up with the fast developments and consequences of this research. The National Health Act provides for new principles relating to stem cell research in chapter 8. However, the regulation of the research is mostly placed within the regulatory powers of the Minister, which raises further concerns. Before these issues and concerns are discussed, the next chapter provides a clinical overview of the research.

CHAPTER 2 EMBRYONIC STEM CELL RESEARCH AND CLONING: A CLINICAL OVERVIEW

2 1 INTRODUCTION

In the beginning of human development, one cell becomes two, two become four, and four become eight. Being fruitful, they multiply into a ball of many cells, a sphere of human potential. Scientists have long dreamed of plucking those cells from a young human embryo and coaxing them to perform, in sterile isolation, the everyday miracle they perform in wombs by transforming into more or less 200 kinds of cells that constitute a human body. The dream is to launch a medical revolution in which ailing organs and tissues might be repaired, not with mechanical devices like insulin pumps and titanium joints, but with living, home-grown replacements. It would be the dawn of a new era of regenerative medicine, one of the holy grails of modern biology.[33]

The excitement generated by embryonic stem cell research and cloning, specifically therapeutic cloning, is certainly justifiable. The importance of stem cells in scientific research cannot be overstated. For example, scientists need such early-stage cells to understand how genes are turned on and off in development. More specifically, scientists envision a new era of cell therapies. Thomas Okarma, Chief Executive Officer of Geron, a company specialising in stem cell technology, believes that "(l)iving cells will be tomorrow's pharmaceuticals".[34] Perhaps the most important potential application of human stem cells is the generation of cells and tissues that could be used for cell-based therapies. Today, donated organs and tissue are often used to replace ailing or destroyed tissue, but the need for transplantable tissue and organs far outweighs the available supply. Stem cells directed to differentiate into specific cell types offer the possibility of a renewable source of replacement cells and tissues to treat diseases.[35]

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[33] Weiss (2005) *Nat Geogr Mag* 3 *at* 5-7. See in general Annas, GJ (2005) "I want to live: Medicine betrayed by ideology in the political debate over Terri Schiavo" *Stetson L Rev* 35(1):39-47.

[34] Hazuka, CD (2002) "Supporting the work of lesser geniuses: An argument for removing obstructions to human embryonic stem cell research" *U Miami L Rev* 57(1):157.

[35] United States. National Institutes of Health (2001a) "Stem cell information: Report on stem cells" [Web:] www.stemcells.nih.gov/info/basics2.asp [Date of access: 13 September 2005].

The purpose of this chapter is to describe the science underlying stem cell research and cloning, as well as its most important applications. The potential advantages of this research are also discussed. The sources of stem cells are identified, as well as the different techniques used to harvest them.

There is much confusion over what cloning is. The distinction between "reproductive cloning" and "therapeutic cloning" is made, and it is explained how stem cell research fits into this framework. There are many ethical and legal implications regarding stem cell research. However, an analysis of these implications would only be possible after a detailed discussion of exactly what stem cell research entails. The ethical and legal issues are discussed in the next chapters.

2 2 THE SCIENCE AND BACKGROUND OF STEM CELLS

2 2 1 Stem cells and their power to divide: An overview

Stem cells are defined as undifferentiated cells that have the ability to self-replicate for indefinite periods into any cell type in the human body through the process of differentiation.[36] In the course of human development, a single cell – the fertilised egg – ultimately gives rise to more than 200 cell types such as blood cells, liver cells and neural cells that make up the human body. This process, whereby less specialised cells turn into more specialised cell types, is called "differentiation". As more or less all the cells in the body have the same genes, differentiation occurs mainly by expressing[37] or repressing[38] different subsets of these genes. For example, red blood cells express the gene that makes hemoglobin[39], but neural cells do not. Therefore, differentiated cell types express

[36] Enmon (2002) *Utah L Rev* 621. See also Dhai, A *et al* (2004) "Ethical and legal controversies in cloning for biomedical research – A South African perspective" *SAMJ* 94(11):906. See in general Slabbert, MN (2003) "Cloning and stem cell research: A critical overview of the present legislative regime in Australia and the way forward" *JLM* 10(4):514 *at* 515,516. See also Miller, J (2003) " A call to legal arms: Bringing embryonic stem cell therapies to market" *Alb LJ Sci & Tech* 13(2):555.

[37] Expressing literally means the switching on of the different subsets of genes.

[38] Repressing literally means the switching off of the different subsets of genes.

[39] Hemoglobin is the protein that carries oxygen through the body. See United States. National Institutes of Health (2001b) "Report on stem cells: Appendix F: Glossary and terms" [Web:] www.stemcells.nih.gov/info/scireport/appendixF.asp [Date of access: 7 October 2005]. See also Bioteach. (2006) "Stem cell bioengineering" [Web:] www.bioteach.ubc.ca/Bioengineering/Stem Cells [Date of access: 10 January 2006].

different subsets of genes. As cells become more specialised or differentiated, the subset of genes that they can express becomes more restricted. Stem cells from different sources differ in their potential for differentiation and in the number of cell types to which they can normally give rise. These cells are best understood in terms of how committed they are to becoming any particular type of cell. The categories into which they fall include "totipotent stem cells", "pluripotent stem cells", and "multipotent stem cells".[40]

2 2 1 1 Totipotent stem cells

Human cells can be divided into sex or germ cells[41]; eggs[42] and sperm cells; and somatic cells (the rest of our cells).[43] When a sperm cell and an egg cell unite, they form one – called a fertilised egg.[44] After fertilisation, the egg starts dividing to form first two, then four, then eight identical cells. These cells are totipotent, which means that they have the potential to give rise to any and all human cells such as heart cells, brain cells and liver cells. These cells, if isolated and allowed to develop, can form a new embryo. In fact, this is the explanation for the formation of identical twins.[45] The first few cell divisions in embryonic development produce more totipotent cells. After about three days of embryonic cell division, the cells begin to specialise and lose the ability to form a new embryo.[46]

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40 United Kingdom. Parliament: House of Lords (2002) "Stem cell research report" [Web:] www.parliament.the-stationery-office.co.uk/pa/Id200102/dselect/Idstem/83/8301.htm-14k [Date of access: 25 September 2005].

41 Germ cells are cells found in a specific part of the embryo/fetus called the gonadal ridge that normally develop into mature gametes.

42 An egg cell is also referred to as an oocyte. An oocyte is a developing egg that is usually a large and immobile cell. Section 1 of the National Health Act defines an oocyte as a developing human egg cell. The predecessor of the National Health Act, The Human Tissue Act, does not define an oocyte in section 1.

43 Slabbert (2003) *JLM* 514 *at* 517.

44 Miller (2003) *Alb LJ Sci & Tech* 555 *at* 558.

45 Identical twinning is the process by which genetically identical organisms arise from symmetrical division and separation of totipotent cells. See United States: National Institutes of Health (2001b) www.stemcells.nih.gov/info/scireport/appendixF.asp.

46 Slabbert (2003) *JLM* 514 *at* 515. See also Miller (2003*) Alb LJ Sci & Tech* 555 *at* 558.

2 2 1 2 Pluripotent stem cells

On the fourth day of embryonic development, the ball of cells forms into an outer layer known as a "blastocyst". The blastocyst is a small, hollow ball that consists of around 100 relatively undifferentiated cells.[47] Embryonic stem cells are derived from the blastocyst. The blastocyst consists of two layers, the outer cell mass, which develops into extra-embryonic tissues such as the placenta[48] and other tissues needed for fetal development in the uterus, and the inner cell mass, which is a group of about 30 cells that will produce tissues for the resulting child.[49] These cells are pluripotent, which means that each cell has the capacity to develop into any of the 200 cell types that make up the human body.[50] Pluripotent stem cells can eventually differentiate into any bodily tissue, but they cannot develop into a human being themselves, because they are unable to give rise to the placenta and other tissues required for full human development. Therefore, they would not be able to develop into a fetus if placed in a woman's uterus. They are stem cells and can develop into any of the three major tissue types, namely endoderm, mesoderm or ectoderm.[51]

2 2 1 3 Multipotent stem cells

The pluripotent cells further specialise into other types of stem cells. These cells, which can only develop into a few tissues, are called multipotent stem cells.[52] Multipotent stem cells give rise to cells that have a particular function. For example, haematopoietic stem

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47 Princeton University: Department of Molecular Biology. "Stem cell basics" [Web:] www.molbio.princeton.edu/courses/mb427/2001/projects/09/SObasics.htm [Date of access: 20 September 2005].

48 The placenta is defined as the oval or discoid spongy structure in the uterus from which the fetus derives its nourishment and oxygen.

49 Blackbeard, M (2002) "Therapeutic cloning – OK?" *DJ* 35(2):318 *at* 321. See also Enmon (2002) *Utah L Rev* 621 *at* 622.

50 Laurie, G (2004) "Patenting stem cells of human origin" *Eur Int Prop Rev* 26(2):59 *at* 60.

51 The endoderm is the lower layer of a group of cells derived from the inner cell mass of the blastocyst and it later becomes the lungs and digestive organs. The mesoderm is the middle layer of the embryonic disk, which consists of a group of cells derived from the inner cell mass of the blastocyst. This middle germ layer is known as gastrulation and is the precursor to bone, muscle, and connective tissue. The ectoderm is the upper, outermost of the three primitive germ layers of the embryo, and it gives rise to skin, nerves, and the brain. See Moore, KL & Persaud, TVN (2003) *Before we are born: Essentials of embryology and birth defects* 41, 47, 48, 60.

52 Enmon (2002) *Utah L Rev* 621 *at* 622.

cells[53] give rise to red blood cells, white blood cells and platelets, while skin stem cells give rise to the different types of skin cells.[54] These organ-specific stem cells form during fetal development, and remain, though less numerous, in adult individuals.[55] Multipotent stem cells can be isolated in a number of tissues such as bone marrow, and are used in therapeutic procedures such as bone marrow transplants. Adult stem cells are usually characterised as multipotent stem cells. These stem cells can differentiate in vitro[56] and are currently being studied for their possible uses in regenerative medicine.[57]

2 2 2 The unique properties of stem cells

Because stem cells differ from other kinds of cells in the body all stem cells, regardless of their source, have three general properties: they are capable of dividing and renewing themselves for long periods; they are unspecialised; and they can give rise to specialised cell types.[58]

2 2 2 1 Proliferation and self-renewal

Unlike muscle cells, blood cells and nerve cells, which do not normally replicate themselves, stem cells may replicate many times.[59] When cells replicate themselves many times over it is called "proliferation". A starting population of stem cells that proliferate for many months in the laboratory can yield millions of cells.[60] The cells then differentiate into the specialised cells needed for therapeutic treatment. In this way the cells are continuously replenished as they die.[61] If the resulting cells are identical in terms of being unspecialised themselves and are capable of generating specialised cells to the

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53 A haematopoietic stem cell is a blood stem cell from which all types of blood cells develop.
54 Princeton University: Department of Molecular Biology (2006) www.molbio.princeton.edu/courses/mb427/2001/projects/09/SObasics.htm.
55 Slabbert (2003) *JLM* 514 *at* 515.
56 In vitro literally means "in glass". The egg is fertilised in a laboratory dish or test tube in an artificial environment. This is in contrast with "in vivo", which means in the living subject, in a natural environment. It literally means "in life". See Slabbert (2000) 8.
57 Van Wyk (2004) *THRHR* 1 *at* 14.
58 United States: National Institutes of Health (2001b) www.stemcells.nih.gov/info/scireport/appendixF.asp.
59 Bioteach (2006) www.bioteach.ubc.ca/Bioengineering/Stem Cells.
60 Laurie (2004) *Eur Int Prop Rev* 59 *at* 60.
61 This process is called homeostasis.

parent stem cells, the embryonic stem cells are said to be capable of long-term self-renewal. Scientists are greatly interested in determining specific factors and conditions that allow stem cells to remain unspecialised in the laboratory for long periods of time.[62]

2 2 2 2 Stem cells are unspecialised "blank" cells

One of the fundamental properties of a stem cell is that it does not have a tissue-specific structure that allows it to perform specialised functions. A stem cell cannot work with its neighbours to pump blood through the body like a heart muscle cell; it cannot carry molecules of oxygen through the bloodstream like a red blood cell. However, unspecialised stem cells can give rise to complex cells or tissues, including heart muscle cells, blood cells or nerve cells.[63] They do this by coordinating their gene expression in an elaborate and complex pattern spanning many generations of cells.

2 2 2 3 Stem cells can be manipulated to give rise to particular specialised cell types

When unspecialised stem cells give rise to specialised cells, the process is called differentiation.[64] Scientists are just beginning to understand the signals inside and outside cells that trigger stem cell differentiation. The internal signals are controlled by a cell's genes,[65] which are interspersed across long strands of DNA,[66] and carry coded instructions for all the structures and functions of a cell. The external signals for cell differentiation include chemicals secreted by other cells, physical contact with

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62 Sax, K (2006) "The state's 'race' with federal government for stem cell research" *Annals Health L* 15:1 *at* 2-7.

63 Casell, JH (2001) "Lengthening the stem: Allowing federally funded researchers to derive human pluripotent stem cells from embryos" *U Mich JL Ref* 34(3):547 *at* 551.

64 United Kingdom. Parliament: House of Lords (2002) www.parliament.the-stationery-office.co.uk/pa/Id200102/dselect/Idstem/83/8301.htm-14k. For an explanation of the process of differentiation see paragraph 2.2.1.

65 A cell's genes are defined as a unit of heredity that is a segment of DNA located in a specific site on a chromosome. Chromosomes contain genes, working stretches of DNA that carry the genetic code for specific proteins. The Y chromosome is the chromosome that determines male gender. The X inactivation is the normal inactivation of one of the two X chromosomes in females. Normal human cells contain 46 chromosomes and mature normal human gametes have 23 chromosomes. Section 1 of the Human Tissue Act as well as section 1 of the National Health Act define a gamete as "either of the two generative cells essential for human reproduction".

66 DNA is the abbreviation for "deoxyribonucleic acid". It is defined as the genetic material that contains the instructions for making an entire organism.

neighbouring cells, and certain molecules in the microenvironment. One question that needs to be answered is whether specific sets of signals could be identified as responsible for the promotion of differentiation into specific cell types. The answer to this question is critical in order to learn how to maintain pools of stem cells. The development of stem cell-based technologies will depend on scientists' ability to reproducibly drive the differentiation of stem cells into specific tissue lineages. This is important for the development of embryonic stem cell cell-based technologies, where the differentiation of certain subsets of cells and tissues is uncommon. The generation of embryonic stem cell-derived heart muscle cells[67] is one example where significant improvements in tissue-specific differentiation are needed.[68]

2 2 3 The potential of stem cells

Because of the cells' abilities to reproduce themselves, and to differentiate into other cell types, stem cells offer the prospect of developing cell-based treatments, both to repair or replace tissues damaged by fractures, burns and other injuries and to treat a wide range of very common neurodegenerative diseases, such as Alzheimer's disease, diabetes, and Parkinson's disease.[69] These cells could also be useful for a number of tissue engineering[70] applications, such as the production of complete organs including livers, kidneys, eyes, hearts, or even parts of the brain. This represents a considerably greater challenge, beyond the generation of specialised cell types, and requires considerable time and effort to develop.

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67 Under default mechanisms, only about 1% of embryonic stem cells form cardiac tissue.

68 Bioteach (2006) www.bioteach.ubc.ca/Bioengineering/Stem Cells.

69 Holland *et al* (2002) 3. See also United Kingdom. Parliament: House of Lords (2002) www.parliament.the-stationery-office.co.uk/pa/Id200102/dselect/Idstem/83/8301.htm-14k.

70 One controversial option in biomedicine is to create organs through the technique of tissue engineering. It includes a range of transplantable material, from hearts, brain tissue, corneas and intestines. The source of these materials could range from, for example, the person's own blood or bone marrow, to the use of materials from other human beings, which could either be from cadaveric donors or live donors. It could also be from fetal origin, for example islet cells, for the treatment of diabetes, or tissues from other species. It includes the development and manipulation of cells, tissue or organs outside the body in a laboratory. Since the original genetic information would be derived from the recipient, the new material would be a genetic match, thereby reducing rejections and need for autoimmune suppression. Autoimmune diseases are various diseases characterised by the body's failure to distinguish its own tissues, causing the body to attack it. See Blackbeard (2002) *DJ* 318.

Other areas that would benefit from a better understanding and control of stem cell proliferation in vitro are drug testing, cancer research and fundamental research on embryonic development.[71] Researchers also hope that stem cell research and cloning will lead to the application of another therapeutic treatment called gene therapy. By understanding the human genome, scientists can identify genetic inconsistencies that lead to disease and modify them by introducing a corrective genetic remedy. Cells cloned from the patient's own body will eliminate the problem of rejection.[72] Stem cell treatments, unlike most conventional drug treatments, have the potential to become a life-long cure. There is almost no realm of medicine that would not be touched by this innovation. It is not too unrealistic to say that this research has the potential to revolutionise the practice of medicine and improve the quality and length of life.[73] However, to exploit the therapeutic potential and promises of stem cells, extensive research is required on the risks and benefits of their use.[74]

2 2 4 Stem cells and the treatment of serious diseases[75]

2 2 4 1 Spinal cord injuries

The University of Florida College of Medicine and Brain Institute in Gainesville, Florida, announced plans to graft human fetal nerve tissue into the cystic cavities of several human subjects. By implanting the nerve tissue directly into the damaged areas of the spine, researchers hoped to slow the progression of a rare degenerative condition called

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71 Kincaid, S (2003) "Oh, the places you'll go: The implications of current patent law on embryonic stem cell research" *Pepp L Rev* 30(3):553 *at* 579. See also Makdisi, JMZ (2003) "The slide from human embryonic stem cell research to reproductive cloning: Ethical decision-making and the ban on federal funding" *Rutgers LJ* 34(2):463 *at* 468.

72 Hartman, C (2002) "Understanding biotech stories: Embryonic stem cell research without the embryo" [Web:] www.facsnet.org/tools/sci_tech/biotek/lanza.php3 [Date of access: 25 January 2006].

73 Miller (2003) *Alb LJ Sci & Tech* 555 *at* 560, 561.

74 Regnier, ME & Knoppers, BM (2003) "Spare embryos and stem cell research: consent issues" *Health L Rev* 11(3):3.

75 Dr Harold Varmus suggests that more than half of the world's population will benefit significantly from the future applications of stem cell research. Some of the conditions for which scientists believe there is evidence to suggest that therapeutic stem cell treatments will have a major impact include cancer, stroke, sickle cell, Aids, burns, diabetes, Parkinson's disease, heart disease, Huntington's disease, multiple sclerosis, Alzheimer's disease, arthritis, retinal disease, spinal cord injury, Down's syndrome and mental retardation. Only a few of these diseases were chosen to be discussed in the text.

syringomyelia.[76] Fetal cells are injected into the damaged cystic cavities in hopes they will grow to replace the damaged spinal tissue. Researchers insisted that the goal of the experimental surgery was not to restore mobility of feeling to the damaged spine, but to see if the procedure could be done safely. This treatment might be able to benefit patients with spinal cord injuries.[77]

2 2 4 2 Parkinson's disease

Parkinson's disease is a slowly progressing degenerative disease affecting a small area of cells in the middle part of the brain. The degeneration of these cells can lead to one or more of the typical signs of Parkinson's disease, including tremors, slow movement, stiff limbs, balance problems and depression. In a study conducted at the University of Colorado in Denver, 40 patients with advanced Parkinson's disease received surgical implants of fetal dopaminergic cells[78] or underwent a sham surgical procedure. Positron emission tomography[79] demonstrated that dopamine activity increased more than 20% in more than half of the patients in the group receiving implants, compared with none of the placebo group. More than half of the patients under the age of 60 who received implants experienced significant improvements in movement. These patients were younger and had greater brain plasticity – their brains were able to repair injured tissue more easily, which may account for the bigger improvement in their movement.[80]

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[76] Washington, R (1997) "Fetal tissue transplant debated" *The Gainesville Sun*, 15 July [Available on internet:] www.sunone.com/news/articles/07-154.html [Date of access: 10 October 2005].

[77] University of Washington: Department of Rehabilitation Medicine (1998) "How close is a cure for SCI?" *SCI Update Newsletter*. [Available on internet:] www.depts.washington.edu/rehab/sci/update-cure8-2.shtml [Date of access: 10 October 2005].

[78] Dopamine is a chemical in the brain that plays a crucial role in movement and cognition. The degeneration of dopamine leads to the symptoms of Parkinson's disease. Fetal dopaminergic cells can replace the lost dopamine in Parkinson's patients.

[79] This technology monitors biochemical changes within the body by detecting and modelling concentrations of radioactivity in particular regions of the body.

[80] Casell (2001) *U Mich JL Ref* 547 *at* 549. See also United States: National Institutes of Health (2001b) www.stemcells.nih.gov/info/scireport/appendixF.asp.

2 2 4 3 Diabetes

Human pluripotent stem cells show great promise for curing type 1 diabetes, or juvenile diabetes, which is characterised by the body's inability to produce insulin, a hormone necessary for glucose metabolism.

Pluripotent stem cells have the potential to provide a limitless supply of islet cells[81]; the cells needed for transplantation in type I diabetes patients. Owing to the shortage of islet cells, only about 5% of patients with diabetes who received islet cell transplants have been able to stay off insulin for more than a year. Utilising pluripotent stem cells to generate a vast source of islet cells could dramatically increase the current low success rate of islet cell transplants. In a breakthrough, scientists from the National Institute of Health used the embryonic stem cells of mice with type 1 diabetes to generate cells expressing insulin and other pancreatic endocrine hormones. The cells self-assembled to form three-dimensional clusters similar to normal pancreatic islets where pancreatic cell types are closely associated with neurons. Glucose triggered insulin release from these cell clusters, and when injected into the mice, the insulin-producing cells maintained a clustered islet-like organisation enabling the mice to live longer.[82]

2 3 THE SOURCES OF STEM CELLS

2 3 1 The potential sources of stem cells

Human stem cells have several actual or potential sources, namely human embryonic stem cells (which are created through the process of in vitro fertilisation), cadaveric fetal tissue or embryonic germ cells (derived from human fetal tissue which remains after spontaneous or elective abortions), cloned human embryos (where somatic cell nuclear transfer is used to create an embryo for research purposes), cloned chimera embryos (where the somatic cell of a human is introduced into an enucleated animal ovum), and

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[81] Islet cells, or Islets of Langerhans, are groups of specialised cells in the pancreas that produce insulin and make and secrete hormones. See MedicineNet.com (1998) Definition of Islets of Langerhans [Web:] www.medicinenet.com/Script/Main/Art.asp?li=MNI&ArticleKey=4054 [Date of access: 14 January 2006])

[82] Casell (2001) *U Mich JL Ref* 547 *at* 549. See also Stevens, D (2003) "Embryonic stem cell research: Will President Bush's limitation on federal funding put the United States at a disadvantage? A comparison between US and international law" *Hous J Int'l L* 25(3):623 *at* 629; Monachello, JJ (2003) "The cloning for biomedical research debate: Do the promises of medical advances outweigh the ethical concerns?" *Tul J Comp & Int'l L*10 (2):591 *at* 593.

adult cells (which are usually obtained from such areas as bone marrow, skin, blood or even fat of live adult donors)[83]. These sources are discussed individually below.

2 3 2 Human embryonic stem cells

Human embryonic stem cells capture the imagination because they are immortal and have an almost unlimited developmental potential.[84] Embryonic stem cells are undifferentiated cells that differ from specific adult cells, but have the ability to provide an unlimited source of specific, clinically important adult cells such as bone, muscle, liver or blood cells. The reason for this is that these stem cells can proliferate indefinitely in cell cultures.[85] Embryonic stem cells, as their name indicates, are derived from early embryos that can be propagated indefinitely in the primitive undifferentiated state while remaining pluripotent. Specifically embryonic stem cells are derived from embryos that develop from eggs that have been fertilised in vitro at an in vitro fertilisation clinic. They are never derived from eggs fertilised inside a woman's body. Embryonic stem cells are isolated from the inner cell mass of the blastocyst, which comprises between 16 and 140 cells.[86] These stem cells are also obtained from aborted fetuses and could also be derived through somatic cell nuclear transfer techniques for therapeutic purposes.[87] These techniques are discussed in the paragraphs below. In order to understand human embryonic stem cell research, it is necessary to understand the basic properties of the development of early human embryos.

The term embryo[88] has different usages and therefore the embryo may be described in various ways. In a general sense an embryo is referred to as a living entity that comes into

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83 Slabbert (2003) *JLM* 514 *at* 517, 518.
84 Holland *et al* (2002) 15.
85 University of Wisconsin-Madison (2001) "Embryonic stem cells: Research at the University of Wisconsin- Madison" [Web:] www.news.wisc.edu/packages/stemcells/ facts.html [Date of access: 27 October 2005].
86 Slabbert (2003) *JLM* 514 *at* 517.
87 Bioteach (2006) www.bioteach.ubc.ca/Bioengineering/Stem Cells.
88 Section 1 of the National Health Act defines an embryo as a human offspring in the first eight weeks from conception. The Human Tissue Act does not define the term. Section 1(1) of the United Kingdom Human Fertilisation and Embryology Act defines an embryo as a live human embryo where fertilisation is complete, and references to an embryo include an egg in the process of fertilisation and, for this purpose, fertilisation is not complete until the appearance of a two-cell zygote. It is also necessary to

existence as the result of either in vivo or in vitro fertilisation of a human egg by a human sperm, which develops in the uterus of a woman or is physically separated from the woman's body but is incapable of surviving and developing outside the uterus.[89] The development of the embryo can be described in the following seven stages:

(a) Fertilisation[90] occurs in the oviduct when the female egg is fertilised by the male sperm.[91] Human oocytes are usually fertilised within 12 hours after ovulation. In vitro observations have shown that oocytes cannot be fertilised after 24 hours, and they degenerate shortly thereafter. Most human sperm do not survive for more than 48 hours in the female genital tract.[92] The process of fertilisation involves a number of steps that ultimately result in a single cell, the zygote.[93] The egg and sperm each carry half the genes of a normal cell. The zygote contains all the genes necessary for the development of an individual – half derived from the mother and half derived from the father.[94]

(b) The zygote undergoes a series of cell divisions starting about 36 hours after fertilisation. Initially, all the cells are essentially identical and all have the potential, if placed in the right environment, to develop into an individual.[95] First, the zygote divides into two blastomeres, which then divide into four blastomeres, then eight. After the eight-cell stage, the blastomeres change their shape and tightly align

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draw a distinction between the embryo outside the womb (also known as the embryo *extra uterum*), and the embryo and fetus inside the womb (called the embryo *in utero*).

89 Slabbert (2000) 8.

90 It is difficult to determine exactly when fertilisation occurs because the process cannot be observed within the living body. Physicians calculate the age of the embryo or fetus from the first day of the last normal menstrual period. This is the gestational age, which is about two weeks longer than the fertilisation age because the oocyte is not fertilised until about to weeks after the preceding menstruation. Consequently, when a physician states the age of an embryo or fetus, two weeks must be deducted to determine the actual or fertilisation age. See Moore & Persaud (2003) 2. The gestation period is the period of pregnancy of a woman calculated from the first day of the menstrual period that, in relation to the pregnancy, is the last. See section 1 of The Choice on Termination of Pregnancy Act.

91 Holland *et al* (2002) 15.

92 Moore & Persaud (2003) 26.

93 This cell, formed by the union of an oocyte and a sperm, is the beginning of a new human being. The expression "fertilised ovum" refers to a secondary oocyte that has been impregnated by a sperm. When fertilisation is complete, the oocyte becomes a zygote. In terms of section 1 of the National Health Act, a zygote is the product of the union of a male and a female gamete. The Human Tissue Act does not define the term zygote.

94 Odendaal, HJ (1989) *Ginekologie* 21, 22, 23.

95 United Kingdom. Parliament: House of Lords (2002) www.parliament.the-stationery-office.co.uk/pa/Id200102/dselect/Idstem/83/8301.htm-14k.

themselves against each other to form a compact ball of cells.[96] About three days after fertilisation, this ball of blastomeres (called the morula[97]) enters the uterus. As fluid increases in the cavity, the blastomeres are separated into two parts, namely the trophoblast[98] and the inner cell mass.[99]

(c) At this stage of development the embryo has about 100 cells, and is known as a blastocyst.[100] The blastocyst is a small hollow ball of relatively undifferentiated cells. The inner cell mass now projects into the blastocystic cavity, and the trophoblast forms the wall of the blastocyst. The trophoblast then encloses the embryoblast and blastocystic cavity and later forms extra embryonic structures and the embryonic part of the placenta and umbilical cord.[101] As the source of embryonic stem cells, the blastocyst is the primary focus of much of the debate on the use of embryos in stem cell research and therapy. It is sometimes referred to as the "preimplantation embryo" or the "early embryo".

(d) About a week after fertilisation, implantation of the blastocyst in the womb takes place, which is completed by the end of the second week.[102] If implantation does not take place, the blastocyst does not develop further. At this stage the cells are still relatively undifferentiated and there is no trace of human structures such as a nervous system.[103]

(e) About 14 days after fertilisation, the early embryo consists of about 2 000 cells.[104] It is only at this stage that the cells begin to become differentiated into more specialised

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96 Moore & Persaud (2003) 31.

97 The morula is also known as "morus mulberry" because of its resemblance to the fruit of the mulberry tree.

98 The trophoblast is a thin outer cell that gives rise to the embryonic part of the placenta.

99 Odendaal (1989) 23. The inner cell mass (also referred to as the embryoblast) is a group of about 30 centrally located blastomeres that gives rise to the embryo.

100 The blastocyst consists of three structures, namely the inner cell mass, the blastocystic cavity (a fluid-filled space) and the trophoblast.

101 Moore & Persaud (2003) 35, 105. The umbilical cord, which connects the embryo to the placenta, is usually attached near the centre of the fetal surface, but it may be found at any point. The placenta is the primary source of nutrient and gas exchange between the mother and fetus. The placenta and umbilical cord function as a transport system for substances passing between the mother and fetus. Shortly after the birth of a baby, the placenta and fetal membranes are expelled from the uterus as the afterbirth.

102 Blastocysts may implant outside the uterus. Extra-uterine implantations result in ectopic pregnancies and 95 to 97% of ectopic implantations occur in the uterine tube. See Odendaal (1989) 173.

103 United Kingdom. Parliament: House of Lords (2002) www.parliament.the-stationery-office.co.uk/pa/Id200102/dselect/Idstem/83/8301.htm-14k.

104 *Ibid*.

cell types and the primitive streak,[105] from which the central nervous system eventually develops, begins to appear[106].

(f) After about eight weeks' development, individual organs become recognisable and the embryo can be described as a proper fetus. The transformation of an embryo to a fetus is gradual. Development during the fetal period is concerned primarily with rapid body growth and differentiation of tissues, organs and systems.[107]

(g) At around 38 weeks, given normal gestation, the baby is born. Cord blood stem cells can be extracted from the blood that remains in the umbilical cord at the time of birth. Postnatal stem cells can be extracted from the placenta waste following birth.[108] Haematopoietic stem cells can be retrieved from the umbilical cord blood at birth, though care must be taken to ensure that the baby receives enough cord blood.

2 3 3 The science of artificial insemination and in vitro fertilisation technology

2 3 3 1 Artificial insemination[109]

In recent years, considerable ethical and legal problems have arisen because of the development of medical techniques surrounding methods of initiating pregnancy other

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[105] The primitive streak is a thickened, linear band of epiblast and appears caudally in the median plane of the dorsal part of the embryonic disc. The primitive streak results from the proliferation and migration of cells of the epiblast to the median plane of the embryonic disc. Neither the Human Tissue Act nor the National Health Act provides a definition for the primitive streak. It is, however, defined in section 3(4) of the United Kingdom Human Fertilisation and Embryology Act, which reads as follows: "For the purpose of subsection (3) above, the primitive streak is to be taken to have appeared in an embryo not later than the end of the period of 14 days beginning with the day when the gametes are mixed, not counting any time during which the embryo is stored." The Human Fertilisation and Embryology Act is discussed thoroughly in chapter 5. See also Odendaal (1989) 23.

[106] Odendaal (1989) 23.

[107] Moore & Persaud (2003) 78.

[108] Daley (2001) www.law.mq.edu.au/ANZIHLE/daley%20cp%2001.pdf.

[109] Artificial insemination is the production of pregnancy in a woman by introducing seminal fluid directly into the cervix or uterus by means of a cannula. AIH is usually performed because of some anatomical or pathological difficulty in normal insemination. According to the Human Tissue Act, "(a)rtificial fertilisation of a person means the introduction by other than natural means of a male gamete or gametes into the internal reproductive organs of a female person for the purpose of human reproduction, including – (a) The bringing together outside the human body of a male and a female gamete or gametes with a view to placing the product of a union of such gametes in the womb of a female person; or (b) the placing of the product of a union of a male and a female gamete or gametes which have been brought together outside the human body, in the womb of a female person." Artificial insemination is also defined in section 5(3) of the Children's Status Act, 1987 (Act 82 of 1987), (hereafter refereed to as the Children's Status Act), and read as follows: "For purposes of the following section 'artificial insemination,' in relation to a woman (a) means the introduction by other than natural means of a male gamete or gametes into the internal reproductive organs of that woman; or (b) means the placing of the product of a union of a male and a female gamete or gametes which have been brought together outside the human body in the womb of that woman, for the purpose of human reproduction."

than normal sexual intercourse. There are legal, moral and religious controversies over these matters, and opinions vary widely from country to country.[110] There are two types of artificial insemination, namely artificial insemination where the husband's semen is used (AIH), and artificial insemination where use is made of donor semen (AID).[111] Currently, artificial insemination is a lawful procedure. (The statutory regulations are discussed in chapter 4.)

2 3 3 2 The creation of life outside the womb

The in vitro fertilisation procedure was done for the first time in 1978, when a so-called "test-tube" baby was conceived and born in England. The woman, Mrs Lesley Brown, could not fall pregnant on account of an abnormal condition of her fallopian tubes.[112] In vitro fertilisation includes the processes of ovulation induction, egg retrieval, fertilisation and embryo transfer.[113] Drugs are injected into the female to manipulate the hormones and to promote ovulation. After an appropriate interval to allow oocyte maturation, eggs are typically retrieved with ultrasound-guided aspiration through the cervix, and are incubated with 50 000 to 100 000 sperm cells for 14 to 18 hours. Following transfer to a new growth medium, the eggs are examined for the presence of two pronuclei, an indication that normal fertilisation has occurred. About three days later the embryos are morphologically assessed for quality, and then two to four embryos chosen by the

[110] Knight, B (1997) *Simpson's forensic medicine* 114.

[111] The main reason for AID is the husband's inability to reproduce. Infertility affects 10 to 15% of married couples and in about 30 to 40% of these cases the problem is one of male infertility. Semen from a donor male can also be used where an unmarried woman desires a child without normal sexual intercourse. The semen may be obtained from a known donor, but is usually obtained from an unknown source, collected from a panel of volunteers. See Knight (1997) 114. See also Strauss (1991) 181.

[112] The fallopian tubes extend laterally from the horns of the uterus. The tubes carry oocytes from the ovaries and sperm entering from the uterus to reach the fertilisation site in the ampulla of the uterine tube. The fallopian tube also conveys the dividing zygote to the uterine cavity. Each tube opens into a horn of the uterus at its proximal end and into the peritoneal cavity at its distal end. See Strauss (1991) 187. See also Moore & Persaud (2003) 10.

[113] For the female, the in vitro fertilisation procedure is intricate, difficult, and potentially harmful. Blood is frequently drawn to monitor estrogen levels. Ovary-stimulating medications may cause pain, bloating, or, in rare, cases ovarian hyper-stimulation syndrome, which can cause kidney failure, thrombosis and death.

embryologist are flushed into the uterus trough a catheter for the remainder of gestation.[114] This allows the following permutations:

(a) The woman's own ova is fertilised by her husband's sperm and re-introduced into her uterus.
(b) The woman's own ova is fertilised by a donor sperm and returned to her own uterus.
(c) The woman's own ova is fertilised by her husband's sperm and returned to another woman's uterus (a "surrogate").
(d) The woman's own ova is fertilised by a donor sperm and returned to a surrogate woman's uterus.
(e) An infertile woman may have another woman's ova implanted into her, fertilised either by her husband or by a male donor.[115]

More eggs are attained and fertilised than can actually be implanted in the uterus. After selecting embryos to be used for implantation attempts, the surplus embryos are frozen, often with the expectation of future use if the present attempt at impregnation fails. Not all of these surplus embryos are used in attempts at a successful pregnancy. Typically they are disposed of no later than five years after being stored. [116] The freezing and storing of surplus embryos is known as "cryopreservation".[117] Because these embryos can be frozen for an indefinite period, they could be used for medical research. [118]

According to a recent report, there are about 400 000 cryopreserved embryos in storage in the United States alone. It seems unlikely that these embryos will be used in attempted pregnancies and therefore, given informed donor consent, it is submitted that they should

[114] Clemmens, EW (2005) "Creating human embryos for research: A scientist's perspective on managing the legal and ethical issues" *Ind Health L Rev* 2(1):95. A recent scientific report suggests that stem cells can be induced to become oocytes, potentially sidestepping donation, but the experiments were performed on mouse embryonic stem cells and there is no guarantee that the procedure would work on human embryonic stem cells.
[115] Knight (1997) 114.
[116] Momeyer, RW (2003) "Embryos, stem cells, morality, and public policy: Difficult connections" *Cap U L Rev* 31(1):93.
[117] Enmon (2002) *Utah L Rev* 621 *at* 637.
[118] Knight (1997) 114.

be used in research rather than be discarded.[119] Spare in vitro fertilisation embryos, which are of a lesser quantity and quality than those used for implantation, can still be useful for developing stem cell lines of enough quantity and quality for therapeutic application. Embryo creation is also critical for the advancement of therapeutic cloning (discussed below). Science appears to have reached the point where studies with human embryos are necessary to acquire new information on human embryonic development. Therefore, furthering the understanding of human embryonic development to the benefit of science and medicine will require research with human embryos. Yet, both the use and creation of human embryos for basic scientific research and for therapeutic purposes demand a careful consideration of policy and ethics.[120]

2 3 3 3 The special nature of the embryo

Ethical concerns involving stem cell research arise from what bio-ethicists often call the moral or special nature of the embryo. The embryo has qualities of a living being and a human being, but is not a human life because it lacks the neurological attributes ascribed to humans. An embryo is biologically alive in a general sense, but it does not have cerebral functions that give rise to consciousness. Cryopreservation further complicates the classification of the embryo, since the question then is whether the frozen embryo is indeed alive.[121]

The frozen embryo, with all its molecules at a standstill, exists in a state of suspended animation. In this sense, the frozen embryo is indistinct from an inanimate object and is not alive. Yet, the frozen embryo also retains the structure and genetic information of a living organism for an indefinite period, making it alive in this sense. Another question is whether the frozen embryo has the potential to become reanimated. This question has no definite answer, since procedures for cryopreservation yield completely living embryos,

[119] BBC News (1998) "Modern fertility techniques boost success rates" [Web:] www.news.bbc.co.uk/1/hi/health/235510.stm [Date of access: 24 January 2006].
[120] Clemmens (2005) *Ind Health L Rev* 95 *at* 97, 98.
[121] United Kingdom. Parliament: House of Lords (2002) www.parliament.the-stationery-office.co.uk/pa/Id200102/dselect/Idstem/83/8301.htm-14k. See in general Holland *et al* (2002) 29, 45, 46-47, 177-178, 209, 213-214.

completely dead embryos and embryos combining living and dead cells. Therefore, the frozen embryo is neither alive nor dead, but rather in a completely different state altogether.[122] In addition, it is inevitable that in vitro fertilisation clinics would vie for ownership rights to these embryos.[123] The legal status of the embryo, the question of whether embryos are property or persons, and further ethical issues pertaining to the embryo and frozen embryos are discussed in the next chapters.

2 3 3 4 The process of growing embryonic stem cells in the laboratory

In order to exploit stem cells to the full it would likely be necessary to grow the cells in a laboratory under hygienic conditions so that they, or cells derived from them, can be transplanted back into patients. Growing cells in a laboratory is known as cell culture. The process begins where human embryonic stem cells are isolated by transferring the inner cell mass of the blastocyst into a plastic laboratory culture dish that contains a nutrient broth known as culture medium.[124] The cells divide and spread over the surface of the dish. The inner surface of the culture dish is coated with embryonic skin from mice cells that have been treated so they will not divide.[125] This coating layer of cells is called a feeder layer and is necessary for the prevention of embryonic stem cell differentiation.[126] Over the course of several days, the cells of the inner cell mass proliferate[127] and begin to crowd the culture dish. When the cell concentration is high

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[122] Son, HJ (2005) "Artificial wombs, frozen embryos, and abortion: Reconciling viability's doctrinal ambiguity" *UCLA Women's LJ* 14(1):213 *at* 228-233. See also Moses, LB (2005) "Understanding legal responses to technological change: The example of in vitro fertilisation" *Minn JL Sci & Tech* 6(2):505; Schaefer, K (1990) "In vitro fertilisation frozen embryos, and the right to privacy – Are mandatory donation laws constitutional?" *Pac LJ* 22(1):87.

[123] Enmon (2002) *Utah L Rev* 621 *at* 637. See also *Davis v Davis*, 842 SW 2d 588, 594. One of the fundamental issues of the inquiry is whether pre-embryos should be considered "persons" or "property" in contemplation of the law. (The case is discussed in chapter 5.)

[124] Featurewell, DF (2005) "Would it be possible to engineer embryos without human potential?" *Pop Mech Mag* 29(5):29 *at* 33.

[125] United States: National Institutes of Health (2001b) www.stemcells.nih.gov/info/scireport/appendixF.asp. The reason for having mice cells in the bottom of the culture dish is to give the inner cell mass cells a sticky surface to which they can attach. Also, the feeder cells release nutrients into the culture medium. Scientists have recently begun to devise ways of growing embryonic stem cells without the mouse feeder cells. This is a significant scientific advancement, since it eliminates the risk that viruses or other macromolecules in the mouse cells may be transmitted to human cells.

[126] Bioteach (2006) www.bioteach.ubc.ca/Bioengineering/Stem Cells.

[127] Proliferation means the expansion of a population of cells by the continuous division of single cells into two identical daughter cells.

enough, they are carefully removed and plated into several fresh culture dishes. The process of replanting the cells is repeated many times and for many months, and is called sub-culturing.[128] Each cycle of sub-culturing the cells is referred to as a passage.[129] After six months or more, the original thirty cells of the inner cell mass yield millions of embryonic stem cells. Embryonic stem cells that have proliferated in cell culture for six months or more without differentiating are pluripotent, and if they appear genetically normal it is called an embryonic stem cell line.[130] Once cell lines are established, or even before that stage, batches of them can be frozen and shipped to other laboratories for further culture and experimentation. Doctors must, however, be certain that the properties of the cells have not changed in the laboratory, and that there are no contaminants that might cause harm if the cells are used to treat patients.

2 3 3 5 Laboratory tests used to identify embryonic stem cells

At various points during the process of generating embryonic stem cell lines, scientists test the cells to see whether they exhibit the fundamental properties that make them embryonic stem cells. This process is called characterisation. Laboratories that grow embryonic stem cell lines use several kinds of tests.[131] These tests include:

(a) Growing and sub-culturing the stem cells for many months. This ensures that the cells are capable of long-term self-renewal.
(b) Using specific techniques to determine the presence of surface markers that are found only on undifferentiated cells. One important test is for the presence of a protein called "Oct-4", which undifferentiated cells typically make[132]
(c) Examining the chromosomes under a microscope. This is a method to assess whether the chromosomes are damaged or if the number of chromosomes has changed.

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[128] Featurewell (2005) *Pop Mech Mag* 29 *at* 33.
[129] A passage is defined as a round of cell growth and proliferation in cell culture.
[130] United States: National Institutes of Health (2001b) www.stemcells.nih.gov/info/scireport/appendixF.asp.
[131] United States: National Institutes of Health (2001a) www.stemcells.nih.gov/info/basics2.asp.
[132] Oct-4 is a transcription factor, meaning that it helps turn genes on and off at the right time, which is an important part of the process of cell differentiation and embryonic development.

(d) Determining whether the cells can be sub-cultured after freezing and replating.[133]

(e) Testing whether the human embryonic stem cells are pluripotent by allowing the cells to differentiate spontaneously in cell culture, manipulating the cells so they will differentiate to form specific cell types, and injecting the cells into an immunosuppressed mouse to test for the formation of a tumour called a teratoma.[134]

2 3 4 The history and development of fetal tissue research

The use of fetal tissue for the purposes of biomedical research dates back to the late 1920's. As early as 1928 unsuccessful attempts were made to transplant fetal pancreatic cells into diabetics.[135] The extensive use of fetal tissue for medical research began in the 1950's when Dr Jonas Salk from the United States used human fetal kidney cells to develop the polio vaccine. Researches soon transplanted fetal thymus glands[136] into children with thymus deficiencies to allow the recipients' immune rejection systems to operate normally.[137]

Cadaveric fetal tissue is obtained after spontaneous abortions[138] or after elective or therapeutic abortions[139] are carried out.[140] These cells are derived from specific cells

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133 United States: National Institutes of Health (2001a) www.stemcells.nih.gov/info/basics2.asp.

134 Teratomas typically contain a mixture of many differentiated or partly differentiated cell types, which is an indication that the embryonic stem cells are capable of differentiating into multiple cell types.

135 American Life League (2006) "Recycling babies: The practice of fetal tissue research" [Web:] www.all.org/article.php?id=10154&search=fetal%20tissue" [Date of access: 17 January 2006].

136 During fetal development, the thymus gland processes many of the body's lymphocytes, which travel through the bloodstream seeding lymph nodes and lymphatic tissue. A heterogeneous group of cells, known as T-cells, undergoes this process, which is essential in establishing the body's immune system. See Casell (2001) *U Mich JL Ref* 547.

137 Casell (2001) *U Mich JL Ref* 547.

138 Spontaneous abortions include both miscarriages and ectopic pregnancies. However, tissue obtained through miscarriages and ectopic pregnancies usually has pathological flaws. This is why scientists prefer first-trimester fetuses aborted through elective procedures. Tissue from a healthy, electively aborted fetus is useful for a multitude of research and transplantation purposes, whereas the usefulness of tissue obtained from miscarried fetuses and ectopic pregnancies is usually limited to searching for treatments and cures for diseases and conditions related to pregnancies only. See Casell 2001 *U Mich JL Ref* 547, 549, 550.

139 The Choice on Termination of Pregnancy Act makes provision for and regulates elective and therapeutic abortions. Termination of pregnancy means the separation and expulsion, by medical or surgical means, of the contents of the uterus of a pregnant woman (see section 1 of the Act). An elective abortion may be carried out upon the request of the pregnant woman up to the twelfth week of

obtained from fetuses aborted five to nine weeks after fertilisation. Researchers have been able to generate pluripotent cells from the initial cultures of the fetal cells capable of long-term self-renewal.[141] Recent developments in fetal tissue research have led to a dramatic breakthrough in the search for cures for Parkinson's disease, Alzheimer's disease, diabetes and a host of neurological disorders.[142]

2 3 4 1 Ethical considerations involving fetal tissue research

Research with stem cells obtained from human embryos poses moral dilemmas that do not exist in the case of fetal tissue. The life of the fetus has already been terminated when the researcher receives tissue from an aborted fetus, while the life of embryonic tissue resulting from infertility treatment must be terminated.[143] However, some people claim that the ethical acceptability of deriving stem cells from the tissue of aborted fetuses is closely connected with the morality of abortion. Those who believe this also fear that the possibility of donating fetuses for stem cell research will encourage women to have more abortions or justify abortions that could not be justified otherwise.[144] However, the concern about women aborting fetuses for research seems to be displaced by the fear that a black market would develop for selling fetal tissue. Similar black market dangers may exist for embryonic stem cells.[145] The legal and ethical issues are addressed in the next chapters.

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gestation. Thereafter, termination of the pregnancy may take place in certain specified circumstances. For a discussion of the Act see chapter 4.

140 Van Wyk (2004) *THRHR* 1 *at* 17.

141 Enmon (2002) *Utah L Rev* 621 *at* 624.

142 Planned Parenthood Federation of America (2006) "Donating fetal tissue for medical treatment and research" [Web:] www.ppatp.org/FetalTissue.httm [Date of access: 17 January 2006].

143 AAAS (2006) "Dialogue on science, ethics and religion" [Web:] www.aaas.org/spp/dser/bioethics/perspectives/pstatement.shtml [Date of access 17 January 2006].

144 Oldham, R (2000) "Fetal tissue transplantation research" [Web:] www.pillowrock.com/ronnie/fetalresearch.htm [Date of access 15 January 2006].

145 Gelfand, G & Levin, TR (1993) "Fetal tissue research: Legal regulation of human fetal tissue transplantation" *Wash & Lee L Rev* 50(2):647-694. They argue in favour of the moral propriety of using fetal tissue. See also Babbo, TJ (2000) "Begging the question: Fetal tissue research, the protection of human subjects, and the banality of evil" *De Paul J Health Care L* 3(3):383-409; Shapiro, HT (2004) "What is an embryo? A comment "*Conn L Rev* 36(4):1093-1098.

2 3 4 2 The advantages of fetal tissue research

Fetal tissue is preferred to adult tissue because fetal cells maintain their plasticity (to change shape enabling them to be placed in the correct location), are able to integrate and grow in new surroundings, and are less immunogenic than adult cells, reducing the changes of immunological rejection.[146] Additionally, there is a much larger supply of fetal tissue than of tissue voluntarily donated by adults.[147] One degenerative brain disorder in particular, Huntington's disease[148], has attracted the attention of researchers in France. Clinical trials are underway to treat the disease using fetal tissue. Five patients with Huntington's disease have had fetal cells that had already begun differentiating into nerve tissue implanted into the part of their brain controlling movement. Three of the five patients demonstrated improved movement and cognitive function. The promising results of clinical trials such as these will lead to more studies of this kind.[149]

2 3 5 Adult stem cells

The research on adult stem cells began about 40 years ago. In the 1960's, researchers discovered that bone marrow contains at least two kinds of stem cells. One population, called haematopoietic stem cells, forms all types of blood cells in the body. A second population, called bone marrow stromal cells,[150] was discovered a few years later.

An adult stem cell is an undifferentiated cell found among differentiated cells in tissue or a organ. It can renew itself and can differentiate to yield the major specialised cell types of the tissue or organ.[151] Stem cells typically generate an intermediate cell type before

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[146] The risk of immunological rejection is less when using fetal tissue, because fetal cells do not carry protein markers, whereas adult cells do.

[147] Casell (2001) *U Mich JL Ref* 547.

[148] Huntington's disease is a neurological disease that destroys neurons in areas of the brain involved in emotions, intellect, and movement. The patient experiences uncontrollable movement of the limbs and face, loss of mental abilities and they develop psychiatric problems.

[149] Casell (2001) *U Mich JL Ref* 547 *at* 555, 556. See also Coletti, S (2004) "Taking account on partial exemptors in vaccination law, policy, and practice" *Conn L Rev* 36(4):1341-1396; Noah, L (2004) "A postmodernist take on the human embryo research debate" *Conn L Rev* 36(4):1133-1162.

[150] Stromal cells are a mixed population of cells that generate bone, cartilage, fat and fibrous connective tissue.

[151] Campbell, A (2005) "Ethos and Economics: Examining the rationale underlying stem cell and cloning research policies in the United States, Germany and Japan" *Am JL & Med* 31(1):47 *at* 48-63. See also Infofilter. (2005) "Stem cell research" [Web:] www.infofilter.info/medical%20research/Stem%20Cell%20Research.htm [Date of access: 10 January 2006].

they achieve their fully differentiated state. The intermediate cell is called a progenitor cell. Progenitor cells are partly differentiated cells in the sense that they are committed to a particular cell lineage and, upon division, give rise to differentiated cells. Of all the adult stem cells identified so far, haematopoietic stem cells are the best defined.[152] The primary role of adult stem cells in a living organism is to maintain and repair the tissue in which they are found. Unlike embryonic stem cells, which are defined by their origin (the inner cell mass of the blastocyst), the origin of adult stem cells in mature tissue is unknown. [153]

There are several approaches in human clinical trials that utilise mature stem cells, such as blood-forming cells, neuron-forming cells and cartilage-forming cells. Because adult cells are already specialised, their potential to regenerate damaged tissue is very limited. For example, skin cells will only become skin, and cartilage cells will only become cartilage. Adults do not have stem cells in many vital organs; therefore, when that tissue is damaged, scar tissue develops.[154] However, a number of experiments over the past years have raised the possibility that stem cells from one tissue type may be able to give rise to cell types of a completely different tissue. This phenomenon is known as stem cell plasticity.[155] Exploring the possibility of using adult stem cells for cellular therapies has become an active area of research recently.[156] The apparent plasticity of adult stem cells has forced scientists to reconsider many fundamental concepts of stem cell biology. Many new questions arise from these studies. For instance, are the recently characterised stem cells typical tissue-specific stem cells? Might they be a sub-population of stem cells with a developmental potential closer to that of embryonic stem cells? It seems that stem cell plasticity results from in vitro manipulations and does not reflect normal behaviour in vivo. Regardless, this phenomenon has clinical implications.[157]

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[152] Bioteach (2006) www.bioteach.ubc.ca/Bioengineering/Stem Cells.
[153] Stayn, J (2005) "The new Massachusetts stem cell research law" *Bost BJ* 49(4):16 *at* 17.
[154] University of Wisconsin-Madison (2001) www.news.wisc.edu/packages/stemcells/facts.html. Only embryonic stem cells, which have the capacity to become any kind of human tissue, have the potential to repair vital organs.
[155] Examples of such plasticity include bone marrow stem cells becoming neurons, or pancreatic islet cells that are capable of producing insulin.
[156] Holland, S (2005) "Many suspect that new kinds of adult stem cells may be found that are as versatile as those found in embryos" *Nat Geogr Mag* 208(1):18-20.
[157] Bioteach (2006) www.bioteach.ubc.ca/Bioengineering/Stem Cells.

Scientists do not agree on the criteria that should be used to identify and test adult stem cells. They often use one or more of the following methods:

(a) Labelling the cells in a living tissue with molecular markers and then determining the specialised cell types they generate;
(b) Removing the cells from a living animal, labelling them in a cell culture, and transplanting them into another animal to determine whether the cells repopulate their tissue of origin; or
(c) Isolating the cells, growing them in a cell culture, and manipulating them, often by adding growth factors or introducing new genes, to determine what differentiated cell types they can become.[158]

2 3 6 Post-natal placenta and umbilical cord stem cells[159]

As indicated above, stem cells can be extracted from the blood cells of the umbilical cord at the time of birth, as well as from the placenta waste following birth. On the basis of reports that mesenchymal[160] can be isolated from the placenta/umbilical cord stroma, researchers undertook a study to isolate and characterise mesenchymal stem cells from the human umbilical cord veins. A cell population was isolated, which was derived from the endothelium/sub-endothelium layers of 20 umbilical cord veins obtained from term deliveries using a solution of 0,1% collagenase type IV. Results suggest that these cells possess morphological, immunophenotypical and cell differentiation capacities similar to the bone marrow-derived mesenchymal stem cells. These findings indicate that umbilical

[158] Walsh, P (2005) "Stemming the tide of stem cell research: The Bush compromise" *J Mars L Rev* 38(3):1061 *at* 1063-1066.

[159] Nutrients and oxygen pass from the maternal blood through the placenta to the fetal blood, and waste materials and carbon dioxide pass from the fetal blood through the placenta to the maternal blood. The umbilical cord usually attaches to the fetal surface, and its epithelium is continuous with the amnion adhering to the chorionic plate of the placenta. The chorionic vessels radiate to and from the umbilical cord and are clearly visible through the smooth, transparent amnion. The umbilical vessels branch on the fetal surface, forming the chorionic vessels, which enter the chorionic villi. Shortly after the birth of a baby, the placenta and fetal membranes are expelled from the uterus as the afterbirth. See Moore & Persaud (2003) 90, 103.

[160] Mesenchymal cells are a population of adhering cells derived from mononuclear cells having the capacity for self-renewal, supporting haematopoiesis, and differentiating into different cell lineages such as adipocytes, osteocytes, chondrocytes and astrocytes.

cord obtained from term deliveries is an important source of mesenchymal stem cells, which could have an important application in cell therapy protocols.[161]

2 4 CLONING:[162] THE CREATION OF EMBRYOS

The creation of embryos in the laboratory has generated considerable controversy for the past three decades. This debate has recently been reenergised by the creation of embryos for stem cell research, a marvel touted as perhaps "the most remarkable breakthrough since man walked on the moon". Embryonic stem cell lines can be derived from human embryos created specifically for their use in stem cell research.[163] The announcement by British scientist Ian Wilmut and his colleagues at the Roslin Institute in Scotland, in 1997, that they had successfully cloned a sheep immediately sparked reaction of shock and alarm.[164] At first, Dolly the sheep was a "clone alone", but in August 1998 a group of scientists in Hawaii published a report of the cloning of over 50 mice by nuclear transfer. Since then, research groups around the world have reported the cloning of cattle, sheep, mice, goats, and pigs.

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[161] Kadivar, M *et al* (2005) "Isolation, culture and characterisation of postnatal human umbilical vein-derived mesenchymal stem cells" *J Fac Phar Teh Un Med'l Sci* 13(4):170 *at* 171.

[162] It creates much confusion and even misconception when people read the word "clone". The definition of biological cloning includes: (a) A group of genetically identical individuals descended from the same parent by asexual reproduction. Many plants show this by producing suckers, tubers, or bulbs to colonise the area around the parent. (b) A group of genetically identical cells produced by mitotic division from an original cell. This is where the cell creates a new set of chromosomes and splits into two daughter cells. This is how replacement cells are produced in our bodies when the old ones wear out. (c) A group of DNA molecules produced from an original length of DNA sequences produced by a bacterium or a virus using molecular biology techniques. This is what is often called molecular cloning or DNA cloning. (d) The production of genetically identical animals by embryo splitting. This can occur naturally at the two-cell stage, forming identical twins. In cattle, when individual cells from four- and eight-cell embryos are implanted in different foster mothers, they can develop normally into calves and this technique has been used routinely in cattle-breeding schemes for over ten years. (e) The creation of one or more genetically identical animal by transferring the nucleus of a body cell into an egg from which the nucleus has been removed. This is also known as nuclear transfer or cell nuclear replacement and is the procedure that was used to create Dolly the sheep. (f) Cloning for the purpose of stem cell research involves creating an embryo from one's own DNA, extracting the stem cells and then discarding what is left of the cloned embryo. See Roslin Institute (2000) "Cloning" [Web:] www.roslin.ac.uk/public/cloning.html [Date of access: 10 January 2006]. "Human cloning" is defined as "the asexual production of a new human organism that is, at all stages of development, genetically virtually identical to a currently existing or previously existing human being". See Van Wyk (2004) *THRHR* 1. See also Jordaan, DW (2002) "Human reproductive cloning: A policy framework for South Africa" *SALJ* 119(2):294 *at* 296.

[163] Clemmens (2005) *Ind Health L Rev* 95.

[164] Gusman (2005) *Annals Health L* 361.

Equally competent groups have had no success in cloning rabbits, rats, monkey, cats or dogs.[165] There is currently little consensus of whether these techniques should be used to create embryonic stem cells, which holds great promise for curing or ameliorating several devastating diseases.[166] Determining the best public policy for this potential research requires addressing the ethical issues and practical drawbacks presented by cloning.[167] In order to provide a scientific background, the different techniques of cloning are discussed below.

2 4 1 The science of somatic cell nuclear transfer[168] and stem cell-based therapies

Somatic cell nuclear transfer is the process of inserting the nucleus[169] of an adult cell into an unfertilised enucleated[170] egg. The fertilised egg is then induced by an electrical charge to begin the process of division. At this stage a new embryo forms. This was the first step in the process by which Dolly the sheep was created.

Cell nuclear replacement is a potential way of producing compatible tissue that will not be rejected by patients' immune systems.[171] It would involve creating a zygote by cell

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165 Roslin Institute (2000) www.roslin.ac.uk/public/cloning.html.

166 These diseases include, for example, Parkinson's disease, Alzheimer's disease, cardiac failure, diabetes and a host of other neurological diseases. See Elster, N (2002) "Ethical issues for women in donating eggs and embryos" *Hum Rts Sum* 23.

167 Gusman (2005) *Annals Health L* 361 *at* 364.

168 Somatic cell nuclear transfer is an artificial cloning technology. Another artificial cloning technology is embryo splitting. This occurs when the newly formed embryo is divided into two or more genetically identical individuals.

169 The nucleus is the central protoplasm of a cell that contains the chromosomes.

170 Enucleated literally means "deprived of its nucleus" See Slabbert (2003) *JLM* 514 *at* 516.

171 Immunological rejection is a particularly important consideration for stem cell based therapies. The human body has an immune system which recognises cells that are not its own, and rejects them. The immune system has evolved primarily as a protection against micro-organisms that cause disease. However, the body also rejects human cells or tissues that do not belong to it. Immune rejection is one of the major causes of organ transplant failure, and is one of the problems that will need to be overcome for any stem cell-based therapy to be effective. There are three main ways of avoiding or repressing immune rejection of transplanted cells or tissues: (a) The use of immuno-suppressant drugs: These drugs have been refined over many years, as part of organ transplantation research. However, they are not always effective; they must normally be taken over the lifetime of the patient, and they leave the patient open to infection. (b) Using matching tissues: Sometimes during transplants it is possible to get matching tissue type, usually from a close relative. This is often sought for bone marrow transplants. Finding a matching donor is unlikely to be a useful approach for most cell-based therapies. Because stem cells can, in principle, be cultured indefinitely it might be possible to establish stem cell banks of sufficient size to comprise stem cells with a reasonable match to the majority of individuals in the population. (c) Using the individuals own cells or tissues: This would be the surest means of avoiding immune rejection. Adult stem cells isolated from an individual and then used to treat him or her, offer

nuclear replacement, using a nucleus from an adult cell of the individual to be treated, and growing it to the blastocyst stage.[172] Embryonic stem cells are isolated from the blastocyst, which would be destroyed in the process, and differentiated in vitro to produce cells or tissue for implantation.

The use of embryonic stem cells produced in this way for therapy has a potential advantage over the use of embryonic cells isolated from early embryos created by in vitro fertilisation, because the genetic material would be derived from the individual to be treated and would not be rejected by the host's immune system. Somatic cell nuclear transfer has significant potential as a research technique, since it would provide a powerful approach to studying the process of dedifferentiation.[173] In producing Dolly the sheep, cell nuclear replacement has shown that dedifferentiation of adult cells is possible and this boosted research into that process. The biochemical signals that control the process of dedifferentiation and maintain the genetic material in a pluripotent state are contained in the oocyte.[174] At present, somatic cell nuclear transfer research provides the only realistic means of identifying these factors and establishing how to reverse the signals that "mark" the DNA during differentiation and the signals that should be erased during dedifferentiation.[175]

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one possible way of achieving this. See The United Kingdom. Parliament: House of Lords (2002) www.parliament.the-stationery-office.co.uk/pa/Id200102/dselect/Idstem/83/8301.htm-14k.

172 Roslin Institute (2000) www.roslin.ac.uk/public/cloning.html.

173 Dedifferentiation is the process where mature adult tissue cells can be reprogrammed to behave like stem cells. This technique has not been researched properly and very little is known about the risks and benefits involved. See Slabbert (2003) *JLM* 514 *at* 518.

174 A process akin to cell nuclear transfer, called oocyte nucleus transfer, may have the potential for treating mitochondrial diseases. Mitochondria are small energy-producing structures present in every cell. Most of a cell's DNA is contained in the nucleus, but a very small amount is found in the mitochondria. Alterations in the mitochondrial DNA result in a number of relatively rare but very serious disease. Mitochondria are present in the female egg, but are not transferred from the male sperm during fertilisation, so the mitochondrion of the embryo is derived exclusively from the mother and a mitochondrial disease can only be transmitted through the maternal line. Using this technique, the nucleus would be extracted from the woman's egg and transferred to a donated egg from which the nucleus has been removed. The egg could then be fertilised in vitro and re-implanted in the mother. The resulting embryo would receive the vast majority of its genes from the mother and father in the normal way, therefore it would not be a clone, but the small number of mitochondrial genes would come from a third person. This sometimes results in the baby having two genetic mothers. See The United Kingdom Parliament: House of Lords (2002) www.parliament.the-stationery-office.co.uk/pa/Id200102/dselect/Idstem/83/8301.htm-14k.

175 The United Kingdom Parliament: House of Lords (2002) www.parliament.the-stationery-office.co.uk/pa/Id200102/dselect/Idstem/83/8301.htm-14k.

2 4 2 Therapeutic cloning[176]

Pluripotent embryonic stem cell and cloning technology can be combined in what is referred to as therapeutic cloning. Therapeutic cloning recently made headlines when Advanced Cell Technology, a Massachusetts-based company, announced the cloning of a human embryo. The embryo was not created for reproductive purposes, and was never intended to become a person. Instead, the blastocyst was created as a source of embryonic stem cells. Therapeutic cloning represents a treatment where the patient's own cells are used; thereby avoiding the risk of rejection or a lifetime of immunosuppressive therapy.[177] To generate embryonic stem cells, blastocysts created through somatic cell nuclear transfer are tricked into thinking they are still at a stage where cell division is supposed to occur without differentiation. This is done by placing the blastocyst in a Petri dish overloaded with molecular signals that foster the proliferation of millions of identical, undifferentiated cells. By exposing this undifferentiated cell mass to growth factors, researchers then force the embryonic cells down specific pathways of differentiation into, for example, bone marrow or nerve cells.[178] The blastocyst development is stopped about five days after fertilisation by harvesting the inner cell mass cells.[179] In future, scientists might discover which signals are needed to convert embryonic cells into any kind of tissue that occur in the human body.[180]

2 4 2 1 The advantages of therapeutic cloning

A major argument against therapeutic cloning is that other alternatives exist for creating stem cells, and that scientists need not resort to nuclear transfer. However, the fact remains that stem cells derived from human embryos have particularly desirable characteristics. Ian Wilmut[181] said: "For human cloning at the cellular level to achieve its medical promise, it will become necessary to do research on very early embryos, created specifically for this purpose." Adult stem cells are generally thought to be less than ideal

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[176] In terms of section 57(6)(b) of the National Health Act, therapeutic cloning means the manipulation of genetic material from adult, zygotic or embryonic cells in order to alter, for therapeutic purposes, the function of cells or tissues. The Human Tissue Act does not define the term therapeutic cloning.
[177] Enmon (2002) *Utah L Rev* 621 *at* 626.
[178] Sax (2006) *Annals Health L* 1 *at* 2.
[179] Enmon (2002) *Utah L Rev* 621.
[180] Gusman (2005) *Annals Health L* 361 *at* 365.
[181] Ian Wilmut is one of the scientists at the Roslin Institute in Scotland who cloned Dolly the sheep.

for research since they have already begun forming specific cells and are less elastic. Furthermore, they have not been isolated for all cell and tissue type, are present only in minute quantities, are difficult to isolate and purify, and may lose their potency over time because they do not always grow well in laboratory culture dishes.[182] Embryonic stem cells, in contrast, can proliferate indefinitely, and their chromosomal composition remains stable throughout many cell cycles. Embryonic stem cells work best because they produce large quantities of undifferentiated cells.[183] Adult stem cells, on the other hand, have restricted development potential.[184]

2 4 3 Reproductive cloning[185]

Reproductive cloning is cloning aimed at the birth of an individual who is genetically identical to someone in his or her own or in a previous generation.[186] The procedure followed in therapeutic cloning differs from the procedure followed in reproductive cloning. Therapeutic cloning is envisaged only as a means of generating embryonic stem cells for direct application in treatment and therapies. The embryo itself is grown only to the blastocyst stage and is not implanted or allowed to develop further. This is in contrast with reproductive cloning, in which the blastocyst would be implanted in a woman's uterus with a view to producing a baby. Therefore, the distinction between therapeutic and reproductive cloning is based on the steps following cell nuclear transfer, and reflects

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182 Gusman (2005) *Annals Health L* 361 *at* 365.

183 MyDr.com.au. (2006) "Stem cell research and cloning: What you need to know" [Web:] www.mydr.com.au/default.asp [Date of access: 12 December 2005]. See also Goldberg, D (2006) "Cloning around with stem cells" [Web:] www.abc.net.au/science/slab/stemcells/default.htm [Date of access: 4 January 2005].

184 It is not necessary for the purpose of this dissertation to address the issue of whether adult stem cells and cord blood stem cells are alternatives to embryonic stem cells in detail. These sources have not been shown to offer commensurate potentiality with embryonic stem cells. Nevertheless, there are still scientists working with adult stem cells who are reporting a greater ability for the cells to differentiate than was once thought possible. Opponents of embryonic stem cell research suggest that there is no practical need to continue research with these ethically more questionable sources. Unfortunately, there is no scientific agreement on the potential of adult stem cells and most evidence suggests that diverse clinical applications using adult stem cells will not only take much longer to develop, but are also much less likely to ever occur at all. The bottom line is that it is too early to make any definitive claims on this issue.

185 In terms of section 57(6)(a) of the National Health Act, reproductive cloning of a human being means the manipulation of genetic material in order to achieve the reproduction of a human being and includes nuclear transfer or embryo splitting for such purpose. The Human Tissue Act 65 of 1983 does not define the term reproductive cloning.

186 Jordaan (2002) *SALJ* 294 *at* 296.

the purpose for which it is undertaken. The initial process, to the blastocyst stage, is however identical.[187]

The scientific objections to reproductive cloning are currently overwhelming. It required 277 attempts to produce Dolly, and it might prove even more difficult in humans. In recent studies there has been a high rate of malformations and premature death. Many clones are also excessively large.[188]

One of the strongest arguments against reproductive cloning is the familial and child welfare consideration. Slabbert illustrates the following results: A woman, whose own somatic cell provides the nucleus for an enucleated egg (also from her own body), will not be creating her own child, but her own genetically identical sister. If a woman's husband provides the somatic cell whose nucleus is introduced into her enucleated egg, she will not be bearing her biological son, but her brother-in-law. If the nucleus from the somatic cell of a parent's dying child is introduced into the woman's egg in the hope of replicating the dying child, the primary parent of the new cloned child will be the dying child.[189] The legal and ethical issues surrounding cloning are discussed in the next chapters.

2 4 4 Cloned chimera[190] embryos

The technique of somatic cell nuclear transfer is used in creating cloned chimera embryos. The somatic cell of a human is introduced into an enucleated[191] animal ovum, for example a cow, creating a hybrid embryo that takes on human DNA.[192] These embryos are then used in stem cell-based treatments.[193] Slabbert argues that the use of

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187 MyDr.com.au (2006) www.mydr.com.au/default.asp.

188 The United Kingdom. Parliament: House of Lords (2002) www.parliament.the-stationery-office.co.uk/pa/Id200102/dselect/Idstem/83/8301.htm-14k.

189 Slabbert (2003) *JLM* 514 *at* 520.

190 Chimera refers to a single living organism that has a mixed genetic origin as a result of combined cells derived from different human embryos or humans and other species.

191 Slabbert (2003) *JLM* 514 *at* 518.

192 The transplantation of cells, tissues and organs from one species into another is also referred to as xenotransplantation. See Blackbeard (2002) *DJ* 318.

193 See in general Newman, SA (2003) "Averting the clone age: Prospects and perils of human developmental manipulation" *J Contemp Health L & Pol'y* 19(2):431-464.

therapeutic chimera cloning may provide some relief to the supply of spare eggs for therapy. Since obtaining eggs from women is a difficult and painful procedure, the availability of animal gametes may be a solution to the problem. It is also difficult to see how the creation of hybrid embryos for the derivation of human stem cells differ from widely accepted practices, for example the use of animal proteins to create drugs such as insulin; or the use of animal genes and cells to create transplantable organs or tissues.[194] However, bio-ethicists are still debating the issue. There is an underlying objection and intuitive objection to hybrid embryo creation based on the concern for mixing genes across species and the uncertainty of the risks involved. Others argue that these embryos should be used for stem cell-based treatments, but only until the appearance of the primitive streak.[195] Notwithstanding the fact that the promotion of creating hybrid embryos for research purposes is not a new idea, or that it is usually met with condemnation from review boards, the reasons for allowing such techniques should be articulated.[196] In addition, ethical problems associated with the moral status of the hybrid embryo may be easier to overcome than ethical problems associated with the moral status of the human embryo.[197]

2 4 5 The science of new reproductive technologies

Reproductive technologies traditionally refer to a range of devices and procedures for assisting, preventing, and/or manipulating contraception, fertility and reproductive practices.[198] What makes "new" reproductive technologies different is not only their increasing effectiveness and invasiveness, but the globalised system of profit-seeking and control in which they are being advanced. Vast amounts of resources are being put into these discoveries. Yet, bio-ethicists feel that potential dangers and the consequences to women's bodies remain largely uncritical and unbalanced, often neglecting to examine

[194] Slabbert (2003) *JLM* 514 *at* 518. See also Zelony, A (2005) "Don't throw the baby out with the bathwater: Why a ban on human cloning might be a threat to human rights" *Loy Los An Int'l & Comp L Rev* 27(3):541-568; Adams, NA (2004) "Creating clones, kids and chimera: Liberal Democratic compromise at the crossroads" *Issues L & Med* 20(1):3-72.

[195] Newman (2003) *J Contemp Health L & Pol'y* 431 *at* 460.

[196] See in general Van Dyk, JC (2004) "SA kry bank vir stamselle van mense en diere" *S-B*:1, September 2; Van Dyk, JC (2004) "Diereryk staan voor 'n stamselbank-tou" *S-B*:3, September 2.

[197] Dhai *et al* (2004) *SAMJ* 906 *at* 908.

[198] These technologies are used to manipulate contraception, fertility and reproductive practices, and are also creating new ways to influence the characteristics of potential children.

the different experiences to new reproductive technologies depending on location, class race, and gender. Two new reproductive technologies, namely human parthenogenesis and pre-implantation genetic diagnosis are discussed below.

2 4 5 1 Human parthenogenesis[199]

Human parthenogenesis is defined as the process of manipulating the genetic material of a human egg cell without introducing the genetic material from any other cell into the oocyte[200] in a way that causes it to become a human embryo. An unfertilised egg keeps two sets of chromosomes and begins developing as if it had been fertilised.[201] This phenomenon is a promising source of embryonic stem cells. Researchers are on the brink of obtaining human stem cells for the first time, and animal experiments suggest that such cells are indistinguishable for normal stem cells. It also produces embryos that could never become human beings. Therefore, destroying these embryos to obtain stem cells would avoid the ethical concerns that led to restrictions or bans on embryonic stem cell research in many countries.[202]

Although the technique works in mice and monkeys, attempts with human eggs have not been researched properly until now.[203] A team, led by fertility specialist David Wininger, at the biotech firm Stemron in Maryland has for the first time grown parthenogenetic human embryos to the blastocyst stage (at which stem cells can be obtained). The next step is to get the cells to grow in a cell culture for an indefinite period. In monkeys, such cell lines have been growing for over two years, and it makes the human experiments all

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[199] Parthenogenesis is also known as "virgin birth". See more encyclopaedia articles at "Electronic Encyclopaedia (2006) "Parthenogenesis" *Col U Press* [Available on internet:] www.factmonster.com/ce6/sci/A0837738.html [Date of access: 14 February 2006]. See also Kimball, J (2006) "Asexual Reproduction" [Web:] www.users.rcn.com/jkimball.ma. ultranet/BiologyPages/A/ AsexualReproduction.html [Date of access: 14 February 2006].

[200] The egg is therefore not fertilised by male sperm.

[201] Some insects and reptiles can reproduce in this way, but even though an electrical or chemical stimulus can induce parthenogenesis in mammals, the resulting embryos die after a few days.

[202] Pagan, S (2003) "'Virgin birth' method promises ethical stem cells" [Web:] www.newscientist.com/ article.ns?id=dn3654 [Date of access: 24 January 2006].

[203] Johnson, JA (2003) "Report for congress: Human cloning" [Web:]www.usinfo.state.gov/ usa/infousa/tech/biotech/rl31358.pdf [Date of access: 10 December 2005].

the more relevant. Jerry Hall of the Institute for Reproductive Medicine and Genetics in Los Angeles says that a lot of work still has to be done to ensure any tissues made from parthenogenetic stem cells are absolutely normal. Since eggs are needed to make parthenogenetic stem cells, one potential problem is that the technique could not be used to make matching stem cells for men, or for women after menopause. Therapeutic cloning, by contrast, could provide matching stem cells. Because these cells have identical sets of chromosomes (rather than one set each from the father and the mother), they have less variation in the surface proteins on cells that can trigger immune reactions. Wininger suggests that a parthenogenetic stem cell bank that could provide cells to suit most individuals should be established. Such banks would be much cheaper than creating stem cells from scratch for each individual.[204]

2 4 5 2 Pre-implantation genetic diagnosis[205]

Pre-implantation genetic diagnosis was first performed in the United Kingdom in 1989 and was used to avoid creating a child inflicted with a genetic-based disorder. Pre-implantation genetic diagnosis has since been successfully applied to a variety of genetic diseases, either single gene disorders or chromosomal abnormalities. Before pre-implantation genetic diagnosis was used, prenatal testing was performed during the first trimester using chorionic villus sampling by ultrasound or amniocentesis. Pre-implantation genetic diagnosis is most commonly used for couples that have had one child affected with a genetic disorder and/or one or more termination(s) of pregnancy following the conventional testing described above. Pre-implantation genetic diagnosis reduces the chance that parents will be faced with the difficult decision of whether or not to terminate a pregnancy of affected embryos. The possibility of saving a couple from enduring a series of terminated pregnancies is an obvious advantage of pre-implantation genetic diagnosis. The terminations can be very stressful physically and psychologically

[204] Pagan (2003) www.newscientist.com/article.ns?id=dn3654.

[205] Pre-implantation diagnosis of genetic disorders refers to the use of the techniques of micromanipulation and DNA application currently available, where a cleaving zygote known to be at risk for a specific genetic disorder may be diagnosed before implantation. The sex of the embryo can be determined from a blastomere taken from a six- to eight-cell zygote and analysed by DNA amplification of sequences from the Y chromosome. This procedure has been used to detect female embryos during in vitro fertilisation procedures in cases where a male embryo would be at risk for a serious X-linked disorder. See Moore & Persaud (2003) 35.

because "each aborted fetus is potentially a wanted child". Pre-implantation genetic diagnosis allows couples to create their family with increased confidence that they will neither give birth to an affected child nor subject themselves to the chance of having to terminate a pregnancy.[206]

Pre-implantation genetic diagnosis is a diagnosis through the process of in vitro fertilisation that allows parents or doctors to choose which embryos to implant in the uterus.[207] In vitro fertilisation techniques are used to obtain ova from the mother, which are then fertilised in the laboratory with sperm obtained from the father. One or more cells are then removed from the developing embryo two to four days after fertilisation. This highly sophisticated technique called micromanipulation does not adversely affect further development of the embryo. The cells removed are then used for analysis, and the results can be obtained within 12 to 24 hours. The embryos without the genetic defects are then transferred into the uterine cavity to develop into a normal pregnancy.[208]

The study of pre-implantation genetic diagnosis reports a new approach to human embryonic stem cell derivation. Embryo surplus to therapeutic requirements following pre-implantation genetic diagnosis were used. Although unsuitable for embryo transfer owing to the high risk of genetic disease, these embryos are taken from fertile couples, and may therefore be of better quality than fresh embryo surplus to assisted reproduction treatment cycles. Embryos donated after cryopreservation was also used, and putative human embryonic stem cell lines were derived from both sources of embryos. The cell lines described here are thought to be the first reported human embryonic stem cell lines to have been derived in the United Kingdom.[209] There are only a few centres in the world today that offer pre-implantation genetic diagnosis to couples at high risk or those who

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206 Vacco, LA (2005) "Pre-implantation genetic diagnosis: From preventing genetic disease to customising children. Can the technology be regulated based on the parents' intent?" *St Louis ULJ* 49(4):1181 *at* 1181, 1182, 1183.

207 *Ibid*.

208 Dokras, A (2006) "Pre-implantation genetic diagnosis" [Web:] www.hygeia.org/poems5.htm [Date of access: 20 January 2006].

209 Pickering, SJ *et al* (2003) "Pre-implantation genetic diagnosis as a novel source of embryos for stem cell research" *Reprod Biomed Online* 7:353-364 [Available on internet:] www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list-uid [Date of access 24 January 2006].

already have an affected child. Efforts are continuously focused on improving methods of obtaining an accurate diagnosis from only one or two cells.[210]

Pre-implantation genetic diagnosis is a powerful and controversial technology that has revolutionised genetic testing and assisted reproduction while helping families worldwide. The scope and uses of pre-implantation genetic diagnosis, as well as the ethical and legal issues surrounding it, have greatly increased since it was first developed. As the technology further refines itself and our scientific understanding improves, researchers are likely to develop even more genetic tests utilising pre-implantation genetic diagnosis. This potential expansion and increased public awareness of this technology could certainly increase its demand. Unregulated use of pre-implantation genetic diagnosis could result in serious harm to society and children, necessitating control over the technology and ensuring it will be used for therapeutic purposes only.[211]

2 5 CONCLUSION

Stem cell treatments and therapeutic cloning techniques entice us with their endless medical potential, but challenge us with equally limitless questions about their legal and ethical consequences. Therefore, stem cell research presents an intriguing dilemma.[212] If the above medical information is considered carefully, it is clear that embryonic stem cells appear to have great therapeutic potential for the treatment of many disorders, both common and serious, and also for the repair of damaged tissue. Recent research on adult stem cells, including stem cells from the placenta and umbilical cord, also holds promise for therapies, and research on them should strongly be encouraged. To ensure maximum medical benefit it is necessary at present to keep both routes to therapy open, since neither alone is likely to meet all therapeutic needs.[213]

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[210] Dokras (2006) www.hygeia.org/poems5.htm.
[211] Vacco (2005) *St Louis ULJ* 1181 *at* 1228.
[212] Fujikawa, R (2005) "Federal funding for human embryonic stem cell research: An institutional examination" *S Cal L Rev* 78(4):1075.
[213] The United Kingdom Parliament: House of Lords (2002) www.parliament.the-stationery-office.co.uk/pa/Id200102/dselect/Idstem/83/8301.htm-14k.

For the full therapeutic potential of all stem cells to be realised, fundamental research on embryonic stem cells is needed, particularly to understand the processes of cell differentiation and dedifferentiation. Future developments might eventually make further research on embryonic stem cells unnecessary. This is however unlikely in the foreseeable future. Therefore, in the meantime there is a strong scientific and medical case for continued research on human embryonic stem cells.[214]

It should be recognised that much of the recent debate over embryonic stem cell research has focused on the use of embryonic stem cells collected from cadaveric fetal tissue and "unused" in vitro fertilisation embryos. Attempts by philosophers, lawyers and scientists alike to justify embryonic stem cell research have centred on issues such as lack of complicity with abortion or the best use of unwanted materials. These attempts have, however, not answered the critics of this research and have left everyone in an ethical stalemate.[215]

Because research also involves the deliberate production, use, and ultimate destruction of cloned embryos, it reawakens the debate on the moral status of the embryo. Other moral anxieties include the possibility that women, as donors of ova, would be exploited, and that this research could land on the slippery slope of reproductive cloning.[216]

The starting point for examining the legal and ethical issues and implications surrounding embryonic stem cell research and cloning in South Africa, is an investigation into the provisions of the South African Constitution. Consideration must also be given to South African common law. This legal framework is discussed in the next chapter.

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[214] Scientists have turned an ordinary skin cell into what appears to be an embryonic stem cell. The process may eventually eliminate the controversial step of destroying human embryos for stem cell research. The new technique involves fusing a skin cell with an existing, laboratory-grown embryonic stem cell. The fused, or hybrid, cell is "reprogrammed" to its embryonic state. This is, however, just the beginning and research on embryos is still necessary. See Roach, J (2005) "Stem cell breakthrough: No more need to destroy embryos?" [Web:] www.news.nationalgeographic.com/news/2005/08/0823_050823_stemcells.html [Date of access: 27 September 2005].

[215] Daley (2001) www.law.mq.edu.au/ANZIHLE/daley%20cp%2001.pdf.

[216] Dhai *et al* (2004) *SAMJ* 906.

CHAPTER 3 THE CONSTITUTIONAL FRAMEWORK: AN INTERPRETATION OF FUNDAMENTAL HUMAN RIGHTS ISSUES PERTAINING TO EMBRYONIC STEM CELL RESEARCH AND CLONING

3 1 INTRODUCTION

The impact of the Constitution on embryonic stem cell research and cloning is threefold: First, the Constitution is considered to be the supreme law in South Africa, and any legislation that is irreconcilable with it is invalid to the extent of the conflict.[217] Second, according to section 39 of the Constitution, the Bill of Rights applies to all law and binds the executive, legislature, judiciary and all organs of state. Every court, tribunal, or forum must promote the spirit and objects contained in the Bill of Rights in the interpretation of legislation and the development of the common law.[218] Third, the Bill of Rights instructs the state to use the power that the Constitution provides for in ways that do not violate fundamental rights. There are specific fundamental human rights protected in the Bill of Rights that are applicable to embryonic stem cell research and cloning. These rights are discussed in detail below. The first is section 36 of the Constitution – the general limitation clause. If a court determines that a law or the conduct of a respondent impairs a fundamental right, it must then consider whether the infringement is nevertheless a justifiable limitation of the right in question.[219]

The right to dignity and to be treated with respect is one of the most important rights protected in the Bill of Rights.[220] The most obvious implication of the application to the right of dignity is that this right will now have to compete for protection with all of the

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[217] Section 2 of the Constitution reads as follows: "This Constitution is the supreme law of the Republic; law or conduct inconsistent with it is invalid, and the obligations imposed by it must be fulfilled."

[218] Section 39 of the Constitution reads as follows: "39(1) When interpreting the Bill of Rights, a court, tribunal or forum – (a) must promote the values that underlie an open and democratic society based on human dignity, equality, and freedom; (b) must consider international law; and may consider foreign law. (2) When interpreting any legislation, and when developing the common law or customary law, every court, tribunal, or forum must promote the spirit, purport, and objects of the Bill of Rights. (3) The Bill of Rights does not deny the existence of any other rights or freedoms that are recognised or conferred by common law, customary law, or legislation, to the extent that they are consistent with the Bill."

[219] Currie, I & De Waal, J (2005) *The Bill of Rights Handbook* 26.

[220] *S v Makwanyane and Another* 1995 (3) SA 391 (CC).

other rights enumerated in the Bill of Rights. Clashes between fundamental rights will require resolution not at the first stage of defining the scope of the right, but as part of the balancing of interests contemplated by the limitation clause.[221]

Now that the death penalty has been declared unconstitutional, the ambit and nature of the "right to life" will be contested on a wide range of issues that extend beyond the obvious cases of abortion, in vitro fertilisation, and now also embryonic stem cell research and therapeutic cloning. The words "everyone", "person" and "life"[222] will need to be defined by the Constitutional Court. Judgments handed down so far by the Constitutional Court reveal that the interpretive process will be generous and purposive. This perspective could be helpful in creating a picture of the "life" that is protected by section 9 of the interim Constitution and section 11 of the final Constitution.[223] One of the purposes of this chapter is to answer the question of whether the fetus is a constitutional bearer of the "right to life".

This discussion commences with the question: When does human life begin? Many people have thought of possible answers to this question. In fact, the question should be considered more carefully as stated, for the reason that there are different possible meanings that are relevant to the status of the human fetus. In this chapter alternatives – from conception to birth – are considered to answer this question.[224]

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[221] O'Sullivan, M & Bailey, C "Reproductive rights", as published in Chaskalson, M *et al* (2005) *Constitutional law of South Africa* 37-2.

[222] The word "life" can be used in the biological or mechanical sense. When one says "I am alive" after narrowly escaping death, it is used in a mechanical way, and the intended meaning is "I breathe, I speak, I walk, I exist" in some instinctive sense. But there is more to life than the exhibition of biological characteristics. Starving children still "live". Terminally ill patients are "alive". Both materially and philosophically, life depends upon resources essential for the preservation and quality of existence. Inherent in a broader notion of life is a value judgment about what constitutes an acceptable quality of life. So, while life may be a value in and of itself; without water, food, livelihood, friendship, and recreation it may not be worth living.

[223] O'Sullivan & Bailey, as published in Chaskalson *et al* (2005) 37-2. See also *Makwanyane* fn 220 *supra*; *S v Zuma & others* 1995 (2) SA 642 (CC) 1995(4) BCLR 401 (CC).

[224] Macer, DRJ (1990) "Shaping genes: Ethics, law and science of using new genetic technology in medicine and agriculture" [Web:] www.csu.edu.au/learning/eubios/Papers.html [Date of access: 25 October 2005].

The question of whether parents have a fundamental right to decide the fate of the embryo, including the right to destroy it if they choose not to have an offspring, should be examined in light of the right to reproduce (as protected in section 12 of the Constitution), the right to privacy (as protected in section 14 of the Constitution), as well as the right to equal treatment before the law (as protected in section 9 of the Constitution). It is submitted in the paragraphs below that these rights include the right to procreate, the right to abort a fetus and donate it for research purposes, the right to use contraceptives, and the privacy interests inherent in the marital relationship. Most people would agree that the parents, as creators of the embryo, have some degree of decisional authority over the embryo. However, the scope of the parents' rights over the embryo is unclear. These issues are also discussed in the paragraphs below.[225]

At one time, biomedical experimentation using human subjects proceeded almost routinely. Researchers justified their activities as benefiting mankind and the subjects were generally happy to oblige or to be reasonably recompensed, and research was of manageable quantity. Currently, embryonic stem cell research is essential to the study and conquest of genetic disease. Systematic study in this field depends upon a supply of human embryos, for there always comes a time when animal models are inadequate for human research purposes. The different arguments for and against embryo research are also examined below in an attempt to answer whether embryo research should be allowed and how it should be regulated in terms of section 16 of the Constitution.[226]

Section 27 guarantees the right to access to healthcare, which includes reproductive health care, within the availability of state recourses conductive to health and well-being, and compels government to take steps to ensure the protection of these rights. The scope of this right is also examined below.

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[225] See Schaefer (1990) *Pac LJ* 87. See in general *Carey v Population Services Int'l*, 431 US 678, 685 (1977). See also *Webster v Reproductive Health Services*, 109 S Ct 3040, 3058 (1989); *Roe v Wade*, 410 US 113, 152 (1973).

[226] Mason, JK *et al* (2002) *Law and Medical Ethics* par 19.6.

Another question that needs to be answered is whether the right to reproduce,[227] as envisaged in section 12(2)(a) of the Constitution, includes a right to "reproductive cloning". It is submitted that as far as a prohibition on cloning for reproductive purposes is concerned, its legitimacy would have to be argued on the basis of a justifiable limitation of rights in terms of section 36 of the Constitution (if cloning falls within the scope of the right to reproduce). Therefore, the purpose of this chapter is to outline these basic principles of fundamental human rights as protected in the Bill of Rights in the context of embryonic stem cell research and cloning.

3 2 SECTION 36 OF THE CONSTITUTION: LIMITATION OF RIGHTS

Fundamental rights and freedoms, as protected in the Bill of Rights, may be limited or restricted, and are therefore not absolute. Section 36, the general limitation clause, sets out specific criteria for the restriction of the fundamental rights in the Bill of Rights.[228] However, given the importance of the rights and the total and irremediable negation of it caused by an infringement, the justification for a limitation[229] would have to be exceptionally compelling.[230] Therefore, where an infringement can be justified in an open and democratic society based on human dignity, equality and freedom, it will be constitutionally valid.[231] The limitation of the rights in context of this dissertation is

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227 Section 12(2)(a) of the Constitution.

228 Section 36 of the Constitution read as follows: "Limitation of rights – (1) The rights in the Bill of Rights may be limited only in terms of law of general application to the extent that the limitation is reasonable and justifiable in an open and democratic society based on human dignity, equality and freedom, taking into account all relevant factors, including – (*a*) the nature of the right; (*b*) the importance of the purpose of the limitation; (*c*) the nature and extent of the limitation; (*d*) the relation between the limitation and its purpose; and (*e*) less restrictive means to achieve the purpose. (2) Except as provided in subsection (1) or in any other provision of the Constitution, no law may limit any right entrenched in the Bill of Rights."

229 "Limitation" is a synonym for "infringement" or, perhaps, "justifiable infringement". A law that limits a right infringes that right.

230 Currie & De Waal (2005) 163, 164.

231 One consequence of the inclusion of a general limitation clause in the Bill of Rights is that the process of considering the limitation of fundamental rights must be distinguished from that of the interpretation of the rights. If it is argued that a provision of the law infringes a right in the Bill of Rights, it will first have to be determined whether that right has in fact been infringed. Limitations on rights are established by means of interpretation of the right by a court. Even if a respondent makes no attempt at justification, the court must nevertheless consider the issue of limitation. In *National Coalition for Gay and Lesbian Equality v Minister of Justice*, the court *mero motu* considered whether a limitation argument could be made in favour of the laws, despite the fact that the Minister indicated that he would abide by the decision of the court and did not attempt to defend the laws in question. See *National*

discussed below, together with the applicable fundamental rights protected in the Constitution. To understand the general limitation of rights it is necessary to explain exactly what section 36 entails.

Devenish explains the general limitation of rights as follows:

> It is widely accepted in the domestic law of most states, in international law and according to international and other human rights documents, that only a very limited number of rights, if any, are absolute. These include freedom from torture, the abuse, and exploitation of children and possibly freedom from servitude, freedom of conscience, belief, thought, and opinion. The overwhelming majority of human rights and liberties are of necessity restricted by the inherent duty, which should be perceived as the inextricable counterpart of a corresponding right, to respect the rights of others. The classical example in this regard is that freedom of speech does not allow one person to defame another nor would it sanction a person shouting 'fire' in a full theatre when there is no fire.[232]

The relationship between the state and the individual is not one of equality, and therefore a Bill of Rights was traditionally designed to protect individuals against the abuse of state power. However, section 8 of the Constitution makes it clear that the Bill of Rights applies vertically (which is in relation to the state) and horizontally (which is in relation to private persons).[233] Section 38 of the Constitution provides that anyone listed in the section[234] has a right to approach a competent court, alleging that a right in the Bill of Rights has been infringed or threatened, and the court may grant appropriate relief, including a declaration of rights.

Coalition for Gay and Lesbian Equality v Minister of Justice 1999 (1) SA 6 (CC). See also *Makwanyane* fn 220 *supra*.

232 For a discussion of the limitation clause, and other human rights protected in the Constitution see in general Devenish, GE (1998) *A commentary on the South African Constitution*.

233 Section 8 of the Constitution reads: "(1) The Bill of Rights applies to all law, and binds the legislature, the executive, the judiciary and all organs of state. (2) A provision of the Bill of Rights binds a natural or a juristic person if, and to the extent that, it is applicable, taking into account the nature of the right and the nature of any duty imposed by the right. (3) When applying a provision of the Bill of Rights to a natural or juristic person in terms of subsection (2), a court – (a) in order to give effect to a right in the Bill, must apply, or if necessary develop, the common law to the extent that legislation does not give effect to that right; and (b) may develop rules of the common law to limit the right, provided that the limitation is in accordance with section 36(1). (4) A juristic person is entitled to the rights in the Bill of Rights to the extent required by the nature of that juristic person.

234 The persons who may approach a court are – (a) Anyone acting in their own interests. (b) Anyone acting on behalf of another person who cannot act in their own name. (c) Anyone acting as a member of, or in the interest of, a group or class of persons. (d) Anyone acting in the public interest. (e) An association acting in the interest of its members.

According to section 36, the rights in the Bill of Rights may only be limited in terms of "law of general application", which is the expression of a basic principle of liberal political philosophy and of constitutional law, known as the "rule of law".[235] According to the decision in *Khala v Minister of Safety and Security*,[236] the word "law" includes legislation, common law and customary law. Legislative bodies may only limit rights when they regulate matters within their sphere of competence.[237] The limitation must also be "reasonable and justifiable in an open and democratic society based on human dignity, equality and freedom", which describes the kind of balance that must exist between the limitation and its purpose. In considering the legitimacy of a limitation, reference should be made to the following paragraph as stated in *Makwanyane*:

> The limitation of Constitutional rights for a purpose that is reasonable and necessary in a democratic society involves the weighing up of competing values, and ultimately an assessment based on proportionality. This is implicit in the provisions of s 33(1)[IC]. The fact that different rights have different implications for democracy, and in the case of our Constitution, 'for an open and democratic society based on freedom and equality,' means that there is no absolute standard which can be laid down for determining reasonableness and necessity. Principles can be established, but the application of those principles to particular circumstances can only be done on a case-by-case basis. This is inherent in the requirement of proportionality, which calls for the balancing of different interests. In the balancing process, the relevant considerations will include the nature of the right that is limited, and its importance to an open and democratic society based on freedom and equality; the purpose for which the right is limited and the importance of that purpose to such a society; the extent of the limitation, its efficacy, and particularly where the limitation has to be necessary, whether the desired ends could reasonably be achieved through other means less damaging to the right in question. In the process regard must be had to he provisions of a s 33(1)[IC], and the underlying

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235 Currie & De Waal *(*2005) 168.

236 *Khala v Minister of Safety and Security* (1994) 2 BCLR 89 (W).

237 It was argued in *Makwanyane* that section 277 of the Criminal Procedure Act, 1977 (Act 51 of 1977) (hereafter referred to as the Criminal Procedure Act) did not constitute a law of general application, since it did not apply uniformly to the whole of South Africa. The death sentence had already been abolished in Ciskei in 1990, and therefore a person could not be sentenced to death in that part of South Africa. The court rejected the argument and remarked as follows: "Such a construction would defeat the apparent purpose of section 229[IC], which is to allow different legal orders to exist side by side until a process of rationalisation has been carried out, and would inappropriately expose a substantial part if not the entire body of our statutory law to challenges under s 8 of the Constitution. It follows that disparities between the legal orders in different parts of the country, consequent upon the provision of s 229 of the Constitution, cannot for that reason alone be said to constitute a breach of the equal protection provision of s 8, or render the laws such that they are not of general application." See *Makwanyane* fn 220 *supra*. In contrast, it was decided in *Hoffmann v South African Airways* that the policy of an organ of state that HIV-positive persons were not qualified to be employed as airline cabin attendants does not constitute a "law of general application". See *Hoffmann v South African Airways* 2001 (1) SA 1 (CC).

> values of the Constitution, bearing in mind that as a Canadian Judge has said, 'the role of the court is not to second-guess the wisdom of policy choices made by legislators.[238]

In addition to "all relevant factors" as stated in section 36, five factors must be considered in determining whether the limitation is "reasonable and justifiable" in an open and democratic society based on human dignity, equality and freedom. These factors are examined in short below:[239]

(a) The nature of the right: This entails the weighing up of the infringement of a fundamental right against the benefits that the law seeks to achieve.[240]

(b) The importance of the purpose of the limitation: At a minimum, reasonableness requires the limitation of a right to serve some purpose. The purpose has to be one that is worthwhile and important in a constitutional democracy.[241]

(c) The nature and extent of the limitation: This requires the court to assess the way in which the limitation affects the right concerned.[242]

(d) The relation between the limitation and its purpose: To serve as a legitimate limitation of a right, a law that infringes the right must be reasonable and justifiable. Therefore, there must be a good reason for the infringement.[243]

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238 *Makwanyane* fn 220 *supra*. See also *S v Bhulwana* 1996 (1) SA 388 (CC), where the court said: "In sum, therefore, the Court places the purpose, effects, and importance of the infringing legislation on one side of the scale and the nature and effect of the infringement caused by the legislation on the other. The more substantial the inroad into fundamental rights, the more persuasive the grounds of justification must be."

239 See in general Currie & De Waal (2005) 163-188.

240 See *Makwanyane* where O'Regan J said: "The right to life is, in one sense, antecedent to all the other rights in the Constitution. Without life in the sense of existence, it would not be possible to exercise rights or to be the bearer of them. But the right to life was included in the Constitution not simply to enshrine the right to existence. It is not life as mere organic matter that the Constitution cherishes, but the right to human life: the right to live as a human being, to be part of a broader community, to share in the experience of humanity. This concept of human life is at the centre of our constitutional values." Therefore, this must be demonstrated by the state in everything that it does, including the way it punishes criminals. Very compelling reasons would therefore have to be found to justify the limitation of such important rights (*Makwanyane* fn 220 *supra*). See also *Ex parte Minister of Safety and Security: in re S v Walters* 2002 (4) SA 613 (CC); *New National Party v Government of the Republic of South Africa* 1999 3 SA 191 (CC), 1999 (5) BCLR 489 (CC).

241 For an explanation of this factor see *National Coalition for Gay and Lesbian equality* fn 231 *supra*. See also *Ferreira v Levin NO* 1996 (1) SA 984 (CC); *Harksen v Lane NO* 1998 (1) SA 300 (CC).

242 "It is the effect of the limitation on rights and not the effect of the limitation on a particular right-holder that is of concern to this part of the analysis." See *S v Meaker* 1998 (8) BCLR 1038 (W). See also *S v Mamamela* 2000 (3) SA 1 (CC).

(e) Less restrictive means to achieve the purpose: To be legitimate, a limitation of a fundamental right must achieve benefits that are in proportion to the costs of the limitation. The limitation will not be proportionate if other means could be employed to achieve the same ends that will either not restrict rights at all, or will not restrict them to the same extent.[244]

Each individual fundamental human right as protected in the Bill of Rights and its possible limitation in the context of embryonic stem cell research and cloning is discussed below.

3 3 SECTION 10 OF THE CONSTITUTION: HUMAN DIGNITY[245]

In *Carmichele v Minister of Safety and Security* it was said that human dignity is a central value of the objective, normative value system.[246] Chaskalson, in this regard wrote:

> The affirmation of human dignity as a foundational value of the constitutional order places our legal order firmly in line with the development of constitutionalism in the aftermath of the second world war.[247]

He continues to say that, as an abstract value common to the core values of our Constitution, dignity informs the content of all the concrete rights and plays a role in the balancing process necessary to bring different rights and values into harmony. It too, however, must find place in the constitutional order. O'Regan J remarked in *Makwanyane*

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[243] In *Makwanyane*, Didcott J said: "According to the state the death penalty was designed to serve the purposes of deterrence and prevention of violent crimes … The protagonists of capital punishment bear the burden of satisfying us that it is permissible under s33(1) [IC]. To the extent that their case depends upon the uniquely deterrent effect attributed to it, they must therefore convince us that it indeed serves such a purpose. Nothing less is expected from them in any event when human lives are at stake, lives which may not continue to be destroyed on the mere possibility that some good will come of it. In that task they have failed, and as far as one can see, could never have succeeded."

[244] *Makwanyane* fn 220 *supra*. See also *Larbi-Odam v MEC for Education* 1998 1 SA 745 (CC).

[245] Section 10 of the Constitution reads: "Everyone has inherent dignity and the right to have their dignity respected and protected." International instruments also refer to the importance of preserving human dignity. Article 1 of the Council of Europe's *Convention on Human Rights and Biomedicine* of 1996 refers to the aim of the Convention, which is to secure the dignity and identity of human beings in the application of biology and medicine. It is suggested that human dignity has to be respected as soon as human life begins. The preamble to the *Universal Declaration on the Human Genome and Human Rights* states that research on the human genome should fully respect human dignity, freedom, and human rights. See Slabbert (2000) 339.

[246] *Carmichele v Minister of Safety and Security* 2001 (4) SA 938 (CC).

[247] Chaskalson, A (2000) "Human dignity as a foundational value of our Constitutional order" *SAJHR*, 16(2):193 *at* 196.

that recognising a right to dignity is an acknowledgment of the intrinsic worth of human beings: human beings are entitled to be treated as worthy of respect and concern. This right is therefore the foundation of many of the other rights that are specifically entrenched in the Bill of Rights.

In *Dawood v Minister of Home Affairs*[248] Van Heerden J held that the right to dignity must be interpreted to afford protection to the institutions of marriage and family life. According to Slabbert, the promotion of the constitutional values of human life and dignity oblige the state to regulate abortion in order to protect potential life. On the other hand, the state also has an interest in maternal health, which cannot be dissociated from the abortion decision. She submits that the state must reconcile these duties in order to give effect to both.[249] The state would also be obliged to regulate stem cell research and cloning, which also derives from the constitutional values of life and human dignity. It is submitted that respect for human dignity lies at the core of the developing South African rights jurisprudence; it is the core value that justifies respect for women's personal privacy and the need to eradicate gender inequality.

Mokgoro J[250] pointed out that life and dignity are like two sides of the same coin: a violation of the right to life is a violation of the right to dignity. It is sometimes argued that abortion or the destruction of embryos for therapeutic purposes affronts the dignity of the fetus; not only in so much as it violates its right to life, but also in the manner abortions are carried out. Therefore, a mother's rights to dignity, equality and privacy – even when they are infringed – are outweighed by the fetus' rights to life and dignity.[251] These arguments are examined below in context of all the applicable rights protected in the Bill of Rights.[252]

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248 *Dawood v Minister of Home Affairs* 2000 (1) SA 997 (C), as quoted in Currie & De Waal (2005) 278.
249 Slabbert (2000) 340.
250 *Makwanyane* fn 220 *supra*.
251 See in general the arguments as set out in McGregor, M & Moore, R (1995) "The constitutionality of abortion on request in South Africa" *Mur U Elec JL* 2(3) [Available on internet:] www.murdoch.edu.au/elaw/issues/v2n3/moore23.html [Date of access: 15 August 2005].
252 Schüklenk and Ashcroft express a different view of human dignity and state the following: "Dignity-related claims have pretty much the same effect on the cloning debate [and stem cell debate, in this context] as the neutron bomb has on modern warfare. They kill everything in their way. For a start they kill every argument in their way: who would dare to defend cloning if it is so obviously violating the

3 4 SECTION 11 OF THE CONSTITUTION: THE RIGHT TO LIFE

3 4 1 Introductory remarks on the right to life

The right to life as protected in section 11 of the Constitution is the most basic human right on which all other rights are premised.[253] This explains why issues of social policy, such as abortion and the destruction of human embryos for therapeutic and research purposes, are readily associated with the right to life. With the possible exception of human dignity, life itself is the most basic value protected by the Constitution.[254] In addition, The *Universal Declaration of Human Rights*[255] reads: "Everyone has the right to life, liberty, and security of the person." The *International Convention on Civil and Political Rights*[256] also qualifies the right to life as follows: "Every human being has the inherent right to life. This right shall be protected by law. No one shall be arbitrarily deprived of his life." The right to life is however not absolute.

In *Makwanyane*, the Constitutional Court described the rights to life and dignity as the "most important of all human rights, and the source of all other personal rights in [the Bill of Rights]". By committing ourselves to a society founded on the recognition of human rights, we are required to value these two rights above all others.[257]

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human dignity? Who would want to be seen as supporting such a vicious attack on our dignity ... Human dignity covers pretty much everything and nothing. Human dignity related rhetoric is the continental European bioethics equivalent to shifting goal posts in a street soccer match. Human dignity is not based in or derived from a coherent philosophical framework. Hence it is easy to employ it whenever it suits the needs of those lacking a decent argument for or against whatever they are concerned about. If human dignity is to be invoked in philosophical argument, we must either derive it from such a framework, or give and account of how it is a 'primitive term' of moral language. But if the latter move is made, we are still owed some account of how this term is to be used correctly, and what criteria distinguish legitimate from illegitimate appeals to it." See Schüklenk, U & Ashcroft, R (2000) "The ethics of reproductive and therapeutic cloning" *Monash Bio Rev* 19(2):34.

253 *Makwanyane* fn 220 *supra*. In this case, the two accused were convicted of murder in the Witwatersrand Local Division and were sentenced to death. They appealed to the Appellate Division against the death sentences. After hearing argument and coming to the conclusion that, in the circumstances of the case, the death sentence was the proper sentence, the court postponed the further hearing of the appeals until the Constitutional Court had decided whether the death sentence in terms of section 277(1)(a) of the Criminal Procedure Act was in conflict with the provisions of the Constitution or not. The Constitutional Court issued, in terms of section 98(5) of the interim Constitution, an order declaring that, with effect from the date of the order, the provisions of section 277(1)(a), (c), (d), (e), and (f) of the Criminal Procedure Act and all corresponding provisions of other legislation sanctioning capital punishment (which were in force in any part of the national territory of South Africa in terms of section 229 of the interim Constitution), were inconsistent with the Constitution, and therefore invalid.

254 Chaskalson *et al* (2005) 37-1.

255 Article 3 of the Universal Declaration of Human Rights.

256 Article 6(1) of the International Convention on Civil and Political Rights.

257 *Makwanyane* fn 220 *supra*.

The right to life is textually unqualified and may only be limited in terms of the limitation clause.[258] The unqualified nature of the right to life was referred to by several judges in *Makwanyane*. In this case, Chaskalson P rejected an argument that those who are convicted of murder have forfeited their right to life. He wrote the leading opinion, signed by all the other judges, and did not invalidate the death sentence on the basis of its conflict with the right to life, but held the death sentence to be a form of cruel, inhuman or degrading punishment.[259] A majority of the members of the Constitutional Court nevertheless found the death penalty to violate the right to life. Although no comprehensive definition of the right to life was put forward by any of these judges, most of them agreed that the right must, at least, incorporate the right not to be deliberately and systematically killed by the state. Since the right to life has remained unqualified in the 1996 Constitution, it appears that the Constitutional Assembly decided not to interfere with the Constitutional Court's decision in *Makwanyane*. This means that unless the Constitution is amended, the death penalty remains an unconstitutional form of punishment.[260]

When it comes to the right to life, abortion raises difficult questions about moral philosophy. Abortion is readily associated with embryonic stem cell research, for the use of aborted fetal tissue for therapeutic purposes, and also because of the destruction of embryos for the use in research. Mahomed J in *Makwanyane* described it as follows:

> [W]hat does the [right to life] mean? What is a 'person? When does 'personhood' and 'life' begin? Can there be a conflict between the 'right to life' in s9 IC and the right of a mother to 'personal privacy'[261] in terms of s13 IC and her possible right to the freedom and control of her body?

From a constitutional perspective, the issues of abortion and embryonic stem cell research both call for the resolution of conflict between the right to freedom and physical

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[258] Section 36 of the Constitution.

[259] Section 11(2) in chapter 3 of the interim Constitution refers to cruel and inhuman punishment.

[260] Currie & De Waal (2005) 281. See also *S v Ntsang* 1995 (4) BCLR 426. See also *Ex parte Minister of Safety and Security: In re S v Walters* fn 240 *supra*: "[The state's] role in our violent society is rather to demonstrate that we are serious about the human rights the Constitution guarantees for everyone, even suspected criminals." In *Makwanyane*, Chaskalson P said: "… (R)ights vest in every person, including criminals convicted of vile crimes. Such criminals do not forfeit their rights under the Constitution and are entitled, as all in our country now are, to assert these rights, including the right to life …" See *Makwanyane* fn 220 *supra*.

[261] For a discussion of privacy see paragraph 3 4 2 12 below.

integrity and the state's duty to protect life, which is developing life in the case of abortion and embryonic stem cell research. Historically, most jurisdictions have favoured the protection of life at the cost of freedom and physical integrity. This has resulted in a number of freedom-based challenges to restrictive laws. Increasingly, however, laws have begun to favour freedom of choice, resulting in court challenges by proponents of strong government intervention to protect life.[262]

3 4 2 The fetus and the right to life

The starting point for consideration on the ethics of research on human embryos is the status of early embryos. This is one of the most fundamental questions, since it is intimately bound with the questions of when human life begins and what the definition of a person is. Society remains divided on the highly controversial issue of the moral status of the embryo and what is owed to developing human life.[263] The issue of whether the human embryo is or is not a person seems to be the most crucial one in current debates on the morality of interventions in reproduction such as abortion, in vitro fertilisation and embryonic stem cell research.[264] Even in vitro fertilisation involves the death of some embryos, and for this reason it can be associated with abortion. Those who oppose abortion can mount a criticism of in vitro fertilisation on the same grounds: they hold that both practices are immoral because the embryo is a person from conception, and

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[262] Currie & De Waal (2005) 287, 288. See also Meyerson, D (1999) "Abortion: the constitutional issues" *SALJ*, 116(1):50 *at* 59; Naude, T (1999) "The value of life: A note on the Christian Lawyers Association of SA v Minister of Health" *SAJHR* 15(4):541-562.

[263] The view of, for example, the Roman Catholic Church is that embryos and fetuses constitute actual life instead of potential life. They believe that a human being comes into existence at the moment of fertilisation. The Christian faith holds that two independent cells are united into a new, non-reversible being at the moment of fertilisation. The argument is that because an embryo is a human being in nature, although not fully developed, it holds a sense of sacredness. Some argue that fertilisation represents the phase of genetic completion, at which moment the entire constitution of a human person is clearly spelled out. Slabbert submits that personhood itself cannot be equated with genetic completeness. She argues that the zygote has the potential to develop into a human being, and that because of this potential, human personhood begins upon the completion of fertilisation. However, medical science has shown that this potential is already present in the pre-zygote, when fertilisation has scarcely commenced. See Slabbert (2000) 30-32.

[264] Momeyer (2003) *Cap UL Rev* 95. See also Casell (2001) *U Mich JL Ref* 547.

therefore, any embryo's destruction is a form of homicide.[265] Embryonic stem cell research also involves the destruction of human embryos.

Since there is widespread agreement about condemning homicide in Western societies, it is clear why the question whether or not the embryo is a person, has a central position in the debate concerning assisted reproduction. Critics make the following two statements:

(a) An embryo is a person from conception, and therefore the destruction of any embryo is immoral and a form of homicide.
(b) If the embryo was not a person, it would not deserve any protection at all and therefore all destruction of embryos would be permissible.[266]

The answers to this question can greatly affect, and even prohibit, embryonic stem cell research and therapeutic cloning, since granting "person status" to an embryo would necessarily grant constitutional rights to the embryo – rights that would certainly be violated if the embryo were subjected to medical research.[267]

Section 9 of the interim Constitution reads: "Every person shall have the right to life," and section 11 of the final Constitution reads: "Everyone has the right to life." It is important to note that the interim Constitution refers to "every person" and the final Constitution refers to "everyone". This distinction will be explained in the discussion below.

In South Africa, the question of whether the fetus is a bearer of constitutional rights was raised in 1998 when the Christian Lawyers Association argued that section 11 of the Constitution applies to an embryo and fetus from the moment of conception and that the Choice on Termination of Pregnancy Act[268] is in conflict with section 11 of the

[265] The argument that an individual exists at fertilisation is strongly criticised by many, for example by the theologian Ford in his paper. See Ford, NM (1989) "When did I begin?" *Cam U Press* 74(1120):217-221. See also Evans (1996) 162.
[266] Evans (1996) 151.
[267] Enmon (2002) *Utah L Rev* 621 *at* 626.
[268] For a discussion of the Act see chapter 4.

Constitution. The plaintiffs sought an order against the defendants declaring the Choice on Termination of Pregnancy Act to be unconstitutional and for it to be struck down in its entirety.[269]

It is clear from the case that the plaintiffs relied solely on the provisions of section 11 of the Constitution to substantiate their cause of action. McCreath J restricted his determination of the matter to an investigation of whether a fetus is included under "everyone" in terms of section 11 of the Constitution. However, the absence of explicit constitutional protection does not mean that fetal life can never be protected.[270] A perusal of the Constitution indicates that the terms "everyone" and "every person" are used interchangeably. Therefore, the Bill of Rights generally protects "everyone", but frequently refers to the holders of those rights as "people" or "persons", which enshrines the rights of all "people".[271] McCreath J further mentioned that in the interim Constitution a general protection was afforded in the Bill of Rights. The change to the word "everyone" was presumably to meet the requirement of Constitutional principle that "everyone shall enjoy all universally accepted fundamental rights, freedoms, and civil liberties". He stated that this change across the board could never, in his judgment, have been intended to introduce a significant new class of rights-bearers. It is inconceivable that any new category could have been introduced by the legislature in this obscure way, and that as far as the Republic of South Africa is concerned the terms "every person" and "everyone", as used in the Constitution, and more particularly in section 11 thereof, are synonymous.[272]

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269 *Christian Lawyers Association of South Africa and Others v Minister of Health and Others* 1998 (4) SA 1113 (T); (1998) 11 BCLR 1434 (T).

270 Slabbert uses the example that although all people are equal before the law, the employment opportunities of white South Africans may sometimes be limited by affirmative action programmes to promote the rights of persons or categories of persons previously disadvantaged by unfair discrimination. The fact that white South Africans are constitutionally recognised subjects does not prevent the state from possibly infringing their equality rights in order to protect or promote the rights of other groups. See Slabbert (2000) 295.

271 For example, section 7(1) of the Constitution enshrines the rights of "all people". Section 38, again, confers *locus standi* on "everyone" listed in the section to approach the court for relief under the Bill of Rights, but goes on in the list to describe "the persons" who may do so.

272 *Christian Lawyers Association of South Africa and Others v Minister of Health and Others* fn 269 *supra*.

The plaintiffs' cause of action founded solely on section 11 of the Constitution, was therefore dependent for its validity on whether "everyone" or "every person" applied to an unborn child from the moment of the child's conception. The answer did not depend on medical or scientific evidence as to when the life of a human being commences and the subsequent development of the fetus up to its date of birth. Nor was it the function of the court to decide the issue on religious or philosophical grounds. The issue was a legal one, to be decided on the proper legal interpretation given to section 11.[273] Counsel for the plaintiffs also argued that, in the interpretation of a constitution, it is permissible to lead evidence of the legislative history and the circumstance existing at the time such constitution was adopted in order to arrive at the correct interpretation thereof. The general rule is that evidence of surrounding circumstances to interpret a statute is not permissible.[274] An exception to this rule is where reference is made to the report of a judicial commission of enquiry whose investigation shortly preceded the passing of the statute.[275]

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[273] McCreath J referred to the dictum of the Canadian Supreme Court in *Tremblay v Daigle*: "The respondent's argument is that a fetus is an *'etre humain'*, in English 'human being', and therefore has a right to life and a right to assistance when its life is in peril. In examining this argument is should be emphasised at the outset that the argument must be viewed in the context of the legislation in question. The court is not required to enter the philosophical and theological debates about whether or not a fetus is a person but, rather, to answer the legal question of whether the Quebec Legislature has accorded the fetus personhood. Metaphysical arguments may be relevant but they are not the primary focus of enquiry. Nor are scientific arguments about the biological status of a f[o]etus determinative in our inquiry. The task of properly classifying a fetus in law and in science is different pursuits. Ascribing personhood to a fetus in law is a fundamentally normative task. It results in the recognition of rights and duties – a matter which falls outside the concerns of scientific classification. In short, this Court's task is a legal one." See *Tremblay v Daigle* (1989) 62 DLR (4th) 634 (SC) at 650 a-c, as quoted in *Christian Lawyers Association of South Africa and Others v Minister of Health and Others* fn 269 *supra*.

[274] In this regard, Steyn JA said the following in *Consolidated Diamond Mines of South Africa Ltd v Administrator, SWA and Another*: "To the extent to which the interpretation of a statute should be based upon surrounding circumstances requiring evidential proof, it would be an interpretation which could operate *inter partes* only. If the leading of evidence were to be admissible, no other person, when affected by the statute, could be denied the right to bring other evidence proving other surrounding circumstances or disproving those accepted in a previous case, and in every case the evidence, unless the parties are in agreement as to its effect, would have to be led anew. The result would be that the interpretation of the same provision in an enactment may for good reason differ from case to case. The uncertainty and confusion which would arise from that, needs no elaboration. I consider, therefore, that generally speaking such evidential proof would not be admissible." See *Consolidated Diamond Mines of South Africa Ltd v Administrator, SWA and Another* 1958 (4) SA 572 (A) at 657H-658A, as quoted in *Christian Lawyers Association of South Africa and Others v Minister of Health and Others* fn 269 *supra*.

[275] *Attorney-General, Eastern Cape v Blom and Others* 1988 (4) SA 645 (A) at 669D, as quoted in *Christian Lawyers Association of South Africa and Others v Minister of Health and Others* fn 269 *supra*.

Counsel for the plaintiffs also relied on the following remarks of the President of the Constitutional Court, Chaskalson P, in *Makwanyane and Another*:[276]

> In countries in which the constitution is similarly the supreme law, it is not unusual for the courts to have regard to the circumstances existing at the time the constitution was adopted, including the debates and writings which formed part of the process … Background evidence may, however, be useful to show why particular provisions were or were not included in the Constitution. It is neither necessary nor desirable at this stage in the development of our constitutional law to express any opinion on whether it might also be relevant for other purposes, nor to attempt to lay down general principles governing the admissibility of such evidence. It is sufficient to say that where the background material is clear, is not in dispute, and is relevant to showing why particular provisions were or were not included in the Constitution, it can be taken into account by a court in interpreting the Constitution. These conditions are satisfied in the present case.[277]

The exact nature of the evidence of the plaintiffs to substantiate their cause of action is not clear. The pleadings did not address that. There were no obvious facts from which the court could deduce that there was evidence of circumstances surrounding the enactment of the Constitution, which could cast a light on the meaning to be attached to the term "everyone" or "every person" therein; and more particularly to section 11. McCreath J stated that he did not consider there to be ambiguity in section 11 of such a nature that extraneous facts might be relevant in the interpretation thereof. Nothing was pleaded in the particulars of the claim to indicate that resort should have to been extrinsic evidence to elucidate the content of the section. Under these circumstances he referred to the remarks of Miller J[278] in *Davenport Corner Tea Room (Pty) Ltd v Joubert*:[279]

> It is clear from these decisions and from many others which it is not necessary to quote in this judgment that, where the whole contract is not before it, the Court will not assign a meaning to particular words or clauses thereof at the exception stage if there is room for a contention, *ex facie* the pleadings, that the omitted terms of the contract, whether considered with or without additional evidence of surrounding circumstances, might have a significant bearing on the issue before the Court. The Court's reluctance to decide issues of interpretation in such circumstances has undoubtedly placed an effective weapon in the hands of respondents in exception proceedings. This weapon in the litigant's armoury is frequently used as a shield rather than a sword, if I may borrow from the lore of *estoppel*. When it is properly

[276] *Makwanyane* fn 220 *supra*.
[277] *Ibid*.
[278] The remarks of Miller J were, in McCreath J's view, particularly relevant. Although dealing with the interpretation of a contract, it bears quoting in full.
[279] *Davenport Corner Tea Room (Pty) Ltd v Joubert* 1962(2) SA 709 (D) 715G-716E.

> used as a sword, it is unusual fatal to the exception, for it cuts through the tissue of which the exception is compounded and exposes its vulnerability. This is clearly illustrated in cases where the contract is ambiguous, thus enabling the respondent to attack the soundness of the exception by showing that on the contract as pleaded an interpretation adverse to the incipient is responsible possible, and that extrinsic evidence would resolve the ambiguity in favour of the respondent. The case of *Sacks v Venter* 1954 (2) SA 427 (W), is an example therefore. But whether argument is used as a shield to protect the frail body of the pleading which is being attacked on exception, it is necessary to examine with some care a contention that the whole contract might "possibly" or "conceivably" reveal a situation favourable to the respondent, or that evidence of surrounding circumstances might "possibly" be admissible, and if admissible, might "conceivably" confound the incipient. It is clearly not correct to say that the Court will never interpret a clause in an agreement on exception, or decide an issue as to the rights of the parties under an agreement, merely because the whole agreement is not before it. The Rules of Court expressly permit of extracts from a written agreement being set out in a pleading. Nor do I think that the mere notional possibility that evidence of surrounding circumstances may influence the issue should necessary operate to debar the Court from deciding such issue on exception. There must, I think, be something more than a notional or remote possibility. As usually that something more can be greater from the pleadings and the facts allocate or admitted therein. There may be a specific allegation in the pleadings showing the relevance of extraneous facts, or there may be allegations from which it may be inferred that further facts affecting interpretation may reasonably possibly exist. A measure of conjecture is undoubtedly both permissible and proper, but the shield should not be allowed to protect the respondent where it is composed entirely of conjecture and speculative hypotheses, lacking any real foundation in the pleadings or in the obvious facts.[280]

McCreath J saw no reason why a similar approach should not be adopted in the interpretation of statutory provisions, including the Constitution, where relief is sought to strike down an Act of Parliament.[281]

The next question that needed to be considered was whether the word "everyone" in section 11 of the Constitution includes the unborn child. In the particulars of claim, the plaintiffs alleged that the fetus qualifies for protection under section 11 of the Constitution because "the life of a human being starts at conception" and, by implication, that human beings are persons from conception as envisaged by section 11.[282] The

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[280] *Davenport Corner Tea Room (Pty) Ltd v Joubert* fn 279 *supra*, as quoted in *Christian Lawyers Association of South Africa and Others v Minister of Health and Others* fn 269 *supra*.

[281] *Christian Lawyers Association of South Africa and Others v Minister of Health and Others* fn 269 *supra*.

[282] *Christian Lawyers Association of South Africa and Others v Minister of Health and Others* fn 269 *supra*.

syllogism pointed out by Peter Singer[283] reads: "Every human being has a right to life. A human embryo is a human being. Therefore, the human embryo has a right to life."[284] This syllogism is often employed by opponents of embryo research and abortion.[285] The inadequacy of the standard argument is brought to light in a comparison of the nature of the term "human being" and its use in each of the two premises of the standard argument against embryonic stem cell research. To make the argument hold, the sense of "human being" as used in the first premise is not the same as the sense of "human being" as used in the second premise.[286] Singer calls this an equivocation of the argument's primary term.[287] The use of the term "human being" in the second premise is biological in nature; it has human DNA,[288] where the use of the term "human being" in the first premise – to claim a "right to life" – is strictly relative to the moral qualities and is normative in nature. Therefore, the standard argument fails owing to the equivocation of the term "human being".[289]

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283 Singer, P *et al* (1990) "Individuals, humans and persons: The issue of moral status, embryo experimentation, legal, ethical and social issues" *Cam U Press* 65 *at* 69.

284 This quote was also employed in the plaintiffs particulars of claim in *Christian Lawyers Association of South Africa and Others v Minister of Health and Others* fn 269 *supra*. See also Slabbert (2003) *JLM* 514 *at* 519 for a discussion of the syllogism. Slabbert formulates a strong argument that the syllogism is fundamentally flawed.

285 For example, the Concerned Women for America make a standard argument against embryonic stem cell research and abortion: "Human embryos are *humans* – and therefore, *persons* – and when an embryo is destroyed, a human life is extinguished … The underlying utilitarian belief that some humans need to be sacrificed for the betterment of others is morally and ethically wrong. The rationale used to justify the destruction of embryos for the advancements in medical research and development is the same used to justify the syphilis experiments conducted on African-Americans in Tuskeegee, Alabama … [and in the] medical research Nazi doctors performed in Dachau and Auschwitz … We do not have the license to engage in lethal experimentation, just as we may not experiment on death row prisoners or harvest their organs without their consent." See Vick, HM (2000) "Embryonic stem cell research: Ethically wrong treatment of the tiniest of humans" [Web:] www.cwfa.org/articledisplay.asp?id=1423&department=CWA&categoryid=life [Date of access 22 January 2006].

286 Slabbert (2003) *JLM* 514 *at* 519.

287 Singer & Kuhse (1990) *Cam. U. Press* 65 *at* 70.

288 For the definition of DNA see fn 66.

289 Many philosophers, as far back as Locke, would claim that a human being has rights, but that being human is not a necessary and sufficient condition for having personhood. Being human is a biological condition; being a human being, or to use more exacting language, having personhood, is a normative condition. The question then becomes: What are the necessary and sufficient conditions for moral status and how do they apply to the human embryo? See Daley (2001) www.law.mq.edu.au/ANZIHLE/daley%20cp%2001.pdf. For the purpose of this dissertation it is not necessary to discuss the arguments of legal philosophers in detail, since focus is placed on the law of persons and whether legal protection should be granted to the fetus.

In addition, and with reference to the above syllogism, another argument put forward to protect the embryo is that the embryo constitutes "human life" and must be protected within the legal system. Silver[290] explains the concept as follows:

> There are two very different meanings of the word *life* as it is used in connection with humanness. One meaning is associated with the basic processes of energy utilisation, maintenance, of structure and information, reproduction, and evolution that are shared by all living things. In the context of bio life specifically, life in a general sense is rooted within the individual cell ... In contrast; the second meaning of the word life is rooted within the cerebral functioning that gives rise to consciousness. In human beings, life in a special sense is localised to the region between your ears, but it lies far beyond the level of any individual nerve cell.

The concept of "human life" has also been dealt with in the South African case of *Clarke v Hurst*.[291] The court distinguished between "biological life" and "human life". The court allocated less moral value to biological life than to human life:

> ... (L)ife in the form of certain biological functions such as the heartbeat, respiration, digestion and blood circulation but unaccompanied by any cortical and cerebral functioning of the brain, cannot be equated with living in the human or animal context.[292]

Be that as it may, the question is not whether the *conceptus* is human, but whether it should be granted the same legal protection as born human beings.[293] Although the Constitution is the measure stick for common law and legislation, it is necessary to also discuss the common law position and relevant legislation.[294] The issue that needs to be addressed is whether, objectively, common law conflicts with the value norms laid down by the Constitution. The question is whether common law deems fetal life worthy and

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290 Silver, L (1999) *Remarking Eden* 25, as quoted in Jordaan, DW (2005) "The legal status of the human pre-embryo in the context of the genetic revolution" *SALJ* 122(1):237 *at* 241.

291 *Clarke v Hurst* 1992 (4) SA 630 (D).

292 The case centred on the issue of passive euthanasia. With reference to the above discussion of human life, the court ruled that passive euthanasia is legal. The case is relevant to the present discussion for two reasons: (1) The embryo is not a legal subject, as will become clear in the discussion below, and therefore does not have a "right to life" (it has no legal status). (2) The embryo is not biologically alive in the light of the court's description of biological life in the human context, which entails the presence of organs and biological systems (that the embryo lacks completely). It is clear from the court's description of "human life" as "the presence of a higher brain function", that the embryo cannot qualify; the reason being it does not have a brain. See Enmon (2002) *Utah L Rev* 621 *at* 637. See also Jordaan (2005) *SALJ* 237 *at* 242.

293 Williams, G (1994) "The fetus and the right to life" *Cam LJ* 53(1):71 *at* 78.

294 See chapter 4 for a discussion of the relevant legislation.

whether the fetus is regarded a person in terms of common law. However, if the fetus is not regarded as a person, it still does not mean that it cannot have any protection at all under the Constitution.

3 4 2 1 South African common law: The beginning and end of legal status and personhood

Slabbert submits that the moment at which the fetus attains personhood, although not a question of fact for philosophers, needs to be defined by law. If one considers the two limiting propositions (firstly, that the advent of human life takes place no earlier than conception, and secondly that it takes place no later than birth), one may conclude that human personhood begins at some point between conception and birth, including either of these.[295] A natural person's legal personality begins when birth is complete.[296] Before birth, the fetus is not a legal subject but merely forms part of the mother or her internal organs. The legal requirements for the beginning of legal personality are the following:

(a) The birth must be fully completed, that is there must be a complete separation between the body of the mother and the fetus.[297] For birth to be completed it is not required that the umbilical cord be severed.
(b) The child must be alive after the separation even if only for a short period. Legal personality is not obtained by a stillborn fetus or a fetus which dies during birth.[298]

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[295] Slabbert (1997) *TSAR* 234 *at* 238.
[296] A natural person's legal personality is terminated by death. See Boberg, PQR (1999) *Boberg's Law of persons and the family* 28.
[297] For the purposes of section 1 of the Births and Deaths Registration Act, 1992 (Act 51 of 1992) (hereafter referred to as the Births and Deaths Registration Act), "birth" is defined as "in relation to a child … the birth of a child born alive". There is no requirement that the child must be separated from the body of the mother. Therefore, the definition differs from the legal definition of birth as the moment at which legal subjectivity commences.
[298] Cronje, DSP & Heaton, J (2003) *The South African law of persons* 9. See also Barnard, AH *et al* (1991) *Die Suid-Afrikaanse persone- en familiereg* 13.

In South African law it has not yet authoritatively been decided how life must be proved after birth.[299] In this regard one can refer to section 239(1) of the Criminal Procedure Act,[300] which provides as follows:

> At criminal proceedings at which an accused is charged with the killing of a newly-born child, such child shall be deemed to have been born alive if the child is proved to have breathed, whether or not the child had an independent circulation, and it shall not be necessary to prove that such child was, at time of death, entirely separated from the body of its mother.

This section does not mean that the only test to prove life after birth is whether the child breathed, because the Criminal Procedure Act does not purport to set out the material requirements for determining life after birth.[301]

3 4 2 2 The interests of the unborn child

Because legal personality of a person begins at birth, the conceived but unborn fetus is not a legal subject and cannot have rights, duties or capacities. Almost all legal systems accept the live birth of a person as the starting point of human personhood. Although not recognised as human persons, embryos and the fetuses are nevertheless acknowledged as forms of human life. Live birth is also easily determined.[302] From very early times the law has, however, taken into account that in the normal course of events the fetus will become a legal subject, and that before birth situations could arise that could be advantageous to the fetus had he already been born; for example if he could have been a beneficiary under a will.[303] Whenever such a situation arises, the law protects the potential interest of the fetus by employing the fiction that the fetus is regarded as having

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[299] Since the time of Roman law, various signs of life have been required to prove that children had lived, for example, they must have opened their eyes and turned them upwards, they must have cried so that they could be heard outside the maternity room, and they must have breathed. Already in those days, the fetus was not regarded as a legal subject because it still formed part of its mother's body. See Slabbert (2000) 20.

[300] The Criminal Procedure Act, 1977 (Act 51 of 1977).

[301] Cronje & Heaton (2003) 9.

[302] Slabbert (2000) 20.

[303] Boberg (1999) 31. See also *Ex parte Boedel Steenkamp* 1962 (3) SA 954 (O), where the court decided: "Still by a fiction of law they [children in *ventre matris*] are regarded as already born whenever it is a question of their advantage …" In *Ex parte Administrators Estate Asmall*, the *nasciturus* rule was applied to give effect to a testator's intention that all his children should benefit from his estate, including a child born posthumously. See *Ex parte Administrators Estate Asmall* 1954 (1) PH G4 (N).

been born at the time of conception whenever it is to his/her advantage. This fiction is referred to as the "*nasciturus* fiction".[304] The *nasciturus* fiction also formed part of the Roman-Dutch law. For the *nasciturus* fiction to come into operation, the following three requirements must be met:

(a) The fetus must have been conceived at the time that the benefit would have accrued to him/her.
(b) The benefit must be to the child's advantage.
(c) The child must subsequently be born alive.

If the child is not born alive it is assumed, with regard to his/her interests, that he/she was never conceived.[305] This fiction also plays an important role in the legal protection of the interests of the embryo and fetus. Therefore, the *nasciturus* fiction is relevant for the purposes of debate on embryonic stem cell research and cloning, as well as on the different views on the beginning of personhood, as it is argued that the fiction in effect recognises the fetus or embryo as a person via the legal recognition of the above rights and interests.[306]

In 1963 the question arose whether the fetus is also entitled to protection of his/her personality rights, for example his physical integrity in the case of *Pinchin & Another v Santam Insurance Co Ltd.*[307] An expected mother was seriously injured in a motor vehicle accident, for which the defendant admitted liability, and the child was subsequently born with brain damage. At the time of the accident she was six months pregnant, and her injuries caused her to lose a considerable amount of amniotic fluid as a result of a ruptured membrane. Four months after the child's birth, it was discovered that the child suffered from cerebral palsy.[308] The father of the child, in his capacity as

[304] The Latin expression reads: *Nasciturus pro iam nato habetur quotiens de commodo eius agitur. Nasciturus* literally means a child who is conceived, but not yet born. A fiction is said to be a *pons asinorum*, which literally means "a bridge for an ass". See Slabbert (1997) *TSAR* 234 *at* 244.
[305] Cronje & Heaton (2003) 12.
[306] Slabbert (2000) 23.
[307] *Pinchin & Another NO v Santam Insurance Company Ltd* 1963 (2) SA 254 (W).
[308] Many children suffering from cerebral palsy have a congenital malformation of the brain, meaning that the malformation exist at birth and was not caused by factors occurring during the birthing process. Not

guardian of the child, sued for damages for the disability. It was argued for the plaintiff that the loss of amniotic fluid had resulted in anoxia, or deprivation of oxygen for the fetus, and that anoxia was a well-known cause of cerebral palsy.[309]

The legal question was whether a person could have an action for injury inflicted on them while still a fetus in their mother's womb. The judge pointed out that the only starting point in our common law sources for the protection of the interests of the fetus was to be found in the *nasciturus* fiction. He came to the conclusion that the principles of our law are flexible enough to extend the fiction to the field of delict. Accordingly, he held that a child does have an action to recover damages for prenatal injuries. The plaintiff was therefore successful on the question of law. Hiemstra J held that:

> … (A) child does not have an action to recover damages for pre-natal injuries. This view is based on the rule of the Roman law, received into our law, that an unborn child, if subsequently born alive, is deemed to have all the rights of a born child, whenever this is to its advantage. There is apparently no reason to limit this rule to the law of property and to exclude it from the law of delict.

However, it was found on the facts that it had not been proved that the brain damage was caused by the accident and the action was turned down.[310]

Various conflicting views have been expressed concerning the effect that the application of the *nasciturus* rule in the Pinchin case has on the legal status of the fetus, and also on the status of the *nasciturus* rule itself. Joubert expresses the view that it is not necessary to invoke the *nasciturus* rule to constitute an action for prenatal injuries. He argues that the action is brought for damage which the child suffers after birth, as a living person, and therefore the fact that this damage results from a wrongful act committed before birth

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all of these malformations can be seen by the physician, even with today's most sophisticated scans, but when cerebral palsy is recognised in a newborn, a congenital malformation is suspected. The word "cerebral" means having to do with the brain. The word "palsy" means a weakness or problem in the way a person moves or positions his or her body. See Miller, F & Bachrach, SJ (2006) "Cerebral palsy: A complete guide for care" [Web:] www.gait.aidi.udel.edu/res695/homepage/pd_ortho/clinics/c_palsy/cpweb.htm [Date of access: 23 February 2006].

309 *Pinchin & Another, NO v Santam Insurance Company Ltd* fn 307 *supra*. See also Cronje & Heaton (2003) 17-19; Boberg (1999) 32-38.

310 *Pinchin & Another, NO v Santam Insurance Company Ltd* fn 307 *supra*.

is immaterial. He continues to say: "If someone were injured by the explosion of a time-bomb it would not matter that the bomb had been placed there before the victim's birth.[311] Du Plessis and Olivier argue that the *nasciturus* fiction is no longer necessary. According to them, although it was originally created to be a fiction, the time has come to accept it as a legal rule that protects the unborn conditionally on the three requirements mentioned above. They further submit that it has evolved to a point where it is invoked to protect those interests that cannot be anything but the actual personality rights of a legally recognised prenatal person.[312] Slabbert does not agree with these arguments. She argues that without the very important requirement for the application of the fiction, namely the eventual birth, the full consequences of that protection cannot be enjoyed, therefore clearly ruling out the possibility of real personality rights of a legally recognised prenatal person. She further asks: if legal subjectivity ought to be recognised automatically, why is there still the subsequent birth requirement? Simply because the arguments lead back to the original maxim that legal subjectivity commences at birth.[313] Smit's argument reads as follows:

> Die ongeborene is geen subjek van regte nie, maar slegs 'n potensiële regsubjek. Voor geboorte is die ongeborene deel van die moederliggaam – *pars mulieris*. Voor 'orgaan' tot regsubjek deur voldoening aan die vereistes vir lewendige geboorte, is die ongeborene geen regsubjek en kan geen regte hom toeval nie. Wel kan en word sodanige 'regte' of belange vir die ongeborene 'verwerf' en swewend gehou tot tyd en wyl hy oorgaan van potensiele regsubjek tot reële regsubjek …[314]

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311 Joubert, WA (1963) "Pinchin & Another NO v Santam Insurance Co LTD 1963 (2) SA 254 (W) *Nasciturus – Besering van – Eis na geboorte?*" *THRHR* 26:291 *at* 296. Boberg distinguishes Joubert's time-bomb example from cases of prenatal injury on the ground that, with the former, no damage is suffered and hence no wrong is committed until the bomb explodes. The act merely has the "potency of peril": the bomber might yet repent of the deed and defuse the bomb, so that no one is harmed in the event. Boberg says with prenatal injury, on the other hand, there is no escaping the fact that the fetus has already been irrevocably harmed. Both elements of the delict, namely the wrongful act and the damage, have occurred. The damage is not sustained only after birth – it is already present, though not perceived until after birth. See Boberg (1999) 218-219.

312 Barnard *et al* (1991) 17-22. See also Du Plessis, LM (1990) "Jurisprudential reflections on the status of unborn life" *TSAR* 1:44 *at* 45-47; *Pinchin & Another, NO v Santam Insurance Company Ltd* fn 307 *supra*.

313 Slabbert (1997) *TSAR* 234 *at* 245.

314 Smit PC (1976) *Die posisie van die ongeborene in die Suid-Afrikaanse reg, met besondere aandag aan die nasciturus - leerstuk* (Thesis – LLD) UOFS (Unpublished) 212, 213, as quoted in Slabbert (1997) *TSAR* 234 *at* 245. See in general Lind, C (1992) "Wrongful-birth and wrongful-life actions" *SALJ* 109(3):428-446.

A consequence of the idea that the *nasciturus* rule antedates legal personality is that it operates as a "rule" rather than a "fiction". Van der Vyver and Joubert argue: "Viewed like this, the *nasciturus* fiction is no longer a fiction but rather a legal *rule*. This legal rule makes conditional provision for the advanced acquisition of legal subjectivity. Since the *nasciturus* already has legal subjectivity, rights can be allocated to it prior to birth."[315] On the contrary, it is submitted that legal personality always begins at birth, and that the *nasciturus* operates as a "fiction" rather than a rule, antedating legal personality. Therefore, it is only at birth that the interests are actually allocated to the child who then, and only then, has legal personality. [316]

Support can also be found in South African case law subsequent to the Pinchin case for the view that it is unnecessary to invoke the *nasciturus* rule to allow a person to claim damages for injuries suffered before birth. In *Christian League of Southern Africa v Rall,*[317] an application for the appointment of a *curator ad litem* to represent the interests of an unborn child in all matters concerning its proposed abortion was dismissed. The court held that a *nasciturus* is not a legal subject. The court endorsed the view that the protection of a fetus is founded upon a fiction. It ensures only that benefits that may accrue to the fetus after birth are kept open until he is born. Consequently, a child cannot have rights enforced on his behalf before he is born alive, since he only becomes a legal subject then. In his judgment, Steyn J agreed with those South African writers who favour the view that the claim in *Pinchin* could, in theory, have been allowed on the basis of ordinary delictual principles rather than on the basis of an extension of the *nasciturus* rule.[318] The application was refused largely on the court's conclusion:

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315 Van der Vyver, JD & Joubert, DJ (1991) *Persone en familiereg* 61, 65. See in general Scott S (1981) "Christian League of Southern Africa v Rall 1981 (2) SA 821 (O)" *THRHR* 44:305-321.

316 Barnard, Cronje & Olivier (1991) 13-14. See also Slabbert (1997) *TSAR* 234 *at* 245.

317 *Christian League of Southern Africa v Rall* 1981 (2) SA 821 (O).

318 In *Friedman v Glicksman*, a case involving a claim for wrongful life, Goldblatt J agreed with the reasoning of the court in *Pinchin*, but held that in the case before him it was unnecessary to invoke the *nasciturus* rule "because the plaintiff's action did not arise when the pregnancy was not terminated, but when she was born". See *Friedman v Glicksman* 1996 (1) SA 1134 (W). (The case is discussed below.) As far as the *Christian League* case is concerned, it did not involve an action for damages for prenatal injury. It involved an application for the appointment of a *curator ad litem* to represent a fetus in circumstances where the mother sought legally to terminate her pregnancy. Therefore, Boberg argues that Steyn J's remarks concerning the necessity of applying the *nasciturus* rule in actions for damages for prenatal injuries are *obiter*. However, there can be no doubt that modern authority is

> [D]ie toepassing van die nasciturus-fiksie nie die ongeborene met enige regspersoonlikheid beklee nie. Dit verseker slegs dat voordele wat die ongeborene vrug na geboorte mag toeval in suspenso gehou word tot sy geboorte.

This dictum undoubtedly directly supports the view that the *nasciturus* rule operates as a fiction and not as a rule.[319]

Seligson J in *G v Superintendent Groote Schuur Hospital*[320] expressed, *obiter*, doubts about the correctness of the decision in the *Christian League* case. He said that in his judgment there is much to be said for recognising that an unborn child has a legal right to representation or an interest capable of protection in circumstance where its very existence is threatened. However, it is questionable to what extent a case seeking to protect the interests of a fetus threatened with abortion can be used to clarify the issue of what effect the *nasciturus* rule has on the legal status of a fetus. Bedil remarks as follows:

> [W]ere "regsubjektiviteit" to be afforded the child as from conception, protection of its right to life would seem at first glace to be possible. But the antedating of legal personality to the moment of conception is considered by the authors[321] to be an application of the nasciturus rule, and since this rule is predicated upon subsequent live birth, it cannot operate in the case of abortion.[322]

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overwhelmingly in favour of granting a remedy to a child for prenatal injury on whatever basis. See Boberg (1999) 37.

319 *Christian League of Southern Africa v Rall* fn 317 *supra*.

320 *G v Superintendent, Groote Schuur Hospital* 1993 (2) SA 255 (C). In this case *a curator ad litem* was appointed to look after the interests of the fetus. Slabbert submits that such an appointment for the sake of promoting the interests of a particular fetus does not seem impossible, provided that such an appointee satisfies the *locus standi* requirement. However, she further submits that it will be restricted to the protection of the fetus' proprietary interests, and not its life. See Slabbert (2000) 160, 161.

321 Van der Vyver & Joubert (1991) 61-65.

322 Bedil, S (1981) "Can a foetus be protected from its mother?" *SALJ* 98(2):462 *at* 464. See also Boberg (1999) 38. In *Friedman v Glicksman* Goldblatt J remarked: "… [T]he plaintiff could neither enter into a contract on behalf of Alexandra prior to Alexandra's birth or at such time make any election on Alexandra's behalf. It is trite law that an agent cannot act on behalf of a non-existent principal. It is similarly trite that legal personality only commences at birth. In these circumstances the allegation that the plaintiff acted on Alexandra's behalf while she was still in utero is legally untenable." Boberg argues that while this dictum appears to deny a fetus legal personality, it should be noted that the court did not at this stage of the judgment give any consideration to the application of the *nasciturus* rule. It was only at the next stage of inquiry, when the court considered the child's claim for delictual damages, that the court considered the *nasciturus* rule and found it unnecessary to apply it in the case. Boberg therefore submits that the *Friedman* judgment is not authority for the view that the *nasciturus* rule does not have the effect of antedating legal personality. See *Friedman v Glicksman* fn 318 *supra*.

In *Van Heerden v Joubert*[323] the court held that for purposes of the Inquests Act[324], the word "person" does not include an unborn child. It was unnecessary for the court to decide whether an unborn child should be regarded as a legal person or to what extent life before birth should be protected, but the court pointed out that serious problems may arise in, for example, the law relating to abortion, murder and culpable homicide if legal personality were to be extended to a fetus. As mentioned above, similar problems arise in the use of embryos for stem cell research and therapeutic cloning.

As previously discussed, one of the requirements for the protection afforded by the *nasciturus* rule is that the fetus be born alive. There is no provision in the Constitution to protect the fetus pending the fulfilment of that condition. Therefore, the *nasciturus* rule will not protect the embryo if used in embryonic stem cell research, or in therapeutic cloning techniques, since the embryo is destructed and would therefore not be born alive.
The principle that prenatal injury can lead to delictual liability on the part of the person who negligently injured the fetus has been recognised in South African decisions. These actions are not regulated by statute, but originate from the common law. For this reason the courts played a major role in the development of such actions. Today, three different categories of claims are distinguished:[325]

(a) "Wrongful pregnancy" or "wrongful conception"; where a healthy but unwanted child is born, for example as a result of medical negligence in performing a sterilisation or abortion.[326] A claim is then brought by the parents for damages in respect of medical expenses involved in the pregnancy, confinement and maintenance of the child.[327] The *Edouard* case[328] is the only successful "wrongful

[323] *Van Heerden v Joubert NO* 1994 (4) SA 793 (A).
[324] The Inquests Act, 1959 (Act 58 of 1959) (hereafter referred to as the Inquests Act.)
[325] Strauss (1991) 197.
[326] In *Chalk v Fassler*, the plaintiff's claim for damages in respect of the birth of her child following the allegedly negligent performance of an abortion by the defendant gynaecologist failed. Expert evidence indicated that even with the exercise of due skill and care, it was possible for abortions to fail. See *Chalk v Fassler* 1995 WLD *unreported*, as quoted in Pearson, FL (1997) "Liability for so-called wrongful pregnancy, wrongful birth, and wrongful life" *SALJ* 114(1):91.
[327] In *Behrmann and Another v Klugman,* the first case in which this claim arose, the action was unsuccessful because the plaintiffs failed to prove that the doctor had expressly or impliedly guaranteed the success of the sterilisation. See *Behrmann and Another v Klugman* 1988 WLD *unreported* as

pregnancy" case based on breach of contract in point and the court awarded damages for maintenance of the child, because the loss was an economic one that does not need to be weighed against the value of the child. Because the action was only based on contract and not in delict, the court held that non-patrimonial damages were not recoverable.[329]

(b) "Wrongful birth"; where a claim is brought by the parents of an abnormal or disabled child for the same kind of damages as mentioned above. The basis for the action is that the doctor's negligence deprived the parents of their choice to decide whether to have the child or not. In *Friedman v Glicksman*,[330] the plaintiff alleged that she consulted the defendant, a gynaecologist, while she was pregnant for advice about the risk of carrying a potentially abnormal or disabled fetus. They agreed that the plaintiff wished to terminate the pregnancy if there was any above average risk of the unborn child being born abnormal or disabled. The defendant told Mrs Friedman that her risk was no greater than normal of having an abnormal child, and that it was quite safe for her to proceed to full term and give birth. The child was however born disabled. Mrs Friedman claimed in her personal capacity for the expenses of maintaining and rearing the child, and for all future medical and hospital treatment and other special expenses. She also claimed, in her capacity as mother and natural guardian of the child, for general

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discussed in Strauss, SA (1990) "Voluntary sterilisation for convenience: The case of the unwanted child" *Consult* 3(2):93.

328 *Edouard v Administrator, Natal* 1989 (2) SA 368 (N).

329 In this case the plaintiff's wife, Mrs Edouard, was pregnant with their third child when the couple decided that because of their poor financial circumstances they could not afford to have any more children. They entered into an agreement with the defendant, in terms of which it was agreed that an employee of the hospital would sterilise Mrs Edouard in the course of performing a caesarean section on her. Mrs Edouard duly gave birth to the child, but in breach of its obligation, the doctor of the defendant failed to carry out the sterilisation procedure. Shortly thereafter Mrs Edouard fell pregnant and in due course gave birth to a fourth child. In this case, Thirion J described the action as "an action for wrongful birth". This terminology is incorrect, and fails to distinguish between the actions for "wrongful birth", "wrongful life" and "wrongful pregnancy". The case actually dealt with the action for "wrongful pregnancy" or "wrongful conception". In *Mukheiber v Raath*, the parents of an unwanted child brought an action against the doctor based on a negligent misrepresentation by him. They alleged that the doctor told them that he had sterilised Mrs Raath, but he in fact failed to do so. The Raaths did not see the need to use contraceptives, and the result was a pregnancy and the birth of a healthy but unwanted child. This caused economic loss in the form of confinement costs and the costs of maintaining the child until the child became self-supporting. In this case the plaintiff's claim was based on delict, and not breach of contract. See *Mukheiber v Raath* 1999 (3) SA 1065 (SCA).

330 *Friedman v Glicksman* fn 318 *supra*.

damages and future loss of earnings on behalf of the child. The court allowed for a "wrongful birth claim".[331]

(c) "Wrongful life";[332] where a claim for damages is brought by or on behalf of the abnormal or disabled child itself. The essence of this type of claim is a violation of an alleged right not to be born with defects, which under the circumstances amounts to a right not to be born at all.[333] The basis of the child's claim is that, had the parents been adequately informed, the pregnancy would have been terminated and the deformed existence prevented. The child therefore does not claim that the doctor's negligence caused his birth defects, but that it has led to his existence in such a defective form. In *Friedman v Glicksman*[334] – the first case of its kind in South Africa – Goldblatt J held that there is no legal basis in our law for a "wrongful life" claim. In his view it would be contrary to public policy for courts to hold that it is better for a party not to have the unquantifiable blessing of life rather than to have such life albeit in a marred way.[335] The defendant argued that such claims are against public policy as they would encourage abortion and therefore be inimical to the right to life enshrined in the Constitution.[336] Although the consequences of the action is debatable, if the courts would allow such an action it could open the door to undesirable consequences for the child's parents. While one can only speculate, the values of society are continuously changing, and the legal convictions of the community may in future change the law on this

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331 "Thus the legislature has recognised, as do most reasonable people, that cases exist where it is in the interests of the parents, family and possibly society not to allow a foetus to develop into a seriously defective person causing serious financial or emotional problems to those who are responsible for such person's maintenance and well-being ... In my view the contract entered into between the plaintiff and the defendant was sensible, moral and in accordance with modern medical practice. The plaintiff was seeking to enforce a right, which she had, to terminate her pregnancy if there was a serious risk that her child might be seriously disabled."

332 Slabbert also discusses the action of "wrongful death". Recovery of damages with reference to a child who dies in utero as a result of the defendant's negligent conduct is allowed under various "wrongful death" acts in some states in the United States. However, actions on behalf of a child born dead appear impossible in England. See Slabbert (2000) 100-102. There are currently no reported cases in South Africa that address the action of "wrongful death".

333 Strauss (1991) 197.

334 *Friedman v Glicksman* fn 318 *supra*.

335 In *Udale v Bloomsbury Area Health Authority* [1983] 2 All ER 522 (QB), the following was said: "It has been the assumption of our culture from time immemorial that a child coming into the world, even if, as some say, 'the world is a vale of tears', is a blessing and an occasion for rejoicing."

336 The argument cannot be upheld, as the Choice on Termination of Pregnancy Act legalises abortion in certain circumstances. For a discussion of the Act see chapter 4.

subject. It is submitted that the community's perception of justice would however not be served if the courts were to open the door for a child to bring an action against his/her parents for the above reasons. As long as the reasoning above is accepted, these claims would appear to be unaffected by the constitutional "right to life".

3 4 2 3 Critical stages of embryonic development

Several theories have been formulated, for example philosophical, religious, legal, and scientific, in which different people have suggested the marking of the beginning of human life. Some of these theories are discussed in short below to show their significance in terms of common law principles. The theories include the emerge of developmental individuality at the appearance of the so-called "primitive streak" at two weeks, the emergence of motility at six to seven weeks, viability at about twenty weeks, the first neocortical circuitry and connection to the bodily sensorium (or brain birth) at twenty to twenty-three weeks, and morphophysiology and sleep/wake cycles similar to full-term newborns at twenty-eight to thirty-two weeks.[337]

3 4 2 4 The primitive streak[338]

The significance of the appearance of the primitive streak lies in the impossibility of identifying which cells will develop in which ways before it appears, because the cells are "pluripotential" and "totipotential". Only after the primitive streak appears, reference can be made to individual or specific human life. The question, however, is: What is the usefulness of this scientific fact in a moral and legal analysis? As noted in the dissent to the Warnock Report,[339] the determination of what constitutes "[t]he beginning of a person is not a question of fact but a decision made in the light of moral principles". Speaking of

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[337] For a discussion of these theories see Macer (1990) www.csu.edu.au/learning/eubios/Papers.html.
[338] For the definition and discussion of the "primitive streak" see fn 105.
[339] The Warnock Report was compiled by the Committee of Inquiry into Human Fertilisation and Embryology, chaired by Baroness Warnock. It was set up in 1982, and reported in 1984. The Act largely implemented the recommendations of the committee. See The United Kingdom. Parliament: House of Lords (2002) www.parliament.the-stationery-office.co.uk/pa/Id200102/dselect/Idstem/83/8301.htm-14k.

the scientific significance of the primitive streak, Lord Kennet said that it may be true, but wondered if it was morally important. Brazier characterised the "verdict" on the moral status of the embryo as "not proven". This description seems to have a factual cast to it, but moral status cannot be a fact. What does the law do with scientific and moral facts? The Human Fertilisation and Embryology Authority[340] accepts the scientific fact of the primitive streak as a bright-line rule. For reasons of public policy, one must draw the line somewhere and this seemed to be as good a place as any other.[341]

Yet, these legal lines do not settle moral disagreements. Although they may offer legal certainty, they are often found to be inadequate from a moral point of view. The American abortion decision in *Roe v Wade*[342] regulates abortion "based upon the viability of the foetus" as yet another scientific fact. More than twenty years later, the controversy still rages on.

Sarkin-Hughes[343] suggested viability and brain birth as appropriate cut-off points for South African abortion law. These suggestions are challenged below.

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[340] The Human Fertilisation and Embryology Authority is the regulatory authority established under the Human Fertilisation and Embryology Act.

[341] Frankowski, S & Cole, GF (1987) *Abortion and protection of the human fetus: Legal problems in a cross-cultural perspective* 311.

[342] In this case, an unmarried pregnant woman brought a class action suit, challenging the constitutionality of the Texas criminal abortion law, which prohibits all abortions except those for the purposes of saving the life of the mother. She wished to terminate her pregnancy by an abortion performed by a competent and licensed physician under safe and clinical circumstances. The court held that "the unborn have never been recognised in the law as persons in the whole sense, because the Constitution did not justify the position that fetuses are 'persons'". There are no cases that held a fetus to be "person", and none of the uses of "person" in the Constitution could be interpreted as referring to an unborn human being. The court decided that only after the point of viability can the state regulate and even proscribe abortion in the interest of protecting potential life. See *Roe v Wade* fn 225 *supra*.

[343] Sarkin-Hughes, J (1993) "A perspective on abortion legislation in SA's Bill of Right's era" *THRHR*, 56(1): 83. See in general Sarkin-Hughes, J & Sarkin-Hughes, N (1990) "Choice and informed request: The answer to abortion" *Stell L Rev* 1(3):372 *at* 382.

3 4 2 5 Viability[344]

Fetal viability as the stage at which the fetus presumably has the capability of meaningful life outside the mother's womb, is often referred to as the point at which it can be determined that human personhood and legal personhood begun. Fetal viability can be described as the stage of fetal development when the life of the unborn may be continued indefinitely outside the womb by natural or artificial life-support systems. Therefore, viability refers to an advanced state of fetal development and, for example, refers to survivability.[345] Viability in this context is as follows: The child must have reached a certain stage of development within the mother's body. The most important organs must have developed to such a degree that the child could live independently, with or without aids, but definitely without being fed from the mother's bloodstream. Most recent modern South African writers reject viability as a requirement for birth in the legal sense.[346] It appears that viability may have been regarded as a requirement for distinguishing between the birth and abortion or the miscarriage of a fetus. If a fetus was viable, it would have been regarded as having been born and hence as having acquired legal personality, albeit that its survival was short-lived. On the other hand, if the fetus was undeveloped or not yet viable, then birth in the legal sense would not have taken place and legal personality could not have been accorded even if, technically, it was possible that the fetus has breathed. The question of whether or not fetal viability is a requirement for the commencement of legal personality remains open.[347]

Slabbert submits that the concept of viability is complicated by a variety of factors for various reasons. First, despite the normative significance of the viability line, the term is often regarded as a measure of the fetus's biology instead of as a measure of our technology. An artificial womb has already been developed by British and Japanese

[344] Viability, in a medical context, is defined as the ability of fetuses to survive in the extra-uterine environment, for example after premature birth. Fetuses weighing less than 500 g at birth usually do not survive. However, if given expert postnatal care, some fetuses weighing less than this may survive, and are referred to as extremely low birth-weight or immature infants. Intra-uterine growth retardation is the cause of many full-term babies having a low birth weight. Most fetuses weighing between 1 500 g and 2 500 g survive, but complications may occur. They are referred to as premature infants. Prematurity is one of the most common causes of morbidity and prenatal death. See Moore & Persaud (2003) 78.

[345] Slabbert (1997) *TSAR* 234 *at* 247.

[346] Van der Vyver & Joubert (1991) 60, 61. See also Barnard *et al* (1991) 12..

[347] Boberg (1999) 29.

scientists.[348] These artificial wombs and the availability thereof will definitely impact on fetal viability, because fetuses will then be viable throughout the pregnancy. Furthermore, embryos conceived in vitro or in utero can be implanted into another woman's uterus and carried to term, suggesting that fetuses become viable the moment of conception.[349] Slabbert further submits that limiting viability to the fetus's capacity to survive outside any womb is also not satisfactory, as this threatens to render the concept of viability entirely arbitrary.[350]

In addition, according to Tribe[351], the concept of viability is in fact very tenuous. Life always requires a favourable environment. How viable is an adult at the South Pole? In fact, viability is really just a question of the degree of outside support needed to preserve life. As medicine progresses, the stage of viability will move closer and closer to the time of conception, until it coincides with conception, especially if one considers the development of an artificial placenta. The viability guidelines laid down in *Roe v Wade*[352] already became obsolete in 1975 when an infant weighing 395 g and less than 20 weeks old survived. At present, the viability of a fetus, in essence, depends on whether its lungs are inflatable, thereby allowing it to breathe. This, as Fortin points out, is merely a physiological stage in fetal development that has no more significance than any other. Both viability and brain birth as yardsticks decide the fate of the embryo by external factors, and not on its own merits.[353]

3 4 2 6 Brain birth as a marker of the commencement of personhood[354]

Brain birth, which is accompanied by the production of electroencephalograph waves between the 22nd and 24th week of pregnancy, is seen to be significant because it marks the appearance of our higher intelligence; and this supposedly distinguishes humans from

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348 The artificial womb was successfully tested on a goat.
349 Slabbert (1997) *TSAR* 234 *at* 248.
350 *Ibid.*
351 Tribe, LH (1990) *Abortion: The clash of the absolutes* 117, as quoted in McGregor & Moore (1995) www.murdoch.edu.au/elaw/issues/v2n3/moore23.html.
352 *Roe v Wade* fn 225 *supra.*
353 McGregor & Moore (1995) www.murdoch.edu.au/elaw/issues/v2n3/moore23.html.
354 For a discussion of the brain birth theory see in general Slabbert (1997) *TSAR* 234 *at* 249.

animals. It refers to the stage of fetal development when neocortical brain activity begins. However, although neocortical circuitry – required for human higher intelligence – only appears at twenty weeks, the brain actually begins to direct the operation of bodily systems and organs at eight weeks already. In fact, electrical activity has been observed as early as the fifth week, probably associated with embryonic brain stem function. The question has been asked whether it would be possible to measure electrical activity at an earlier stage if we had finer instruments.[355]

The use of the concept "the death of the brain"[356] has given rise to the similar use of "the birth of the brain" as a means of determining the beginning of personhood.[357] Shannon criticises this theory, and argues that no immediate connection can be drawn between brain death and brain life. As the definition of death entails the cessation of the organism as a whole, brain life, correspondingly, would imply the commencement of the functioning of the organism as a whole, which of course is questionable.[358]

3 4 2 7 Personhood or "ensoulment"[359] begins at conception

Proponents of this belief hold the view that a fetus constitutes actual life as opposed to potential life.[360] Some people agree that the new life begins at conception, or in the following 24 hours, when the genetic information from the egg, and sperm join to form

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355 McGregor & Moore (1995) www.murdoch.edu.au/elaw/issues/v2n3/moore23.html.

356 In *S v Williams*, the trial court found that, according to traditional medical standards, the moment of death is when brainstem death sets in. See *S v Williams* 1986 (4) SA 1188 (A).

357 Slabbert (2000) 30, 31.

358 Shannon, TA "The moral significance of brain integration in the fetus", published in Humber, JM and Almeder, RF (1990) *Bioethics and the fetus: Medical, moral and legal issues* 123,131, as quoted in Slabbert (1997) *TSAR* 234 *at* 248.

359 It is necessary to consider some philosophies on the human soul, as this would seem to be the essence of a person. For as long as man has known of the soul, there have been ideas on where it is located and whether it is in the body as a whole, or in the heart, or in the air that we breathe, or liver, or brain, or some combination of these. This thinking has moulded our concepts of what is essential to human life; and is relevant to the questions of when we believe human life or personhood begins and when it ends.

360 A joint statement by archbishops worldwide reads as follows: "At the time of conception there comes into existence a new life. There is a union in which a living cell from the father fertilises a living cell from the mother. That union, a transmission of life, is the beginning of a new life. Each such new life is the life of not a potential human being but of a human being with potential. The development of this potential is normally a process of profound continuity. No one can point to say, the fourth week of that process, or the eighth, the twelfth, the twentieth, the twenty-fourth or the twenty-eighth, and say 'that is when I began being me'", as quoted in Slabbert (1997) *TSAR* 234 *at* 240, 241.

the new genotype. However, although the egg and sperm are alive, they are not a new life.[361] According to Slabbert, the theory that life begins at conception is fraught with problems. The moral consequence of this belief would be that any destruction of the fertilised ovum would represent the destruction of a human embodied soul or the killing of a human person – be it through the discarding of ova fertilised in vitro, by means of experimentation on them, through the use of intra-uterine devices or other contraceptives that would prevent the fertilised ovum from implanting in the lining of the womb, or by abortion.[362] Most people agree that a fertilised egg and early embryo is of a higher status than two gametes alone (the egg and sperm), though the consequentialist approach would say that the fertilised egg and gametes are indistinguishable.[363]

This approach is rejected by the majority of moral philosophers who believe that personhood cannot be defined in reference to the presence of an immaterial human soul, but by reference to an intricate combination of mental and physical properties. Furthermore, since conception or fertilisation is a process that extends over several hours, the personification of the fertilised egg becomes problematic. One can only be sure that the egg is truly fertilised once it cleaves and forms two cells.[364]

3 4 2 8 The embryo and fetus classified as res and personae

Drgonec proposes that the German Civil Code, as opposed to other European civil codes, opened the door for the introduction of the theory that the human body and parts of the human body are things in the juridical sense.[365] Hereby he submits that the embryo and fetus can be classified as "things". However, in the United Kingdom the Warnock

[361] Macer (1990) www.csu.edu.au/learning/eubios/Papers.html.
[362] Slabbert (1997) *TSAR* 234 *at* 241.
[363] There are several major difficulties with the view that life begins at conception. High percentages (perhaps more than 70%) of fertilised eggs do not implant naturally or result in a live birth. Most failures occur during the first few days, including fertilisation itself, during which time many abnormalities, mostly chromosomal in nature, occur. It is argued that this is a very inopportune moment for "ensoulment" to occur. At this stage the actual embryo might not even develop into a human being, but instead form a hydatidiform mole, which develops into a tumour. Critics see that in cases of infant mortality – which is as high in many countries as was in earlier times. But in this case it is not said that a newborn infant is not a human person. Often the cause of pregnancy loss is genetic, but genetic diseases kill people throughout the human lifespan.
[364] Slabbert (1997) *TSAR* 234 *at* 242. See also Du Plessis (1990) *TSAR* 44 *at* 56.
[365] Drgonec, J (1994) "The status of the fetus" *Med & L* 13(3):215 *at* 224, 225.

Committee rejected the concept of "ownership" in embryos. In South Africa the Human Tissue Act provides for a right of determination or decision-making of donors in respect of their donations. The receiver of the gametes acquires "exclusive rights" in respect of the gametes used for artificial fertilisation. It is submitted that these "exclusive rights" rather be interpreted as rights of disposition or determination.

Another argument put forward is that the embryo and fetus be regarded as persons. However, the legal nature of such a construction is objectionable for the reason that the legal status of juridical persons consists of both rights and duties. The embryo and fetus can never be bearers of duties.[366]

3 4 2 9 Conclusive remarks on the problem of personhood

There appears to be very limited legislation worldwide which defines the legal status of the embryo and the fetus. Very few legislatures and courts have attempted to answer the question of when life begins, or whether the human embryo and the fetus can be considered to be persons before the law.[367] It will be impossible to satisfy the variety of strongly held views on what time limit, if any, is acceptable for human embryo research. It is submitted that we should work towards a society that maintains a high respect for human life, while at the same time recognising the dilemmas faced. It is, however, submitted that personhood must occur at some precisely defined point.[368] According to the common law position, live birth is an acceptable point for the beginning of personhood. Slabbert indicates that the question of the status of prenatal life has been left open. As the human embryo and fetus are neither full subjects of the law, nor things, nor tissue, the legal status of these entities can be described as special or differential.[369]

Now that the common law position has been discussed and it is clear that the fetus is not a legal subject, it is necessary to return to the provisions of the Constitution. There is no express provision affording the fetus legal personality or protection. According to

366 Slabbert (1997) *TSAR* 234 *at* 252.
367 Slabbert (1997) *TSAR* 234 *at* 238.
368 Macer (1990) www.csu.edu.au/learning/eubios/Papers.html.
369 Slabbert (1997) *TSAR* 234 *at* 238.

McCreath J,[370] if the drafters of the Constitution intended to enshrine the rights of the unborn child in the Bill of Rights, they would have made express provision therefore. That would have cured any uncertainty in common law and case law denying the fetus legal personality. But the matter goes further than that. Had the drafters of the Constitution wished to protect the fetus in the Bill of Rights at all, one would have expected this to have been done in section 28 (which specifically protects the rights of the child). It is therefore necessary to examine the provisions of section 28 of the Constitution.

3 4 2 10 Section 28 of the Constitution: The protection of children's rights[371]

Section 28 sets out a range of rights that provide protection for children, which are additional to the protection they are given by other sections of the Bill of Rights. However, as important as these rights are, children's rights do not have a special status in the Bill of Rights. In *De Reuck v Director of Public Prosecutions*,[372] Epstein AJ held that "a child's best interests … is the single most important factor to be considered when balancing or weighing competing rights and interests concerning children. All competing rights must defer to the rights of children unless unjustifiable." This decision was overruled by the Constitutional Court in *De Reuck v Director of Public Prosecutions.*[373]

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[370] *Christian Lawyers Association of South Africa and Others v Minister of Health and Others* fn 269 *supra*.

[371] Section 28 read as follows: "Every child has the right – (a) to a name and a nationality from birth; (b) to family care or parental care, or to appropriate alternative care when removed from the family environment; (c) to basic nutrition, shelter, basic health care services and social services; (d) to be protected from maltreatment, neglect, abuse or degradation; (e) to be protected from exploitative labour practices; (f) not to be required or permitted to perform work or provide services that – (i) are inappropriate for a person of that child's age; or (ii) place at risk the child's well-being, education, physical or mental health or spiritual, moral or social development; (g) not to be detained except as a measure of last resort in which case, in addition to the rights a child enjoys under sections 12 and 35, the child may be detained only for the shortest appropriate period of time, and has the right to be – (i) kept separately from detained persons over the age of 18 years; and (ii) treated in a manner, and kept in conditions, that take account of the child's age; (h) to have a legal practitioner assigned to the child by the state expense, in civil proceedings affecting the child, if substantial injustice would otherwise result; and (i) not to be used directly in armed conflict, and to be protected in times of armed conflict. (2) A child's bets interests are of paramount importance in every matter concerning the child. (3) In this section 'child means a person under the age of 18 years'."

[372] *De Reuck v Director of Public Prosecutions*, Witwatersrand Local Division 2003 (3) SA 389 (W), as quoted in Currie & De Waal (2005) 600.

[373] *De Reuck v Director of Public Prosecutions*, Witwatersrand Local Division 2004 (1) SA 406 (CC), as quoted in Currie & De Waal (2005) 600.

To say that section 28(2) of the Constitution "trumps" other provisions of the Bill of Rights is "alien to the approach adopted by this Court that constitutional rights are mutually interrelated and interdependent and form a single constitutional value system".[374]

The importance of section 28[375] of the Constitution lies in the question of whether the fetus is included and protected under this section. The right of every child to family or parental care;[376] to basic nutrition, health care and social services;[377] to protection against maltreatment, neglect, abuse or degradation;[378] and to legal representation;[379] as well as the provision that a child's best interests are of paramount importance in every matter concerning the child,[380] would have been particularly suitable to protect the fetus as well. However, it is clear that the safeguards as provided for in section 28 do not protect the fetus, the reason being that a "child" for the purposes of section 28 is defined in subsection (3) as a "person under the age of eighteen years". From the above discussion of the common law it is clear that age commences at birth. The protection afforded by section 28 is dependent on the "child's" age. A fetus is not a child of any age.[381] Some of

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374 *De Reuck v Director of Public Prosecutions*, Witwatersrand Local Division 2004 (1) SA 406 (CC), as quoted in Currie & De Waal (2005) 600.

375 It is not necessary for the purpose of this dissertation to discuss the children's rights in detail, since the only question that needs to be answered is whether the fetus is protected under section 28.

376 Although the Constitution contains no express right to family life, the Constitutional Court held that this right is indirectly protected via the right to dignity. For a discussion of section 28(1)(b) see Currie & De Waal (2005) 605.

377 Section 28(1)(c) of the Constitution clearly states that if parents do not fulfil their common law and statutory obligations, the state has a duty to step in and support the children. For a discussion of this right see *Government of the Republic of South Africa v Grootboom* 2001 (1) SA 46 (CC). See also *Grootboom v Oostenberg Municipality* 2000 (3) BCLR 227 (C).

378 The right to family, parental and alternative care recognises the importance of the family in meeting the needs of children. For a discussion of section 28(1)(d) see *S v Williams* 1995 (3) SA 632 (CC), as quoted in Currie & De Waal (2005) 614.

379 The right applies to children as it does to adults, and it seems clear that, in most cases, substantial injustice would result from allowing a child to attempt to conduct criminal proceedings without legal assistance. The right is extended to children involved in civil litigation. For a discussion of this right see *Du Toit v Minister of Welfare and Population Development* 2003 (2) SA 198 (CC).

380 The concept of the best interest of the child is not without difficulty. It has become controversial because it has failed in the past to provide a reliable or determinate standard. See for example *Smith v Smith* 2001 3 SA 845 (SCA).

381 *Christian Lawyers Association of South Africa and Others v Minister of Health and Others* fn 269 *supra*.

the rights as protected in this section, for example those relating to armed conflict,[382] must accordingly also exclude the fetus.

McCreath J[383] stated that if section 28 of the Constitution does not include the fetus within the ambit of its protection then it can hardly be said that the other provisions of the Bill of Rights, including section 11, designed to protect "everyone's right to life", were intended to do so. This conclusion finds further support in the fact that in all the provisions of the Bill of Rights, other than those in which a specific class of persons is singled out for special protection, the rights are conferred on "everyone". Therefore, it is clear that the term "everyone" could not have been intended to include the fetus within the scope of its protection. To include the fetus in the meaning of the term "everyone" in section 11, would ascribe to it a meaning different to the one it bears everywhere else in the Bill of Rights.

To take the matter even further, section 12(2) of the Constitution provides that everyone has the right to make decisions concerning reproduction and to security in and control over their body. Nowhere are a woman's rights in this respect qualified in terms of the Constitution in order to protect the fetus. The state may, however, still restrict or regulate abortion and embryonic stem cell research by invoking section 36 of the Constitution for that purpose "to the extent that the limitation is reasonable and justifiable in an open and democratic society based on human dignity, equality and freedom" and taking into account all relevant factors, including those specified in the section.[384] For the purposes of this discussion it is now imperative to examine the provisions of section 12.

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[382] This subsection prevents the conscription or recruitment into the armed forces of children in times of armed conflict. For a discussion of the right see Currie & De Waal (2005) 617.

[383] *Christian Lawyers Association of South Africa and Others v Minister of Health and Others* fn 269 *supra*.

[384] For a discussion of section 36 of the Constitution see paragraph 3.2.

3 4 2 11 Section 12 of the Constitution: Freedom and security of the person[385]

Section 12(2)(a) and section 12(2)(b) read:

> Everyone has the right to bodily and psychological integrity, which includes the right –
> (a) to make decisions concerning reproduction;
> (b) to security in and control over their body …

Section 12 combines a right to freedom and security of the person with a right to bodily and psychological integrity, where section 11(1) of the interim Constitution stated that "every person shall have the right to freedom and security of the person, which shall include the right not to be detained without trial".[386] Chaskalson P held in *Ferreira v Levin* [387] that the primary purpose of section 11(1) was to ensure the protection of the physical integrity of the individual. The right therefore protects a right to physical liberty and a right to physical security. He conceded: "This does not mean that we must construe section 11(1) as dealing only with physical integrity. The subsection may protect more than this. The new section 12(1) is more specific in its formulation and the debate is unlikely to be re-opened." [388]

The right to procreate and the use of contraceptives, to make decisions about reproduction, are recognised internationally. It is submitted that the right not to reproduce

[385] For the purposes of this discussion focus is placed on section 12(2). This is the section that deals with reproduction, consent and bodily integrity that is applicable to embryonic stem cell research, and fetal tissue research. It is, however, important to note that it is clear from the reading of section 12(1) that the term “everyone” could not have been intended to include the fetus within the scope of its protection. Section 12(1) states: "Everyone has the right to freedom and security of the person, which includes the right- (a) not to be deprived of freedom arbitrarily or without just cause; (b) not to be detained without trial; (c) to be free from all forms of violence from either public or private sources; (d) not to be tortured in any way; and (e) not to be treated or punished in a cruel, inhuman or degrading way."

[386] Currie, De Waal (2005) 292.

[387] In *Ferreira v Levin NO* fn 241 *supra*, Ackerman J proposed a "broad and generous" reading of subsection 11(1). He held that the section should be read disjunctively. It protected a "right to freedom" and a separate "right to security of the person". The argument Ackerman J put forward was that the "right to freedom" was a constitutional protection of a sphere of individual liberty. He further said: "I would … define the right to freedom negatively as the right of individuals not to have obstacles to possible choices and activities … placed in their way by … the State". His interpretation of the right was rejected by the majority of the Constitutional Court.

[388] *Ferreira v Levin NO* fn 241 *supra*, as quoted in Currie & De Waal (2005) 292.

includes a woman's right to control her fertility by exercising the decision to terminate her pregnancy.[389]

(a) Section 12(2)(a): Decisions concerning reproduction

The specific inclusion of the right to make decisions concerning reproduction is the recognition that the power to make decisions about reproduction is a crucial aspect of control over one's body. The right is certain to have an impact on the dispute about the constitutionality of the permissive abortion legislation[390] that was adopted in South Africa.[391]

To return to the question of whether the fetus has a right to life – if section 11 were to be interpreted as affording constitutional protection to the life of a fetus it would have far-reaching and anomalous consequences for the interpretation of section 12(2)(a). The life of the fetus would enjoy the same protection as that of the mother. Abortion would be constitutionally prohibited even though the pregnancy constitutes a serious threat to the life of the mother. Abortion in certain circumstances has been permissible since 1975.[392]

The medical model of pregnancy and birth can produce and encourage attitudes that are antithetical to the best interest of the pregnant woman. It has paved the way for the development of the movement to protect separately the rights of the fetus, and as the characteristics of fetal "personhood" are emphasised, "the characteristics of personhood belonging to the mother are correspondingly devalued."[393] If, for example, a woman consents to antenatal screening, she may acquire information about the fetus which forces her to confront difficult decisions such as abortion, fetal therapy, fetal surgery or other medical interventions in a context where her interests are treated as being in competition

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389 Davis, D *et al* (1997) *Fundamental rights in the Constitution: Commentary and cases* 87.

390 The Choice on Termination of Pregnancy Act.

391 Currie & De Waal (2005) 308. In McCreath J's view, if the fetus were to be protected under section 11 of the Constitution, the termination of a woman's pregnancy would no longer constitute the crime of abortion, but that of murder. In his view, the drafters of the Constitution could not have contemplated such far-reaching results without expressing themselves in no uncertain terms.

392 The Abortion and Sterilisation Act repealed by The Choice on Termination of Pregnancy Act. For a discussion of both Acts see chapter 4.

393 For a discussion of the medical model of pregnancy and birth see Mclean, SAM & Peterson, K (1996) "Patient status: The foetus and the pregnant woman" *Austl J Hum Rts* 2(2):229-241.

with the interests of the fetus. Kolder[394] conducted a study in the 1980's investigating the scope and circumstance of court-ordered obstetric interventions. It was said:

> Although … discussions of fetal status are interesting, they distract attention from the central legal question posed by treatment refusals during pregnancy. The question is really whether doctors or the government may usurp patient's decision-making rights and appropriate or invade their bodies to advance what they perceive to be the therapeutic interest of a second patient, the fetus.[395]

The commencement point for a discussion of these developments, however, must firstly concern the rights of the "person" involved – that is, the pregnant woman. These rights are particularly threatened by those who, apparently merely cautioning that we must make decisions that involve fetuses carefully employ language implying the equation of fetal existence to a human life and all that this entails.[396]

It is submitted, with reference to section 12(2)(b), that the issue of abortion is not about what grounds justify abortion, but instead a much wider issue involving a woman's right to autonomously[397] make choices about her procreative freedom.[398]

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394 Kolder, VEB *et al* (1987) "Court-ordered obstetrical interventions" *New Eng J Med* 316(19):1192 *at* 1196.

395 This medical model has also promoted the popularity of the expression "maternal/fetal conflict". The term implies a relationship of conflict between a pregnant woman and her fetus, therefore distorting the complexity and intimacy of this unique relationship. It also disguises a number of suppositions. First, the fetus is correctly identified as a fetus, while the pregnant woman becomes a "mother" with all the implications concerning caring, protection, etc implied by the term. Second, the use of the word "conflict" suggests a battle of equals where in fact there is only one party and that is the pregnant woman. There are no adversaries in this relationship; there is one person and one potential person. Moreover, the word "conflict" seems to imply hostilities, sentiments that could really only come from the pregnant woman, since the fetus has no capacity to be hostile and cannot deliberately harm the woman who is pregnant. The woman, therefore, must be the person who is hostile, not making decisions in her own best interest, but in hostility to the fetus. Perhaps because the law lacks the framework necessary to conceptualise the debate as anything other than an all or nothing attribution of rights, the fetus is viewed as "… an entity independent from the pregnant woman with interests that are potentially hostile to hers". For a detailed discussion of "maternal/fetal conflict," see Johnsen DE (1986) "The creation of fetal rights: Conflicts with women's constitutional rights to liberty, privacy, and equal protection" *Yale LJ* 95(3):599-626.

396 Poplawski, N & Gillett, G (1991) "Ethics and embryos" *J Med'l Eth* 17:62 *at* 62, 63.

397 The word "autonomy" comes from the Greek words "autos", which means "self"; and "nomos", which means "rule of law". Van Wyk provides a definition for "autonomy": "An autonomous, moral agent is an individual who is capable of forming a rational plan of life, of rational deliberation about alternative plans of action with the aim of making choices that are compatible with his or her life plan, and who assumes responsibility for the consequences of his or her choices." See Van Wyk, C (2001) "Guidelines on medical research ethics, medical "experimentation" and the Constitution" *THRHR* 64(1):3. If the courts were to recognise fetal rights to life, it could potentially open a pandora's box of pervasive

According to Tribe, the question of fetal personality distracts us from the real question involved in abortion namely "… whether the state may force a woman to incubate an embryo, and to serve as its life support system against her will … (F)orced motherhood does not only involve asking a mother to refrain from killing another, but involves asking her to make profound affirmative sacrifice." Fetal life is very different from any other form of life in that it is wholly dependent on the mother and only the mother.[399] Denying a woman the freedom to exercise her choice to abort fails to respect her ability to make a private decision, which is a violation of psychological integrity guaranteed by section 12(2)(a) and 12(2)(b). This denial compels her to carry an unwanted fetus to term or to resort to an illegal abortion involving possible legal risks[400] and medical danger,[401] which is a violation of security in a physical sense. It also seems as if the Choice on Termination of Pregnancy Act[402] creates the impression that every woman has a right to an abortion.[403] It is therefore submitted that the woman's right to autonomously make decisions concerning reproduction includes a right to terminate her pregnancy, and that this right is stronger than the fetus's right to protection under the Constitution.

(b) Section 12(2)(b): *Security in and control over one's body*

According to De Waal and Currie, the essence of the right to freedom and security of the person is a right to be left alone. And, at least in relation to one's body, the right creates a sphere of individual inviolability.[404] Section 12(2)(b) has two components: "security in" and "control over" one's body. These components are not synonymous. "Security in" denotes the protection of bodily integrity against intrusion by the state and others.

limitations on women's autonomy and equality. What would prevent legislation requiring, in the interests of minimising risk of injury to the fetus, that pregnant women avoid active lifestyles, avoid smoking, riding in a car, skiing, or living at high altitudes? It is submitted that it is not implausible that such legislation could be extended even to potentially pregnant women. All these ubiquitous inroads on the woman's fundamental rights would conceivably be justified as protecting the fetus's right to life.

398 McGregor & Moore (1995) www.murdoch.edu.au/elaw/issues/v2n3/moore23.html.

399 Tribe (1990), as quoted in McGregor & Moore (1995) www.murdoch.edu.au/elaw/issues/v2n3/moore23.html.

400 See section 10 of The Choice on Termination of Pregnancy Act as discussed in chapter 4.

401 Prohibiting abortion would force women to undergo back-street abortions. An estimated 42 000 to 43 000 back-street abortions are performed annually. The women involved face a high risk of permanent infertility, disability, and mortality from septic abortions.

402 The provisions of the Act and the question of whether the Act creates a right to abortion are discussed in chapter 4.

403 Slabbert (2000) 372, 373.

404 Currie & De Waal (2005) 308.

"Control over" denotes the protection of what could be called bodily autonomy or self-determination[405] against interference. The former is a component of the right to be left alone in the sense of being left unmolested by others. The latter is a component of the right to be left alone in the sense of being allowed to live the life one chooses.[406]

Mill gave eloquent expression to the idea of personal autonomy:

> [T]he only purpose for which power can rightfully be exercised over any member of a civilised community, against his will, is to prevent harm to others. His own good, either physical or moral, is not a sufficient warrant. He cannot rightfully be compelled to do or forbear because it will be better for him to do so, because it will make him happier, because in the opinions of others, to do so would be wise or even right … It is, perhaps, hardly necessary to say that this doctrine is meant to apply only to human beings in the maturity of their faculties.[407]

Because section 12(2)(b) recognises a right to security in and control over one's body, it is relevant in determining whether the Constitution recognises a woman's right to terminate a pregnancy, and also whether it recognises a right to donate her aborted fetus for the purposes of stem cell research. These issues are discussed in the next chapter, together with the provisions of the Choice on Termination of Pregnancy Act. The decision to terminate a pregnancy concerns both reproduction and control over the body and it is submitted that it falls within the scope of section 12(2)(b).

Further, in the context of abortion, it can be implied that the right not to bear children does not necessarily include the right to destroy the fetus – states may absolutely prohibit abortions after viability to promote their interest in potential life, unless the health or life of the mother is at stake. This would allow states to force women to give birth to their biological children, perhaps against their will. It

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[405] In *Phillips v De Klerk*, the right of an individual to dispose over one's own body, in so far as that right is not in conflict with the overriding social interest, was recognised. In the absence of an overriding social interest, the mentally competent individual's right to control his own destiny in accordance with his own value system, his "selfbeskikkingsreg", must be rated even higher than his health and life. Strauss respectfully submitted that the decision must be welcomed. See *Phillips v De Klerk* 1983 TPD (unreported), as quoted in Strauss (1991) 30, 31.

[406] Currie & De Waal (2005) 308.

[407] Mill, JS (1859) "On liberty" *Cam U Press* (1989) 13, as quoted in Strauss (1991) 31, 32.

can be argued that women would then never be allowed to destroy the fetus if they decided they did not want to have children. The state then protected women's privacy interests in their bodies, but in doing so, has found it necessary to allow the fetus to be destroyed under certain circumstances.

Since a woman's body is not involved in in vitro fertilisation, it can be argued that there is no right to destroy the embryo. Assuming that this is true, in vitro fertilisation parents should still have a right to avoid having biological children if they act before the embryo becomes viable, since, by definition, before viability the fetus could not live outside of a woman's body. Arguably under the *Roe* decision, the woman's rights are paramount to the state's interest in potential life until the point of viability. A preimplantation embryo is not viable, and it would not be possible to save the embryo if the couple decide not to have the embryo implanted in the woman. Although a state could argue that the preimplantation embryo could be saved by donating the embryo to another couple, this would treat infertile and fertile couples differently by taking away any right in vitro fertilisation parents may have to decide not to have offspring from the fertilised eggs. In the context of abortion, the woman may choose whether or not to have children by deciding to have an abortion before the embryo is viable. Similarly, the court should allow the in vitro fertilisation couple to choose not to have children by destroying a frozen embryo, since the embryo is not viable at this stage.[408]

Intrusions on bodily integrity warranting constitutional attention also occur in the context of the investigation or prevention of crime. In *Minister of Safety and Security and another v Xaba*,[409] in the Durban and Coast Local Division, Southwood AJ held that the Criminal Procedure Act did not authorise a police official to use violence to obtain the surgical removal of a bullet from the leg of a criminal suspect for purposes of evidence. In the absence of a law of general application authorising the constitutional infringements of the rights in section 12(1)(b) and section 12(1)(c), the requirements of the limitation

[408] Schaefer (1990) *Pac. L. J.* 87 *at* 94-96.
[409] *Minister of Safety and Security and another v Xaba* 2004 (1) SACR 149 (D).

clause could not be met. The applicants applied for the confirmation of a rule *nisi*, which would declare the second applicant, a police officer, to be entitled to "use reasonable force, including necessary surgical procedure performed by a medical doctor to remove a bullet lodged in the respondent's thigh, and directing the respondent to subject himself to the procedure, failing which the Sheriff was to furnish the necessary consent on his behalf". It appeared that the respondent was a suspect in a motor-vehicle hijacking case and that the police believed the bullet would connect him to the crime. The respondent refused. The applicants relied on section 27 and 37 of the Criminal Procedure Act.[410]
The applicable section of the Constitution, namely section 12, guarantees the right to freedom and security of the person, and the right to bodily and psychological integrity, which includes the right to security and control over one's body. Section 36[411] of the Constitution provides that fundamental rights such as those in section 12 may be limited by a law or general application in certain circumstances. The court held that section 12 would clearly be infringed if the proposed surgery were to take place without the respondent's consent and not under some law limiting its protection as intended in section 36 of the Constitution. The legislature should deal with the issue of striking a balance between the interests of the individual and those of the community in resolving crimes by surgical intervention in cases such as this.[412]

In a similar case, *Minister of Safety and Security v Gaqa*,[413] the applicants applied for an order compelling the respondent to submit himself to an operation for the removal of a bullet from his leg. The applicants alleged that they had reason to believe that the

[410] Section 27 of the Criminal Procedure Act authorises a police official to use such force as may be reasonably necessary to overcome any resistance against a lawful search of any person or premises. Section 37(1)(c) of the Act authorises a police official to take such steps as he may deem necessary to ascertain whether the body of a person has any mark, characteristic or distinguishing feature, or shows any condition or appearance, provided that no police official shall take any blood sample. Section 37(2)(a) allows any medical officer of any prison or any district surgeon or, if requested thereto by any police official, any registered medical practitioner or registered nurse to take such steps including the taking of a blood sample as may be deemed necessary to ascertain whether the body of any person has any mark, characteristic, or distinguishing feature or shows any condition or appearance.
[411] For a discussion of section 36 see paragraph 3.2.
[412] The court further held that since a police official was not entitled to search a suspect by operating on his leg, he could not use the reasonable force authorised by section 27 to do so. Since he could not delegate his powers to search, he could not ask a doctor to do so instead.
[413] *Minister of Safety and Security v Gaqa* 2002 (1) SACR 654 (C).

respondent had been shot and injured in the course of an attempted robbery in which two people were killed.

The respondent's counsel argued that the violence envisaged by the applicants would result in several constitutionally guaranteed rights being infringed, including the right to freedom and security of the person, as well as the right to bodily and psychological integrity.[414] The court held that section 27 of the Criminal Procedure Act permitted the granting of the order. The court held that the police would be hamstrung in fulfilling their constitutional duty if the order were not granted. Southwood AJ, in his judgment in *Minister of Safety and Security v Xaba*, held that this case was wrongly decided.

Once it has been determined that the bodily integrity right has been implicated, the courts will be required to find criteria for distinguishing justifiable from unjustifiable invasions. It is submitted that the decision in the *Minister of Safety and Security v Xaba* case is more consistent with the concept of both the right to bodily integrity and a right to health, since health in its broader sense is based as much on psychological integrity as it is on bodily integrity, and the power of a person to refuse a surgical invasion of his or her person is essential for both.[415]

3 4 2 12 Section 14 of the Constitution: The right to privacy[416]

The debate around privacy is an emotional one. It impacts on bodily privacy, communications, and personal information. The debate is also complex, as the right to privacy is not absolute and can be limited in terms of section 36 of the Constitution.

[414] Other rights that could be infringed include the right to a fair trial, which includes the right to be presumed innocent. The right to remain silent and not to testify during the proceedings could also be infringed. It also includes the right not to be compelled to give self-incriminating evidence as stated in section 35(3)(h) and 35(3)(j) of the Constitution. Another right referred to, which is potentially infringed by the relief sought, includes the right to have one's dignity respected and protected, which is provided for in section 10. For the purposes of this dissertation it is not necessary to discuss these rights in detail.

[415] See in general Pearmain (2004) *A critical analysis of the law of health service delivery in South Africa* (Thesis – LLD.) University of Pretoria. (Unpublished).

[416] Section 14 of the Constitution read as follows: "Everyone has the right to privacy, which includes the right not to have – (a) their person or home searched; (b) their property searched; (c) their possessions seized; or (d) the privacy of their communications infringed." It is interesting to note that in section 13 of the interim Constitution reference was made to "every person" and not to "everyone". The interim Constitution also referred to "personal privacy" and not only to "privacy" as referred to in the final Constitution.

There are also competing interests that need to be balanced. These interests are discussed below. The same considerations that led to the entrenchment of a right to privacy in the Bill of Rights have long been recognised by the common law as important reasons for protecting privacy.[417] In terms of the common law, every person has personality rights such as the rights to physical integrity, freedom, reputation, dignity and privacy. The right to privacy has been recognised as an independent personality right that applies to both natural and juristic persons. The so-called "wrongfulness" of an infringement of privacy is determined by means of the criteria of reasonableness or *boni mores.* A court must have regard for the particular facts of the case and judge them in light of contemporary *boni mores* and the general sense of justice in the community as perceived by the court.[418]

McGregor and Moore submit that the Constitution recognises an "inviolable sphere of privacy beyond the reach of public authority". In other words, recognition that certain matters that arise in this private sphere of autonomy cannot be judged upon or regulated by the state. They further submit that decisions about marriage, child rearing, family size or contraception are widely acknowledged as falling beyond the reach of the state, being a question of individual conscience and morality. Therefore, the decision of a woman to choose whether or not to carry a pregnancy to term or not, and whether to donate the aborted fetus for research purposes or not, should be treated analogously.[419]

Ginsberg points out that placing the right to choose abortion in the privacy cubby-hole has made it easier for the court to justify limiting women's access to abortion. She suggests that analysing the issue in terms of the right of women to the equal protection of the law would have made it more difficult for the court to rule, for example, that neither the Constitution nor the federal statute requires medical aid reimbursements for elective abortions.[420] Research in America suggests that restrictions on abortion and the lack of access to publicly funded abortion facilities have fallen most heavily on poor, young,

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[417] For a discussion of the right to privacy see Slabbert (2000) 374-377.
[418] For a discussion of the *boni mores* see Neethling, J *et al* (2002*) Deliktereg* 23.
[419] McGregor & Moore (1995) www.murdoch.edu.au/elaw/issues/v2n3/moore23.html.
[420] Ginsburg, RB (1992) "Sex equality and the Constitution: The state of the art" *Women's Rts L Rep* 14:361 *at* 362.

rural, and battered women in dysfunctional families. It is possible that locating the right to choose an abortion exclusively in the right to privacy will have a similar effect in South Africa. Indeed, there is a real danger that the current position of the most vulnerable women in South African society will remain unchanged.[421] It is however submitted that the privacy argument should not be dismissed altogether. It should be used in conjunction with, rather than in contradistinction to, an equal protection analysis. This approach makes sense in South Africa where there is a long history of state-regulated reproduction.[422]

Another reason for protecting privacy is related to the reasons for protecting human dignity. It guarantees the right of a person to have control over the use of private information.[423] The right is closely related to the right to dignity, since the publication of

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[421] In the United States Supreme Court decision of *Roe v Wade* it was held that a woman's constitutional right to privacy prevented a state from forbidding abortion. O'Sullivan and Bailey argue that this recognition of women's autonomy in the "private" sphere of reproduction, however, is what has been used to justify failures on the part of the federal government to provide funding necessary to make the abortion choice meaningful to those women who cannot afford medically acceptable procedures. The duty of the state not to prohibit abortion in this sphere of privacy has come to mean that it also has no duty to intervene to protect this choice that its non-interventions guarantee. The negative right does not translate into a positive claim to safe, subsidised abortion facilities. See *Roe v Wade* fn 225 *supra*; O'Sullivan & Bailey, as published in Chaskalson (2005) 16-7.

[422] Dworkin, R (1992) "Unenumerated rights: Whether and how Roe should be overruled" *U Chi L Rev* 59(1):381 *at* 417.

[423] In *Jansen van Vuuren v Kruger*, the plaintiff, Mr McGeary, instituted an action for damages for breach of privacy against his general practitioner, the first defendant. The plaintiff applied for life insurance cover. A report on the patient's HIV status was required. The plaintiff asked the first defendant to prepare the report. The HIV test result was positive and the first defendant was notified. The first defendant arranged a consultation with the plaintiff, who was extremely upset and distressed, and concerned about a possible leak of the information. The first defendant promised to keep the information confidential. However, the following day the first defendant disclosed the information during the course of a golf game to two of his colleagues. The news that the plaintiff was HIV positive spread. The plaintiff became aware of the fact that the defendant breached their confidentiality. The first defendant raised an absence of wrongfulness on three alternative bases: (a) The communication had been made on a privileged occasion. (b) It was the truth and was made in the public interest. (c) It was objectively reasonable in the public interest in the light of the *boni mores*. The plaintiff died during the course of the trial, and the appellants were appointed executors of his estate. In his appeal court decision, Harms J remarked: "In determining whether the first defendant had a social or moral duty to make the disclosure and whether Van Heerden (the general practitioner) and Vos (the dentist) had a reciprocal social or moral right to receive it, the standard of the reasonable man applies … With that in mind, I am of the view that he had no such duty to transfer, nor did Van Heerden and Vos have the right to receive, the information … I see the matter in this light: AIDS is a dangerous condition. That on its own does not detract from the right to privacy of the afflicted person, especially if that right is founded in the medical practitioner-patient relationship. A patient has the right to expect due compliance by the practitioner with his professional ethical standards: in this case the expectation was even more pronounced because of the express undertaking by the first defendant. Vos and Van Heerden had not,

embarrassing information or information that places a person in a false light is most often damaging to the dignity of the person.[424] The right to seek, receive, and impart information is one of the requirements for the successful realisation of reproductive health.[425] Freedom of information is closely connected to and overlaps with the right to privacy.[426]

The question of whether parents have a fundamental right to decide the fate of their embryos, including the right to destroy the embryo if they choose not to have an

objectively speaking, been at risk and there was no reason to assume that they had to fear a prospective exposure. The real danger to the practitioner lies with the patient whose HIV condition had not been established or (due to the incubation period) cannot yet be determined." See *Jansen van Vuuren v Kruger* 1993 (4) SA 842 (A).

424 In the case of *C v Minister of Correctional Services*, the plaintiff instituted an action for damages against the Department of Correctional Services for breach of privacy. The plaintiff was a prisoner in the custody of the defendant at the Johannesburg Prison. His duties involved the preparation of food. One day the prisoners were informed that a blood sample would be taken for purposes of testing for HIV and other sexually transmitted diseases, and that they had the right to refuses to undergo such tests. This information was repeated, in the presence of a fellow prisoner, who assisted the medical aid with the drawing of blood. The plaintiff was subsequently advised that he had tested positive for HIV. Prior to this incident, the Department had adopted the concept that informed consent was a prerequisite for testing prisoners and had specified what norms were applicable. Kirk-Cohen J rejected the contention advanced on behalf of the defendant that the medical aid's deviation from the accepted norm of informed consent laid down by the department was minimal and not wrongful for the following reasons: The first information about the test, its object, and the right to refuse to submit to the test was communicated to the plaintiff as a member of a group of prisoners standing in a row in a passage, with no privacy and little time to reflect. What was repeated to each prisoner in the consulting room was not said by anyone trained in counselling and was also not said privately but in the presence of a fellow prisoner. No reasonable time for consideration and reflection was afforded to each prisoner in the consulting room before he was asked whether he consented to the test. See *C v Minister of Correctional Services* 1996 (4) SA 292 (T).

425 Slabbert (2000) 366. See in general *Mistry v Interim National Medicinal and Dental Council of South Africa and others* 1997 (7) BCLR 933 (D). The central problem in this case was whether the powers of entry, examination, search, and seizure given to inspectors by section 28(1) of the Medicines and Related Substances Control Act, 1965 (Act 101 of 1965) (hereafter referred to as the Medicines and Related Substances Control Act), are consistent with the provisions of section 13 of the interim Constitution, which guarantees personal privacy. It was decided that section 28(1) of the Act is inconsistent with section 13 of the interim Constitution, and was declared invalid. The legislative provisions with regard to privacy and confidentiality are discussed in chapter 4.

426 See, for example, section 32 of the Constitution that reads: "(1) Everyone has the right of access to – (a) any information held by the state; and (b) any information that is held by another person and that is required for the exercise or protection of any rights. (2) National legislation must be enacted to give effect to this right, and may provide for reasonable measures to alleviate the administrative and financial burden on the state." See also section 9 of the Promotion of Access to Information Act, 2000 (Act 2 of 2000) (hereafter referred to as the Promotion of Access to Information Act). This Act regulates the mandatory protection of privacy of a third party who is a natural person in section 34. According to section 34(1), the information officer of a public body must refuse a request of access to a record of the body if its disclosure would involve the unreasonable disclosure of personal information about a third party, including a deceased individual. See also section 34(2).

offspring, should be examined in light of court decisions involving the right to privacy. It is submitted that the right to privacy includes the right to procreate, the right to abort a fetus, the right to use contraceptives, and the privacy interests inherent in the marital relationship. The issue is whether the right to privacy encompasses the parents' right to destroy the embryo. Most would agree that the parents, as creators of the embryo, have some degree of decisional authority over the embryo. However, the scope of the parents' rights over the embryo is unclear, and unresolved in South Africa. Viewed most narrowly, the interest in destroying preimplantation embryos is not an interest that has been "traditionally protected by society". Taking a somewhat broader view, however, one can argue that, although this particular method of destroying embryos is new, the concept of embryo destruction has been protected by society since the Supreme Court decision protecting abortion in *Roe v Wade*.[427] Further birth control methods such as the intra-uterine device involve the destruction of embryos, and these have been consistently protected by courts as falling within the right to privacy. Contraception, abortion, and embryo destruction share the same privacy interest: the right to decide whether or not to have children without state interference. Courts have consistently found that decisions by married couples concerning reproduction and family are inherently private, and therefore are protected from unjustified governmental intrusion. Because of the fundamental nature of this right, regulations imposing burdens on these decisions must be justified by a compelling state interest.[428]

In the abortion context, however, the fundamental right to privacy is pitted against an equally important command: One should not take the life of another except to save a life. The abortion cases weigh the right to privacy against a competing state interest in preserving potential life. The state interest in protecting potential life is the same interest involved when the state seeks to impose a mandatory embryo donation law, and the right to privacy involved in abortion is essentially the same privacy right involved when a couple decides to destroy a preimplantation embryo. Because of these similarities between in vitro fertilisation, cryopreservation, and abortion, an analysis of court

[427] *Roe v Wade* fn 225 *supra*.
[428] Schaefer (1990) *Pac LJ* 87 *at* 100-105.

decisions relating to abortion may give some insight into the question of whether a couple has a privacy right to decide not to have biological children by destroying a preimplantation embryo. It is submitted that for a court to protect a fundamental right such as a couple's decision to destroy a preimplantation embryo, that court will have to find that the decision to destroy the embryo is similar to the privacy interests that courts have previously protected.[429]

Many similarities exist between the decision to destroy an embryo in the context of in vitro fertilisation and the right to seek an abortion. In determining that a fundamental right to terminate a pregnancy exists, the court in the *Roe* case considered the psychological impact an unwanted child could have on the mother, as well as the distress that is attributable to the stigma of being a single mother. As in abortion, there are psychological interests that the in vitro fertilisation parents may want to avoid by destroying the embryo. Even though a woman in the context of in vitro fertilisation does not physically bear or raise the child, there is an emotional attachment between the biological parents and the child. Therefore, the destruction of the in vitro fertilisation embryo is similar to the abortion cases in that there are psychological interests that the parents may want to avoid by destroying the embryo, for example the emotional distress of knowing that another couple would raise their child.

When granting this right, courts should undoubtedly consider that because the woman's body is involved, forcing a woman to have the child intrudes upon her bodily privacy. Even if the woman's body was not involved, however, the court should still recognise that there is a privacy right encompassing the decision to avoid biological children, so long as the state does not have a compelling interest in protecting the embryo. Therefore, in the case of in vitro fertilisation, parents should be able to destroy their embryo based on courts' privacy decisions relating to abortion and reproductive choice.[430]

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[429] See in general *Carey v Population Services Int'l* fn 225 *supra*; Robertson, JA (1987) "Gestational burdens and fetal status: Justifying Roe v Wade" *Am JL & Med* 13(2):189-212.

[430] Schaefer (1990) *Pac LJ* 87 *at* 115-117.

The privacy interest in destroying an embryo is similar to the interests protected in using contraception. The interest protected in contraception cases can be compared to the privacy interest present in the in vitro fertilisation context, since, in both cases, the couple decides not to have children, one by using contraception, and the other by destroying the preimplantation embryo. The preimplantation embryo that is destroyed is essentially identical to the embryo that is destroyed when one uses an intra-uterine device or other form of post-fertilisation birth control. The only difference between the privacy interests in destroying an in vitro fertilisation embryo and those implied by using contraceptives, is that the destruction of the embryo takes place in the context of in vitro fertilisation.

Policy considerations may exist allowing a couple some latitude when deciding whether or not to destroy an embryo. One consideration may be that if a couple with the ability to conceive normally decides to have an abortion, a couple using in vitro fertilisation should also have that same choice. A woman who decides to have the embryo implanted inside her could later have an abortion. It is submitted that the woman should therefore be allowed to destroy the embryo before having it implanted.

Looking at the similarity between the interests protected in abortion and contraception cases, and the decision to destroy the embryo, along with the policy considerations that favour allowing a couple to destroy the embryo, a court considering the issue should hold that there is a fundamental privacy right to decide not to have children by destroying the preimplantation embryo. Although there are differences between in vitro fertilisation, abortion, and contraception, this should not have an impact on the court classifying the right to destroy a preimplantation embryo as a fundamental right, since the privacy rights in all contexts are substantially similar. The parents' individual interests are not the only interests that a court will have to consider, however. While a court may determine that the couple has a fundamental right to decide whether or not to destroy the embryo, the court must still consider the state's interest in the embryo.[431]

[431] Schaefer (1990) *Pac LJ* 87 *at* 119.

3 4 2 13 Section 9 of the Constitution: The equality clause[432]

Equality has a special place in the Bill of Rights, and sets its face against laws and practices that reinforce the subordination of disadvantaged groups.[433] Equality is also a dominant theme running through the Constitution. It is mentioned expressly in the following sections:

(a) Section 9: "Everyone is equal before the law";
(b) Section 36: "In an open and democratic society based on freedom, and equality;
(c) Section 39: "When interpreting the Bill of Rights, a court, tribunal, or forum … must promote the values that underlie an open and democratic society based on human dignity, equality, and freedom".[434]

In *Harksen v Lane*[435] the criteria in determining whether the equality clause may in fact be invoked, requires an inquiry into the fact whether there is differentiation between people or categories of people. If such differentiation exists, it must be determined if there is a rational connection to a legitimate government purpose. The court went on to say that even if there is such a rational connection it might nevertheless still amount to discrimination.

The second step is to distinguish if the differentiation amounts to unfair discrimination, which requires a three-stage analysis: Firstly, it must be established whether the

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[432] Section 9 of the Constitution read as follows: "(1) Everyone is equal before the law and has the right to equal protection and benefit of the law. (2) Equality includes the full and equal enjoyment of all rights and freedoms. To promote the achievement of equality, legislative and other measures designed to protect or advance persons or categories of persons, disadvantaged by unfair discrimination may be taken. (3) The state may not unfairly discriminate directly or indirectly against anyone on one or more grounds, including race, gender, sex, pregnancy, marital status, ethnic or social origin, colour, sexual orientation, age, disability, religion, conscience, belief, culture, language and birth. (4) No person may unfairly discriminate directly or indirectly against anyone on one or more grounds in terms of subsection (3). National legislation must be enacted to prevent or prohibit unfair discrimination. (5) Discrimination on one or more of the grounds listed in subsection (3) is unfair unless it is established that the discrimination is fair."

[433] *Brink v Kitshoff NO* 1996 (4) SA 197 (CC), 1996 (6) BCLR 752 (CC). See also *Makwanyane* fn 220 *supra*.

[434] See also section 7(1) of the Constitution: "This Bill of Rights is a cornerstone of democracy in South Africa. It enshrines the rights of all people in our country and affirms the democratic values of human dignity, equality, and freedom."

[435] *Harksen v Lane* fn 241 *supra*.

differentiation amounts to discrimination. The court was of the opinion that, if the allegation of unfair discrimination is not based on a listed ground, it must be resolved objectively whether the ground is based on "attributes and characteristics which have the potential to impair the fundamental human dignity of persons as human beings or to affect them adversely in a comparably adverse manner". Secondly, it must be found that if it amounts to discrimination, such discrimination is unfair. If it is found to be on a listed ground, then the court will presume unfairness. However, if on an unspecified ground, such as in the case of women choosing to have an abortion or donating their fetuses for stem cell research, the test of unfairness primarily focuses on the impact of the discrimination on the complainant and other women in the same situation.[436] Thirdly, if the discrimination is found to be unfair, it must be determined whether it can be justified under the limitation clause.[437]

Reproductive autonomy is a precondition for the sexual and social equality of women. The abortion question must also be seen in the broader context of reproductive freedom and, therefore, of sexual equality. The state's interest in the protection of life, whether it is that of the mother or that of potential fetal life, can be less prohibitively pursued by investing in family planning programmes, contraception facilities and general sex

[436] The Promotion of Equality and Prevention of Unfair Discrimination Act, 2000 (Act 4 of 2000) (hereafter referred to as the Promotion of Equality and Prevention of Unfair Discrimination Act), also contains a general prohibition provision, and states that "neither the state nor any person may unfairly discriminate against any person". Although this Act does not specifically make reference to discrimination against social and sexual equality of women, it is submitted that it may nevertheless be argued that the straightforward general prohibition includes the reproductive autonomy of women. See section 6. The strong link between human dignity and equality is also conceptualised in the value of *ubuntu*. Although not expressly mentioned in the Constitution, it was nevertheless recognised as a constitutional value in *S v Makwanyane*. See *Makwanyane* fn 220 *supra*. This culture emphasises the fact that, in treating human beings with dignity, the state is required to act in a reasonable manner to eradicate poverty and is obliged to take steps to ensure the equal treatment of those who are vulnerable in society and have been historically deprived.

[437] Section 36 of the Constitution of the Republic of South Africa. (For a discussion of this section see paragraph 3.2.) In *President of the Republic of South Africa v Hugo*, Kriegler J suggested that the factors that would or could justify interference with the right to equality under the limitation clause should be distinguished from those relevant to the enquiry as to whether there has been unfair discrimination under the equality clause. The former are concerned with justification, possibly notwithstanding unfairness, and the latter are concerned with fairness and with nothing else. See *President of the Republic of South Africa v Hugo* 1997 (4) SA 1 (CC). In *Harksen v Lane*, the Constitutional Court stated that the limitation analysis involves "a weighing of the purpose and effect of the provision in question and a determination as to the proportionality thereof in relation to the extent of its infringement of equality". See *Harksen v Lane* fn 241 *supra*. See also Currie & De Waal (2005) 238.

education, but not by overriding a woman's fundamental rights of equality, privacy and dignity. Law argues that "[l]egal structures that support the dominance of men and subservience of women are fundamentally inconsistent with the constitutional ideals of individual worth and equality of opportunity [and] control of reproduction is the *sine qua non* of women's capacity to live as equal people". She remarks that courts should be wary of emotional moral arguments in the guise of a legal analysis.[438]

Therefore, a question arising in the context of the delivery of reproductive health care is whether a restrictive abortion law would offend against the prohibition of discrimination against women. In Slabbert's view, a restrictive abortion law denying a woman the choice of terminating her pregnancy during the early stages thereof not only significantly exacerbates the inequality resulting from the biological fact that women carry the exclusive burden of contraceptive failure, but also compels a woman with an unwanted pregnancy to carry it to term with all the legal, moral and social responsibilities associated with it. A balancing of the state's protection of fetal life and the woman's right to reproductive self-determination is possible and can produce a result that protects fetal life while still being consistent with women's equality rights.[439]

Pregnancy involves burdens of, among other things, health, mobility, independence and sometimes life itself. These hardships are borne by pregnant women alone, while men will by definition never find themselves pregnant. According to Law, forced motherhood affects a woman's ability to plan her life, sustain relationships with others, and make a positive contribution through her career and social life.[440] It is submitted that laws that restrict access to abortion are laws that discriminate on the basis of a biological reality that only affects women.

Grisez, again, argues to the effect that those who approve abortion or the destruction of embryos for use in therapeutic research show characteristic signs of a deep-seated prejudice. He calls this kind of prejudice "prenatalism" (we are already born while they

[438] Law, SA (1984) "Rethinking sex and the Constitution" *U Penn L Rev* 132(5):955 *at* 1028.
[439] Slabbert (2000) 350.
[440] Law (1984) 955 *at* 1028.

are unborn). He notes that the fetus is distinguishable by an obvious characteristic, namely that it is impossible for it to alter. He also notes inconsistencies typical of systems based on prejudice, such as adjacent medical articles describing on the one hand the latest abortion technique, and on the other the latest advance in in utero surgery. However, the fetus does not qualify as a constitutional person in South Africa and consequently does not enjoy the protection of equality as envisaged in section 9.[441]

3 4 2 14 Section 15 of the Constitution: Conscience, religion, thought, belief, and opinion[442]

Chaskalson P used the following definition to describe the essence of the concept of freedom of religion in *S v Lawrence*:[443]

> The right to entertain such religious beliefs as a person chooses, the right to declare religious beliefs openly and without fear of hindrance or reprisal, and the right to manifest religious belief by worship and practice or by teaching and dissemination.[444]

According to Currie and De Waal, the limitation clause should play a crucial role in resolving disputes involving the individual right to the free exercise of religion. This is because the wide scope of the right increases the likelihood of its infringement. In their

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[441] Opponents of abortion argue that certain *dicta* from the recent death penalty judgment do have a bearing on the issue of "prenatalism". O'Regan J cited a dictum condemning punishments that "treat members of the human race as non-humans, as objects to be toyed with and discarded". She also said that part of the job of the Bill of Rights is to protect those who are "marginalised, the dispossessed and the outcasts of our society, because they are the test of our commitment to a common humanity and cannot be excluded from it". "Weakest", "marginalised", "outcasts of society", and "objects to be toyed with and discarded" – these descriptions clearly fit prenatal human beings. Opponents argue that, bearing in mind the significance of the right to freedom from discrimination in South Africa's new Constitution, discrimination against the class of prenatal human beings must not become law. Fetuses must be regarded as persons and accorded rights under the Constitution. According to McCreath J's judgment in the *Christian Lawyers* case, this argument cannot stand. See *Christian Lawyers Association of South Africa and Others v Minister of Health and Others* fn 269 *supra*.

[442] Section 15 of the Constitution reads as follows: "(1) Everyone has the right to freedom of conscience, religion, thought, belief and opinion. (2) Religious observations may be conducted at state or state-aided institutions provided that – (a) those observances follow rules made by the appropriate public authorities; (b) they are conducted on an equitable basis; (c) attendance at them is free and voluntary. (3)(a) This section does not prevent legislation recognising – (i) marriages concluded under any tradition, or a system of religious, personal or family law; or (ii) systems of personal and family law under any tradition, or adhered to by persons professing a particular religion. (b) Recognition in terms of paragraph (a) must be consistent with this section and the other provisions of the Constitution."

[443] *S v Lawrence* 1997 (4) SA 1176 (CC).

[444] *R v Big M Drug Mart* [1985] 1 SCR 295 *at* 336, as quoted in *S v Lawrence* fn 443 *supra*.

view, it makes little sense to question the degree of commitment of an applicant to his or her convictions – a religious or other belief must be taken as a given. Moreover, both the purpose and effect of legislation may violate the freedom of religion.[445] In the context of embryonic stem cell research, abortion, in vitro fertilisation and cloning technologies, the National Health Act, the Human Tissue Act and the Choice on Termination of Pregnancy Act[446] violate the freedom of religion of certain specified religious groups.[447]

In *Christian Education SA v Minister of Education*,[448] Liebenberg J summarised the position as follows:

> In cases of this nature a court will in the first place consider whether the belief relied upon in fact forms part of the religious doctrine of the religion practised by the person concerned. Once it is found that the belief does form part of that doctrine, the court will not embark upon an evaluation of the acceptability, logic, consistency, or comprehensibility of the belief. But, the court will then inquire into the sincerity of the person's claim that a conflict exists between the legislation and the belief which is indeed burdensome to the person.

The right to freedom of religion and thought is contained in most human-rights treaties. However, members of religious communities may seek to use the freedom of religion as a shield to fend off attacks on constitutionally offensive group practices.[449] Important in the context of reproductive rights is the freedom to express religious, philosophical and social convictions regarding reproductive self-determination. According to Slabbert, this means that on the one hand individuals may enjoy human rights of reproductive choice, and on the other hand that health care providers must be free not to participate in practices that they find offensive on religious grounds (for example, performing abortions or sterilisations or assisted reproduction procedures and embryo research). Conscience or

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445 Currie & De Waal (2005) 341.
446 For a discussion of these Acts see chapter 4.
447 Some religious groups argue that to be willing to kill what for all we know could be a person, is to be willing to kill it if it were a person. Therefore, a judicial body that holds that a fetus is not a person and takes responsibility for its abortion or destruction cannot evade moral responsibility for killing a person. This, it is suggested, is a cogent reason for courts to find that the fetus is a person.
448 *Christian Education South Africa v Minister of Education* 2000 (4) SA 757 (CC).
449 *Ibid*.

religion cannot however be used to justify a health care provider's refusal to participate in a life-saving procedure where there is no suitable method or person available.[450]

In conclusion, now that a balance has been struck between the competing constitutional rights of the mother and the fetus, and a brief survey of the law on the status of the unborn child in common law was given, it is necessary to return to the *Christian Lawyers* case. McCreath J came to the conclusion that the particulars of claim did not make out a cause for action. He held that the Choice on Termination of Pregnancy Act could not be declared unconstitutional and that the fetus is not a bearer of constitutional rights. The embryo, therefore, does not have a "right to life" in terms of section 11 of the Constitution.[451]

McCreath J however restricted his determination of the matter to an investigation of whether a fetus is a bearer of constitutional rights. But the fact that the fetus is not explicitly protected in terms of the Constitution does not mean that fetal life can never be protected. He also neglected to discuss the role of criminal law as the traditional source of protection of the fetus. Unfortunately, there is no deliberation either on the state's role or its duty in the protection of the fetus. Slabbert points out that his approach to resolving the question by a consideration of the word "everyone" reflects a text-based or literalist approach to constitutional interpretation. This approach is unsatisfactory for the reason that the Bill of Rights requires a value-orientated or value-based approach of interpretation. Naude argues that, if a whole statute is constitutionally challenged, the court should consider whether each section thereof is constitutional, unless the applicants are denied standing or if the issue is not "ripe".[452]

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[450] Slabbert (2000) 363, 364.

[451] *Christian Lawyers Association of South Africa and Others v Minister of Health and Others* fn 269 *supra*.

[452] For a detailed discussion of the criticism with regard to the *Christian Lawyers* case see Slabbert (2000) 295-298. See also Naude (1999) *SAJHR* 541-562.

3 5 THE CONSTITUTIONAL FRAMEWORK PERTAINING TO MEDICAL RESEARCH AND EXPERIMENTATION[453]

3 5 1 Introductory remarks

Scientific research[454] and experimentation have produced substantial social benefits and have made an enormous contribution to human progress. However, it still confronts society with difficult ethical problems.[455] As the focus point of this dissertation is embryonic stem cell research, focus is placed on research and experimentation on human embryos.[456] Whether it is ethical to experiment on early human embryos is a contentious question worldwide. It is one of several bioethical issues that stand in the way of consensus on bioethics. This lack of agreement obviously reflects deep-seated divergences in assessing the ethical standing of the early embryo. It also reflects differences in the way the political debate and the law-making process of various countries have either sought a minimum procedural consensus, or allowed one particular moral conviction to prevail.[457] The South African Constitution provides the framework on how these issues should be addressed, and the applicable sections are discussed below.

3 5 2 Section 12(2)(c) and section 16(1)(d) of the Constitution

Section 12(2)(c) of the Constitution reads:

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[453] Medical or scientific "experimentation" probably means nothing other than medical or scientific research. See Van Wyk (2004) *THRHR* 1 *at* 8.

[454] Section 1 of the National Research Foundation Act, 1998 (Act 23 of 1998) defines "research" as the generation, preservation, augmentation and improvement of knowledge by means of scientific investigations and methods in the field of science and technology.

[455] Van Wyk (2001) *THRHR* 3 *at* 6.

[456] Embryo research is often classified as either therapeutic or non-therapeutic. Therapeutic research is undertaken to benefit specifically the embryo on which it is performed. Non-therapeutic research is not designed to benefit the specific embryo on which the research is performed. Another distinction that seems more to the point in ethical terms is between invasive and non-invasive research. Whatever its purpose, embryo research is non-invasive whenever it is compatible with the ensuing transfer of the embryo to a patient. This can include various observational investigations and also non-destructive biochemical analyses such as metabolic measurements or the identification of substances secreted by the embryo into the culture medium. Invasive research is defined as incompatible with further use of the embryo for transfer and further development in the patient's womb. Invasive embryo research is opposed by those moral traditions that assert that personhood starts at conception, or more broadly, by those who believe the early embryo to be the locus of considerable moral stakes, even if they are not quite as high as those invested in persons in the ordinary sense.

[457] Frankowski & Cole (1987) 281. See in general Lang (1992*) Crim L Forum Int'l J* 419-440.

> Everyone has the right to bodily and psychological integrity, which includes the right –
> (c) not to be subjected to medical or scientific experiments without their informed consent.

An analysis of this right can be broken down into two parts: Firstly, the question of what constitutes medical or scientific experiments should be examined, and secondly, what counts as informed consent should be defined. According to Currie and De Waal, what constitutes a medical or scientific experiment is not as simple as it sounds.[458] Many of the medical or scientific experiments with which we would be concerned manifest as, for example, gauging the reactions of elderly patients injected with cancer cells, calculating the death-rates of concentration camp internees subjected to an array of pathogens. But, day to day medical care and therapy also amounts to experimentation, even though of a slightly different kind.[459]

Claassen and Verschoor indicate that there is no other profession in greater need of continuous progress than medicine. It is therefore unavoidable that a measure of experimentation will avail during the manufacture of new drugs or the development of new methods of treatment. In an experimental situation two opposing interests must be balanced, namely –

(a) the interest of the patient not to be subjected to any abuse that may result from an uncontrolled experiment; and
(b) the interest of the physician and of society in furthering knowledge of diseases and their treatment.[460]

Section 16(1)(d) of the Constitution reads: "Everyone has the right to freedom of expression, which includes … academic freedom and freedom of scientific research."[461]

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[458] Currie & De Waal (2005) 310.
[459] Currie & De Waal indicate that when doctors prescribe approved drugs or engage in accepted practices on their patients, they are still experimenting, because no two patients react exactly alike to the same drug or procedure. Often doctors do not know the side-effects and untoward reactions of various courses of treatment until after years of treatment on a willing and large population of patients. Medical knowledge is therefore controversial and partial.
[460] Claassen, NJB & Verschoor, T (1992) *Medical negligence in South Africa* 54.

The "academic freedom right" was initially part of the right to freedom of religion, belief, and opinion in the interim Constitution.[462] The final Constitution's formulation of the right is broader than in the interim Constitution. The right no longer applies only to "institutions of higher learning". Therefore, any academic enterprise is now protected.[463]

The core of the right to academic freedom is the right to do research. This right vest in individual academics, not only in universities. Currie and De Waal point out that, if the state could prescribe to universities that no research critical of the government may be funded by the university or that no researchers critical of the government may be appointed, academic freedom would be left stranded. Currently, the area where freedom of scientific research contradicts most frequently with state regulation is in the field of human genetics. Here regulation, for example bans on embryonic stem cell research, human cloning or germ-line engineering, is motivated less by political than by ethical concerns – concerns that are frequently at odds with the impetus of scientific discovery. Section 16 implies a positive duty of the state[464] to promote research and teaching by providing functional academic and scientific institutions, or at least the financial and organisational backup needed to exercise the right to academic freedom and scientific research.[465]

The most important question that needs to be answered is whether embryo research should be permitted in terms of the Constitution. A generation ago the big debates in many countries of the world surrounded embryo research. Since then, so many reproductive technologies have been developed that use embryo research or its results,

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461 Section 16 reads: "16(1) Everyone has the right to freedom of expression, which includes – (a) freedom of the press and other media; freedom to receive or impart information or ideas; (c) freedom of artistic creativity; (d) academic freedom and freedom of scientific research. (2) The right in subsection (1) does not extend to – (a) propaganda for war; (b) incitement of imminent violence; (c) advocacy of hatred that is based on race, ethnicity, gender or religion, and that constitutes incitement to cause harm."

462 Section 14 of the interim Constitution read: "Every person shall have the right to freedom of conscience, religion, thought, belief and opinion, which shall include academic freedom in institutions of higher learning."

463 Currie & De Waal (2005) 370.

464 Section 16 only refers to "academic freedom" and therefore does not confer a right to state financial support for specific research projects.

465 Currie & De Waal (2005) 371. See in general Malherbe, EFJ (1993) "'n Handves van menseregte en onderwys" *TSAR* 4:686 *at* 699.

that these controversies can be considered to be of relatively marginal interest.[466] Issues in embryo research include –

(a) up to what point in embryonic development research is possible;
(b) whether it is admissible to create embryos solely for research purposes; and
(c) what uses can be made of embryonic stem cells or fetal tissues.

The significance of these issues depends on whether or not it is permissible to destruct embryos for research purposes, and up to what point in embryonic development such permissibility extends.

There are numerous arguments for and against embryo research. These arguments can be conducted at either a practical, legal or philosophical level.[467] It is important to examine the different arguments for and against embryo research. It is submitted that embryo research is justified in terms of the Constitution on the following grounds:

(a) It is highly beneficial in the development of assisted reproduction as a "treatment" for infertility and as a method of preventing the inheritance of genetic disease.
(b) The embryo up to a certain stage of development[468] has no morally relevant physical or other properties; for example, no rudimentary nervous system. There are arguments that the embryo has neither interests to be preserved, nor the capacity to be harmed,[469] although the contingent future person into whom the embryo might develop could be harmed, nor does it even have a stable identity.[470]
(c) The law only affords legal capacity and status to human persons. A human embryo, on the other hand, is not a person or even a potential person. It is merely

[466] One's attitude regarding embryo research most significantly reflects one's attitude regarding abortion. For the purposes of the present discussion on embryo research, it is not necessary to rehearse arguments about abortion, but it is sufficient to say that most countries do permit it in some form, and most countries also permit embryo research, on certain grounds, which should constantly be regulated.
[467] Lupton (1992) *TSAR* 466 *at* 467, 468.
[468] This stage is fourteen days in the United Kingdom. The legal position of embryo research in the United Kingdom is discussed in chapter 5.
[469] See in general Tanner, JM (2005) "Medici stry nog oor fetusse se pyn" *Persp*: 4, 28 August.
[470] The embryo up to a certain development stage has no stable identity, because twinning and the reabsorption of twins are still possible.

a collection of cells that, if not implanted into a human uterine environment, has no potential for development. There is therefore no reason to accord these cells a protected status.

(d) A less radical view is that the human embryo is entitled to a measure of respect beyond that accorded to animal subjects. However, this respect is not absolute and may be weighed against the benefits arising from research.

(e) There is no substitute for the use of human embryos to research matters affecting human beings.

(f) Research should be permitted subject to certain controls.

(g) Even the 14-day cut-off for research on embryos is questioned by a philosopher like Michael Lockwood, who argues that there is no person until brain birth occurs at about six weeks, the brain being the *sine qua non* for human existence.[471]

The benefits of embryo research that could not be obtained in any other way falls into four main categories:

(a) Improving the treatment of infertility
(b) Gaining further knowledge about factors leading to congenital disease
(c) Developing more effective forms of contraception
(d) Detecting gene or chromosome abnormalities before implantation[472]

The only live area of controversy within this field is the issue of whether embryos can be created specifically for research purposes. Most embryos used in research are "spare embryos" created as "by-products" of in vitro fertilisation.[473] The justification by some for the use of "spare embryos" for research purposes is that it is better to use such embryos for some good purpose than simply to destroy them.[474] One might argue that the intention to create an embryo in order to create a child is different to the intention to

[471] Lupton (1992) *TSAR* 466.
[472] *Ibid* 467.
[473] United Kingdom. Parliament: House of Lords (2002) www.parliament.the-stationery-office.co.uk/pa/Id200102/dselect/Idstem/83/8301.htm-14k.
[474] Blackbeard (2002) *DJ* 318.

create an embryo for use in research, or for use as a source of stem cells. It is submitted that this argument is correct, but it is still of no help to the moral and ethical issues relating to this research. Schüklenk and Ashcroft argue that even if the intention is to create embryos for reproductive purposes, one creates spare embryos as an unavoidable consequence of acting on this intention, which means that the line between creating embryos for reproduction and creating them for research is blurred. Secondly, they refer to a Kantian argument about intention to "use" such embryos as "means" to other ends can only get going if we establish that such embryos are persons, which most parties now agree that they are not. Third, the motives underlying such intentions may not all be altruistic, but we cannot infer from this that embryo experimentation is wrong.

The arguments against research and experimentation on human embryos can be summarised as follows:

(a) Because these embryos are in fact human, it is morally wrong to use them in research.
(b) The human embryo is seen as having the same status as a child or an adult by virtue of its potential for human life.
(c) The right to life is held to be the fundamental human right, and the taking of human life is always abhorrent from this viewpoint.[475]
(d) It is totally unacceptable to make use of a child or an adult for research purposes if it may cause them harm or death. Nor is research permitted without prior informed consent of the subject. It is therefore equally unacceptable to carry out research on a human embryo that by its very nature cannot give consent.
(e) There is an instinctive opposition by many people to research that is seen to be tampering with the creation of human life.

Obtaining stem cells for research from embryos is a type of embryo research in general, and its ethical status is identical. More controversial will be the use of stem cells in

[475] As previously discussed, the fetus is not a constitutional bearer of the "right to life", but still deserves some protection under the Constitution. See *Christian Lawyers Association of South Africa and Others v Minister of Health and Others* fn 269 *supra*.

"routine" clinical treatment. Suppose that one day all the research is so successful that stem cell technologies become usable standard therapies in transplantation: Where will all the stem cells come from? The concern is that embryos will be mass-produced in order to harvest stem cells, and destroyed in the process. This seems unlikely, because the main reason for the use of these stem cells is that, in their nuclei, they are genetically identical, or differ only in a tiny number of genes from those of the recipient. At present, the efficiency of the process that produces embryonic stem cell lines from cloning is not high, but this research is still in its early stages. Be that as it may, the image of "industrialisation" of life is much exaggerated. There are ethical issues such as the possibility that women, as donors of ova, would be exploited,[476] that this research would land on the slippery slope of reproductive cloning,[477] and that promises made too early could lead to false hope among sick patients.[478] It also raises the question of intellectual

[476] Women donating embryos for research may be problematic. First, donation or payment for embryos to be used for research purposes is illegal in many states. Additionally, current restrictions on federal funding for research involving embryos impose a further limitation. Currently, thousands of women donate eggs annually to assist infertile couples to achieve parenthood. In the reproductive context, the demand for egg donors far exceeds the supply. In part, this has increased the concern that pursuing therapeutic cloning would even further increase the demand for egg donors to the point where eggs would become commodities and women would become exploited. Some altruistic volunteers may be willing to be egg donors, but the reality is that women with limited financial resources will be the primary providers of human eggs to enterprises that offer what appear to be lucrative payments. Additionally, due to the heightened demand for donors it is likely that many women will become repeat donors, and that there will be a massive expansion in the use of women as paid "egg producers". The need to protect egg donors is not new; however, the increased demand highlights the urgency with which this issue must be addressed. Such protection should not be unduly paternalistic, as respect for autonomy is still a cornerstone of biomedical ethics. However, there is often a fine line between respect for autonomy and paternalism, highlighted in this context, which requires a delicate balance to ensure that the interests of all participants are safeguarded. See Elster (2002) *Hum Rts Sum* 23. Cloning for biomedical research would also require ova from women donors. This raises concerns regarding the exploitation of women and re-opens debate on the co-modification of human body parts. Hormonal treatment for the stimulation of the ovaries in order to produce excess ova is not without risk. However, the ethical codes regulating research on human participants are protective against harms. It is expected that intensive ethical review of proposals for cloning for biomedical research purposes would optimise subject protection. Using ova from other species in creating stem cells by nuclear transfer techniques may be a way to overcome the problems of ova scarcity and the ethical issues associated with using women donors in this research. This possibility has met with scepticism from scientists despite an American firm, Advanced Cell Technology, patenting such a technique. In addition, ethical problems associated with the moral status of the hybrid embryo may be easier to overcome than ethical problems associated with the moral status of the human embryo. See Dhai *et al* (2004) *SAMJ* 906 *at* 907.

[477] The line between therapeutic cloning and reproductive cloning is quite clear. Despite the possibility that the technology generated could be misused, appropriate legislation permitting therapeutic cloning and proscribing reproductive cloning could be instituted. This reflects the South African position. For a discussion of the National Health Act see chapter 4.

[478] Society has been promised extensive and instant benefits from stem cell research. It is morally unacceptable to raise false hope in gravely ill people. Researchers need to be honest in their public

and actual property rights in human cell lines and the techniques by which they are produced.[479] It is submitted that these issues should be addressed, and require regulatory and legislative responses to protect the interests of society.[480]

In conclusion, Schüklenk and Ashcroft submit that these new cell technologies present "no harms and many benefits". They believe that a lot of the so-called debate in this area is merely hysteria, because on closer examination these technical advances represent no new issues. All of them can be translated back into issues arising in more familiar, ethically well-understood, and well-regulated contexts. They believe that our common interests in liberty, respect for persons and medical advance require us to promote these new technologies rather than preventing them on what was shown to be entirely spurious grounds.[481]

Because the trend toward the protection of the embryo leads to a regression of constitutional values, a new approach is needed. It is submitted that the state should allow the scientific community the right to research and explore all the avenues of stem cell

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presentation on the benefits of stem cell research with regard to time intervals between theoretical possibility and clinical practice. See Dhai *et al* (2004) *SAMJ* 906 *at* 906, 907.

479 There are issues that arise in obtaining stem cells and using them to generate a cell line, which leads to concerns about the patenting and commercialisation of biological material. It could be argued that the patents on stem cells are invalid because stem cells are not patentable subject matter. There are two potential arguments for why embryonic stem cells are not a patentable subject matter. First, they are found in nature, and second, they are a human life form. See Miller (2003) *Alb LJ Sci & Tech* 555. Patents granting broad property rights (which include the human embryonic stem cell) to the Wisconsin Alumni Research Foundation (WARF) will limit exploration of the properties and potential uses of embryonic stem cells. WARF now owns property rights covering the human embryonic stem cell, a product of nature, whose existence was already known. WARF's inventive leap was not the discovery of the human embryonic stem cell but rather the method for maintaining stem cells in an artificial environment in such a way that they retain the ability to transform into different cell types, and the production of some unique human embryonic stem cell lines. The contribution described in the WARF patents is important because it enables scientists to use these cells to make mature cells, organs and tissues that can be used therapeutically. Nevertheless, now that WARF owns broad property rights to any human embryonic stem cell rights that are not coextensive with the inventive contribution to society, any researcher must negotiate with WARF before using human embryonic stem cells, even if that researcher isolates new human embryonic stem cells or uses a new method to do so. The human embryonic stem cell patent product claims serve as an example of the phenomenon whereby downstream improvement-type research is stifled when patents containing broad claims to basic research discoveries are issued. Because these issues are not the focus point of this dissertation, it is not discussed in detail, Schüklenk and Ashcroft argue that the issue of patenting stem cell lines requires regulation of the technologies, and should not put "moral" bans on stem cell research. For a discussion of stem cell lines see Laurie (2004) *Eur Int Prop Rev* 59 *at* 60-66. See also Enmon (2002) *Utah L Rev* 621 *at* 621-648; Miller (2003) *Alb LJ Sci & Tech* 555 *at* 592.

480 Schüklenk & Ashcroft (2000) *Monash Bio Rev* 34 *at* 42, 43, 44.

481 *Ibid* 44, 45.

research under ever watchful governmental supervision following heavy-handed and strict ethical guidelines. The solution would be to set a bright-line rule to establish a date when the clump of fertilised cells is "alive" for the purposes of the law. A seven- or fourteen-day approach, like the one used in the United Kingdom, is equally good starting points for regulation. South Africa follows the 14-day limit, as stipulated in section 57(4) of the National Health Act. However, the regulation of research is subject to the unpublished regulations and is also placed in the regulator powers of the Minister.

3 5 3 Consent as a requisite in medical research and experimentation

3 5 3 1 Introductory remarks

Section 12(2)(c) of the Constitution explicitly states that no one may be subjected to medical or scientific experimentation without their informed consent. Van Oosten points out that the word "their" in section 12(2)(c) makes it patently clear that the only person who is capable of giving consent to medical research is the research subject and that proxy consent to medical research is out of the question. In this respect, section 12(2)(c) is, according to him, clearly out of step with current local and international medical research ethics.[482] If this statement of Van Oosten is taken to its logical consequences, it would imply that all medical research would be covered by section 12(2)(c), and it would therefore mean that all medical research would need the informed consent of the research subject himself.[483] Would the fact that research is not permitted without the prior informed consent of the subject therefore mean that it is unacceptable to carry out research on a human embryo, which by its very nature cannot give consent? Fetuses become available for research either as a result of spontaneous miscarriage or therapeutic abortion. It is clear that only the mother can give any necessary consent to research, and

[482] Van Oosten, FFW (2000) "The law and ethics of information and consent in medical research" *THRHR* 63(1):5 *at* 9.

[483] However, Van Oosten submits that therapeutic research could in some instances be allowed without the informed consent of the research subject. Without subjecting the Mental Health Care Act, 2002 (Act 17 of 2002) (hereafter referred to as the Mental Health Care Act) to constitutional scrutiny in terms of section 36, it is concluded that therapeutic research seems to be included under the notion of "medical treatment or operation on" mentally ill patients, for which proxy consent can be given. Strauss is essentially of the same view. For a discussion of the statutory provisions pertaining to proxy consent and embryo research, see chapter 4. See also Van Wyk (2001) *THRHR* 3 *at* 4; Van Oosten (2000) *THRHR* 5 *at* 17.

her attitude and that of her physicians may be different in the two cases. The question remains the same: When and to what extent can the benefits that accrue to society for medical and scientific research outweigh considerations of individual dignity and autonomy?[484] Before these issues are addressed in the next chapter, it is necessary to explain what informed consent, in context of medical law, entails.

3 5 3 2 The doctrine of informed consent

The point about the nature of medical research also carries with it a lesson as to the meaning of informed consent. The discussion below on the doctrine of informed consent is to provide background on exactly what "informed consent", as stated in section 12(2)(c) of the Constitution, means. This background information serves as the basis for the interpretation of the statutory provisions pertaining to this doctrine.

Pursuant to or apart from statute, the doctrine of informed consent generally requires a physician or other health care provider to furnish an individual with information sufficient to enable him or her to give intelligent, informed consent to a proposed medical treatment or the performance of a particular medical procedure. Such doctrine takes full account of the probability that, unlike a physician, a patient is untrained in medical science, and therefore completely depends on and trusts in the skill of his physician, for the information on which he makes his decision. Due to the fiduciary relationship between a physician and patient, the scope of the disclosure required can be expanded by a patient's instructions to the physician. In addition, if a physician knows or should know of a patient's unique concerns or lack of familiarity with medical procedures, such knowledge may also expand the scope of the required disclosure.[485]

3 5 3 3 Consent to treatment

There is ample authority for the statement that the patient's consent or the consent of a person acting on his/her behalf to medical interventions is essential to establish a proper doctor-patient relationship. Failure by a medical practitioner to obtain a patient's

[484] Currie & De Waal (2005) 311.
[485] Claassen & Verschoor (1992) 57-60.

informed consent may, notwithstanding the absence of negligence in administering the treatment in question and irrespective of whether or not such treatment eventually proves to have been beneficial to the patient, result in legal liability. The concept of consent in a medical context can be described as the moral, ethical and legal expression of the human right to respect for autonomy and self-determination.[486]

3 5 4 Consent as a requisite for medical interventions

For medical interventions consent means a voluntary decision made by a competent person on the basis of adequate information.[487] The leading case on compliance with the consent requisite is *Stoffberg v Elliott*,[488] where in an action for damages for assault, Watermeyer J instructed the jury as follows:

> In the eyes of the law, every person has certain absolute rights which the law protects. They are not dependent upon a statute or upon a contract, but they are rights to be respected, and one of those rights is the right of absolute security of the person. Nobody can interfere in any way with the person of another, except in certain circumstances … Any bodily interference with or restraint of a man's person which is not justified in law, or excused in law, or consented to, is a wrong, and for that wrong the person whose body has been interfered with has a right to claim such damages as he can prove he has suffered owing to that interference. A man, by entering a hospital, does not submit himself to such surgical treatment as the doctors in attendance upon him may think necessary … By going into hospital, he does not waive or give up his right of absolute security of the person, he cannot be treated in hospital as a mere specimen, or as an inanimate object which can be used for the purposes of vivisection; he remains a human being, and he retains his rights of control and disposal of his body; he still has the right to say what operation he will submit to, and unless his consent to an operation is expressly obtained, any operation performed upon him without his consent is an unlawful interference with his right of security and control of his own body, and is a wrong entitling him to damages if he suffers any.[489]

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[486] The term "informed consent" has been held in *Sidaway v Bethlem Royal Hospital* in England to be meaningless or at least inapplicable. At the same time, the term is used by courts to uphold the ethical principle of self-determination, which underlies the legal principle of informed consent to medical treatment. Van Oosten, FFW (1989) *The Doctrine of informed consent in medical law* (Thesis – LLD) University of South Africa (Unpublished) 31. See also *Sidaway v Board of Governors of the Bethlem Royal Hospital and the Maudsley Hospital* 1984 QB 493 (CA), 1984 1 ALL ER 1018, 1985 AC 871 (HL), 1985 1 ALL ER 643. See in general Earle, M (1995) "Informed consent – Is there room for the reasonable patient?" *SALJ* 112(4):629-642.

[487] Earle (1995) *SALJ* 629.

[488] *Stoffberg v Elliot* 1923 CPD 148.

[489] In *Stoffberg v Elliott* fn 488 *supra*, the patient had contracted cancer of the penis. He was operated on in hospital. After the operation he discovered that his penis had been amputated. See Van Oosten (1989) 31-53, for a discussion of the "doctrine informed consent". Failure to obtain the required consent was also the basis for the decision in another leading case, namely *Esterhuizen v Administrator Transvaal*. The patient and her father had consulted a doctor about a small nodule, which had caused her some

3 5 4 1 Duty of disclosure

Doctors and patients enjoy a fiduciary relationship where mutual trust and confidence are essential. Out of this relationship arises the physician's obligation to obtain the patient's informed consent to medical treatment. However, for a patient's consent to be informed, it must be given after the doctor offers a fair and reasonable explanation of the contemplated treatment or procedure.

This duty of disclosure came up for decision in the case of *Lymbery v Jefferies*.[490] The patient suffered from fibroses of the uterus. The doctor advised X-ray treatment. The treatment caused the patient to sustain severe burns, which resulted in a great deal of pain and discomfort. The patient contended that the doctor had been negligent in –

(a) failing to warn her that her ovaries would be destroyed and, as a result of that, she would be sterile; and

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discomfort. The doctor treated the injury and excised the nodule, which he submitted for analysis. It was identified as a manifestation of Kaposi's sarcoma. The doctor advised the patient's mother to take her to hospital for X-ray treatment. Both parents agreed that the patient should be subjected to the recommended treatment. Superficial X-ray treatment was administered and the patient's wound healed completely. Three months later, fresh nodules on both her feet and right hand appeared. She was again subjected to superficial X-ray treatment at the same institution with the same result. Four years later more nodules appeared on the patient's body. This time another doctor took charge of the patient. He concluded that the patient's disease was progressing and estimated her life expectancy at one year. For this reason he decided to administer X-ray treatment of a radical nature, knowing that the patient would suffer severe irradiation of the tissues in the treated areas, and would possibly sustain ulceration of these tissues, become disfigured or deformed in the sense that permanent harm would be done to her growing bone ends in the treated areas, causing a shortening of the limbs and cosmetic changes, and that the treated limbs would possibly have to be amputated.. The doctor did not obtain the mother's consent to the treatment, despite there being ample time and opportunity to do so. As a result of the treatment, both the patient's legs and her right hand had to be amputated. She was also faced with the prospect of losing her left hand. In an action for damages for assault, the court held that the degree of urgency did not justify the radical X-ray treatment without consent. Bekker J rejected the contentions advanced on behalf of the doctor: The fact that the patient was brought to hospital, at the request of her mother, constituted proof of lawful consent to the ultimate radical treatment on the basis that the hospital should do what is best for the patient in order to preserve her life, regardless of the consequences; and that the hospital authorities were entitled to assume implied consent in view of the fact that the patient had on previous occasions been treated for the same condition. Bekker J decided that the first contention could not be supported because the last X-ray treatment was different in form and substance and more dangerous than the previous. The first contention could also not be upheld because, in the absence of knowledge and appreciation on the patient's part of the increased risks attached to the ultimate radical treatment, there could be no question of the necessary consent to subject her to them. See *Esterhuizen v Administrator Transvaal* 1957 (3) SA 710 (T).

[490] *Lymbery v Jefferies* 1925 AD 236. See also Van Oosten (1989) 39.

(b) failing to warn her that the treatment was dangerous and might cause pain and suffering.

With reference to the first contention, Wessels JA reasoned that since the doctor had told the patient that she would not see her menstrual periods again, she must have understood this to mean that she would not be capable of bearing children after the X-ray treatment. With reference to the second contention, the learned judge accepted that it may well have been the duty of a surgeon, before operating, to inform the patient that the operation was dangerous and may result in death, or cause great pain, and to have obtained the patient's consent to such operation. However, no danger was foreseen in the treatment ordered by the doctor and burns were rare in procedures like these. Therefore, the court held that a duty to disclose this information could not be imposed on the doctor.[491]

Although the doctor's duty to disclose has been part of South African law for a long time, the pertinent recognition and acceptance recently of the so called "doctrine of informed consent" by the landmark decision in *Castell v De Greef*[492] is a new development that is likely to make a considerable impact on the doctor-patient relationship in general and particularly on doctor-patient communication in South Africa. The facts of the case can be summarised as follows: On 7 August 1989, the plaintiff underwent a surgical operation known as subcutaneous mastectomy. The defendant, a plastic surgeon, performed the operation. The plaintiff had a family history of breast cancer. In 1989 further lumps were diagnosed. In view of her family history, her gynaecologist recommended a mastectomy as a prophylaxis and referred her to the defendant, who saw her in June 1989. It was common cause that on this occasion the plaintiff and her husband discussed the operation with the defendant at some length. What was proposed was a surgical procedure involving the removal of as much breast tissue as possible with the

[491] In *Dube v Administrator Transvaal*, the patient contracted Volkmann's ischemia after having been treated for a fractured arm that had been set too tightly in plaster. The hospital was held liable for damages based on negligence in not discharging its duty to inform. There was no contributory negligence on the part of the patient, since his failure to return to the hospital was attributable to the hospital's failure to warn the patient clearly and unambiguously to return immediately once any abnormal symptom became manifest. See *Dube v Administrator Transvaal* 1963 (4) SA 260 (W). According to the decision in *Rompel v Botha*, there is at least a duty on medical practitioners to inform their patients of the serious risks they run. See *Rompel v Botha* 1953 (T), as quoted in *Esterhuizen v Administrator Transvaal* fn 489 *supra*.

[492] *Castell v De Greef* 1994 (4) SA 408 (K).

simultaneous reconstruction of the plaintiff's breast using silicone implants. The plaintiff decided to go ahead with the operation.[493]

However, as a result of the operation a discolouration of the plaintiff's areolae, necrosis of the tissues and an offensive-smelling discharge developed. Furthermore, the plaintiff contracted a *Staphylococcus Aureus* infection, suffered considerable pain, embarrassment and psychological trauma, and had to undergo several further surgical procedures to repair the damage.[494]

The plaintiff asserted that the defendant had had a duty to warn her of the material risks and complications attached to the procedure, and to inform her of any specific alternative procedures that might minimise such risks or complications. In breach of such duty, the plaintiff claimed, the defendant had failed to advise her that –

(a) a transposition of her areolae, which increased the risk of necrosis developing post-operatively, was intended;
(b) the transposition of the areolae was not essential, that it was done for cosmetic reasons, and that it was the plaintiff's choice whether or not she wanted it done;
(c) there was an alternative surgical procedure involving less risk of necrosis and/or infection;
(d) the intended operation had a complication rate as high as 50%; and
(e) it is virtually impossible to avert or curtail necrosis once it arises post-operatively.[495]

Many of the grounds of negligence were subsequently abandoned or not persisted in on appeal. The issue of the defendant's negligence was limited to the following three grounds:

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[493] For a discussion of *Castell v De Greef* see Dreyer, L (1995) "Redelike dokter versus redelike pasiënt: Castell v De Greef 1994 4 SA 408 (K)" *THRHR* 58(3):532-539. See also Earle (1995) *SALJ* 629; Van den Heever (1995) *DR* 53; Van Oosten, FFW (1995) "Castell v De Greef and the doctrine of informed consent: Medical paternalism ousted in favour of patient autonomy" *DJ* 28(1):164-179.
[494] *Castell v De Greef* fn 492 *supra*.
[495] *Ibid*.

(a) The defendant's failure to warn the plaintiff of the material risks and complications of the operation;[496]

(b) The defendant's failure to prevent the onset of or limit the extent of necrosis in the plaintiff's breast; and

(c) The defendant's failure to adequately or timeously treat the post-operative sepsis that had allegedly developed in the plaintiff's breasts.[497]

After a detailed examination of local and foreign case law and legal opinion, Ackermann J, Friedman JP, and Farlam J, concurring, gave a careful judgment on the following terms: Firstly, the learned judges rejected the notion that the reasonable doctor test of disclosure is well-established in our law, as well as the notion that the reasonable doctor does not leave the determination of a legal duty to the judgment of doctors. There is not only a justification, but indeed a necessity for introducing the patient-orientated doctrine of informed consent into South African law: "It is clearly for the patient to decide whether he or she wishes to undergo the operation, in the exercise of the patient's fundamental right to self-determination."[498]

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[496] See in general *Richter v Estate Hammann* 1976 (3) SA 226 (C). The patient, a woman, had fallen on the sharp edge of a chair, as a result of which her coccyx was injured. The doctor, a neuro-surgeon, gave her an injection to affect a phenol block of the lower sacral nerves. Her pain was relieved, but the injection had unfortunate consequences for the patient namely: (a) Loss of control of the bladder and bowel; (b) Loss of sexual feeling; and (c) Loss of power in the right leg and foot. The plaintiff's action for damages was based on negligence on the doctor's part in that he failed to inform the patient of the dangers associated with a phenol block. Watermeyer J adopted a doctor-based, professional standard approach and made the following remarks: "It may well be that in certain circumstances a doctor is negligent if he fails to warn a patient, and if that is so, it seems to me in principle that his conduct should be tested by the standard of the reasonable doctor faced with the particular problem. In reaching a conclusion a court should be guided by medical opinion as to what a reasonable doctor, having regard to all the circumstances of the particular case, should or should not do. The court must, of course, make up its own mind, but it will be assisted in doing so by medical evidence." The court held that even if the patient indicated she would have refused to undergo the treatment had she been warned of the incidence of risk, the possibility of such complications was too remote to establish negligence on the doctor's part for his failure to warn her of such risks.

[497] *Castell v De Greef* fn 492 *supra*.

[498] In *Phillips v De Klerk*, the court confirmed the principle of patient self-determination by recognising the patient's right to refuse a blood transfusion. The case is of special significance in relation to the refusal of medical treatment by a patient. According to Strauss, if there is a conflict between the desire of a person to go his own way, to forego medical treatment and to expire in his own manner on the one hand; and the desire of the doctor to cure him of his disease or to secure his health on the other, the former should be accorded preference. He submits that our law allows a person to refuse medical treatment or a particular form of treatment, even if that may result in the patient's health deteriorating or in his death. See *Phillips v De Klerk* fn 405 *supra*. As far as married couples are concerned, the general rule is that each spouse is fully entitled to consent independently to any medical treatment. In *Palmer v*

Secondly, the learned judges took the view that the issue of the doctor's duty of disclosure is "(i)n South African law … treated not as one of negligence, arising from the breach of a duty of care, but as one of consent to the injury involved and the assumption of an unintended risk". In the South African context, the doctor's duty to disclose a material risk must be seen in the contractual setting of an unimpeachable consent to the operation and its *sequelae*.[499]

Thirdly, the learned judges concluded that for the patient's consent to constitute a justification that excludes the wrongfulness of medical treatment and its consequences, the doctor is obliged to warn the patient of the material risks[500] inherent in the proposed treatment. A risk is material if in the particular circumstances –

(a) a reasonable person in the patient's position, if warned of the risk, would be likely to attach significance to it; or
(b) the doctor is or should reasonably be aware that the particular patient, if warned of the risk, would be likely to attach significance to it.

This accords the fundamental right of individual autonomy and self-determination, and sets its face against medical paternalism. However, the duty to warn is subject to the therapeutic privilege.[501] A practitioner may withhold information regarding the diagnosis or the potential effect of treatment from his patient where, after thorough consideration,

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Palmer the judge ruled that the personal guardianship of a husband over his wife does not give the husband the right to interfere with the wife's personal freedom to the extent that he can force her to undergo a medical examination against her will. See *Palmer v Palmer* 1955 (3) SA 56(0).

499 See *Behrmann v Klugman* fn 327 *supra*. For a discussion of the case see Strauss *(*1991) 176-177. See also *Stoffberg v Elliot* fn 488 *supra*; *Esterhuizen v Administrator Transvaal* fn 489 *supra*; *Oldwage v Louwrens* (2004) 1 ALL SA 532 (C); *Louwrens v Oldwage* (2005) JOL 15618 (SCA); *Richter v Estate Hammann* fn 496 *supra*; *Broude v McIntosh* 1998 (3) SA 60 (SCA).

500 Under certain circumstances physicians are exempted from their duty to warn and disclose, and the concomitant requirement to obtain a patient's informed consent: (1) In the event of an emergency. (2) Where a patient is brought to hospital in a critical, unconscious condition it is not necessary to try and obtain his permission before treating him. The physician will be able to rely on the doctrine of *negotiorum gestio* to justify his conduct. (3) In cases where the patient indicates that he does not wish to be informed of the nature of the proposed treatment, the risks involved or the probable consequences. See Claassen & Verschoor (1992) 69.

501 Van den Heever (1995) *DR* 53 *at* 56; Van Oosten (1995) *DJ* 164 *at* 173-178.

he is of the opinion that the disclosure of such information will be detrimental to the patient's recovery.[502]

Finally, it is necessary for the use of expert evidence in determining what risks are inherent in or the result of particular treatment.[503]

On the facts, the learned judge found that the evidence in respect of the plaintiff's claims was to the effect that –

(a) the plaintiff had been aware of the intended transposition of her areolae and the risks involved in the procedure;
(b) the particular type of subcutaneous mastectomy and prosthesis insertion involved a materially higher risk than the two-stage procedure alluded to, and the defendant had explained the two-stage procedure to the plaintiff, who opted for the procedure practised by the defendant; and
(c) the plaintiff knew that the damage caused by the operation was not reversible without reconstructive surgery, that it was quite unnecessary for the defendant to explain to the plaintiff the intermediate pathological process, and that an explanation would have influenced the plaintiff's decision.[504]

In conclusion, the decision of *Castell v De Greef* is of importance for both the medical and legal professions because –

(a) medical paternalism is ousted in favour of patient autonomy;
(b) the court rightly proceeds from the assumption that the decision to undergo or refuse a medical intervention is, in the final analysis, that of the patient and not that of the doctor;[505]

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[502] Claassen & Verschoor (1992) 78.
[503] *Castell v De Greef* fn 492 *supra*. See also *Michael v Linksfield Park Clinic (Pty) Ltd* 2001 3 SA 1188 (SCA); Carstens, PA (2002) "Setting the boundaries for expert evidence in support or defence of medical negligence" *THRHR* 65(3):430-436.
[504] *Castell v De Greef* fn 492 *supra*.
[505] See also *Phillips v De Klerk* fn 405 *supra*.

(c) the question now is whether or not the reasonable patient would have regarded the risk or danger as significant, or whether or not the doctor was or could have been aware that the individual patient would regard the risk or danger as significant;[506]

(d) although the court gave recognition to the so-called therapeutic privilege,[507] its approach to the defence is to some extent ambivalent (On the one hand, the court appears to accept that the therapeutic privilege sets a limit to the doctor's duty of disclosure, while on the other it seems to associate the defence with medical paternalism. The appropriate legal defence in this regard would then be necessity as a justification.);

(e) the court prefers to place the doctor's duty of disclosure and its concomitant – that the patient's informed consent – within the framework of the wrongfulness element rather than the fault element;[508] and

(f) the court remarks that the doctor is also under a contractual obligation to furnish the patient with information.

Castell v De Greef provided a basis from which further developments within the context of informed consent may follow. With reference to this case, the doctrine of informed consent was recently applied in the case of *Oldwage v Louwrens*.[509] The plaintiff experienced back pain and was referred to the defendant for an examination. After examining the plaintiff, the defendant concluded that the plaintiff had a vascular condition. The plaintiff underwent an electrocardiogram and an angiogram, which confirmed the vascular problem, and the plaintiff was informed that an operation was necessary to relieve his pain. On discharge, the plaintiff was still in pain. A few days later, the plaintiff went for a walk and experienced cramps and pains in his leg. The plaintiff complained of this to the defendant. He continued to experience pain in his leg

506 Van Oosten (1995) *DJ* 164 *at* 176, 177.

507 For a discussion of the therapeutic privilege see Welz, D (1999) "The boundaries of medical therapeutic privilege" *SALJ* 116(2):299-322.

508 The wrongfulness element, namely *volenti non fit injuria*, or voluntary assumption, is where the risk of harm is used as a justification. The fault element refers to intention or negligence in delict. See Dreyer (1995) *THRHR* 532 *at* 534.

509 *Oldwage v Louwrens* fn 499 *supra*. For a discussion of the case see Wilson, M (2006) "When is a risk of medical treatment material?" *DR* 451:22-25.

for the following week and consulted another specialist, Dr Kieck. Dr Kieck operated on the plaintiff's back and performed a right L4 laminotomy. The plaintiff's pain was immediately gone after the lumber operation and he was discharged from hospital four days later. The issues in this case, in the final analysis, that will call for determination are whether the defendant acted in breach of his obligation arising from the agreement entered into between the plaintiff and the defendant; whether the defendant misrepresented to the plaintiff that the vascular procedure performed would relieve the plaintiff of the severe pain; and whether, in that event, the defendant's conduct constitutes assault rendering him liable for whatever damages the plaintiff might prove. The court held that a medical practitioner is bound to employ reasonable skill and care and is liable for the consequences if he does not. The defendant had failed to correctly diagnose the source of the plaintiff's pain. Had the defendant not so failed, he would in all probability have referred the plaintiff to a neurosurgeon, and if that had been done, the neurological problem would have been addressed first, alleviating the need for the procedure performed by the defendant. The standard adopted by the defendant had not been the reasonable standard expected from a man of his calling. With reference to *Castell v De Greef,* the plaintiff had not been properly counselled before the operation, other options had not been properly discussed with him, and he had not been advised of the material risks associated with the operation. It was concluded that the plaintiff had not given an informed consent to the operation. The defendant's conduct had amounted to an assault upon the plaintiff.

On 21 September 2005, the Supreme Court of Appeal delivered judgment in the matter of *Louwrens v Oldwage*[510] Although the court referred to *Castell v de Greef* and approved the medical opinion/reasonable doctor test as set out in *Richter v Estate Hamman,*[511] it appears from the judgment that the court did not apply either of the tests. The court found that a remote risk need not have been disclosed. It found support for the decision in the *Richter* case. However, in its judgment, the court did not consider exactly what was meant by "remote" in the circumstances of the *Richter* case. The court held that the risk of claudication occurring was remote and need not be disclosed. The court further held

[510] *Louwrens v Oldwage* fn 499 *supra*
[511] *Richter v Estate Hammann* fn 496 *supra*

that the harm the plaintiff had suffered had not in any event been caused by the risk and the harm had not been caused by the defendant. According to Wilson, the judgment was disappointing. While the court did not apply the subjective patient-centred approach, it did not overrule it. There is, therefore, as yet no binding judgment by the Supreme Court of Appeal as to what the correct approach to determining the boundaries of a material risk to medical treatment may be. In the absence of such a judgment, courts are still free to follow the patient-centred approach, which was extensively and cogently argued in *Castell v de Greef*.[512]

3 5 4 2 Scope of information

There are some indications in a number of court decisions on the scope of information required from medical practitioners. In *Rompel v Botha*, Neser J made the following statement:

> There is no doubt that a surgeon who intends operating on a patient must obtain the consent of the patient … I have no doubt that a patient should be informed of the serious risks he does run. If such dangers are not pointed out to him then, in my opinion, the consent to the treatment is not in reality consent – it is consent without knowledge of the possible injuries. On the evidence defendant did not notify plaintiff of the possible dangers, and even if plaintiff did consent to shock treatment he consented without knowledge of injuries which might be caused to him. I find accordingly that plaintiff did not consent to the shock treatment.[513]

It is clear from the above that lawful medical interventions require the informed consent of the patient, apart from the specific exceptions mentioned above. Therefore, a medical intervention without the required informed consent amounts to a violation of a person's physical integrity, and may amount to criminal assault, civil or criminal *injuria*, or result in an action for damages based on negligence.

[512] Wilson (2006) *DR* 22 *at* 24, 25.
[513] *Rompel v Botha* 1953 (T) unreported, as quoted in Van Oosten (1989) 47.

3 6 THE CONSTITUTIONAL FRAMEWORK PERTAINING TO REPRODUCTIVE CLONING[514]

Reproductive cloning is discussed separately because this technique does not involve the destruction of human embryos, and the question of whether the fetus is a constitutional bearer of "the right to life" is therefore irrelevant in this context. It must be noted that reproduction is neither synonymous with, nor dependent on, sexual intercourse. Currently, thousands of couples that experience fertility problems are making use of methods of assisted, non-sexual reproduction. It is often argued that reproductive cloning is simply another form of infertility treatment and that people have a right to reproduce themselves and, by extension, to secure this right by whatever means is technically feasible.[515] Therefore, Jordaan submits that a prospective parent has a *prima facie* right to decide to use cloning as his means of reproduction and a prospective parent can, for the purposes of reproduction, choose to use an equal combination of a random assortment of his own genetic material, and that of a chosen and consenting partner of the opposite sex. A prospective parent should, *prima facie*, also be permitted to choose to use only his or her own exact assortment of genetic material, or that of a consenting donor, for reproduction.[516] If reproductive cloning were to be allowed, it is important to note that the right can still be limited if sufficient cause is shown in accordance with the limitation clause of the Bill of Rights.[517] But what is society's attitude towards reproductive cloning?[518]

It is often claimed that reproductive cloning is contrary to human dignity.[519] Another argument is that it could be used for highly undesirable and immoral purposes. It is

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[514] Section 57(6)(a) of the National Health Act prohibits reproductive cloning, and the constitutionality thereof has not been challenged. For a discussion of the National Health Act see chapter 4.

[515] The United Kingdom Parliament: House of Lords (2002) www.parliament.the-stationery-office.co.uk/pa/ Id200102/dselect/Idstem/83/8301.htm-14k.

[516] Jordaan (2002) *SALJ* 119(2):294.

[517] Section 36 of the Constitution.

[518] The Universal Declaration on Human Rights and the Council of Europe have declared, independently, that human reproductive cloning is unethical because it violates "human dignity". The same is true for the advisory commission on human cloning that the European Commission has established. Pretty much every Christian philosopher in Europe and the USA, as well as many secular philosophers, have warned of dire consequences and even more grossly violated dignity should research on reproductive cloning go ahead.

[519] For a discussion of human dignity see paragraph 3.3.

contrary to the principle of equality of human beings, as it permits a racist selection of the human race and it requires experimentation on humans.[520]

One standard argument against reproductive human cloning has its historical roots in the ethical debate over the use of in vitro fertilisation. Various representatives of religious organisations have argue against the use of in vitro fertilisation on the basis that a person who comes into being as a result of in vitro fertilisation would likely be discriminated against by the wider society. It is, however, clear today that these concerns were unwarranted. In vitro fertilisation is a standard procedure in most developed countries, and children born as a result of such fertilisation are as happy as any other. This has not prevented religiously motivated people however to once again raise the spectre of discrimination against human clones as a weapon against human reproductive cloning research, and once it is technically possible, human cloning.[521]

A more commonly expressed view is that the underlying objection to reproductive cloning is concerns about a person's genetic identity. This can however not be an absolute right, since identical twins share a genetic identity and no one suggests that they have less of a personal identity or a lesser worth.[522] Also, reproductive cloning and animal experiments are currently still in their infancy. Therefore, safety considerations raise an important ethical objection. In accordance with the bio-ethical principle of beneficence, human reproductive cloning should not be attempted unless it is certain that the risk of birth defects associated with it would not be greater than that associated with naturally conceived children. Jordaan submits that while all the objections so far relate to some

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[520] For a discussion of the equality clause see paragraph 3.4.2.13.

[521] According to Schüklenk and Ashcroft, bioethicists were too quick to create "nightmare visions of baby farming, of clones cannibalised for spare parts". They argue that slippery-slope rhetoric is seemingly as popular today as it was during the religiously motivated campaigns against in vitro fertilisation. See Schüklenk & Ashcroft (2000) *Monash Bio Rev* 34 *at* 40.

[522] There is, however, an obvious distinction between identical twins and a cloned child, in that the twins' genetic identity is given, whereas that of the cloned child would be chosen for it by the person whose cell was cloned. Hottois remarks as follows on this issue: "Above all, biological identity doesn't exhaust nor even constitute the identity of an individual as far as he is a human being. The identity of a person is psychological, social cultural. Being much more separate than monozygotic twins, clones should have enough room to develop their own personal identity." See Jordaan (2002) *SALJ* 119(2):294 *at* 299. See also The United Kingdom Parliament: House of Lords (2002) www.parliament.the-stationery-office.co.uk/pa/Id200102/dselect/Idstem/83/8301.htm-14k.

permanent aspect of human reproductive cloning, the safety objection is not necessarily permanent, because research could prove reproductive cloning techniques to be safe and feasible for human use.[523]

In conclusion, Schüklenk and Ashcroft argue that there are no serious harms attached to reproductive human cloning. To their knowledge, not one persuasive argument has been presented by opponents of reproductive cloning that would force us to acknowledge that there would be victims of research, or if this research succeeds, that there would be victims of reproductive cloning. They also submit that the benefits of this technology are much easier to grasp. There will be infertile people, heterosexual and homosexual, who would be likely to use such technology if it were available. There is also general condemnation of reproductive cloning undertaken to reproduce a dying child, or to provide subjects for fetal experiments.[524] Given that there are no overwhelming inherent reasons against providing people with access to such technology, we should at the very least allow research on reproductive human cloning to go ahead.[525]

In contrast to the arguments of Schüklenk and Ashcroft, Blackbeard points out that although section 12(2)(a) of the Constitution provides that everyone has the right to make decisions regarding reproduction, this right refers to the traditional forms of reproduction and not to cloning.[526] To date, South African law effectively prohibits reproductive cloning and therefore, until constitutionally challenged, reproductive cloning is prohibited.[527]

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[523] Jordaan (2002) *SALJ* 294 *at* 302.
[524] Slabbert (2003) *JLM* 514 *at* 520.
[525] Schüklenk & Ashcroft (2000) *Monash Bio Rev* 34 *at* 44, 45.
[526] Blackbeard (2002) *DJ* 318 *at* 326.
[527] Section 57(1) of the National Health Act. For a discussion of the Act see chapter 4.

3 7 ENFORCING SOCIO-ECONOMIC RIGHTS[528]

3 7 1 Introduction

A primary characteristic of the Constitution is that it provides extensive recognition and entrenchment of socio-economic rights. The Bill of Rights itself makes no distinction between first, second and third generational rights. Socio-economic rights are therefore accorded the same status as political and civil rights. According to Van Wyk, the content of third generational rights cannot be concretised and are not really enforceable.[529] However, in *Ex parte Chairperson of the Constitutional Assembly: In Re: Certification of the Constitution of the Republic of South Africa*, it was confirmed that socio-economic rights, although not universally accepted, are "at least to some extent justiciable".[530] This case stressed the concept that the rights entrenched in the Bill of Rights are interdependent and indivisible.[531]

The Constitution places both negative and positive duties on the state in relation to socio-economic rights. Section 7(2) of the Constitution requires the state to "respect, promote, and fulfil" the rights contained in the Bill of Rights. This affords the beneficiary a right to require the state to take both negative and positive action. However, the exact nature and scope of this obligation is dependent on the wording of the right and its relationship with other fundamental rights.[532] "Respect" in this context requires negative action on behalf of the state, in that it may not unjustly interfere with an individuals' fundamental rights. In the context of reproductive health, this would require the state to desist from impairing

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See in general Newman, DG (2003) "Institutional monitoring of social and economic rights: A South African case study and a new research agenda" *SAJHR* 19(2):189-216; Bollyky, TJ (2002) "R if C > P + B: A paradigm for judicial remedies of socio-economic rights violations" *SAJHR* 18(2):161-200; Bilchitz, D (2003) "Towards a reasonable approach to the minimum core: Laying the foundations for future socio-economic rights jurisprudence" *SAJHR* 19(1):1-26.

529 Van Wyk, J (1999) *Planning Law in South Africa* 34.

530 *Ex parte Chairperson of the Constitutional Assembly: In Re: Certification of the Constitution of the Republic of South Africa* 1996 (4) SA 744 (CC).

531 The Constitutional Court in *S v Mhlungu* emphasised that constitutional rights must be understood and determined against the background of past human rights abuses and the legacy of inequality and poverty. See *S v Mhlungu* 1995 (3) SA 867 (CC).

532 Fundamental rights are not absolute: A specific right may contain an internal limitation, confining its scope and application. Section 7(3) makes reference to an external limitation of constitutional rights by providing that the Bill of Rights are subject to the limitation clause contained in section 36, in that the limitation must be justifiable in an open and democratic society based on human dignity, equality and freedom.

the realisation of a woman's right to reproductive health care, which would include the right to terminate her pregnancy. The duty to "promote" in essence means that the state must take positive steps to guarantee that relevant executive and legislative frameworks are in place to ensure protection of its citizens, in particular the vulnerable groups in society.[533] The term "fulfil" implies that the state must provide for the realisation of the right by directly providing in the need, for example by making necessary resources available.

However, in *Soobramoney v The Minister of Health*, the Constitutional Court confirmed that socio-economic rights may nevertheless be qualified by the availability of resources and that there is no unqualified obligation imposed on the state to meet existing needs.[534] The case served to entrench a non-interventionist approach by the courts, provided that the measures adopted by the state are reasonable in both their conception and implementation. The case of *Government of the Republic of South Africa and Others v Grootboom and Others*[535] stressed that a balance must be struck between the objectives set out in the Constitution and the means available to achieve these goals. These measures must seek to attain the aims expeditiously and effectively, but the availability of resources may play a significant role in determining what may be construed as reasonable. The court was of the opinion that the yardstick of reasonableness is to be understood within the context of the Bill of Rights. *Grootboom* drew attention to the fact that due regard must be given to both the extent and impact of the historical disadvantage and must ensure that the basic necessities of life are made available, in particular, to those groups that are the most vulnerable in society.

3 7 2 Basic core obligations and essential services

The state, in context of the International Covenant on Economic, Social and Cultural Rights,[536] has "a minimum core obligation to ensure the satisfaction of, at the very least,

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533 *Government of the Republic of South Africa and Others v Grootboom and Others* fn 377 *supra*.
534 *Soobramoney v Minister of Health, KwaZulu-Natal* 1997 12 BCLR 1696 (CC).
535 *Government of the Republic of South Africa and Others v Grootboom and Others* fn 377 *supra*. See also Liebenberg, S (2001) "The right to social assistance: The implications of Grootboom for policy reform in South Africa" *SAJHR* 17(2):232-257.
536 The International Covenant on Economic, Social and Cultural Rights, section 41(6)(d).

minimum essential levels" of these rights.[537] The state only discharges a basic core obligation, provided that it is able to attribute its failure to meet the minimum level of delivery to a lack of available resources. The state has to demonstrate that every effort has been made to meet this minimum level.

3 7 3 Section 27[538] of the Constitution: Access to health care services

Health care is generally considered to be a basic need. Section 27(1)(a) of the Constitution provides specifically that everyone has the right to have access to health care, including reproductive health care. This right is, however, limited internally by section 27(2), which says that the state must take reasonable and legislative and other measures, within its available resources, to achieve the progressive realisation of these rights.[539] It is important to note that the Constitution does not guarantee a right to health, but only the qualified right of access to health care services. A further question that is of importance in understanding the right of access to health care services is that of the nature and level of care to which people are entitled.[540]

In the case of *Soobramoney v Minister of Health Kwazulu-Natal*, the Constitutional Court had to interpret the scope and content of the right of access to health care services guaranteed under section 27(1)(b) and 27(3). Mr Soobramoney, the appellant, was a 41-year old diabetic suffering from heart disease, vascular disease and irreversible chronic renal failure. His life could be prolonged by means of regular renal dialysis.[541] He sought dialysis treatment from the Addington State Hospital in Durban. He was however not admitted to the dialysis programme of the hospital. Because the hospital did not have

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[537] Although South Africa is not a party to the International Covenant on Economic, Social and Cultural Rights, a court must consider international law in terms of section 39(2) when interpreting the Bill of Rights.

[538] Section 27 of the Constitution read as follows: "Health care, food, water, and social security. (1) Everyone has the right to have access to – (a) health care services, including reproductive health care; (b) sufficient food and water; and (c) social security, including, if they are unable to support themselves and their dependants, appropriate social assistance. (2) The state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of each of these rights. (3) No one may be refused emergency medical treatment."

[539] Section 27(1)(a) and section 27(2) of the Constitution.

[540] For a detailed and valuable discussion of this right see in general Pearmain (2004).

[541] Renal dialysis is a procedure to preserve or extend someone's life when their kidneys have stopped functioning. See *Soobramoney v Minister of Health* fn 534 *supra*.

enough resources to provide dialysis treatment for all patients suffering form chronic renal failure, its policy was to automatically admit those suffering from acute renal failure that could be treated and remedied by renal dialysis, to the renal dialysis programme. Patients suffering from irreversible chronic renal failure were not admitted automatically to the dialysis programme but according to a set of guidelines, which made the primary requirement for admission a patient's eligibility for a kidney transplant. A patient who was eligible for a transplant would be provided with dialysis treatment until an organ donor was found and a kidney transplant had been completed. According to the guidelines, patients were not eligible for kidney transplants unless free of significant vascular or cardiac disease. The appellant was therefore not eligible for a kidney transplant.

In July 1997 the appellant, relying on sections 27(3) and 11 of the Constitution, [542] made an urgent application to a local division of the High Court for an order directing the Addington Hospital to provide him with ongoing dialysis treatment and interdicting the respondent from refusing him admission to the renal unit of the hospital. The application was dismissed. The appellant appealed to the Constitutional Court.[543]

The court held that:

(a) Obligations imposed on the state under section 27 of the Constitution were dependent upon the resources available for such purposes, and the corresponding rights themselves were limited by reason of the lack of resources.[544]

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[542] For a discussion of section 11 of the Constitution see paragraph 3.4.

[543] See *Soobramoney v Minister of Health* fn 534 *supra*. See also Mubangizi, JC (2003) "The Constitutional right of access to health care services in South Africa: From renal dialysis to Nevirapine" *Obt* 24(1):203 *at* 208; Scott, C & Alston, P (2000) "AD Judicating constitutional priorities in a transnational context: A comment on Soobramoney's legacy and Grootboom's promise" *SAJHR* 16(2):206-268; Van Oosten, FFW (1999) "Financial resources and the patient's right to health care: Myth and reality" *DJ* 32(1):1 *at* 11.

[544] "The Appellant's case must be seen in the context of the needs which the health services have to meet, for if the treatment has to be provided to the appellant it would also have to be provided to all other persons similarly placed … It would also put a great strain on the existing dialysis machines which are already showing signs of wear."

(b) The words "emergency medical treatment" in section 27(3) might possibly be open to a broad construction, which would include ongoing treatment of chronic illnesses for the purpose of prolonging life. But this was not their ordinary meaning and, if this had been the purpose that section 27(3) was intended to serve, one would have expected it to be expressed in positive and specific terms.

(c) As to the argument that section 27(3) should be construed consistently with the right to life entrenched in section 11 of the Constitution and that everyone requiring life-saving treatment who was unable to pay for such treatment himself was entitled to have the treatment provided at a state hospital without charge, such a construction of section 27 would make it substantially more difficult for the state to fulfil its primary obligations under sections 27(1) and (2) to provide health care services to "everyone" within its available resources. It would also have the consequence of prioritising the treatment of terminal illnesses over other forms of medical care and would reduce the resources available to the state for purposes such as preventative health care and medical treatment for persons suffering from illnesses or bodily infirmities that are not life-threatening.

(d) The purpose of section 27(3) seems to be to ensure that treatment is given in an emergency, and is not frustrated by reason of bureaucratic requirements or other formalities.

(e) Given that the appellant suffered from chronic renal failure and that to be kept alive by dialysis he would require such treatment two to three times a week, his condition was not an emergency calling for immediate remedial treatment. Section 27(3) did therefore not apply to this situation.

(f) In context of budget constraints and cutbacks in hospital services in KwaZulu-Natal, there were many more patients suffering from chronic renal failure than there were dialysis machines to treat such patients.

(g) The appellant's case had to be seen in the context of the needs that the health services had to meet. If treatment had to be provided to the appellant, it would also have had to be provided to all other persons similarly placed. If all the people in South Africa who suffer from chronic renal failure were to be provided with

dialysis treatment, the cost of doing so would make substantial inroads into the health budget.

(h) A court would be slow to interfere with rational decisions taken in good faith by the political organs and medical authorities whose responsibility it is to deal with matters like these.

(i) The state has a constitutional duty to comply with the obligations imposed on it by section 27 of the Constitution. It was not shown in the *Soobramoney* case that the state's failure to provide renal dialysis facilities for all persons suffering from chronic renal failure constituted a breach of those obligations. Chaskalson P followed a holistic approach to the larger needs of society, and did not focus on the specific needs of particular individuals within society. [545]

Against this background it is important to discuss the *Treatment Action Campaign*[546]case. The Treatment Action Campaign, a campaign for greater access to HIV/Aids treatment, brought an action in the Pretoria High Court in an effort to compel the government to provide Nevirapine to all pregnant women with HIV or Aids as to prevent mother-to-child transmission of the disease. In a unanimous judgment, the Constitutional Court[547] ruled in favour of the respondents and their bid to speed up the provision of Nevirapine to pregnant HIV-positive women. The court concluded as follows:

> Section 27(1) of the Constitution does not give rise to a self-standing and independent positive right enforceable irrespective of the considerations mentioned in section 27(2). Sections 27(1) and 27(2) must be read together as

[545] The Constitutional Court also noted in this case that "(t)he provisions of the Bill of Rights should furthermore not be interpreted in a way which results in courts feeling themselves unduly pressurised by the fear of the gambling with the lives of claimants into ordering hospitals to furnish the most expensive and improbable procedures, thereby diverting scarce medical resources and prejudice the claims of others", as quoted in Mubangizi (2003) *Obt* 203 *at* 208. In *Government of the Republic of South Africa and Others v Grootboom and Others* fn 377 *supra*, the Constitutional Court was called upon to address the enforcement of a socio-economic right. A group of adults and children had been rendered homeless as a result of an eviction from their informal dwellings situated on private land earmarked for low-cost housing. One of the important outcomes of this case is that the Constitutional Court made it clear "that it would not prescribe to the state any particular policy option for giving effect to socio-economic rights". The duty of the court was to review a wide range of measures that it could adopt in trying to meet its obligations against the standard of reasonableness imposed by the constitutional provisions protecting socio-economic rights. See *Government of the Republic of South Africa and Others v Grootboom and Others* fn 377 *supra*. See also Liebenberg (2001) *SAJHR* 232 *at* 250.

[546] *Treatment Action Campaign v Minister of Health* 2002 (5) SA 721 (CC).

[547] *Minister of Health v Treatment Action Campaign* 2002 (5) SA 721 (CC).

> defining the scope of the positive rights that everyone has and the corresponding obligations on the state to 'respect, protect, promote, and fulfil' such rights. The rights conferred by sections 26(1) and 27(1) are to have 'access' to the services that the state is obliged to provide in terms of section 26(2) and 27(2).

This judgment clearly shows that the Constitutional Court will hold government to its constitutional duties, and that the government is also a servant of the Constitution.[548]

Because South Africa acknowledges access to health care services in the Constitution, it is submitted that these include aspects of stem cell therapies and therapeutic cloning, especially if they were the only treatments available and were recognised as appropriate for the purpose and treatment. These therapies could benefit the health and well-being of many South Africans.

3 7 4 Section 27(1)(a) of the Constitution: Reproductive health care[549]

One aspect of reproductive equality is the right to equal access to reproductive health care. Slabbert points out that as both mental and social well-being are components of health, it can be said that an unwanted pregnancy that endangers a woman's mental and social well-being constitutes a threat to her health. She further submits that women may claim the right to have access to safe abortions as a positive right to preserve their health. The right to reproductive health care also includes the right to have access to qualified health personnel who are able to perform safe abortions.[550] A lack of access to terminations of pregnancies and other health care services impact negatively on a

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[548] See Mubangizi (2003) *Obt* 203 *at* 214. With reference to *Soobramoney v Minister of Health* fn 534 *supra*, an issue that should be addressed is whether the state has a duty to fund embryonic stem cell research. This issue falls outside the scope of this dissertation. For a discussion of private and state funding see Van Oosten (1999) *DJ* 1-18. See also Davis *et al* (1997) 358; Casell (2001) *U Mich JL Ref* 547-572; Guerra, R (2005) "States take the initiative to regulate and resolve the stem cell debate" *Flo Coast L Rev* 7(1):35-57.

[549] Reproductive health is "a condition in which the reproductive process is accomplished in a state of complete mental, physical, and social well being and is not merely the absence of disease or disorders of the reproductive process. Reproductive health therefore implies that people have the ability to practice and enjoy sexual relation. It further implies that reproduction is carried to a successful outcome through child and infant survival, growth, and healthy development. It finally implies that women can go safely through pregnancy and childbirth, and that fertility regulation can be achieved without health hazards and people are safe in having sex". See Cook, R (1995) "Human rights and reproductive self-determination" *Am UL Rev* 63(3):1053 *at* 1059.

[550] Slabbert (2000) 383, 384. See also articles 10 and 12 of the Women's Convention, which protect equal access of women to reproductive health care services.

woman's ability to exercise her other human rights, for example the right to make decisions concerning reproduction.[551] Wide access to health care facilities is essential in ensuring real reproductive choice. Therefore, failure by any state-controlled clinic or hospital to provide abortions on the same scale as any other medical or surgical procedure unfairly discriminates against pregnant women.

Article 10(h) of the Women's Convention also makes provision for the following: Women have the right "to specific educational information to help to ensure the health and well being of families, including information and advice on family planning". If women do not have access to information about reproductive health, it will prevent them from exercising their right to reproductive decision-making, which includes making informed choices, and this will consequently limit the control that they have over their bodies.[552]

With reference to section 12(2)(a) of the Constitution, which allows a person to make his or her own decisions concerning reproduction, the question is whether a person would be allowed to reproduce in order to derive stem cells from the baby to treat their other children who suffers from incurable diseases. These issues would have to be argued by weighing and balancing different rights and interests. As previously discussed, section 28 of the Constitution stipulates that a child's interests are of paramount importance; while section 27 provides for access to health care services. It is submitted that this be allowed, especially if it is the only means by which the child can be cured. However, it is further submitted that as far as a prohibition on the right to reproduce in order to treat another ill child is concerned, its legitimacy would have to be argued on the basis of a justifiable limitation of rights in terms of section 36 of the Constitution if this form of reproduction falls within the scope of the right to reproduce.[553]

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[551] Section 12(2)(a) of the Constitution.

[552] See also section 32 of the Constitution, which reads: "(1) Everyone has the right of access to – (a) any information held by the state; and (b) any information that is held by another person and that is required for the exercise or protection of any rights. (2) National legislation must be enacted to give effect to this right, and may provide for reasonable measures to alleviate the administrative and financial burden on the state."

[553] See *The Queen on the application of Bruno Quintavalle on behalf of Pro-Life Alliance v Secretary of State for Health* [2001] EWHC Admin 918. See also *R (on the application of Quintavalle on behalf of*

3 8 CONCLUSION

This chapter sought to examine the constitutional principles pertaining to embryonic stem cell research and cloning. When deciding whether a couple has a right to destroy an embryo, a court should first decide whether the embryo constitutes "life". The question of whether the embryo is a bearer of constitutional rights and whether it constitutes life was raised in the *Christian Lawyers* case.[554] It was decided that the fetus is not a bearer of constitutional rights in terms of the Constitution. However, the state has a constitutional duty to respect, protect and promote both fetal and maternal life and health in terms of sections 7(1) and 7(2) of the Constitution, read together with an interpretation of the sections on human dignity and life. Both maternal and fetal life and health are important state interests, and the state must attempt to strike a balance between maternal and fetal interests in the regulation of abortion.[555]

Most commentators agree that while the embryo should be given more respect than mere property, the embryo should not be given the status of life.[556] If the embryo is not life, the couple should have a right to destroy the embryo, unless there is a state interest that would outweigh that right. Further, the privacy interest and the right to reproduce (thereby being able to decide not to have children), is a right courts protect in the context of abortion, and should logically be extended to the use of embryos for therapeutic research purposes.

It is also submitted that socio-economic rights are directly enforceable and justiciable under the new constitutional dispensation. The inclusion thereof "signals a decisive break with the idea that a Bill of Rights is only a shield which protects citizens against

Pro-Life Alliance) v Secretary of State for Health [2002] EWCA Civ 29. For a discussion of these cases see chapter 5.

554 *Christian Lawyers Association of South Africa and Others v Minister of Health and Others* fn 269 *supra*.

555 Slabbert (2000) 340, 341.

556 Kasimba, P (1988) "Regulating IVF human embryo experimentation: The search for a legal basis" *Austl LJ* 62(3):128 *at* 129. See also *Webster v Reproductive Health Services* fn 225 *supra*; Jonsen, AR (1986) "Transition from fetus to infant: A problem for law and ethics: Symposium: Issues in Procreational Autonomy: Foreword" *Hast LJ* 37(5):697 *at* 700.

governmental interference".[557] The implication is that the Constitution adopts an innovative approach by placing a duty on the state to take positive and negative steps to ensure that constitutional rights, including socio-economic rights, are given effect to. The shift to governmental spheres has the implication that local government has more independence in decision-making and greater freedom to devise and implement policy by devising by-laws. Section 27 of the Constitution not only protects an individual's right to access to health care services, which is conductive to an individual's health and well-being, but it is also interrelated with other rights that have a considerable impact on people's dignity and the quality of life. The significance of this interrelationship of rights contained in the Bill of Rights was confirmed in *Grootboom*.[558] The court made it clear that in realising a particular socio-economic right it may require other elements, which form the basis of such a right, to be in place as well, since these rights are mutually supportive and "must be read together in the setting of the Constitution as a whole".[559] The Constitution therefore contains numerous other related fundamental rights, which together provide a basis for interpreting legislation and serve as a measure of evaluating governmental action.

Against the background of the constitutional principles as discussed above, it is necessary to examine the domestic legislation in the field of health. The relevant Acts are discussed in the following chapter.

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[557] See in general De Vos, P (1997) "Pious wishes or directly enforceable human rights? Social and economic rights in South Africa's 1996 Constitution" *SAJHR* 13(1):67-101.

[558] *Government of the Republic of South Africa and Others v Grootboom and Others* fn 377 *supra*.

[559] *Ex parte Chairperson of the Constitutional Assembly: In Re: Certification of the Constitution of the Republic of South Africa* fn 530 *supra*.

CHAPTER 4 DOMESTIC LEGISLATION: THE IMPACT ON EMBRYONIC STEM CELL RESEARCH AND CLONING

4 1 INTRODUCTION

The controversy over whether the law ought to permit or forbid abortion leads to a dispute as to the primacy that should be afforded to conflicting constitutional rights, as discussed in the previous chapter.[560] Although the fetus is not, legally speaking, a human being, its potential for human existence and its human qualities evoke the view that its destruction is ethically and morally wrong.[561] This is so strongly believed by certain people[562] that abortion, in certain circumstances, is prohibited under threat of criminal sanction. Although the crime of abortion was recognised in South Africa, there was little by way of a formulation of its elements. In particular, there was considerable obscurity as to when an abortion could be said to be unlawful. In 1971, a magistrates' court held that it was not unlawful for a medical practitioner to perform an abortion under clinical conditions for purposes other than the preservation of the life of a pregnant woman.[563] This decision resulted in the appointment of a commission of enquiry to consider the law relating to abortion.[564] The recommendations of the commission were enacted into law as the Abortion and Sterilisation Act. This Act was however repealed by the Choice on Termination of Pregnancy Act insofar it relates to abortion. The Choice on Termination of Pregnancy Act introduced a new era of abortion law, and swept away the elaborate system of bureaucratic and administrative barriers that, under the previous dispensation,

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560 As discussed in the previous chapter, the view that the fetus has a right to life is placed against the view that a woman has the right to decide whether she wishes to bear a child, or whether she is free to decide to terminate her pregnancy.

561 See in general Lupton, ML (1988) "The legal status of the embryo" *AJ* 197-215. See also Lupton, ML (1985) "Does the destruction of a blastocyst constitute the crime of abortion" *SALJ* 102(1):92-102.

562 For example, the Christian Church holds the view that life commences before birth, and abortion is therefore regarded as murder. It is interesting to note that the following is written in the Hippocratic Oath: "I swear by Apollo Physician and Asclepius and Hygieia and Panaceia and all the gods and goddesses, making them my witnesses, that I will fulfil according to my ability and judgment this oath and this covenant: … I will not give to a woman an abortive remedy." The Hippocratic Oath is an oath traditionally taken by physicians pertaining to the ethical practice of medicine. See Edelstein, I (1943) The Hippocratic Oath: Text, translation, and interpretation [Web:] www.pbs.org/wgbh/nova/doctors/oath_classical.html [Date of access: 2 February 2006].

563 *S v Van Druten* (unreported). For a discussion of the case and a summary of the judgment see Strauss, SA (1972) "Regverdiging van vrugafdrywing: Twee belangwekkende uitsprake" *THRHR* 35:56-64.

564 Burchell, JM (2005) *Principles of criminal law* 662.

significantly impeded the ability of a woman to obtain a lawful abortion. Currently, the decision-makers regarding termination of pregnancies are the medical practitioners and the women themselves.[565] (For a discussion of these statutory regulations see the paragraphs below.)

The Human Tissue Act and the National Health Act provide a legal framework, based on consent, for issues relating to the taking, retention and use of human tissue and organs from adults or children. The Acts make provision for tissue and gametes, which are removed or excised from a living donor, to be used only for medical and dental purposes. This includes the transplantation of tissue, the production of a therapeutic, diagnostic or prophylactic substance, and in the case of a gamete, artificial insemination. There is no reference in the Acts to purely scientific investigations and experimentation and it is doubtful if these activities can be described as "medical". It is a criminal offence for anyone to obtain tissue or gametes for any purpose other than those stipulated in the Acts. The provisions of both these Acts with reference to embryonic stem cell research, fetal tissue research and cloning, are discussed in the paragraphs below. The relevant statutory provisions with regard to informed consent are also examined.

Certain areas of research in reproductive biology may give rise to complex ethical problems, particularly because various moral, cultural, religious, family, and personal factors are involved. The question of how the Medical Research Council's guidelines provide answers to these problems is also investigated. Although international medical research guidelines, for example the Declaration of Helsinki, is evidently not directly enforceable, South African research ethics committees generally appear to consider them as binding. It is therefore necessary to refer to these guidelines in short.[566]

The purpose of this chapter is therefore to expound and examine the legal requisites and ethical guidelines, both nationally and internationally, on embryonic stem cell research and cloning.

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[565] Sarkin-Hughes & Sarkin-Hughes (1990) *Stell L Rev* 372 *at* 383.
[566] Van Oosten (2000) *THRHR* 5 *at* 7.

4 2 STATUTORY PROVISIONS PERTAINING TO THE TERMINATION OF PREGNANCIES: THE EMBRYO IN UTERO

4 2 1 The Abortion and Sterilisation Act

Since the Abortion and Sterilisation Act was repealed by the Choice on Termination of Pregnancy Act, it is not necessary to discuss the provisions of it in detail. It is, however, necessary to provide some background on how the Act regulated therapeutic abortion,[567] and how it differs from the current position. This Act did not intend to bring about abortion on demand. Abortion was not "legalised" in that sense. The purpose of the Act was to clear up legal uncertainties, and in a positive context give legal affirmation to a practice of therapeutic abortion, which had for many years become settled in the medical profession. Prior to this Act, the only legal certainty was that pregnancy could be medically terminated to save the life of a woman.[568]

The Act did not define a "fetus", and medical evidence was therefore necessary to establish whether a live fetus was aborted, and whether what was aborted, was a fetus or a viable infant. This question came up for decision in 1979 in the Cape Provincial Division of the Supreme Court in *S v Collop*.[569] In this case the accused, Dr Collop, was charged in the Magistrate's Court with several counts of criminal abortion. She had treated her patients by injecting a mixture of soap, glycerine and an antibiotic into their wombs. In respect of one of the charges, the accused raised the defence that because the patient had conceded that she was between seven and eight weeks pregnant, the state had failed to prove that the accused had procured an abortion of a "live fetus". At the trial, medical witnesses testifying for the prosecution distinguished between a fetus and an embryo, although describing the term "abortion" as referring to the termination of

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[567] Abortion is defined in section 1 of the Act as "the abortion of a live fetus of a woman with intent to kill such fetus". The Afrikaans text reads: "Die afdrywing van 'n lewende vrug." In terms of this definition, there must be a killing as well as an expulsion. Strauss points out that even where a fetus is still alive after expulsion, but is medically a fetus, and is then killed, the act amounts to abortion, which would be lawful if the requirements of the Act are complied with. Conversely, in the case of an abortion not falling under the Act, the deed would constitute criminal abortion and not infanticide. If, however, the expulsion of an unborn child amounts to live birth and the child is then killed, it would seem to constitute infanticide or at least culpable homicide. See Strauss (1991) 207.

[568] Strauss (1991) 207.

[569] *S v Collop* 1979 (4) SA 381 (C). For a discussion of the case see Strauss (1991) 222-224.

pregnancy at any time after conception resulting in a fertilised ovum in the uterus of the mother. One of the medical witnesses testified that the term "fetus" covers the whole period from conception to childbirth, but that for a certain time during that period, the fertilised ovum is also described as an embryo. The accused was convicted and appealed to the Supreme Court. It was expressly held by this court that a mere admission by the defence that the accused interfered with the pregnancy so that it was terminated does not include an admission that the fetus aborted "was living at the time of abortion".

The appellant took the case on appeal to the Appellate Division.[570] Counsel argued on the basis of medical evidence and dictionary meanings that the unborn offspring in the human uterus is an embryo and not a fetus before eight weeks of pregnancy, and therefore falls outside the definition of abortion as stipulated in the Act:

> It is at least clear that, whether the word be spelt fetus or foetus, it has in common parlance more than one meaning. It may be used in the wider or general sense to mean the unborn young of any vertebrate, or it may be used in a narrower or specific sense to mean the unborn young which has developed from an embryo. There is also wide difference of opinion as to whether the embryo stage ceases at the end of the second month, the third month or the fourth month, or alternatively, after it has passed through the earliest development stages, or after its parts are distinctively formed, or after it has attained the basic structural plan of its kind ... I can find no *indiciae* in the Act to give support to the inference that the Legislature intended to distinguish between an embryo and a fetus and for the further inference that the time of transition should be after two months or any other defined period. Moreover to adopt the interpretation contended for, must result in the spread of the evil which the lawgiver sought to control and prohibit. Furthermore the prosecution in an abortion case would undoubtedly be faced with practical difficulties if the *onus* rested on it to prove the stage of maturity of the fetus.[571]

The court also examined the common law position to decide whether a distinction should be drawn between the embryo and fetus, and came to the conclusion that there was no foundation for the proposition that in common law the crime of abortion could be committed only on a woman whose pregnancy has advanced beyond what counsel was pleased to describe as "the embryonic stage". No support for this proposition was found in the South African case law. A developing fetus could only mean a live fetus and the

[570] *S v Collop* fn 569 *supra*.
[571] Jordaan, RA & Davel, CJ (1992) *Personereg Bronnebundel* 14-16.

termination of the pregnancies for which the appellant admitted responsibility, must accordingly have meant, in common parlance, that she caused the abortion of live fetuses in each case. Therefore, the effect of the decision was that there was legally no distinction between a zygote, an embryo or a fetus, and that the legislature had intended to protect the fetus from the moment of conception.[572]

According to the Abortion and Sterilisation Act, there are six different legal indications for abortion, which may be procured only by a medical practitioner, namely –[573]

(a) where the continued pregnancy endangers the life of the woman;[574]

(b) where the continued pregnancy constitutes a serious threat to her physical health;[575]

(c) where the continued pregnancy constitutes a serious threat to the woman's mental health, and is of such a nature as to create the danger of permanent damage to her mental health and the abortion is necessary to ensure her mental health;[576]

(d) where there is a serious risk that the child to be born would suffer from a physical or mental defect of such a nature that he will be irreparably seriously handicapped;[577]

(e) where the fetus was conceived in consequence of a rape or incest;[578] or

(f) where the fetus was conceived in consequence of illegitimate carnal intercourse with a woman who suffers from a permanent mental handicap or defect with the result that she would be unable to comprehend the implications of or bear the responsibility for the fruit of coitus.[579]

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572 Slabbert (2000) 134.
573 Section 3(1).
574 Section 3(1)(a).
575 *Ibid.*
576 Section 3(1)(b).
577 Section 3(1)(c).
578 Section 3(1)(d). The Act refers to "unlawful carnal intercourse" meaning rape and incest. See section 1 of the Abortion and Sterilisation Act for the definitions.
579 Section 3(1)(e).

An abortion that falls outside the scope of these provisions constituted a criminal offence, and was punishable by a fine not exceeding R5 000,00 and/or imprisonment not exceeding five years.[580] In all cases of proposed abortions, certification by two other medical practitioners other than the doctor performing the abortion was required. At least one of them had to have practised for four years. In the case of the psychiatric indication, one of them had to be a psychiatrist employed by the state. In the case of rape or incest, one of the doctors had to be a district surgeon who examined the woman if a complaint had been lodged with the police.[581]

It is clear from the above that the Abortion and Sterilisation Act permitted the abortion of a fetus only under narrowly defined circumstances. The performance of abortion in any other circumstances was a crime. In the case of abortion, the fetus's interests are never protected with the aid of the *nasciturus* fiction, because the fetus is not born alive.[582] The protection is then merely a side effect of the protection of the community interests by criminal law. As previously mentioned, the Abortion and Sterilisation Act was repealed by the Choice on Termination of Pregnancy Act.[583] The provisions of this Act are considered below.

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580 Section 10(1).

581 In these cases, the Abortion and Sterilisation Act also required a further certificate to be issued by a magistrate to the effect that: (a) A complaint had been lodged with the police or that there was a good and acceptable reason why a complaint had not been lodged. (b) After an examination of any relevant documents and such interrogation of the woman as he may consider necessary, that on a balance of probabilities, unlawful intercourse had taken place. (c) In the case of incest, that the woman was related within the prohibited degree to the man. The magistrate further had to state that the woman had stated under oath that the pregnancy was the result of rape or incest, as the case may be. "Magistrate" includes an additional and an assistant magistrate of the district in which the offence is alleged to have been committed. It need not be a regional magistrate. See section 6. See also *Rall NO v Landdros vir die Distrik Heilbron* 1980 (3) SA 287. For a discussion of the Abortion and Sterilisation Act see Strauss (1991) 207-224.

582 For a discussion of the *nasciturus* fiction see chapter 3.

583 The radical departure alluded to from the Abortion and Sterilisation Act is immediately apparent from the title of the Choice on Termination of Pregnancy Act. The phenomenon dealt with by the Act is significantly no longer called "abortion", nor even "termination of pregnancy", but "choice on termination of pregnancy". Van Oosten points out that not only is the phrase "termination of pregnancy" more neutral and less emotional than the term "abortion", and largely untainted by overtones of moral, social and other kinds of opprobrium, but the emphasis also clearly falls on "choice" of termination of pregnancy. In this respect, the provisions of the Act are to some extent consistent with its title. See Van Oosten, FFW (1999) "The Choice on Termination of Pregnancy Act: Some comments" *SALJ* 116(1):60 *at* 62.

4 2 2 The Choice on Termination of Pregnancy Act

4 2 2 1 Introductory remarks

The Act was promulgated on 1 February 1997. It definitely shows a change in society's attitude toward abortion, and can no longer be regarded as being against public policy. Society had to face the reality that despite anti-abortion laws, many South Africans were having illegal and dangerous abortions performed because they could not afford raising a child. By condoning abortion to prevent the birth of for example a defective child, society had made it clear that it was sympathetic to parents who were anxious not to have a baby if it suffered from a serious disability.[584] A termination of pregnancy which in the past was regarded as the product of a cruel fate, is nowadays accepted as an event that might be partly controlled and legally dealt with by society.

The preamble of the Act recognises the values of human dignity, the achievement of equality, security of the person, non-racialism and non-sexism, and the advancement of human rights and freedoms that underlie a democratic South Africa. It also recognises that the Constitution protects the right of persons to make decisions concerning reproduction, and to security in and control over their bodies. It further states that both women and men have the right to be informed about and have access to safe, effective, affordable and acceptable methods of fertility regulation of their choice; and that women have the right of access to appropriate health care services to ensure safe pregnancies and childbirth. In addition, the Act recognises that the decision to have children is fundamental to a woman's physical, psychological and social health, and that universal access to reproductive health care services includes family planning and contraception, termination of pregnancy, as well as sexual education and counselling programmes and services. The state has the responsibility to provide reproductive health to all, and also to provide safe conditions under which the right of choice can be exercised without fear or harm. Also, the termination of pregnancy is not regarded as a form of contraception or

[584] Meintjies-Van der Walt, L (1991) "The right to be born?" *DR* 286:745.

population control,[585] and the Act promotes reproductive rights and extends freedom of choice by affording every woman the right to choose whether to have an early,[586] safe and legal termination of pregnancy according to her individual beliefs.[587]

With reference to the above, Van Oosten submits that the fetus, as a non-human or non-person for legal purposes, is evidently not entitled to any protection afforded to humans by the criminal law. It is simply a "member" of the pregnant woman's body and, in that capacity, is subject to her right "to security in and control over her body", which includes the right to have her embryo killed.[588]

4 2 2 2 The provisions of the Choice on Termination of Pregnancy Act

A pregnancy may be terminated –[589]

(a) upon request of a woman[590] during the first 12 weeks of the gestation period[591] of her pregnancy;[592]

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[585] Van Oosten submits that the belief that "termination of pregnancy is not a form of contraception" not only states the obvious but also confuses and identifies fact with belief. He states that "contraception" and "pregnancy" are mutually exclusive. Pregnancy means that there was no contraception, and contraception means that there is no pregnancy. The fact that contraceptive measures were taken but were unsuccessful makes no difference. Failed contraception is equivalent to no contraception. He further mentions that the belief that "termination of pregnancy is not a form of population control" needs clarification. It presumably means that the motive for the legalisation of terminations of pregnancy was not to curb population growth. It can hardly mean that the legalisation of termination of pregnancy will not actually curb, at least to some extent, population growth. Killing embryos and fetuses effectively terminates their potential to become human beings and to procreate in that capacity. See Van Oosten (1999) *SALJ* 60 *at* 63.

[586] Van Oosten points out that, in effect, the pregnant women not only has the right to choose an early termination of pregnancy, which is during the first 12 weeks of pregnancy, but also an opportunity, in certain circumstances, to choose a late termination between weeks 13 to birth. See Van Oosten (1999) *SALJ* 60 *at* 62.

[587] The pregnant woman's right to choose a termination of pregnancy according to her individual beliefs includes her right to have her pregnancy terminated in accordance with her belief that the only good fetus is a dead one. See in general the preamble of the Choice on Termination of Pregnancy Act 92 of 1996.

[588] For a discussion of whether the embryo is a bearer of constitutional rights, see chapter 3, in particular *Christian Lawyers Association of South Africa and Others v Minister of Health and Others* fn 269 *supra*.

[589] Section 2(1). Section 1 defines "termination of pregnancy" as the separation and expulsion, by medical or surgical means, of the contents of the uterus of a pregnant woman.

[590] A "woman" is defined in section 1 as any female person of any age.

[591] For a definition of "gestation period" see fn 90.

(b) from the 13th up to and including the 20th week of the gestation period if a medical practitioner[593], after consultation with the pregnant woman, is of the opinion that –

(i) the continued pregnancy would pose a risk of injury to the woman's physical or mental health; or

(ii) there is a substantial risk that the fetus would suffer from a severe physical or mental abnormality; or

(iii) the pregnancy resulted from rape or incest;[594] or

(iv) the continued pregnancy would significantly affect the social or economic circumstances of the woman;[595] or

(c) after the 20th week of the gestation period if a medical practitioner, after consultation with another medical practitioner or a registered midwife,[596] is of the opinion that the continued pregnancy –

(i) would endanger the woman's life;

(ii) would result in a severe malformation of the fetus; or

(iii) would pose a risk of injury to the fetus.[597]

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592 Section 2(1)(a).

593 Medical practitioner means a person registered as such under the Medical, Dental and Supplementary Health Service Professions Act, 1974 (Act 56 of 1974). See section 1 of the Choice on Termination of Pregnancy Act.

594 "Rape" also includes statutory rape as referred to in sections 14 and 15 of the Sexual Offences Act, 1957 (Act 23 of 1957). Section 14 of this Act however concerns voluntary sexual intercourse with a girl under the age of 16 years, and section 15 explicitly states that it is not applicable in rape cases and concerns voluntary sexual intercourse with a female imbecile or idiot. The term "rape" presumably also includes intramarital rape in terms of section 5 of the Prevention of Family Violence Act, 1993 (Act 133 of 1993) that reads as follows: "Notwithstanding anything to the contrary contained in any law or in the common law, a husband may be convicted of the rape of his wife. Incest is the unlawful and intentional sexual intercourse between male and female persons who are prohibited from marrying each other because they are related within the prohibited degrees of consanguinity, affinity, or adoptive relationship. See Snyman, CR (2002) *Criminal Law* 447, 355.

595 Section 2(1)(b).

596 "Registered midwife" means a person registered as such under the Nursing Act, 1978 (Act 50 of 1978). According to the Choice on Termination of Pregnancy Amendment Act, the term "registered midwife" is replaced with "registered nurse".

597 Section 2(1)(c). Slabbert argues that the protection of the mature fetus from the risk of injury means that it is the pregnancy that is not desired, and not the life of the fetus. It would not make sense to terminate the life of a fetus to save it from a "risk of injury". She points out that this explains the title of the Act, which refers to "termination of pregnancy" and not to "abortion". The question of what constitutes abortion will therefore have to be answered by reference to South African common law. See Slabbert (2000) 140.

The termination of a pregnancy may only be carried out by a medical practitioner, except for a pregnancy referred to in subsection (1)(a), which may also be carried out by a registered midwife who has completed the prescribed training course.[598]

Section 3 of the Act deals with the place where surgical termination of pregnancy may take place. Termination of pregnancies may only take place at a facility that gives access to medical and nursing staff; gives access to an operating theatre; has appropriate surgical equipment; supplies drugs for intravenous and intramuscular injection; has emergency resuscitation equipment and access to an emergency referral centre or facility; gives access to appropriate transport should the need arise for emergency transfer; has facilities and equipment for clinical observation and access to in-patient facilities; has appropriate infection control measures; gives access to safe waste disposal infrastructure; has telephonic means of communication; and has been approved by the Member of the Executive Council by notice in the *Gazette*.[599] In addition, section 4(3)(c) of the National Health Act[600] compels the state, clinics and community health centres funded by the state, but subject to any condition prescribed by the Minister, to provide women, subject to the Choice on Termination of Pregnancy Act, with free termination of pregnancy services.[601]

Section 4 of the Choice on Termination of Pregnancy Act deals with counselling and provide for non-mandatory and non-directive counselling before and after the termination of the pregnancy.

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598 Section 2(2).
599 Section 3(1)(a)-(k).
600 Section 4 deals with the eligibility for free health services in public health establishments.
601 Section 5 of the National Health Act provides that a health care provider, health worker, or health establishment may not refuse a person emergency medical treatment. It is not necessary for the purpose of this dissertation to discuss these provisions in detail. See also section 27 of the Constitution and the case of *Soobramoney v Minister of Health* fn 534 *supra*.

4 2 2 3 Section 10 of the Choice on Termination of Pregnancy Act

It is an offence under the Choice on Termination of Pregnancy Act for any person who is not a medical practitioner to procure the termination of a pregnancy.[602] The elements of this offence are "unlawfulness",[603] "termination", "performed by someone other than a medical practitioner", and "fault".[604]

4 2 2 4 Provisions pertaining to consent: Section 5

Section 5(1) states that the termination of a pregnancy may only take place after the informed consent of the woman was obtained.[605] It further states in section 5(2) that no consent other than that of the pregnant woman shall be required for the termination of a pregnancy.

Section 5(3) deals with the situation where a pregnant minor[606] needs to consent to a termination of pregnancy and read as follows: "In the case of a pregnant minor, a medical practitioner or a registered midwife, as the case may be, shall advise such minor to consult with her parents, guardian, family members or friends before the pregnancy is

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602 Section 10 read as follows: "Offences and penalties – (1) Any person who (a) is not a medical practitioner, or a registered midwife or registered nurse who has completed the prescribed training course, and who performs the termination of a pregnancy referred to in section 2(1)(a); (b) is not a medical practitioner and who performs the termination of a pregnancy referred to in section 2(1)(b) or (c); (c) prevents the lawful termination of a pregnancy or obstructs access to a facility for the termination of a pregnancy; or (d) terminates a pregnancy or allows the termination of a pregnancy at a facility not approved in terms of section 3(1) or not contemplated in section 3(3)(a), shall be guilty of an offence and liable on conviction to a fine or to imprisonment for a period not exceeding 10 years. (2) Any person who contravenes or fails to comply with any provision of section 7 shall be guilty of an offence and liable on conviction to a fine or to imprisonment for a period not exceeding six months."

603 A common law abortion was lawful when procured to preserve the life of the mother. The basis of this exception to the general prohibition of abortion was the defence of necessity.

604 On general principles, the fault element of the crime consists in the intention to procure an abortion unlawfully. Therefore, the abortionist must know or foresee that the termination is unlawful. Where the abortionist *bona fide* believes that the woman is not pregnant or the fetus is already dead, or that the abortion is lawful in terms of the Act, he lacks the necessary fault. See Burchell (2005) 663, 664, 665. For a discussion of section 10 of the Choice on Termination of Pregnancy Act see Van Oosten (1999) *SALJ* 60 *at* 73, 74.

605 For a discussion of informed consent see chapter 3.

606 "Minor" is defined in section 1 as "any female person under the age of 18 years." The Children's Bill (B-2003) (hereafter referred to as the Children's Bill) provides in section 13(a) that: "Every child has the right to: have access to information on health promotion, sexuality, reproduction and the prevention of ill-health and disease".

terminated: Provided that the termination of the pregnancy shall not be denied because such minor chooses not to consult them."

Every pregnant woman, irrespective of how young she is and even if she is an infant, not only has the statutory right to a termination of pregnancy, but also the statutory capacity to consent to it. The exceptions to these provisions are discussed in the paragraphs below. Van Oosten submits that although the Act's approach represents a radical departure from the common law and statutory provisions relating to children's capacity to consent, its justification clearly lies in the fact that pregnancy and childbirth could hardly be in the best interest of very young girls and/or their potential offspring.[607] A question that needs to be addressed is whether a minor under the age of 18 years is legally capable of consenting to an anaesthetic should the need arise? The effect of the Child Care Act[608] is that a minor who has attained the age of 18 years is legally competent to consent to a medical operation, and therefore to a termination of pregnancy, inclusive of an anaesthetic. If a pregnant minor is under the age of 18 years, the consent of her parents or guardians is required for medical operations and concomitant procedures. In contradiction to this, the Choice on Termination of Pregnancy Act makes provision for "any female of any age" to consent to a termination of pregnancy. The Choice on Termination of Pregnancy Act can hardly be effective without a corresponding right and capacity to consent to concomitant medical procedures. Van Oosten submits that it would be better if a pregnant woman under the age of 18 years is legally capable of consenting to an anaesthetic and, for that matter, any other concomitant intervention that is medically

[607] Very young pregnant girls also have the right and capacity to express an "informed refusal" to have their pregnancies terminated. "Informed refusal" is the reverse side of informed consent. See Van Oosten (1999) *SALJ* 60 *at* 67.

[608] A "child" is defined in section 1 of the Child Care Act, 1983 (Act 74 of 1983) (hereafter referred to as the Child Care Act) as "a person under the age of 18 years". Section 39(4) provides for the following: "Notwithstanding any rule of law to the contrary any person over the age of 18 years shall be competent to consent, without the assistance of his parent or guardian, to the performance of any operation upon himself; and, any person over the age of 14 years shall be competent to consent, without the assistance of his parent or guardian, to the performance of any medical treatment of himself or his child." See also sections 39(1)-(3) of this Act; Section 53 providing for the transfer of certain parental powers. The Medicines and Related Substances Control Act, 1965 (Act 101 of 1965) provides that Schedule 1, 2, 3, 4, 5 or 6 substances shall not be sold to any person apparently under the age of 14 years except upon a prescription. See also South Africa. Health Professions Council's Medical and Dental Professions Board (2002) *Handbook on ethical rulings* 110, where counsel informed a medical superintendent that he could give consent to operations on minors, provided that it was justified and indicated on purely medial grounds, and that the provisions of the Child Care Act are complied with.

indicated.[609] Human, again, argues that it is arbitrary to allow a minor to decide to terminate a pregnancy in terms of the Choice on Termination of Pregnancy Act, but to require parental consent for any other operation in terms of the Child Care Act.[610]
Bekink submits that the benefits of obtaining parental or guardian consent in the case of a termination of pregnancy of a minor are of much more value than any negative consequences for the child. He further submits that a requirement of co-consent would indeed be a more appropriate requirement, as it would not only be in the child's best interests, which is a constitutional imperative,[611] but it would also ensure that a child who is the victim of sexual abuse and maltreatment is afforded the necessary support and assistance to overcome the trauma of the criminal offence committed against her. Finally, it would also ensure that the criminal justice system is not legally sidestepped through misinformation and the non-prosecution of possible sexual offenders.[612]

The Choice on Termination of Pregnancy Act also deals with situations where a woman is severely mentally disabled to such an extent that she is completely incapable of understanding and appreciating the nature or consequences of a termination of her pregnancy, or in a state of continuous unconsciousness and there is no reasonable prospect that she will regain consciousness in time to request and consent to the termination of her pregnancy in terms of section 2. Her pregnancy may be terminated during the first 12 weeks of the gestation period, or from the 13th up to and including the

609 Van Oosten (1999) *SALJ* 60 *at* 67.

610 Human, S (1998) *Die invloed van die begrip kinderregte op die privaatregtelike ouer-kind verhouding in die Suid-Afrikaanse reg* (Thesis – LLD) University of Stellenbosch 78 (Unpublished), as quoted in Currie & De Waal (2005) 601. In *Christian Lawyers Association of South Africa and Others v Minister of Health and Others* fn 269 *supra*, section 5 of the Choice on Termination of Pregnancy Act was challenged on the grounds that it infringed section 28(1)(b) and (d) of the Constitution by allowing a child to make a decision about termination without the assistance and guidance of her parents or guardian. Mojapelo J held that this argument neglected to take account of the Act's requirement that consent to an abortion had to take place with the "informed consent" of the pregnant woman. In many cases a child under the age of 18 could give adequately informed consent, and in cases where the child is not sufficiently mature to make an informed decision without parental assistance, a child's decision to terminate her pregnancy would not meet the Act's threshold requirement for valid consent.

611 Section 28(2) of the Constitution.

612 An aspect of concern is that in allowing and performing an abortion on a woman under the age of 16, the medical practitioner or registered midwife is in fact destroying critical evidence in a possible case of rape or statutory rape. Bekink, B & Bekink, M (2006) "Aspects of rape, statutory rape and the Choice on Termination of Pregnancy Act 92 of 1996: Do we protect our women?" *THRHR* 69(1):14 *at* 24, 27, 28.

20th week of the gestation period on the grounds set out in section 2(1)(b), upon request of and with the consent of her natural guardian, spouse or legal guardian, as the case may be, or if such persons cannot be found, upon the request and with the consent of her *curator personae*. However, such pregnancy may not be terminated unless two medical practitioners or a medical practitioner and a registered midwife who has completed the prescribed training course consent thereto.[613]

Two medical practitioners or a medical practitioner and a registered midwife or registered nurse who has completed the prescribed training course may consent to the termination of the pregnancy of such a woman in the following circumstances: during the period up to and including the 20th week of the gestation period if the continued pregnancy would pose a risk of injury to the woman's physical or mental health; or there exists a substantial risk that the fetus would suffer from a severe physical or mental abnormality; or after the 20th week of the gestation period if the continued pregnancy would endanger the woman's life; would result in a severe malformation of the fetus; or would pose a risk of injury to the fetus. This may only be done after consulting her natural guardian, spouse, legal guardian or *curator personae*, as the case may be; provided that the termination of the pregnancy shall not be denied if the natural guardian, spouse, legal guardian, or *curator personae*, as the case may be, refuses to consent thereto.[614]

4 2 2 5 Conclusive remarks on the Choice on Termination of Pregnancy Act

The Choice on Termination of Pregnancy Act only regulates abortion, which is the termination of an embryo in utero, but the destruction of embryos outside a woman's body (the embryo extra uterum) – for example embryos in test tubes, cryopreserved embryos and embryos in transit from the donor to the recipient in embryo transfers – falls outside the scope of the Act. For a discussion of the statutory provisions pertaining to the embryo extra uterum see the discussion below.

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613 Section 5(4).

614 Section 5(5). See also Van Oosten (1999) *SALJ* 60 *at* 69-71 for an evaluation and criticism of this particular section of the Choice on Termination of Pregnancy Act. See also sections 6, 7, 8, and 9. It is not necessary to discuss these sections for the purposes of this dissertation.

4 2 3 The Human Tissue Act and the National Health Act

4 2 3 1 The use of fetal oocytes for research purposes[615]

Against the above background, and with regard to stem cell research, a possibility that needs to be addressed is that the lawful practice of elective abortion in terms of the South African Choice on Termination of Pregnancy Act may encourage research on embryos and fetuses prior or subsequent to the elective abortion. Neither the Choice on Termination of Pregnancy Act, nor the Human Tissue Act, nor the National Health Act, nor the Medical Research Council's guidelines[616] addresses the fate of embryos and fetuses aborted as a result of a legal termination of pregnancy. Slabbert recommends that a provision be inserted in the Choice on Termination of Pregnancy Act that specifically regulates any activities pertaining to any fetus aborted following the termination of a pregnancy, or to any organ, member, gamete, or tissue of fetal material resulting from such a termination.[617]

Section 19(c)(iv) of the Human Tissue Act prohibits the use of fetal tissue for transplantation purposes without the consent of the Minister or his nominee.[618] The Act distinguishes between "tissue" and "gametes". There is no reference to "gametes" in this section referring to the fetus. It would therefore appear that the Act, as it is worded, does not prohibit the use of oocytes taken from a fetus.[619] The National Health Act also

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[615] As previously mentioned, cadaveric fetal tissue may be obtained after spontaneous abortions, or after elective or therapeutic abortions have been carried out. Since the termination of pregnancy for purposes of the Choice on Termination of Pregnancy Act consists of the "separation and expulsion of the contents of the uterus of a pregnant woman", the termination of ectopic or extra-uterine pregnancies falls outside the scope of the Act. Van Oosten submits that this is probably attributable to an oversight by the legislator rather than anything else. See Van Oosten (1999) *SALJ* 116:60 *at* 61. For a clinical discussion of fetal tissue research see chapter 1.

[616] Du Toit *et al* (1999) www.sahealthinfo.org/ethics/book2.htm.

[617] Slabbert (2000) 117-119.

[618] Section 19 clearly states that any tissue withdrawn from the body of a living person shall only be used for medical or dental purposes. Strauss points out that it is important to note that this Act makes no reference to purely scientific research and experimentation, and it is doubtful whether such activities could be described as "medical". See Strauss (1991) 147.

[619] Lupton, ML (1996) "Genetic engineering – the legal implications" *TSAR* 1:56 *at* 57, 58. The Human Tissue Act defines "tissue" in section 1 as "(a) any human tissue, including any flesh, bone, organ, gland or body fluid, but excluding any blood or gamete; and (b) any device or object implanted before the death of any person by a medical practitioner or dentist into the body of such person". The National Health Act defines tissue in section 1 as "human tissue, and includes flesh, bone, a gland, an organ, skin, bone marrow or body fluid, but excludes blood or a gamete". Strauss submits that, for the

regulates the use of tissue removed or withdrawn from living persons. A person may use tissue removed from a living person only for such medical and dental[620] purposes as may be prescribed.[621] Embryonic or fetal tissue may only be removed if authorised by the Minister, and the Minister may impose any condition that may be necessary in respect of such removal.[622] Therefore, the latter Act contains no provision prohibiting the use of fetal oocytes taken from a fetus for the purposes of stem cell research.

In addition, section 18 of the Human Tissue Act and section 55 of the National Health Act regulate the requirements for obtaining consent for the removal of tissue from the bodies of living persons. Section 18 of the Human Tissue Act states that no tissue shall be removed from the body of a living person for a purpose referred to in section 19, except in accordance with the prescribed conditions, and unless written consent thereto has been granted:[623] where such person is a major,[624] by that person, and where such person is a minor,[625] by the parents or guardians of that person.[626] But in the case of the removal of tissue that is replaceable by natural processes, from the body of a person who is a competent witness,[627] the consent of that person to the removal of that tissue shall be sufficient, whether it be granted in writing or orally. Also, tissue removed in the interest of health from the body of a living person with his consent or with the consent of any

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purposes of the Human Tissue Act, a "fetus" is tissue of the woman in whose womb it is. The same is submitted for the purposes of the National Health Act. See Strauss (1991) 147. Therefore, throughout this dissertation, where reference is made to "tissue" it also includes "fetal tissue".

620 Again, no reference is made to scientific research and experimentation, and the question of whether these activities could be described as "medical" remains open.

621 Section 56(1).

622 Section 56(2)(a)(iv).

623 Section 18(a) and (b).

624 "Major" or "person of age" means any person who has attained the age of 18 years or who has under the provisions of section 2 of the Age of Majority Act, 1972 (Act 57 of 1972), been declared to be a major, and includes a person under the age of 18 years who has contracted a legal marriage. See section 1 of the Births and Deaths Registration Act. Section 17 of the Children's Bill stipulates that a child, whether male or female, becomes a major upon reaching the age of 18 years.

625 "Minor" or "minor person" means any person who is not a major or a person of age. See Section 1 of the Births and Deaths Registration Act. As previously discussed, a minor may consent to the termination of her pregnancy without the consent of her parents or guardian. It is therefore submitted that she will also be able to consent to the donation of the fetal remains without consent of her parents or guardian. See section 5 of the Choice on Termination of Pregnancy Act.

626 Section 18(b)(i) and (ii).

627 "Competent witness" means a person of the age of 14 years or over and who at the time when in terms of this Act anything is done in his presence or by him is not incompetent to give evidence in a court of law. See section 1.

other person who may in law give consent on his behalf, may be used for any of the purposes referred to in section 19.[628]

Section 55 of the National Health Act states that a person may not remove tissue from the body of another living person for the purpose referred to in section 56 unless it is done –

(a) with the written consent of the person from whom the tissue is removed, granted in the prescribed manner; and
(b) in accordance with prescribed conditions.[629]

Van Wyk points out that international ethical guidelines, to which South Africa adheres, generally hold that when such fetal tissue is to be used for stem cell research, the researchers may in no way be involved in the decision to terminate the pregnancy, and that the possible donation of fetal tissue after abortion should not influence the decision to terminate the pregnancy. The informed consent of the woman should also be sought for the proposed research. She refers to the Department of Health's guidelines for good practice in the conduct of clinical trials in human participants in South Africa, which advise as follows:

> No nonviable fetus may be involved as a subject in any research activity unless vital functions of the fetus will not be artificially maintained; experimental activities which of themselves would terminate the heartbeat or respiration of the fetus will not be employed; and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means. Any activity permitted above may be conducted only if the mother and father are legally competent and have given their informed consent, except that the father's consent need not be secured if; his identity or whereabouts cannot reasonably be ascertained; he is not reasonably available; or the pregnancy resulted from rape…Until it has been ascertained whether or not a fetus *ex utero* is viable, a fetus *ex utero* may no be involved as a subject in any research activity unless there will be no added risk to the fetus resulting from the activity, and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means, or the

[628] Section 18(b)(ii)(aa) and (bb).
[629] See also section 65 that deals with the revocation of a donation and it is important that a donor may, prior to the transplantation of the relevant organ into the donee, revoke a donation in the same way it was made or, in the case of a donation by way of a will or other document, also by the intentional destruction of that will or document.

> purpose of the activity is to enhance the possibility of survival of the particular fetus to the point of viability.[630]

It is also important that no use for profit or remuneration should be allowed.[631] In addition, and according to section 19 of the Human Tissue Act, any tissue removed or withdrawn from the body of a living person shall, subject to the regulations, only be used for medical or dental purposes, provided that any tissue of a person who is mentally ill within the meaning of the Mental Health Act,[632] shall not be used for any of the purposes referred to in section 19(a), (b) or (c). The tissue of a minor, which is not replaceable by natural processes, may also not be used.[633] Section 56 of the National Health Act contains similar provisions. Tissue may not be removed from a person who is mentally ill within the meaning of the Mental Health Care Act, or tissue that is not replaceable by natural processes from a person younger than 18 years. However, the Minister may authorise the removal or withdrawal of tissue in these circumstances, and may impose conditions that may be necessary in respect of such removal or withdrawal.[634]

4 2 3 2 Exclusive rights in respect of fetal tissue

Section 36 of the Human Tissue Act provides that any person who acquires any tissue by virtue or any provision of the Act shall, subject to any restrictions in terms of the Act or any other law, and provided that he uses the tissue for the purposes it has been donated to him, on receipt of that tissue, acquire exclusive rights in respect thereof. Would a hospital where termination of pregnancies are carried out, then be able to use fetal remains for the purposes of donation for stem cell research? It is submitted that this would only be possible after obtaining the informed consent of the woman whose fetus is aborted. (For a discussion of the provisions pertaining to consent and the donation of fetal tissue see section 18 of the Human Tissue Act as discussed above.)

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630 Van Wyk (2004) *THRHR* 1 *at* 18.
631 Strydom (2003) *TSAR* 37 *at* 47.
632 The Mental Health Act, 1973 (Act 18 of 1973) (hereafter referred to as the Mental Health Act.) This Act has been repealed by the Mental Health Care Act.
633 Provisions pertaining to minors and the mentally ill are discussed in the paragraphs below.
634 Section 56(2)(a)(i) and (ii) and section 56(2)(b) of the National Health Act.

In conclusion, it is important to note that in terms of the Choice on Termination of Pregnancy Act, the fruit of coitus is definitely a fetus for the purposes of the Act, on condition that it is still in the mother's womb. A fetus is clearly included under the definition of "tissue" for purposes of the Human Tissue Act and the National Health Act. The abovementioned Acts do not in any way prevent a woman from consenting to the destruction of a stillborn fetus.[635] However, such consent does not amount to an anatomical donation by virtue of the Human Tissue Act or the National Health Act. On the other hand, there is no provision in either of these Acts to prevent a woman from donating a fetus lawfully removed from her body for medical or scientific purposes in terms of the Choice on Termination of Pregnancy Act.[636] In addition, fetal tissue is generally disposed of as medical waste in medical practice.[637]

4 2 4 The regulation of fetal tissue transplants

There are certain requirements specified in the Human Tissue Act and National Health Act with regard to tissue transplants. According to section 20 of the Human Tissue Act, tissue destined for transplants may only be removed in a hospital or other authorised institution.[638] The Human Tissue Act further provides that a medical superintendent of

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635 For a discussion of whether a hospital may destroy the remains of a stillborn fetus, see Strauss (1991) 163-166. It is important to note that nonviable fetal remains cannot qualify as human bodies and should simply be dealt with as tissue removed from the mother's body. Strauss submits that a fetus may lawfully be destroyed in a hospital incinerator, unless the woman has laid claim to it before removal or shortly afterwards. However, according to section 239 of the Criminal Procedure Act, a fetus that has breathed is regarded as a human being for the purposes of murder and culpable homicide.

636 Strauss (1991) 166.

637 See the regulations under the Choice on Termination of Pregnancy Act: "Designation of facilities for the surgical termination of pregnancies" (GN R823 in *GG* 23517 (21 June 2002) and GN R784 in *GG* 23486 (10 June 2002)). It is stated that a facility where terminations of pregnancies are carried out must have access to safe waste disposal infrastructure. It is therefore safe to conclude that fetal tissue is regarded as medical waste.

638 Section 20(a). Section 1 of this Act defines "hospital" as an institution established as a hospital or registered as such in terms of any law. An "authorised institution" is defined as an institution authorised under section 24 to perform the acts referred to in that section. Section 24 reads as follows: "Authorised institutions – The Minister may by notice in the *Gazette* authorise any institution which is not an institution referred to in section 3(1)(a) or (b) and which complies with the prescribed conditions, subject to any further conditions (if any) which the Minister may determine in any particular case and which shall be stated in the said notice, to – (a) acquire, use or supply bodies of deceased persons for any of the purposes referred to in section 4(1); and (b) acquire or use any tissue lawfully imported or removed from the body of a living or deceased person for any of the purposes referred to in section 4(1) or 19, as the case may be; (c) supply any tissue preserved by it to an institution or person referred to in section 3(1)(a), (b), (c), (d) or (e) for any of the purposes referred to in section 4(1) or section 19.

the hospital or institution must provide written authorisation and may not carry out the transplantation himself or take part therein.[639]

A similar provision is included in section 58 of the National Health Act. A person may not remove tissue from a living person for transplantation in another living person or carry out the transplantation of such tissue except in a hospital or an authorised institution.[640] Also, according to section 54(2)(b), an authorised institution may acquire or use any tissue lawfully imported or removed from the body of a living or deceased person for any of the purposes referred to in section 56. According to section 54(2)(c), an authorised institution may supply any tissue preserved by it to an institution or person contemplated in section 63 for any of the purposes referred to in section 58. The transplantation may only be carried out on the written authority of the medical practitioner in charge of clinical services in that hospital or authorised institution, or any other medical practitioner authorised by him.[641] In the case where there is no medical practitioner in charge of the clinical services at that hospital or authorised institution, a medical practitioner is authorised thereto by the person in charge of the hospital or authorised institution.[642] However, the medical practitioner contemplated in subsection (1)(b) may not participate in a transplant for which he has granted authorisation in terms of that subsection.[643]

Section 3(1) of the Human Tissue Act describes the institutions and persons to whom tissue may be donated. Specific tissue may, in terms of section 2,[644] be donated to any of

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639 Section 20(b).

640 Section 58(1)(a). Section 1 defines a hospital as "a health establishment which is classified as a hospital by the Minister in terms of section 35". For the classification of health establishments see section 35 of the Act. "Authorised institution" means any institution designated as an authorised institution in terms of section 54. According to section 54(1) the Minister may, by notice in the *Gazette*, designate any institution other than an institution contemplated in section 63 as an authorised institution.

641 Section 58(1)(b)(i).

642 Section 58(1)(b)(ii).

643 Section 58(2).

644 Section 2 deals with the bodies and tissue of deceased persons and regulates the donation of human bodies and tissue. It is not necessary to discuss this section for the purposes of this dissertation; since the focus is on fetal tissue. The purposes for which a dead body or tissue may be donated are stipulated in section 4 of this Act.

the following institutions or persons: a hospital,[645] a university or technicon,[646] an authorised institution,[647] a medical practitioner,[648] a dentist,[649] and in the case of tissue also any person who requires therapy in which the tissue concerned can be used.[650]

According to section 63 of the National Health Act, tissue may be donated by any person contemplated in section 55(a) (as discussed above) or section 62; or to any prescribed institution or person for any purpose contemplated in section 56 (as discussed above) or section 64(1).[651]

The Human Tissue Act further regulates the control of removal and the use of tissue in section 23. No person other than a medical practitioner or dentist or a person acting under his supervision may remove any tissue from the body of a living person or use or transplant tissue so removed in the body of another living person.[652]

A similar provision is contained in section 59 of the National Health Act. This section regulates the removal, use and transplantation of tissue by a medical practitioner or dentist, and provides for the following: Only a medical practitioner or dentist may remove any tissue from a living person, use tissue so removed for any of the purposes contemplated in section 56, as discussed above, or transplant tissue so removed into another living person.[653]

4 2 4 1 Import and export permits

Fetal tissue research poses a difficult moral problem, and represents a window of opportunity for large Western corporations to exploit impoverished South African

[645] Section 3(1)(a).
[646] Section 3(1)(b).
[647] Section 3(1)(c).
[648] Section 3(1)(d).
[649] Section 3(1)(e).
[650] Section 3(1)(f).
[651] Section 62 regulates the donation of human bodies and tissue of deceased persons. Section 64 deals with purposes for which human bodies and tissue of deceased persons may be donated. It is not necessary for the purpose of this dissertation to examine these provisions.
[652] Section 23(a).
[653] Section 59(1).

women, mining their bodies for fetal tissue to be developed into stem cell lines and shipped elsewhere for research purposes. Dr Eddie Mhlanga, Chief of Maternal, Child and Women's Health in the national Department of Health, says this is "not okay", since money from this research will likely never find its way back to South African shores and benefit the women from which the tissue was taken. It is better to never allow the research in the country, he argues, than permit South Africa to become another Petri dish for greedy Western doctors.[654] The regulatory provisions pertaining to the import, export and selling of tissue are discussed below.

Section 25(1) of the Human Tissue Act regulates the importing and exporting of tissue, and in this context, fetal tissue. No person, except a person to whom the Director-General[655] has issued a permit in terms of subsection (2), may import or export any tissue. The Director-General may on application in writing issue a permit in a form determined by him to a person, authorising such a person to import or export, subject to such conditions as the Director-General may determine and record, the tissue on the permit.[656] Section 57(3) of the National Health Act only refers to zygotes and embryos, and reads: "No person may import or export human zygotes or embryos without the prior written approval of the Minister." An embryo is included in the definition of tissue and therefore section 57(3) is applicable to the provisions pertaining to tissue. The Minister may still make regulations regarding the import and export of tissue.[657]

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[654] Schüklenk, U & Lott, J (2002) "Ethics, politics and embryo stem cell research in South Africa" *SA J Obstetr & Gyn* 8(3) 57 *at* 58, 59.

[655] Director-General refers to the Director-General: National Health and Population Development. See section 1.

[656] Section 25(2). Section 26 regulates the disposal of tissue and reads as follows: "Disposal of tissue … or gametes imported without or contrary to permit. – (1) When any tissue…or gamete has in the opinion of the Director-General been imported contrary to the provisions of section 25 or the conditions of a permit issued under that section, the Director-General may – (a) order the importer concerned in writing to destroy or to remove from the Republic the tissue … or gamete so imported within the period determined by the Director-General and at the expense of that importer; and (b) order that, if the importer concerned does not so destroy or remove the tissue ... or gamete concerned, it shall be forfeited to the State. (2) If such an importer, after receipt of a written order under subsection (1), notifies the Director-General in writing that he does not intend to comply with the order for destruction or removal, or fails to remove the tissue … or gamete concerned from the Republic within the period determined by the Director-General in terms of the said subsection, the Director-General may at the expense of the importer seize the tissue…or gamete and so dispose thereof in such manner as he may deem fit. When the Director-General has disposed of any tissue ... or gamete by virtue of the provisions of subsection (2), he may recover the cost in connection with such disposal from the importer concerned."

[657] Section 68(1)(g).

4 2 4 2 Selling of tissue

This section examines the "trafficking" in human tissue. As previously discussed, recent scientific experimentation has revealed that fetal tissue yielded from abortions has remarkable therapeutic value. It is submitted that the demand for fetal tissue will likely expand to the point where the current supply no longer satisfies it. Therefore, to obtain tissue from women who would not otherwise donate their aborted fetuses, should research organisations, pharmaceutical companies and doctors be allowed to offer women a "financial incentive" for their fetal tissue? That is, should women be allowed to sell their fetal tissue? There is every possibility that the very existence of legal abortion provides a ready market whereby men and women of science can make extraordinary amounts of money and pursue their research while offering financial incentives to women for donation of their fetal remains, believing that sick people would be made well again. Although this emotional sales approach has no basis in fact, the truth is that women in distress could be made to feel quite comfortable with a decision to terminate their pregnancies.

De Klerk discusses the arguments for and against the trafficking in human tissue. A few of the arguments in favour of the trafficking in tissue include:

(a) It can lead to an increase in the supply of human tissue.
(b) A person should have the right to make decisions concerning his or her body.[658]
(c) If a person is allowed to donate tissue, he should also be allowed to sell his or her tissue.

A few of the arguments against the trafficking in human tissue include:

(a) The "product" supplied might not be very reliable.
(b) It would be difficult to calculate the value of a priceless item.
(c) The person might not voluntarily consent to the selling of his or her tissue.[659]

[658] See section 12(2) of the Constitution. See also *Stoffberg v Elliot* fn 488 *supra*.

(d) The economically and socially deprived might be prejudiced.

(e) People might not be willing to donate their tissue if they know they can be financially remunerated.[660]

Section 28 of the Human Tissue Act regulates payment in connection with the import, acquisition, or supply of tissue. No person except an authorised institution or, in the case of tissue or gametes imported in terms of this Act, the importer concerned, may receive any payment in respect of the import, acquisition, or supply of any tissue or gamete for or to another person for any of the purposes referred to in section 4(1) or section 19. The provisions of subsection (1) shall not prevent a medical practitioner or dentist from receiving remuneration for professional services rendered by him to any person. It is clear that the unlawful sale of human tissue is a criminal offence.[661] If payment has been made for tissue or gametes in contravention of the Act, the person who made such payment is entitled to a refund.[662] The Human Tissue Act creates a number of criminal offences that are punishable by a fine of R2 000 or imprisonment for a period not exceeding one year or both.[663]

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659 "The policy behind legislation prohibiting 'body material sales' is ethical and humane: scientific research and medical education should no longer be pursued at the physical cost of the economically and socially deprived, nor should it exploit the needs of the vulnerable … Equally, the poor should not be induced by money to offer the material resources of their bodies, and to convert their own health into a saleable commodity in the market-place of human replacement-parts." See De Klerk, A (1991) "Die handeldryf in of 'met' menslike weefsel" *THRHR* 54(4):600 *at* 614.

660 De Klerk (1991) *THRHR* 600 *at* 608-615.

661 Section 34(j).

662 In 2005, five of South Africa's top surgeons were charged in the Durban Magistrate's Court with performing more than 100 illegal kidney transplants. The charges arose from investigations which revealed that a syndicate was recruiting kidney donors from Brazil and paying them a few hundred dollars for their organs. These were then transplanted into kidney patients, mainly Israelis, who paid over $100 000 to fly to South Africa for the operations. The 110 fraud charges related to documentation in which it was stated that the donors and recipients were blood relatives and no money had changed hands. The 110 assault charges against the surgeons related to allegations that complications and other "important considerations" were not explained to the donors and that the operations were a "serious assault on them". The contraventions of the Human Tissue Act related to the payments to the donors. See Broughton, T (2005) "Top doctors in court for kidney scam: Suspected of links to syndicate trading in organs" *Pta News*:1, August 17. For the statutory provisions pertaining to the allocation and use of human organs, see section 61 of the National Health Act. The scope of this dissertation does not allow for an in-depth discussion of this section.

663 For a list of these offences see section 34(a)-(p). For example, subsection (a) reads: "Any person who – (a) except in so far as it may be permitted by or under any other law, acquires, uses or supplies a body of a deceased person or any tissue … or gamete of a living or deceased person in any other manner or for any other purpose than that permitted by this Act shall be guilty of an offence and liable on

Section 60 of the National Health Act regulates payment of the selling of human tissue and provides for the following:

> (1) No person, except –
> (a) a hospital or an institution contemplated in section 58 (1)(a), a person or an institution contemplated in section 63 and an authorised institution or, in the case of tissue or gametes imported or exported in the manner provided for in the regulations, the importer or exporter concerned, may receive payment in respect of the acquisition, supply, importation or export of any tissue or gamete for or to another person for any of the purposes contemplated in section 56 or 64;
> (b) A person or an institution contemplated in section 63 or an authorised institution, may receive any payment in respect of the importation, export or acquisition for the supply to another person of blood or a blood product.
> (2) The amount of payment contemplated in subsection (1) may not exceed an amount which is reasonably required to cover the costs involved in the importation, export, acquisition, or supply of the tissue, gamete, blood or blood product in question.
> (3) This section does not prevent a health care provider registered with a statutory health professions Council from receiving remuneration for any professional service rendered by him or her.
> (4) It is an offence for a person –
> (a) who has donated tissue, a gamete, blood or a blood product to receive any form of financial or other reward for such donation, except for the reimbursement of reasonable costs incurred by him or her to provide such donation; and
> (b) to sell or trade in tissue, gametes, blood or blood products, except as provided for in this Chapter.
> (5) Any person convicted of an offence in terms of subsection (4) is liable on conviction to a fine or to imprisonment for a period not exceeding five years or to both a fine and imprisonment.

In conclusion, the trafficking in human tissue currently constitutes an offence, and is regarded as *contra bonos mores* by society. One might also note that this poses a very specific legal dilemma: It is illegal to sell human body parts, but there is no law against charging for services related to the handling of body parts. For example, if a person donates a kidney for transplant, it is illegal for the recipient or anyone else to pay for the kidney. But there is no law against the doctor charging for his services in performing the transplant, or against a shipping company receiving money to transport the kidney from the hospital where it is removed to the hospital where it is transplanted into another person. Is this a loophole? Some abortionists defend themselves by claiming that they are

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conviction to a fine not exceeding R2 000 or to imprisonment for a period not exceeding one year or to both that fine and that imprisonment."

not selling body parts, but rather selling their services in "harvesting" and "preparing" these body parts.[664]

To summarise, the Human Tissue Act and the National Health Act legalise tissue transplantation in absolute terms. Strauss remarks that it can be doubted whether a court of law will be prepared to interpret the provisions of the Human Tissue Act as conferring an absolute discretion concerning the removal of tissue upon either the authorising doctor, the surgeon undertaking the removal or the donor. Should such a case come before our courts, section 19(a), and now section 56 of the National Health Act, will probably be interpreted against the background of the common-law principle of *volenti non fit iniuria*. This means that an operation for the removal of tissue will be ruled as unlawful if it is of such a nature that it is considered to be contrary to public policy. A court will have to make a decision by carefully weighing the donor's interests against those of the recipient.[665] It is important to note that section 68 of the National Health Act permits the Minister to make regulations regarding tissue transplants and the supply of tissue.[666]

4 2 4 3 Confidentiality

A controversial issue with regard to tissue transplantation and donation is whether the donor and recipient should be protected against publicity. It has been argued that if the identity of a recipient were known, there would be the possibility of blackmail on the part of the donor or his next of kin. It has also been submitted that the fear of publicity could deter potential donors. Personal freedom of individuals is too important to be fettered by a prohibition against the disclosure of the fact that people were the donor or recipient of human tissue. The legislature made the disclosure of the identities of the parties lawful, in section 33 of the Human Tissue Act, depending on their consent thereto.[667] This section reads as follows:

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664 Johansen, J (2001) "Trafficking in fetal remains" [Web:] www.pregnantpause.org/abort/partexpl.htm [Date of access: 12 March 2006].
665 Strauss (1991) 149.
666 Section 68(1)(d) and (f).
667 Strauss (1991) 157.

> (1) No person shall publish to any other person any fact whereby the identity of …
> (c) a living person from whose body any tissue, blood or gamete has been removed or withdrawn for any purpose referred to in section 19; or
> (d) the person who has given his consent to the removal of any tissue, blood or gamete from the body of a living person for such a purpose,
> may possibly be established, unless consent thereto was granted … by the living person concerned or by another person referred to in paragraph (bb) of the *proviso* to section 18.
> (2) No person shall publish to another person any fact whereby the identity of the recipient of any tissue removed from the body of another person before or after the death of the said person may possibly be established, unless –
> (a) in the case of a recipient who is still alive at the time of such publication, that recipient before such publication granted his consent thereto in writing.

It is submitted that the only person able to consent in the case of fetal tissue is the woman who donates her tissue.

According to section 34(k), the unlawful disclosure of the identity of a donor or recipient constitutes a punishable offence. The Act however exempts a doctor who, for any purposes stated in the Act, in good faith removes any tissue from a dead body or from a living donor, in the event of any donation subsequently being found to be legally invalid. The magistrate or medical practitioner who authorises the removal of the tissue is afforded the same protection.[668]

Section 14 of the National Health Act regulates confidentiality. All information concerning a user,[669] including information relating to his or her health status, treatment or stay in a health establishment is confidential.[670] No person may disclose any information contemplated in subsection (1) unless –

(a) the user consents to that disclosure in writing; or

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[668] Section 35.

[669] "User" means the person receiving treatment in a health establishment, including "receiving … or using a health service", and if the person receiving treatment or using a health service is – (a) below the age contemplated in section 39 (4) of the Child Care Act ... user includes the person's parent or guardian or another person authorised by law to act on the first mentioned person's behalf; or (b) incapable of taking decisions, 'user' includes the person's spouse or partner or, in the absence of such spouse or partner, the person's parent, grandparent, adult child or brother or sister, or another person authorised by law to act on the first mentioned person's behalf. See section 1.

[670] Section 14(1).

(b) a court order or any law requires that disclosure.

Non-disclosure of the information represents a serious threat to public health.[671]

According to section 13(b) of the Children's Bill, "every child has the right to confidentiality regarding his or her health status and the health status of a parent, care-giver or family member, except when maintaining such confidentiality is not in the best interest of the child".[672]

According to Rule 12 of the Health Professions Council's Ethical Rules of conduct for practitioners registered under the Health Professions Act, "[a] practitioner shall only divulge verbally or in writing any information regarding a patient which he or she ought to divulge – (a) in terms of a statutory provision; or (b) at the instruction of a court of law; or (c) where justified in the public interest. Any other information … shall only be divulged … (a) with the express consent of the patient; (b) in the case of a minor under the age of 14 years, with the written consent of his or her parent or guardian; or (c) in the case of a deceased patient, with the written consent of his or her next-of-kin or the executor of such deceased patient".[673] Regarding confidentiality in respect of the nature of illness, ailment or injury of patient, the Executive Committee of the Medical and Dental Professions Board resolved as follows: The fundamental principle of confidentiality between doctor/dentist and patient should be maintained. It should not be obligatory for a medical practitioner or dentist to specify the nature of an illness, ailment

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[671] See also section 15, which reads as follows: "(1) A health worker or any health care provider that has access to the health records of a user may disclose such personal information to any other person, health care provider or health establishment as is necessary for any legitimate purpose within the ordinary course and scope of his or her duties where such access or disclosure is in the interests of the user. (2) For the purpose of this section, "personal information" means personal information as defined in section 1 of the Promotion of Access to Information Act, 2000 (Act 2 of 2000)." "Personal information" means information about an identifiable individual. For the complete definition see section 1 of the Promotion of Access to Information Act. See also section 16 of the National Health Act, dealing with access to health records by health care providers, and section 17 of this Act, which deals with the protection of health records.
Another issue that deserves mention, but falls outside the scope of this dissertation, is whether secrets hidden in people's genes should be protected under the constitutional right to privacy, among under constitutionally protected rights. For a discussion of whether "genetic privacy" will be the major constitutional issue of the next generation, see Lupton (1996) *TSAR* 56.

[672] See the Children's Bill.

[673] South Africa. Health Professions Council's Medical and Dental Professions Board (2002) 36.

or injury and only to do so with the consent of a patient. If a patient consulted another medical practitioner or dentist, full information on the condition of the patient should be made known to that medical practitioner or dentist on request.[674]

4 2 4 4 Appointment of inspectors of anatomy

The Director-General may appoint one or more persons in his department as inspectors of anatomy. Such an inspector may at any reasonable time enter any premises in or upon which a human body or tissue is being used for any purpose referred to in the Human Tissue Act; in or upon which the production from tissue of any therapeutic, diagnostic or prophylactic substance is carried on; and examine any such premises or any body, tissue, product or substance found therein or thereon in order to ascertain whether the provisions of the Act is complied with. An inspector of anatomy may at any time demand from any person in or upon such premises to produce any register, record or other document, and examine such a register, record or other document. Any person in charge of any premises contemplated in this provision of the Act is compelled to render such assistance as an inspector of anatomy may require. An inspector of anatomy is required to furnish yearly reports on his work to the Director-General.[675]

According to section 68 of the National Health Act, the Minister may make regulations regarding the appointment and functions of inspectors of anatomy and investigating officers.[676]

4 3 THE EMBRYO EXTRA UTERUM

4 3 1 Introductory remarks

According to the Human Tissue Act, the Minister may make regulations relating to research with regard to the product of the union of a male and female gamete outside the human body.[677] Section 68 of the National Health Act places the power to make regulations relating to gametes in the hands of the Minister. The Minister may make

[674] South Africa. Health Professions Council's Medical and Dental Professions Board (2002) 40.
[675] The appointment and functions of inspectors are regulated in sections 29 and 32.
[676] Section 68(1)(m).
[677] Section 37(1)(e)(vii).

regulations regarding the supply of oocytes, human stem cells and other human cells or gametes.[678] Further regulations may be published regarding the bringing together outside the human body of male and female gametes, and research with regard to the product of the union of those gametes[679] and the artificial fertilisation of persons.[680] It also includes regulations pertaining to the acquisition, storage, harvesting, utilisation or manipulation of gametes, oocytes or human stem cells for any purpose,[681] and any other matter relating to regulating the control and use of gametes in humans.[682] The South African Medical Research Council has also laid down important ethical guidelines on research relating to in vitro fertilisation and embryo biology.[683] The provisions of the Human Tissue Act, the National Health Act and the Medical Research Council's ethical guidelines are discussed below.

4 3 2 In vitro fertilisation and artificial insemination

As previously discussed, in vitro fertilisation serves a therapeutic purpose, namely to enable couples to reproduce,[684] and is altogether lawful as long as it complies with all the provisions contained in the applicable abovementioned legislation and the applicable regulations thereto.[685] In vitro fertilisation is defined in the regulations as "the bringing

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678 Section 68(1)(f).
679 Section 68(1)(k).
680 Section 68(1)(l).
681 Section 68(1)(p).
682 Section 68(1)(r). See also section 68(2) where the Minister, with concurrence of the cabinet member responsible for finance, may make regulations concerning the payment of persons or institutions in connection with procurement, storage, supply, import, or export of gametes. According to section 68(3) the Minister may, if consistent with the objects of this Act and upon such conditions as the Minister may deem fit, by notice in the *Gazette*, exempt any person or category of persons from any or all of the regulations made under this section.
683 Research on in vitro fertilisation embryos are lawful, but may only be conducted in approved institutions and in accordance with the provisions of the Human Tissue Act and the "Artificial insemination of persons, and related matters" regulations (GN R1182 of June 1986 (20 June 1986)) insofar these regulations are applicable. See Strauss (1991) 200. (These regulations were amended by GN R1354 in *GG* 18362 (17 October 1997).)
684 It is important to mention that the Children's Status Act brought certainty regarding the legal status of children conceived through the process of in vitro fertilisation. According to section 5, a child born to a woman after donor insemination, with the consent of her husband, is deemed for all purposes to be the legitimate child of the woman and her husband.
685 For an explanation of the in vitro fertilisation technique see paragraph 2.3.3.2. The regulations pertaining to the National Health Act are still unpublished at the time of writing. With reference to the Human Tissue Act, the applicable regulations are "Artificial insemination of persons, and related matters" fn 683 *supra*. The regulations are only applicable to in vitro fertilisation where donor sperm is used.

together outside the human body of a male and a female gamete[686] and the placing of the zygote[687] in the womb of a female person". According to section 3 of the regulations, only a medical practitioner may remove gametes for the purpose of in vitro fertilisation. It is uncertain whether the medical practitioner may also remove gametes for other therapeutic purposes, including stem cell research. Section 23 of the Human Tissue Act, regulating the removal and use of tissue and blood, makes no reference to gametes. Section 59 of the National Health Act, with similar provisions, does not refer to gametes either.

Section 18 of the Human Tissue Act and section 55 of the National Health Act regulate the provisions pertaining to consent to the removal of gametes from the bodies of living persons. The purposes for which the gametes from the bodies of living persons may be used are regulated by section 19 of the Human Tissue Act and section 56 of the National Health Act. These provisions were discussed the paragraphs above. The differences between their provisions are pointed out throughout the dissertation. Section 19 of the Human Tissue Act clearly states that gametes removed or withdrawn from the body of a living person shall only be used for medical and dental purposes, including the artificial fertilisation of another person.[688] It seems that medical and dental purposes as stipulated in the Human Tissue Act might also include the derivation of gametes for stem cell research purposes, the reason being the use of the word "including" in the Act. Therefore, the use of gametes includes in vitro fertilisation, but is not restricted to it. In addition, section 56 of the National Health Act states that gametes may not be removed or withdrawn from a living person for medical and dental purposes if that person is younger than 18 years.[689] However, the Minister may authorise the removal or withdrawal of gametes contemplated in section 56(2)(a), and may impose any condition which may be necessary in respect of such removal or withdrawal.[690]

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686 It is important to note that a "gamete" is excluded from the definition of "tissue" in section 1 of both the Human Tissue Act and the National Health Act. An embryo, however, will fall within the scope of the definition of "tissue". See section 1 of both the Human Tissue Act and the National Health Act for the definition of "tissue".

687 See section 1 of the National Health Act for the definition of a "zygote".

688 Section 19(c).

689 Section 56(2)(a)(iii).

690 Section 56(2)(b).

Furthermore, according to section 19 of the Human Tissue Act, a gamete shall not be removed for the purposes referred to in this section from a person who is mentally ill within the meaning of the Mental Health Act. A gamete may also not be used for the above purposes removed from a person who has been declared a habitual criminal in terms of section 286 of the Criminal Procedure Act.[691] A gamete that is not replaceable by natural processes may also not be removed from a minor. Section 56 of the National Health Act also states that a gamete may not be removed, for the above-mentioned purposes, from a person who is mentally ill within the meaning of the Mental Health Care Act. However, the Minister may authorise the removal or withdrawal of gametes, and may impose any condition that may be necessary in respect of such removal or withdrawal.[692]

The provisions of section 25 and section 26 of the Human Tissue Act pertaining to import and export permits, as well as the disposal of tissue without or contrary to permits discussed above also applies to gametes. It is not necessary to discuss these provisions again. Section 57(3) of the National Health Act only refers to zygotes and embryos and reads: "No person may import or export human zygotes or embryos without the prior written approval of the Minister." According to section 68 of the National Health Act, the Minister may still make regulations pertaining to the import and export of gametes.[693]

Artificial insemination is a lawful procedure in South Africa, provided that it is performed by a medical practitioner (or a person acting under his supervision), in accordance with the regulations promulgated by the Minister in terms of the Human Tissue Act.[694] The regulations are generally not applicable to artificial insemination where the husband's sperm is used, but apply to artificial insemination where donor sperm is used.[695] Strict control is exercised over the donation of gametes. No person, except a medical practitioner or somebody acting under his supervision, may remove or

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691 This provision is not included in section 56 of the National Health Act.
692 Section 56(2)(a)(i) and section 56(2)(b).
693 Section 68(1)(g). See also section 33 of the Human Tissue Act as discussed above. Section 36 of the Human Tissue Act, as previously discussed, also applies to gametes. See also section 14 and section 57(3) of the National Health Act, as previously discussed.
694 "Artificial insemination of persons, and related matters" fn 683 *supra*.
695 Only regulation 11 is applicable where donor sperm is used.

withdraw a gamete from the body of a living person for the purpose of artificial insemination. A donor's personal file has to be opened. Comprehensive written consent must be obtained from the prospective donor. The donor must consent to a physical examination and interview by the medical practitioner; the taking of samples of gametes for the purpose of testing, analysing or processing; certain personal details of himself (except his name, date of birth and identification number) being made available to the ultimate recipient; certain personal details, including his family history, being made available to the medical practitioner who will perform the artificial inseminations; and certain confidential details regarding himself being made available to the Director-General.

No further donations may be made if the medical practitioner has reason to believe that at least five children have been artificially produced by means of gametes from the donor. Before the removal of gametes, the medical practitioner must establish that the donor has undergone (no more than one year earlier) medical tests for sexually transmitted diseases, as well as a sperm analysis (in the case of male donors), or a gynaecological examination (in the case of female donors). In the case of a married donor, the spouse's consent must be obtained in writing. There should also be an evaluation of the psychological suitability of the donor for the purposes of artificial insemination. Artificial inseminations may only be effected on married women whose husbands consent in writing.

Before an artificial insemination can take place, the medical practitioner must ensure that the recipient and her husband are informed by appropriate experts of the possibilities of natural conception as well as of all the implications of artificial insemination, including potential problems with the technique, the chances of success, the financial aspects, the consequences for the marriage, and the ethical, psychosocial and educational implications. In addition, the wishes of both the donor and the recipient must be respected regarding the population and religious group of the child to be procreated.

Where a possibility exists that the recipient or donor is the carrier of a defect which can be transmitted by genes or chromosomes, examinations and tests must be carried out. If

the tests are positive, genetic counselling must be given to the recipient couple and the donor's semen may not be used. A proper recipient file containing the prescribed information must also be kept.[696]

4 3 3 Cryopreservation: The so-called "surplus embryos"

One advantage of the in vitro fertilisation procedure is that both fertilised and unfertilised eggs that have been left unused can be frozen. If the woman falls pregnant or decides to abandon her attempts to fall pregnant, unutilised eggs or embryos may become available for research. According to Lupton, not all forms of research are damaging to the embryo. For example, simple observations or diagnostic tests may be carried out without harming the embryo in any way and leaving it fit for implantation. However, other forms of research can destroy or damage the embryo, therefore preventing its subsequent implantation.[697] (The advantages and disadvantages of embryo research were already discussed in chapter 3.) Cryopreservation has also given rise to a host of ethical and legal issues pertaining to the status of frozen embryos. The legal status of frozen embryos is discussed in detail in chapter 5 where the position in the United Kingdom is examined.

The National Health Act permits research on stem cells and zygotes in the following manner: The Minister may permit research on stem cells and zygotes which are not more than 14 days old on a written application and if –

(a) the applicant undertakes to document the research for record purposes; and
(b) prior consent is obtained from the donor of such stem cells or zygotes.[698]

The Minister may make regulations regarding the bringing together outside the human body of male and female gametes, and research with regard to the product of the union of those gametes.[699] The Minister may also make regulations regarding the artificial

[696] Strauss (1991) 181, 182, 183.
[697] Lupton (1992) *TSAR* 466.
[698] Section 57(4)(a) and (b).
[699] Section 68(1)(k).

fertilisation of persons.[700] According to section 90 of this Act, the Minister, after consultation with the National Health Council,[701] may make regulations regarding health research.[702]

Currently all research involving human participants conducted in South Africa must be reviewed by ethics committees. The South African Medical Research Council has ethics committees that are mainly responsible for the ethical review of research protocols. Recently, the Department of Health proposed that a national body should be created which would be empowered to promote and be the watchdog for good ethical practice in South African health research. A national Health Research Ethics Council was established under the National Health Act. This council does not replace the existing committees, but sets standards and arbitrate on matters of ethics.
Firstly, the Minister must establish a national health research committee.[703] This committee must –

(a) determine the health research to be carried out by public health authorities;
(b) ensure that health research agendas and research resources focus on priority health problems;
(c) develop and advise the Minister on the application and implementation of and integrated national strategy for health research; and
(d) coordinate the research activities of public health authorities.[704]

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700 Section 68(1)(l).
701 It is important to note that the power to make regulations as stipulated in section 90 of the National Health Act does not only vest in the Minister, but also in the National Health Council.
702 Section 90(1)(s). The National Health Council refers to the council established under section 22(1). Health research is defined in section 1 and "includes any research which contributes to knowledge of – (a) The biological, clinical, psychological or social processes in human beings; (b) improved methods for the provision of health services; (c) Human pathology; (d) The causes of disease; (e) The effects of the environment on the human body; (f) The development or new application of pharmaceuticals, medicines and related substances; and (g) The development of new applications of health technology". See also section 90(2). This section allows the Minister, subject to the Medicines and Related Substances Control Act and after consultation with the National Health Research Ethics Council, to make regulations regarding research on human subjects. The National Health Research Council means the council established under section 72(1). For a discussion of these councils and committees see the paragraphs below.
703 Section 69(1).
704 Section 69(3)(a)-(d).

Section 69(4) further states that the Minister is compelled to prescribe the manner in which the National Health Research Committee must conduct its affairs, and the procedure to be followed at meetings of the committee, including the manner in which decisions must be taken.[705] The National Health Research Committee must identify and advise the Minister on health research priories.[706]

A council, to be known as the National Health Research Ethics Council, should also be established in terms of section 72(1) of the National Health Act. The National Health Research Ethics Council must determine guidelines for the functioning of health research ethics committees; register and audit health research ethics committees; set norms and standards for conducting research on humans and animals, including norms and standards for conducting clinical trials;[707] adjudicate complaints about the functioning of health research ethics committees and hear any complaint by a researcher who believes that he has been discriminated against by a health research ethics committee; refer to the relevant statutory health professions council matters involving the violation or potential violation of an ethical or professional rule by a health care provider; institute such disciplinary action as may be prescribed against any person found to be in violation of any norms and standards or guidelines set for the conducting of research in terms of the National Health Act; and advise the national department and provincial departments on any ethical issues concerning research.[708]

In addition, every institution, health agency[709] and health establishment[710] at which health

[705] See also section 69(2), which deals with the appointment of members of the committee. Section 69(5) deals with remuneration of members of the committee.

[706] Section 70(1). According to section 70(2) this committee, in identifying health research priorities, must have regard for the burden of disease, the cost-effectiveness of interventions aimed at reducing the burden of disease, the availability of human and institutional resources for the implementation of an intervention at the level closest to the affected communities, the health needs of vulnerable groups such as women, older persons, children and people with disabilities, and the health needs of communities.

[707] "Clinical trials" means a systematic study involving human subjects, which aims to answer specific questions about the safety or efficacy of a medicine or method of treatment. See section 72(7).

[708] Section 72(6)(a)-(g). See also section 72(2)-(5).

[709] "Health agency" means any person other than a health establishment – (a) whose business involves the supply of health care personnel to users or health establishments; (b) who employs health care personnel for the purpose of providing health services; or (c) who procures health care personnel or health services for the benefit of a user, and includes a temporary employment service as defined in the

research is conducted must establish or have access to a health research ethics committee which is registered with the National Health Research Ethics Council.[711] A health research ethics committee must review research proposals and protocols to ensure that research conducted by the relevant institution, agency or establishment will promote health; contribute to the prevention of communicable or non-communicable diseases[712] or disability, or result in cures for communicable or non-communicable diseases;[713] and must grant approval for research by the relevant institution, agency or establishment in instances where research proposals and protocol meet the ethical standards of that health research ethics committee.[714]

4 3 4 The Medical Research Council's guidelines on ethics for medical research[715]

Authorisation for medical research must be procured from the relevant ethics committees. These committees are the Medical Research Council's Ethics Committee and the various ethics committees of academic institutions for medical training and of various other bodies. The Medical Research Council was created by statute, the South African Medical Research Council Act,[716] and one of its objectives is to promote and improve the health and quality of life of the South African population through research development and technology transfer.[717]

The Medical Research Council's control is exercised by way of a codified set of broad guidelines, which cover experimentation or activities involving embryos, fetuses, and in vitro fertilisation. The merits of individual applications for research protocols, financial assistance and any ethical issues involved are carefully scrutinised. Evaluators or

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Basic Conditions of Employment Act, 1997 (Act 75 of 1997), involving health workers or health care providers. See section 1 of the National Health Act.

710 "Health establishment" means the whole or part of a public or private institution, facility, building or place, whether for profit or not, that is operated or designed to provide inpatient or outpatient treatment, diagnostic or therapeutic interventions, nursing, rehabilitative, palliative, convalescent, preventative or other health services. See section 1.

711 Section 73.

712 "Non-communicable disease" means a disease or health condition that cannot be contracted from another person, an animal or directly from the environment. See section 1.

713 Section 73(2)(a).

714 Section 73(2)(b).

715 Revised edition, 1993.

716 The South African Medical Research Council Act, 1969 (Act 19 of 1969). See section 2.

717 Slabbert (2000) 107. See also section 3 of the National Health Act; Van Oosten (2000) *THRHR* 5 *at* 6.

consultants indicate concern for the welfare of human subjects approved in research by exercising *de facto* control over experimentation on an ongoing basis and by following up on reports of committees, It is important to realise that these guidelines do not constitute law, but they are however legally relevant.[718] In the event where both a legal requirement and a guideline applying to a particular issue of health research, the legal requirement will take precedence.[719] According to the Medical Research Council, the ethical guidelines should not be too rigid because of the diversity of reproductive biology research programmes. The basic issues, as stipulated in the guidelines, in the various areas of reproductive research are as follows:

(a) There is consensus that no moral problem intrinsic in using the in vitro fertilisation technique for reproduction in cases where the gametes from the husband and wife are used.
(b) The ethical considerations in gamete intra-fallopian transfer (GIFT) and other methods of artificial reproduction are similar to those applicable to in vitro fertilisation. Research to improve the efficacy of gamete intra-fallopian transfer is therefore ethically acceptable.
(c) The Medical Research Council recommends that research methods in artificial insemination with donor sperm be limited to the essential, and that adequate consent be obtained from all people involved in the donation or reception of gametes.[720]
(d) Treatment of male infertility is one of the main aims of in vitro fertilisation and gamete intra-fallopian transfer. In cases of severe sub-fertility, the use of donor sperm is the only method of treatment. Although the ethical considerations of using donor sperm, and therefore introducing a third party into the fertilisation process, must be considered as controversial, careful counselling and informed consent by all persons involved should help resolve many of the dilemmas.

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[718] Slabbert (2000) 109. Van Wyk submits that the guidelines should be considered as "law of general application" with reference to section 36 of the Constitution. See Van Wyk (2001) *THRHR* 3 *at* 21.
[719] Van Wyk (2004) *THRHR* 1 *at* 3.
[720] Artificial insemination procedures should be performed in full compliance with the regulations promulgated in terms of section 37 of the Human Tissue Act. See fn 683 *supra*.

(e) The use of donor eggs remains controversial. The Medical Research Council finds the use of donor eggs ethically acceptable, provided the donor receives no compensation for donating the egg.[721]

(f) Since the failure rate of in vitro fertilisation is high, three or four pre-embryos are usually transferred. To obtain this number of embryos, super-ovulation needs to be induced. All oocytes are fertilised in vitro. All embryos are not transferred to the womb, and are immediately cryopreserved. If the embryos are no longer required by the couple, they become available for donation. Since these embryos may be used by couples that might otherwise not become pregnancy, research in this field is ethically acceptable.

(g) Uterine lavage for pre-embryo transfer carries the risk that some of the pre-embryos may be retained in the uterus. Research using this procedure is legal in countries where abortion on demand is provided for by law.[722] It is therefore ethically acceptable in South Africa.

(h) Written consent to use gametes or pre-embryos should be obtained from the donor as well as their spouses.[723]

(i) Research on the field of zygote intra-fallopian transfer (ZIFT) should not be restricted.[724]

(j) Maintenance of embryos in vitro beyond the gestational age of two weeks is not ethically justifiable.

(k) Research into the selection of the fetal sex may be inappropriate if it results in a request for an abortion because the sex of the fetus is unacceptable to the parents. On the other hand, gender selection may be beneficial in sex-linked genetic diseases and may be justified under exceptional circumstances.

(l) Pre-embryo manipulation and research may yield valuable medical information. However, it can be regarded as ethical only if the embryos are not specifically

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[721] Attempts to extend childbearing beyond the menopause have many medical, familial and sociological disadvantages, and research in this field is usually unacceptable.

[722] As discussed earlier, the Choice on Termination of Pregnancy Act provides for abortion on demand during the first 12 weeks of pregnancy. The husband's consent is not needed for a lawful abortion, and no age limit is set by the Act for a woman seeking a termination of her pregnancy.

[723] For a discussion of the statutory provisions pertaining to consent see paragraph 4.4 below.

[724] The primary use of this technique is in candidates for gamete intra-fallopian transfer in whom evidence of the fertilising capacity of gametes is also desired.

produced for the purpose of research. The embryos should also not be transferred to the uterus unless there is reasonable certainty that the manipulation carries no potential risks for the fetus.[725]

(m) The zygote must be treated with the "utmost respect because it is a genetically unique, viable human entity" and if it is to be transferred to a woman's uterus, special care should be taken to ensure the welfare of the potential fetus.[726]

4 3 5 Genetic manipulation and cloning

The clinical aspects of therapeutic cloning were explained in chapter 1. As mentioned, the ethical objection to therapeutic cloning is that a potential human being is created and then discarded for research purposes. Opponents of this research think of it as the first step on the slippery slope towards reproductive cloning. Blackbeard submits that there is little risk of therapeutic cloning leading to cloned human beings.[727] Consideration is given in the paragraphs below to the legislative provisions pertaining to therapeutic and reproductive cloning.

The Human Tissue Act, as amended to introduce section 39A, prohibits the genetic manipulation of zygotes or gametes outside the human body. Section 39A read as follows: "Genetic manipulation of gametes or zygotes not permitted. Notwithstanding anything to the contrary contained in this Act or any other law, no provision of this Act shall be so construed as to permit genetic manipulation outside the human body of gametes or zygotes." The Human Tissue Act does not define "genetic manipulation". The ambit of this prohibition is therefore not clear. Lupton submits that cloning is not prohibited in terms of section 39A. He argues that nuclear substitution does not involve the use of gametes or zygotes and therefore falls outside the scope of section 39A.[728] Jordaan, on the other hand, submits that nuclear substitution does involve the use of egg cells, which are gametes. He argues that section 39A is inapplicable because of its vagueness with reference to the key term "genetic manipulation", which is not defined in

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[725] Du Toit *et al* (1999) www.sahealthinfo.org/ethics/book2.htm.
[726] Slabbert (2000) 110.
[727] Blackbeard (2002) *DJ* 318 *at* 321.
Lupton ML (1998) "Artificial reproduction and the family of the future" *Med & L* 17:93 *at* 111, 112. See also Lupton (1996) *TSAR* 56 *at* 66.

the Act. He submits that if it only pertains to the changing of an existing genome, cloning would be permissible, since it copies a genome. If it pertains to the creation of an entire new genome by joining two gametes, cloning would still be permissible for the same reason, but standard in vitro fertilisation practices would not, which is clearly not the intention of the Act to prohibit. He further submits that cell mass division falls outside the scope of section 39A, since this cloning technique is performed on two- to eight-cell embryos and not on gametes or zygotes. It is therefore his contention that the Human Tissue Act does not prohibit human reproductive cloning, either by way of nuclear substitution or cell mass division.[729]

According to Van Wyk, it is clear that any procedure that does not involve the genetic manipulation, engineering or changing of gametes and zygotes outside the human body is permissible. But opinions on the correct interpretation of this provision of the Act are widely divergent. Section 39A has been interpreted by Lupton to mean that somatic and germ-line therapy in general, as well as genetic engineering, is prohibited. Lupton also argues that somatic gene and germ-line therapy in adults and children is not prohibited. Van Wyk, however, submits that it is generally accepted that the cloning of human cells by means of nucleus substitution of an egg cell, even if only for the production of stem cells for research purposes, implies "genetic manipulation of gametes or zygotes outside of the human body" and is forbidden. She also submits that somatic and germ-line gene therapy of zygotes prior to implantation would not be permissible.[730]

Section 16 of the Human Tissue Act deals with the prohibition of the use of gonads for certain purposes and states that a gonad removed from the body of a deceased person shall not be transplanted into the body of a living person if the result of such transplantation may be procreation. According to section 21, a gonad removed from the body of a living person shall not be used in the body of another living person if the result of such use may be procreation, unless the Minister concerned in the case has granted previous written authority thereto.

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729 Jordaan (2002) 119 *SALJ* 294 at 303.
730 Van Wyk (2004) *THRHR* 1 *at* 16.

As mentioned earlier, the Medical Research Council's guidelines regard the exclusive production of embryos for research as unacceptable. A provision was inserted into the National Health Act to regulate the cloning of human beings, namely section 57, which reads as follows:

> (1) A person may not –
> (a) Manipulate any genetic material, including genetic material of human gametes, zygotes or embryos; or
> (b) Engage in any activity, including nuclear transfer or embryo splitting, for the purpose of the reproductive cloning of a human being.
> (2) The Minister may, under such conditions as may be prescribed, permit therapeutic cloning utilising adult or umbilical cord stem cells.[731]
>
> (5) Any person who contravenes a provision of this section or who fails to comply therewith is guilty of an offence and is liable on conviction to a fine or to imprisonment for a period not exceeding five years or to both a fine and such imprisonment.

In principle, nuclear transfer technology could be applied to satisfy the need for therapeutic treatment and research. This technique could provide embryos that would be a potential source of organs or tissues of a predetermined genetic background, namely those of the donor of the nucleus. Van Wyk submits that the definition of therapeutic cloning is to be welcomed, since it refers to the development of specific tissue rather than an entire individual, and steers clear of the possibility that embryos could be created to make available "spare body parts" for the donors of cell nuclei. She also submits that, in light of the many ethical and medical arguments against reproductive cloning, the best approach is to prohibit it.[732]

Setting down guidelines for the research and practice of cloning is only uncontroversial in an environment where the analysis presented fundamentally reflects the norms of the community. The difficulty in a pluralistic community is to determine which set of values to uphold. According to the guidelines,[733] informed consent will have to be given prior to the donation of oocyte, spermatozoa, normal but "surplus" fresh or frozen embryos,

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[731] See chapter 1 for the definitions of therapeutic and reproductive cloning as set out in section 57(6)(a) and (b).
[732] Van Wyk (2004) *THRHR* 1 *at* 21.
[733] Du Toit *et al* (1999) www.sahealthinfo.org/ethics/book2.htm.

nonviable or abnormal embryos, abnormally fertilised eggs, and eggs and sperm used to generate embryos for the purpose of scientific research. It is stated that the practice of therapeutic cloning cannot be equated with abortion where the potential life of the embryo is terminated at a woman's choice, because the reason for the creation of that embryo and the reason for the termination of its potential life are fundamentally different from the reasons of creating an embryo for the sole purpose of destroying it. A more acceptable approach could be the development of specific tissue rather than an entire individual. The growth of entire organs would revolutionise organ transplantation. However, this technique should be more thoroughly investigated in animal systems before experimentation with human tissue is permitted. With regard to reproductive cloning, it is recommended that the reproductive needs of an individual should not override the best interest of the child produced.

It is also recommended that a new expert supervisory body be established to continue supervision of research into and related to cloning. This body should be of sufficient standing to command the confidence of existing research ethics committees, the public, the professions and Parliament. It is recommended that any proposal for research related to cloning be approved by this body and a properly constituted ethics committee.[734] It is also important to refer to some international instruments with regard to research.[735]

4 3 5 1 UNESCO

UNESCO came into being on 4 November 1946. Within the framework of its standard setting activity, UNESCO has adopted a number of international instruments aimed at the realisation of human rights, including the Universal Declaration on the Human Genome and Human Rights of 1997. This declaration emphasised that research on the human genome "should fully respect human dignity, freedom and human rights", as well as prohibiting all forms of discrimination based on genetic characteristics. It is important to note that Article 11 states that "practices which are contrary to human dignity, such as

[734] Du Toit *et al* (1999) www.sahealthinfo.org/ethics/book2.htm.
[735] See section 39 of the Constitution.

reproductive cloning of human beings, shall not be permitted".[736] The declaration only refers to reproductive cloning and remains silent on cloning for the purpose of stem cell research. Strydom submits that the latter possibility is deliberately left open by the declaration – a fact that can be deduced from article 12(b), allowing the application of research concerning the human genome when it is aimed at offering relief from suffering and at improving the health of individuals and humankind as a whole. He argues that this provision is wide enough in scope and intent to allow for scientific processes involving human cloning for the purposes of stem cell research.

4 3 5 2 The Human Genome Diversity Project (HGDP)

The HGDP is a collaborative research project being developed globally under the auspices of the Human Genome Organisation (HUGO). The goal of the project is to arrive at a much more precise definition of the origins of different world populations by integrating genetic knowledge. This knowledge is derived from applying new techniques for studying genes with knowledge of history, anthropology and language. The specific aims of the HGDP are –

(a) to investigate the variation occurring in the human genome by studying samples collected from populations that are representative of all of the world's peoples; and
(b) ultimately to create a resource for the benefit of all humanity and for the scientific community worldwide.[737]

[736] Strydom (2003) *TSAR* 37 *at* 40, 41.
[737] See the Belmont Report, which attempts to summarise the basic ethical principles pertaining to research, identified by the National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research. The commission refers to three basic principles, among others, relevant to the ethics of research involving human subjects, namely the principles of respect for persons, beneficence, and justice. The principles of informed consent, risk/benefit assessment, and the selection of subjects for research are also addressed. See also Benatar, SR *et al* (1999) "Ethics for health research: Book 1: General principles including research on children, vulnerable groups, international collaboration, and epidemiology: Appendix V" [Web:] www.sahealthinfo.org/ethics/book1.htm [Date of access: 10 March 2006].

4 3 5 3 The Declaration of Helsinki

The World Medical Association has developed the Declaration of Helsinki as a statement of ethical principles to provide guidance to physicians and other participants in medical research involving human subjects.[738] The Declaration of Geneva of the World Medical Association binds physicians to the words, "(t)he health of my patient will be my first consideration", and to the International Code of Medical Ethics, which declares that "(a) physician shall act only in the patient's best interest when providing medical care which might have the effect of weakening the physical and mental condition of the patient". Medical progress is based on research that ultimately must rest in part on experimentation involving human subjects. However, research investigators should be aware of the ethical, legal and regulatory requirements for research on human subjects in their own countries, as well as applicable international requirements.

Some basic principles for all medical research included in this declaration are as follows:

(a) Medical research involving human subjects must conform to generally accepted scientific principles; it must be based on a thorough knowledge of the scientific literature, other relevant sources of information, and on adequate laboratory and, where appropriate, animal experimentation.
(b) In medical research on human subjects, considerations related to the wellbeing of the human subject should take precedence over the interests of science and society. The Helsinki declaration notes that this principle must apply to *all* human beings, and that "some research populations", including those who cannot give consent themselves, "need special protection". It seems this principle was intended to extend to the unborn. The World Medical Association's parallel statement on the ethics of the practicing physician, the Declaration of Geneva, provided an oath by which the physician swears: "I will maintain the utmost respect for human life, from the time of conception." Despite this solemn declaration, the utilitarian approach to research ethics has become popular among

[738] Medical research involving human subjects includes research on identifiable human material or identifiable data.

scientists and others who want to justify harmful experiments on human embryos today. When asked in 1994 whether the National Institutes of Health's Human Embryo Research Panel should base its conclusions on the principle that "the end justifies the means", the panel's chief ethicist quoted the man known as the father of situation ethics, Joseph Fletcher: "If the end doesn't justify the means, what does?" He did not mention that Fletcher in turn claimed to be quoting Nikolai Lenin, who reportedly used it to justify the killing of countless men, women and children in the Russian Revolution of 1917. History has provided us with little reason to favour utilitarian thinking about human life, for even judged by its own terms, making moral judgments solely on the basis of consequences has often had terrible consequences.[739]

(c) The responsibility for the human subject must always rest with a medically qualified person, and never on the subject of the research, even though the subject has given consent.

(d) Medical research involving human subjects should only be conducted if the importance of the objective outweighs the inherent risks and burdens to the subject.

(e) For a research subject who is legally incompetent, physically or mentally incapable of giving consent or is a legally incompetent minor, the investigator must obtain informed consent from the legally authorised representative in accordance with applicable law. [740] (The South African statutory provisions pertaining to consent are discussed in paragraph 4.4 below.)

4 3 5 4 The Nuremberg Code

According to this code, the voluntary consent of human subjects to research is essential. The experiments should yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature. The experiments should be so conducted as to avoid all unnecessary physical and mental

[739] Doerflinger, RM (2003) "Embryo research and related issues: Testimony on behalf of the US Conference of Catholic Bishops before the President's Council on Bioethics" [Web:] www.usccb.org/prolife/issues/bioethic/embryo/test61203.htm [Date of access: 10 March 2006].

[740] Benatar *et al* (1999) www.sahealthinfo.org/ethics/book1.htm.

suffering and injury. The degree of risk should never exceed those determined by the humanitarian importance of the problem to be solved by the experiment.

With the Nuremberg Code, the United States and its allies responded to the horrors of the Nazi war crimes by restating the principle ensuring that human dignity would not again be trampled on in the pursuit of medical knowledge. The code's key norms can be summarised as follows:

(a) There should be no unnecessary risk to human subjects. The knowledge gained must be important for the good of society and "unprocurable by other methods or means of study," and the study must be preceded by animal studies and other precautions to minimise any risk to humans.
(b) "The voluntary consent of the human subject is absolutely essential". This must be an informed consent; the research subject must understand the nature and purpose of the experiment and its possible risks before consenting to participate.
(c) One must never cause serious injury or death in the name of medical knowledge. "No experiment should be conducted where there is an a *priori* reason to believe that death or disabling injury will occur."

This code was the inspiration for many later declarations, including the Declaration of Helsinki.[741]

4 4 CONSENT: RESEARCH ON HUMAN SUBJECTS AND THE RELEVANT STATUTORY PROVISIONS

The constitutional principles as envisaged in section 12(2)(c) of the Constitution, as well as the doctrine of informed consent, were discussed in chapter 3. Reference was also made to provisions pertaining to consent as stipulated in the Medical Research Council's guidelines. The National Health Act contains general provisions pertaining to consent to

[741] See Doerflinger (2003) "Embryo research and related issues: Testimony on behalf of the US Conference of Catholic Bishops before the President's Council on Bioethics" www.usccb.org/prolife/issues/bioethic/embryo/test61203.htm for more information on the Nuremberg code pertaining to embryo research.

medical treatment, as well as consent to research. These provisions are discussed in the paragraphs below.

4 4 1 The National Health Act: General consent provisions

Section 6 of the National Health Act requires a user, as defined in the Act, to have full knowledge of the proposed treatment. Every health care provider must inform a user of –

(a) the user's health status, except in circumstances where there is substantial evidence that the disclosure of the user's health status would be contrary to the best interests of the user;
(b) the range of diagnostic procedures and treatment options generally available to the user;
(c) the benefits, risks, costs and consequences generally associated with each option; and
(d) the user's right to refuse health services and the implications, risks and obligations of such refusal.[742]

The health care provider concerned must, where possible, inform the user, as contemplated in subsection (1), in a language that the user understands and in a manner that takes into account the user's level of literacy.[743]

Section 7 of the National Health Act regulates the consent of the user and provides for the following: Subject to section 8,[744] a health service[745] may not be provided to a user without the user's informed consent,[746] unless –

[742] Section 6(1)(a)-(d).
[743] Section 6(2).
[744] Section 8 reads as follows: "Participation in decisions: (1) A user has the right to participate in any decision affecting his or her personal health and treatment. (2)(a) If the informed consent required by section 7 is given by a person other than the user, such person must, if possible, consult the user before giving the required consent. (b) A user who is capable of understanding must be informed as contemplated in section 6 even if he or she lacks the legal capacity to give the informed consent required by section 7. (3) If a user is unable to participate in a decision affecting his or her personal health and treatment, he or she must be informed as contemplated in section 6 after the provision of the health service in question unless the disclosure of such information would be contrary to the user's best interest."

(a) the user is unable to give informed consent and such consent is given by a person mandated by the user, in writing, to grant consent on his or her behalf; or authorised to give such consent in terms of any law or court order;
(b) the user is unable to give informed consent and no person is mandated or authorised to give such consent, and the consent is given by the spouse or partner of the user or, in the absence of such spouse or partner, a parent, grandparent, an adult child or a brother or a sister of the user, in the specific order as listed;
(c) the provision of a health service without informed consent is authorised in terms of any law or a court order;
(d) failure to treat the user, or group of people which includes the user, will result in a serious risk to public health; or
(e) any delay in the provision of the health service to the user might result in his or her death or irreversible damage to his or her health and the user has not expressly, implied or by conduct, refused that service.[747]

A health care provider must take all reasonable steps to obtain the user's informed consent.[748]

Section 9 of the National Health Act regulates health services without consent. Subject to any applicable law, where a user is admitted to a health establishment without his or her consent, the health establishment must notify the head of the provincial department of the province in which that health establishment is situated within 48 hours after the user was admitted of the admission and submit any other information as may be prescribed.[749] If the 48-hour-period contemplated in subsection (1) expires on a Saturday, Sunday or public holiday, the health establishment must notify the head of the provincial department

[745] "Health service" means – (a) Health care services, including reproductive health care and emergency medical treatment, contemplated in section 27 of the Constitution; (b) Basic nutrition and basic health care services contemplated in section 28(1)(c) of the Constitution; (c) Medical treatment contemplated in section 35(2)(e) of the Constitution; and (d) Municipal health services. See section 1.
[746] For the purposes of section 7, "informed consent" means consent for the provision of a specified health service given by a person with legal capacity to do so and who has been informed as contemplated in section 6. See section 7(3).
[747] Section 7(1).
[748] Section 7(2).
[749] Section 9(1).

of the user's admission and must submit the other information contemplated in subsection (1) at any time before noon of the next day that is not a Saturday, Sunday or public holiday.[750] Subsection (1) does not apply if the user consents to the provision of any health service in that health establishment within 24 hours of admission.[751]

4 4 2 Consent to medical research

Section 11 of the National Health Act regulates health services for experimental or research purposes. Before a health establishment[752] provides a health service for experimental or research purposes to any user, and subject to subsection (2), the health establishment must inform the user in the prescribed manner that the health service is for experimental or research purposes or part of an experimental or research project.[753] A health establishment may not provide any health service to a user for a purpose contemplated in subsection (1) unless the user, the health care provider primarily responsible for the user's treatment, the head of the health establishment in question and the relevant health research ethics committee[754] or any other person to whom that authority has been delegated, has given prior written authorisation for the provision of the health service in question.[755]

Section 71 of the National Health Act specifically regulates research on or experimentation with human subjects and reads as follows:

> (1) Notwithstanding anything to the contrary in any other law, research or experimentation on a living person may only be conducted –
> (a) In the prescribed manner; and
> (b) with the written consent of the person after he or she has been informed of the objects of the research or experimentation and any possible positive or negative consequences on his or her health.
> (2) Where research or experimentation is to be conducted on a minor for a therapeutic purpose, the research or experimentation may only be conducted –
> (a) if it is in the best interests of the minor;

[750] Section 9(2).
[751] Section 9(3).
[752] For a definition of "health establishment" see fn 710.
[753] Section 11(1).
[754] Section 73.
[755] Section 11(2).

(b) in such manner and on such conditions as may be prescribed;
(c) with the consent of the parent or guardian of the child; and
(d) if the minor is capable of understanding, with the consent of the minor.

(3) (a) Where research or experimentation is to be conducted on a minor for a non-therapeutic purpose, the research or experimentation may only be conducted –
(i) in such manner and on such conditions as may be prescribed;
(ii) with the consent of the Minister;
(iii) with the consent of the parent or guardian of the minor; and
(iv) if the minor is capable of understanding, the consent of the minor.

(b) The Minister may not give consent in circumstances where –
(i) the objects of the research or experimentation can also be achieved if it is conducted on an adult;
(ii) the research or experimentation is not likely to significantly improve scientific understanding of the minor's condition, disease or disorder to such an extent that it will result in significant benefit to the minor or other minors;
(iii) the reasons for the consent to the research or experimentation by the parent or guardian and, if applicable, the minor are contrary to public policy;
(iv) the research or experimentation poses a significant risk[756] to the health of the minor; or
(v) there is some risk to the health or wellbeing of the minor and the potential benefit of the research or experimentation does not significantly outweigh that risk."

According to the Medical Research Council's guidelines, research subjects should know that they are taking part in research, and research involving subjects should only be carried out with their consent. Furthermore, for consent to be valid it should be offered voluntarily and be based on adequate understanding with due regard for the patient's language and culture.[757]

4 4 2 1 Consent with regard to research on minors

In terms of section 39(4) of the Child Care Act, and in the absence of specific legislation to the contrary, minors who have reached the age of 14 years are legally capable of consenting to medical treatment of themselves and their children. Minors who have

[756] The term "risk" is material to consent in the sense that the risk attached to research undertaken with consent may, depending on whether such research is therapeutic or non-therapeutic, or invasive or non-invasive, not exceed the limits prescribed by the guidelines. In terms of the risk/benefit analysis, the risk to which the patient is exposed "must be justifiable in relation to the value of the information sought". Risk refers to both the probability of a harm resulting from an activity and to its magnitude. Risks are divided into "negligible or less that minimal risk", "minimal risk", and "more than minimal risk". In therapeutic research, the benefits likely to accrue to the patient should outweigh the possible risk of harm and the patient should, as a general rule, not be exposed to greater than minimal risk. In non-therapeutic research, the patient should not be subjected to more that minimal risk. See Van Oosten (2000) *THRHR* 5 *at* 11, 12.

[757] See in general Van Wyk (2001) *THRHR* 3-22.

reached the age of 18 years are legally capable, in addition, of consenting to medical operations on themselves. Such consent is valid only where the minor is sane and sober. The consent of a parent or legal guardian is required for treatment if the minor is under the age of 14 years, and for an operation if the minor is under the age of 18 years. In the event of conflicting views between the child's father and mother, the child's best interest settles the matter. "Medical treatment" is not defined in the Act, but would probably exclude non-therapeutic medical research. Therapeutic research, therefore, may be undertaken with the consent of a minor over the age of 14 years if it takes the form of treatment; and with the consent of a minor over the age of 18 years if it involves an operation. Such minors' competence to consent accordingly extends to health research which is tantamount to treatment or an operation and, hence, to therapeutic research only.

According to the Children's Bill, a child may consent, subject to paragraph (b), to medical treatment or a surgical operation, provided the child is at least 12 years of age; and is of sufficient maturity and has the mental capacity to understand the benefits, risks and social implications of the treatment or operation. A child may not consent to a surgical operation in terms of paragraph (a) without the assistance of the parent of the child; or the primary caregiver of the child. The parent or primary caregiver of a child may, subject to section 43, consent to the medical treatment of or a surgical operation on the child if the child is under the age of 12 years; or over that age but is of insufficient maturity or does not have the mental capacity to understand the benefits, risks and social implications of the treatment or operation.[758]

Non-therapeutic research on minors is not permissible, except where parental consent, and the assent of the minor concerned, is obtained for –

(a) observation research of a non-therapeutic and non-invasive nature, because there is no risk and no interference with the integrity of the minor, provided that the research entails no more than negligible distress or discomfort; or

[758] Section 135(2)(a) and section 135(2)(b). See also section 135(3).

(b) observation research of a non-therapeutic and invasive nature, provided that no more than a normal negligible risk is foreseeable or known from routine clinical practice, and that the distress or discomfort is negligible.

Proxy consent to therapeutic research on incompetent minors younger than 14 years (to treatment) or younger than 18 years (to an operation) must be obtained. Furthermore, the assent of minors must also be obtained, provided they are mentally able to comprehend the issues involved. The research should pertain, directly or indirectly, to the illness or disease from which the child suffers. Where non-therapeutic research is involved, proxy consent may be obtained for the following:

(a) Observation research of a non-therapeutic and non-invasive nature, because there is no risk and no interference with the integrity of the minor, provided that the research entails no more than negligible distress or discomfort to the minor; or
(b) Observation research of a non-therapeutic and invasive nature, provided that normally no more than negligible risk is foreseeable or known from routine clinical practice and that the distress or discomfort is negligible.

In addition to the above, the following requirements must be met in non-therapeutic research:

(a) The proposed research must pertain, directly or indirectly, to a condition from which the minor suffers.
(b) The assent of the minor must be sought and his or her objection must be regarded as decisive.
(c) Research involving minors must significantly benefit minors of the same category as the research participant; and the same scientific results cannot be obtained by research on persons who do not belong to this category, or by other methods.
(d) All types of clinical research on minors are presumed to be non-therapeutic. This avoids labelling clinical research of little or no benefit to the minor as "therapeutic". This ensures that such research is subjected to strict scrutiny and

conditions, and that minors are not abused or unduly influenced for research purposes.[759]

4 4 2 2 Consent and the mentally handicapped

The Mental Health Care Act expressly recognises the international change in attitude towards persons with mental disability in its emphasis on the rights to equality, dignity, and privacy. This Act provides for the care and administration of property of "mentally ill" persons and persons with "severe or profound intellectual disabilities" as defined in the Act. A health care provider or a health establishment may provide care, treatment and rehabilitation services to or admit a mental health care user only if –

(a) the user has consented to the care, treatment and rehabilitation services or to admission[760];
(b) it was authorised by a court order or a review board[761];
(c) due to mental illness, any delay in providing care, treatment and rehabilitation services or admission may result in the death or irreversible harm to the health of the user; or
(d) the user can inflict serious harm to himself or herself or others; or cause serious damage to or loss of property belonging to him or her or others.[762]

Any person or health establishment that provides care, treatment and rehabilitation services to a mental health care user or admits the user in circumstances referred to in subsection (1)(c) of the Mental Health Care Act must report this fact in writing in the prescribed manner to the relevant review board; [763] and may not continue to provide care, treatment and rehabilitation services to the user concerned for longer than 24 hours unless an application in terms of Chapter V is made within the 24-hour period.[764]

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[759] Benatar *et al* (1999) www.sahealthinfo.org/ethics/book1.htm. See also Van Oosten (2000) *THRHR* 5 *at* 21, 22.
[760] Section 9(1)(a).
[761] Section 9(1)(b)
[762] Section 9(1)(c)(i)-(iii).
[763] Section 9(2)(a).
[764] Section 9(2)(b).

Subject to section 9(l)(c), a mental health care user may not be provided with assisted care, treatment and rehabilitation services at a health establishment as an outpatient or inpatient without his or her consent, unless a written application for care, treatment and rehabilitation services is made to the head of the health establishment concerned and he approves it;[765] and at the time of making the application there is a reasonable belief that the mental health care user is suffering from a mental illness or severe or profound mental disability, and requires care, treatment and rehabilitation services for his or her health or safety, or for the health and safety of other people;[766] and the mental health care user is incapable of making an informed decision on the need for the care, treatment and rehabilitation services.[767]

An application referred to in section 26 may only be made by the spouse, next of kin, partner, associate, parent or guardian of a mental health care user,[768] but where the user is under the age of 18 years on the date of the application, the application must be made by the parent or guardian of the user.[769] If the spouse, next of kin, partner, associate, parent or guardian of the user is unwilling, incapable or not available to make such an application, the application may be made by a health care provider.[770] The applicants referred to in paragraph (a) must have seen the mental health care user within seven days before making the application.

Such application must be made in the prescribed manner, and must set out the relationship of the applicant to the mental health care user;[771] if the applicant is a health care provider, state the reasons why he is making the application;[772] and what steps were taken to locate the relatives of the user in order to determine their capability or availability to make the application;[773] set out grounds on which the applicant believes

[765] Section 26(1)(a).
[766] Section 26(1)(b)(i).
[767] Section 26(1)(b)(ii).
[768] Section 27(1)(a).
[769] Section 27(1)(a)(i).
[770] Section 27(1)(a)(ii).
[771] Section 27(2)(a).
[772] Section 27(2)(b)(i).
[773] Section 27(2)(b)(ii).

that care, treatment and rehabilitation services are required;[774] and state the date, time and place where the user was last seen by the applicant within seven days before the application is made.[775]

On receipt of the application, the head of a health establishment concerned must cause the mental health care user to be examined by two mental health care practitioners.[776] Such mental health care practitioners must not be the persons making the application and at least one of them must be qualified to conduct physical examinations.[777] On completion of the examination, the mental health care practitioners must submit their written findings to the head of the health establishment concerned on whether the circumstances referred to in section 26(b) are applicable;[778] and the mental health care user should receive assisted care, treatment and rehabilitation services as an outpatient or inpatient.[779]

A mental health care user must be provided with care, treatment and rehabilitation services without his or her consent at a health establishment on an outpatient or inpatient basis if –

(a) an application is made in writing to the head of the health establishment concerned to obtain the necessary care, treatment and rehabilitation services and the application is granted[780];
(b) at the time of making the application, there is reasonable belief that the mental health care user has a mental illness of such a nature that the user is likely to inflict serious harm to himself or herself or others; or
(c) care, treatment and rehabilitation of the user is necessary for the protection of the financial interests or reputation of the user;[781] and at the time of the application

[774] Section 27(2)(c).
[775] Section 27(2)(d).
[776] Section 27(4)(a).
[777] Section 27(4)(b).
[778] Section 27(5)(a).
[779] Section 27(5)(b). See also section 27(6)-27(10).
[780] Section 32(1)(a).
[781] Section 32(1)(b)(i) and (ii).

the mental health care user is incapable of making an informed decision on the need for the care, treatment and rehabilitation services; and is unwilling to receive the care, treatment and rehabilitation required.[782]

4 5 CONCLUSION

This chapter sought to examine the statutory regulation and ethical guidelines pertaining to embryonic stem cell research and cloning in South Africa. South Africa permits research for specified purposes on embryos of less than 14 days old.[783] However, very strict regulatory criteria have to be fulfilled, namely provisions pertaining to informed consent, as well as authorisation by the Minister for work in this field. Reproductive cloning has been banned in many countries. Some countries have banned all forms of cloning, without making a distinction between reproductive and therapeutic cloning. Although the laws making their way through federal and state legislature all aim to criminalise reproductive cloning, different approaches to therapeutic cloning have been taken.

In South Africa, legislation prohibiting genetic manipulation of gametes and zygotes outside the body, and hence cloning, has been in effect for the last few decades.[784] The Medical Research Council of South Africa recommends that, for the present, cadaveric fetal tissue and embryos remaining after completion of infertility treatments should be the only source of embryonic stem cells for the purposes of research. It is recommended that prospective donors should be given timely, relevant and appropriate information to make informed and voluntary decisions regarding the donation of the embryos, and that embryos and cadaveric fetal tissue should under no circumstances be bought or sold.[785]

According to Dhai *et al*, these recommendations are too restrictive and stifle scientific progress aiming to benefit patients with irreversible and debilitating diseases. Moreover,

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[782] Section 32(1)(c).
[783] Section 57(4) of the National Health Act. As already discussed, the primitive streak, namely the first sign of development of the nervous system, may be observed by day 14. Based on this, some countries permit research on embryos of less than 14 days.
[784] Secton 39A of the Human Tissue Act.
[785] Du Toit *et al* (1999) www.sahealthinfo.org/ethics/book2.htm.

researchers in South Africa have a constitutional right to "freedom of scientific research". Therefore, the freedom to research on embryonic stem cells can only be restricted if such restrictions are "reasonable and justifiable in an open and democratic society based on human dignity, equality and freedom". Given the conflicting approaches to the law in other democratic countries, it may be difficult to show that such restrictions are unreasonable. However, the state is required to use the least restrictive means to achieve its objectives when infringing constitutional rights and it could be for this reason that the national government reviewed its stance on the matter.[786]

In light of the impressive potential of stem cell research and its ethical implications, expert groups in the United Kingdom have examined this issue and produced reports to guide policy development. These groups recommended, subject to conditions that reflect the differences in the social and ethical considerations applicable to the various ways in which stem cells are derived, that stem cell research not be prohibited. These initiatives are discussed in the next chapter.[787]

[786] Dhai *et al* (2004) *SAMJ* 906 *at* 909.
[787] Canadian Biotechnology Advisory Committee (2001) "Stem Cells: Opportunities and challenges" [Web:] cbac-cccb.ca/epic/internet/incbac-cccb.nsf/en/ah00353e.html [Date of access: 13 March 2006].

CHAPTER 5 A COMPARATIVE PERSPECTIVE: THE REGULATION OF EMBRYONIC STEM CELL RESEARCH AND CLONING IN THE UNITED KINGDOM

5 1 INTRODUCTION

In the early 1980's, the United Kingdom took a pioneering role in the era of new reproductive technologies. Significant strides were made, not only in terms of scientific and clinical development, but also in relation to relevant legal and ethical issues.[788] In this chapter the likelihood that the United Kingdom will become the international leader in regulating stem cell research is assessed by way of an examination of the scope of the regulatory framework, namely current legislation, guidelines and reports. In September 2002, the National Institute of Biological Standards and Control was chosen to host the world's first stem cell bank. The United Kingdom Stem Cell Bank provides a repository for all types of human stem cell lines, and supplies cell lines under a quality system. It accepts cell lines developed in the United Kingdom and appropriately accredited cell lines from other countries too. The bank ensures that cell lines are properly handled and stored. An independent steering committee considers applications to deposit and access cell lines at the stem cell bank. Any application to deposit or access cell lines must show that all the necessary licences and authorisations have been granted. The bank has a draft code of practice for the use of human cell lines, which gives guidance for the use of human stem cells.[789]

Termination of pregnancy in the United Kingdom, particularly for reasons of fetal abnormality, is a morally and ethically complex issue. A clear legal framework is therefore needed, and yet proves extremely difficult to create. Medical professionals working in this area are vulnerable to legal liability in a number of contexts. These include actions, for example a wrongful birth following failure to advise a termination of

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788 Herder (2002) www.law.ualberta.ca/centres/hli/pdfs/hlr/v10_2/10.2herderfrm.pdf.

789 Halliday (2004) *Med'l L Rev* 40 *at* 51. See also Twine, R (2005) "From Warnock to the stem cell bank: Evaluating the UK's regulatory measures for stem cell research" *J Int'l Biotech L* 2(1):1-14; Cline, H (2004) "Regulation of human embryonic stem cell research: A comparative review" *Bio Sci L Rev* 6(2):61-67.

pregnancy; the potential illegality of induction of labour outside the terms of the Abortion Act; and possible criminal and/or civil liability for a termination of pregnancy resulting in a live birth. The law remains somewhat ambiguous on all these issues, leaving doctors without the certainty and confidence of clear legal guidance. The law is however ambiguous for a reason. In this ethically ambiguous area parliament has decided, rightly or wrongly, to leave a wide discretion to the medical experts. This is seen in the terms of the Abortion Act of 1967, and its subsequent amendment.[790] Before the provisions of the Abortion Act are discussed, it is necessary to refer to some United Kingdom common law provisions. As previously mentioned, abortion is of extreme importance in the context of stem cell research, as the aborted fetal tissue could be used for therapeutic treatments.

While intended to legalise cadaveric tissue grafts, the United Kingdom's Human Tissue Act of 1961 stood for many years at the centre of the regulatory framework for human tissue and organs.[791] Beyond this Act, common law dealt with confidential information, doctors' duties of care, assault on living persons who did not consent to the removal of their tissue, and property. Data protection legislation covered the automated processing of personal information derived from tissue as from 1984. On 15 November 2004, the much awaited Human Tissue Act of 2004 received Royal Assent. The new Act, which applies to England, Wales, Northern Ireland and, to a limited extent, Scotland, consists of three parts and seven schedules.[792]

Although the legislation was enacted in November 2004, most of its provisions will not be brought into force until April 2006. Part 1 endorses the government's driving motivation. It outlines the activities for which consent is required and the criminal penalties that may apply if consent is not obtained. These laws are likely to be enacted in

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[790] The Abortion Act of 1967 (hereafter referred to as the Abortion Act.) See in general Scott, R (2005) "The uncertain scope of reproductive autonomy in pre-implantation genetic diagnosis and selective abortion" *Med'l L Rev* 13(3):291-327.

[791] Price, D (2003) "From Cosmos and Damian to Van Velzen: The human tissue saga continues" *Med'l L Rev* 11(1):1 *at* 2.

[792] Laing & Oderberg (2005) *Med'l L Rev* 328 *at* 354. See also British Organ Donor Society (2005) "United Kingdom Transplant Law" [Web:] body.orpheusweb.co.uk/uklaw.html [Date of access: 15 March 2006].

July 2006. Part 2 sets up an infrastructure to monitor the regulated activities. It describes the remit and membership of the new Human Tissue Authority and lists the activities for which a licence must be obtained from the authority. The model for this is the Human Fertilisation and Embryology Authority, established under the Human Fertilisation and Embryology Act of 1990. Provisions in this part also regulate organ donation and create a criminal offence for commercial dealings and "trafficking" in a limited range of transplantable material. Part 3 includes definitions; powers to inspect and to make regulations; powers for museums to repatriate human remains; and, more substantively, making it a criminal offence for holding DNA with a view to analysing it without consent. It repeals the Human Tissue Act of 1961, the Anatomy Act of 1984 and the Human Organ Transplants Act of 1989.[793] The uses of fetal tissue, from which embryonic germ cells could be derived, are subject to guidance set out in the Polkinghorne Review of 1989. The development and use of cell lines is the subject of health and safety regulation and good practice guidance.[794]

In the United Kingdom, any research into human embryos is governed by the Human Fertilisation and Embryology Act of 1990. The basic principles underlying the legislation were those set out in the Warnock Report on Human Fertilisation and Embryology.[795] The provisions of the Act are discussed in the paragraphs below.

5 2 ENGLISH COMMON LAW

5 2 1 Legal status of the fetus

The position of South African common law pertaining to the legal status of the fetus was discussed in chapter 3. However, a brief survey of the law in the United Kingdom on the status of the unborn child is useful and instructive. The *nasciturus* fiction operates in English law for the protection of the fetus, but only if it is subsequently born alive. In

[793] Liddell, K & Hall, A (2005) "Beyond Bristol and Alder Hey: The future regulation of human tissue" *Med'l L Rev* 13(2):170 *at* 172.

[794] Nuffield Council on Bioethics (2003) "Stem cell therapy: Regulation in the United Kingdom" [Web:] www.nuffieldbioethics.org/go/browseablepublications/stemcells/report_510.html [Date of access: 24 March 2006].

[795] For a discussion of the Human Fertilisation and Embryology Act see Plomer, A *et al* (2002) "Human fertilisation and embryology: Regulating the reproductive revolution" *Med'l L Rev* 10(1):105-107.

Elliot v Joicey,[796] Lord Macmillan expressed the problems pertaining to the legal status of the unborn child as follows:

> From earliest times the posthumous child has caused a certain embarrassment to the logic of the law, which is naturally disposed to insist that at any given moment of time a child must either be born or not born, living or not living.

The facts of the case can briefly be summarised as follows: A testatrix executed a power of appointing trust funds under her father's will by appointing the funds in favour of all her children surviving her in equal shares, and directed that each child's share should be retained by the trustees of her father's will upon trust for 21 years from her death, and pay the income of such share to such child if he should live that long. If such child should die within the said period of 21 years, the trustees were to hold such share and the income thereof in trust, in default of appointment by the child, upon the trusts:

> "In the event of such child of mine leaving any issue him or her surviving in trust for such child of mine absolutely but in the event of such child of mine not leaving any issue him or her surviving then such share and the income thereof shall go and accrue by way of addition to the share or shares in the appointed funds of my other child or children who shall survive me."

The testatrix died on 12 January 1912, leaving her surviving three sons, of whom one married on 14 April 1931, and died on 11 May 1932. He died intestate without having exercised the power of appointment under the will of the testatrix. On 12 June 1932, a child was born to him posthumously. The House of Lords ruled that this son "did not leave issue him surviving" within the meaning of the will, but that, in the events that happened, his share accrued by way of addition to one of the other sons of the testatrix. It was said that the rule is that the child *en ventre sa mere* is not deemed to be living except where there is a benefit passing directly to the child. In this case it was decided that if the fiction were to be applied, the result would not be to benefit the posthumous child, but to benefit the estate of its deceased father.[797]

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[796] *Elliot v Joicey* (1935) AC 209 (HL), 1935 WL 25142 (HL).

[797] See also the words of Lord Loreburn in *Villar v Gilbey* (1907) AC 139 at 144: "It is certain that a child *en ventre sa mere* (an unborn child) is protected by the law, and may even be a party to an action." There are four principles laid down in this case: (1) Words referring to children born before, or living at, or surviving, a particular point in time, will not in their ordinary or natural meaning include a child

In *C and Another v S and Others*,[798] the Court of Appeal approved and applied the principles of *Paton v Trustees of the British Pregnancy Advisory Service and Another*.[799] It was ruled that the fetus could not in English law have any rights of its own at least until it is born and has a separate existence from the mother. That permeates the whole of the civil law of the country, and is, indeed, the basis of the decisions in those countries where the law is founded on the common law. English law does not try to answer the question of when human life begins, but it gives a clear answer to the question of when human personhood begins. It begins with birth, which means that the child must be completely extruded and must breathe.[800]

5 2 2 Actions for prenatal injuries

English court decisions have addressed the question of whether a child disabled as a result of medical negligence prior to its birth may maintain an action for damages:[801] In England the Congenital Disabilities (Civil Liability) Act of 1976[802] is the primary authority that insures that people who caused prenatal harm to the unborn child are answerable. Before the Act was adopted, the question of whether a child born alive but who suffers from disabilities caused by a defendant's negligence while the child was *in utero* has a cause of action in negligence against the third party, was regulated by common law. In general, in the absence of wrongful death statutes or other regulations akin to those adopted in the United States, action cannot be brought against the third party for tortuous acts resulting in the death of the unborn child in England. The distance that common law has covered to arrive at the approach followed before the Act was great,

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en ventre sa mere at the relevant date. (2) The fictional construction will secure to the child a benefit to which it would have been entitled if it had actually been born on the relevant date. (3) Such a child must necessarily be within the reason and motive of the gift. (4) If the gift is conferred on some one else, it is impossible to affirm either that the fictional construction will secure the child *en ventre sa mere* a benefit to which if born it would be entitled, or that the child *en ventre sa mere* must necessarily be within the reason and motive of the gift made.

798 *C and Another v S and Others* [1987] 1 ALL ER 1241 (CA).

799 *Paton v Trustees of the British Pregnancy Advisory Service and Another* [1978] 2 ALL ER 987 (QB).

800 See Williams (1994) *Cam LJ* 71 *at* 72.

801 See *Burton v Islington Health Authority* [1991] 1 ALL ER 825; and *De Martell v Merton and Sutton Health Authority* [1992] 3 ALL ER 820; and the joint appeals of these cases.

802 The Congenital Disabilities (Civil Liability) Act, 1976 (Act 220 of 1976.) (Hereafter referred to as the Civil Liability Act.)

but the problem of the legal personality of the fetus could not be overcome solely by means of the common law method.

Section 1 of the Civil Liability Act reads as follows:

> If a child is born disabled as a result of such an occurrence before its birth…and a person, other than the child's own mother, is under this section answerable to the child in respect of the occurrence, the child's disabilities are to be regarded as damage resulting from the wrongful act of that pregnancy, or affected her or the child in the course of its birth, so that the child is born with disabilities which would not otherwise have been present… A person is answerable to the child if he was liable in tort to the parent or would, if sued in due time, have been so, and it is no answer that there could not have been such liability because the parent suffered no actionable injury, if there was a breach of legal duty which, accompanied by injury, would have given rise to liability.

According to section 4, "born" means the point at which the child has life separated from its mother and lives for 48 hours.[803] The Act was not yet applicable in *Burton v Islington Health Authority* and *De Martell v Merton and Sutton Health Authority*, since the plaintiffs were born before 1976. However, the Court of Appeal held that, according to the common law, a child could maintain an action for damages for negligent prenatal injury. According to the Civil Liability Act, the defendant is only liable to the child if he is liable to the parent in respect of the Act or omission causing the injury. This means that the child's action is derived totally from rights owing to the parents. If no duty is owed to them, the child cannot sue.[804]

Section 44(1) of the Human Fertilisation and Embryology Act introduced a new section to the Civil Liability Act, specifically to provide for actions that might arise in the course of providing assisted reproduction.[805]

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[803] Section 4(2).

[804] For a discussion of *Burton v Islington Health Authority* fn 801 *supra*, and *De Martell v Merton and Sutton Health Authority* fn 801 *supra*, see Slabbert (2000) 97.

[805] Section 44(1)1A and 44(2) read as follows: "(1) In any case where – a child carried by a woman as the result of the placing in her of an embryo or of sperm and eggs or her artificial insemination is born disabled, the disability results from an act or omission in the course of the selection, or the keeping or use outside the body, of the embryo carried by her or of the gametes used to bring about the creation of the embryo, and a person is under this section answerable to the child in respect of the act or omission, the child's disabilities are to be regarded as damage resulting from the wrongful act of that person and actionable accordingly at the suit of the child. (2) Subject to subsection (3) below and the applied

5 2 2 1 Wrongful conception

In *McFarlane v Tayside Health Board*,[806] the House of Lords held that the parents of a healthy child born following a negligently performed sterilisation procedure could not recover damages for the cost of bringing up the child. However, the cost of caring for a disabled child, whether following a failed sterilisation,[807] or a failure to detect a fetal handicap in antenatal screening which, if discovered would have caused the parents to terminate the pregnancy,[808] is recoverable. The House of Lords also recently awarded a "conventional award" of £15 000 to a disabled woman who conceived following a negligently performed sterilisation; although, overturning the Court of Appeal's decision, it refused to allow her to recover the additional costs involved in raising a child occasioned by her disability.[809]

5 2 2 2 Wrongful birth

An action for wrongful birth exists based on negligent preconception genetic counselling, which induces a couple to bear a child with birth defects, where the parents had engaged in counselling to determine whether one of them was a carrier of a genetic disorder; the physician failed to notify the parents of the result of a blood test showing that there was a

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provisions of section 1 of this Act, a person (here referred to as 'the defendant') is answerable to the child if he was liable in tort to one or both of the parents (here referred to as 'the parent or parents concerned') or would, if sued in due time, have been so; and it is no answer that there could not have been such liability because the parent or parents concerned suffered no actionable injury, if there was a breach of legal duty which, accompanied by injury, would have given rise to the liability. (3) The defendant is not under this section answerable to the child if at the time the embryo, or the sperm and eggs, are placed in the woman or the time of her insemination (as the case may be) either or both of the parents knew the risk of their child being born disabled (that is to say, the particular risk created by the act or omission). (4) Subsections (5) to (7) of section 1 of this Act apply for the purposes of this section as they apply for the purposes of that but as if references to the parent or the parent affected were references to the parent or parents concerned."
"44(2) In section 4 of that Act (interpretation, etc) – at the end of subsection (2) there is inserted – 'and references to embryos shall be construed in accordance with section 1 of the Human Fertilisation and Embryology Act 1990' in subsection (3), after 'section 1' there is inserted '1A', and in subsection (4), for 'either' there is substituted 'any'."

806 *McFarlane v Tayside Health Board* [2000] 2 AC 59.

807 *Parkinson v St James & Seacroft University Hospital NHS Trust* [2002] QB.

808 *Rand v East Dorset Health Authority* (2000) 56 BMLR 39.

809 *Rees v Darlington Memorial Hospital NHS Trust* [2003] 4 All ER 987. For a discussion of these cases see Hoyano, L (2002) "Misconceptions about wrongful conception" *Med'l L Rev* 65(5):883-906. See also *Udale v Bloomsbury Area Health Authority* fn 335 *supra*, where a synopsis of the legal principles relevant in assessing damages in "wrongful conception" claims are provided, and the case also confirmed the legitimacy of the claim for the upbringing of a healthy child.

risk that a future child would suffer sickle cell disease; or the parents had sought genetic counselling after a prior child had suffered from a genetic condition. Doctors who agreed to test and diagnose a child for a genetic disorder have a duty to communicate the results to the mother in order to prevent the harm that could occur if the mother later conceives another child without knowledge of the genetic disorder. Even where a wrongful birth action is not recognised because the injury alleged is the continued existence of a deformed fetus, a cause of action based on the theory that a child was conceived after the defendant's failure to report the results of genetic tests is allowed on the basis that the parents were unable to make an informed choice regarding whether to conceive another child.[810] In the litigious atmosphere of the United States, multimillion dollar settlements are made in respect of such failures to warn, although this is not common practice in the United Kingdom as yet. Wrongful birth is also applicable to cases where an abnormality is missed on ultrasound scanning. The potential for structural abnormalities to be overlooked during a screening scan is high. The more major structural defects are highly likely to be diagnosed but minor abnormalities, which are the first indication of a more global problem, are frequently the source of controversy. The Royal College of Obstetricians and Gynaecologists Working Party defined an anatomical checklist, which reflects common practice in the United Kingdom. This attempt to standardise the mid-pregnancy anatomy scan should simplify the task of deciding whether any particular abnormality should have been identified prenatally, but many other circumstances impact on individual cases and those who undertake ultrasound scanning will know that diagnostic imaging can be difficult.[811] Such wrongful birth claims have been recognised in *Salih v Enfield Health Authority*[812] and *Rance v Mid-Downs Health Authority*.[813]

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[810] See *McAllister v Ha*, 347 NC 638, 496 SE 2d 577 (1998); *Bader v Johnson*, 732 NE 2d 1212 (Ind 2000).

[811] Wicks, E & Wyldes, M (2004) "Late termination of pregnancy for fetal abnormality: Medical and legal perspectives" *Med'l L Rev* 12(3):283 *at* 290, 291. See in general Scott, R (2003) "Prenatal screening, autonomy and reasons: The relationship between the law of abortion and wrongful birth" *Med'l L Rev* 11(3):265-325.

[812] *Salih v Enfield Health Authority* [1991] 3 ALL ER 400 (CA).

[813] *Rance v Mid-Downs Health Authority* [1991] 1 QB 587, [1991] 1 ALL ER 801.

5 2 2 3 Wrongful life[814]

Wrongful life lawsuits in the United Kingdom refer to civil actions brought by or on behalf of a child with disabilities, alleging that the child's very existence is legally wrong, and the child would have been aborted had his disability been known before birth. The child seeks recovery for pain and suffering and for expenses associated with medical care and education.[815] In *Udale v Bloomsbury Area Health Authority*,[816] one of the reasons given for rejecting a claim for damages for wrongful life was that such damages would "reward an unnatural reflection of motherhood". The British opinion of wrongful life action was expressed in *McKay v Essex Area Health Authority*.[817] In this case, Ms McKay came into contact with German measles.[818] After being tested for the disease, Ms McKay was told that neither she nor her baby was infected. Despite that, her daughter was born severely handicapped. The Court of Appeal dealt with the question of the doctor's duty to the fetus and stated that the doctor may be under a duty to the mother to ensure she has the option of abortion, but this duty cannot be owed to the child. Briefly stated, the fetus has no right to its abortion. Stephenson held that "[it] would mean regarding the life of a handicapped child as not only less valuable that the life of a normal child but so much less valuable that it was not worth preserving". The judges also found it difficult evaluating the loss, saying comparison of handicapped existence to non-existence was not simply a difficult task, but an impossible one.

By the time the case was decided, the Congenital Disabilities Act of 1976 was already in force, forbidding children to sue under such circumstances in section 1(2)(b). However, the Act was not in force for McKay, because the infant plaintiff was born before 22 July

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[814] See in general Morris, A & Saintier, S (2003) "To be or not to be: Is that the question? Wrongful life and misconceptions" *Med'l L Rev* 11:167-193.

[815] Pro-Life Infonet (2001) "Wisconsin Right to Life back bill to prohibit wrongful birth suits" [Web:] http://www.priestsforlife.org/news/infonet/infonet01-12-07.htm#WisconsinRTL [Date of access: 14 March 2006].

[816] See *Udale v Bloomsbury Area Health Authority* fn 335 *supra*.

[817] *McKay v Essex Area Health Authority* [1982] Qb 1166, [1982] 2 All ER 771, CA.

[818] This disease is caused by a virus that is easily transmitted from person to person. Under normal circumstances it is not dangerous to human life, but if a pregnant woman contracts German measles during the first three months of pregnancy, her baby is at risk of having serious birth defects or dying. See Vicky (2003) "Pregnancy – birth: German measles" [Web:] http://forums.obgyn.net/ pregnancy-birth/P-B.0302/0123.html [Date of access: 20 March 2006].

1976. To make a distinction here, it is important to say that if the defendant's negligence in fact caused the child's disability, then the child would probably be able to bring an action in its own right against the defendants under the Act. The doctor did not cause the child's condition; the defective conduct of the doctor was a breach of his duties to the parents. The child would not have been born healthy even if the doctor had behaved correctly. This lack of causation is also a significant reason for the general aversion to the wrongful life suits, not only in the United Kingdom but in other countries as well.[819] Wrongful death actions on behalf of a child being born dead also appear impossible in England.[820]

5 3 ABORTION

5 3 1 Introductory remarks

The purpose of this section is to examine the regulatory regime pertaining to abortion in the United Kingdom. Under sections 58 and 59 of the Offences Against the Person Act of 1861, intentionally procuring a miscarriage in oneself or another is a criminal offence, with a maximum sentence of life imprisonment for procuring one's own miscarriage, and five years for procuring a miscarriage in another person. Section 58 of this Act makes it an offence "where a woman, being with child, who, with intent to procure her own miscarriage, shall unlawfully administer to herself any poison or other noxious thing, or shall unlawfully use any instrument or other means whatsoever with the like intent, and whosoever, with intent to procure her miscarriage, whether she be or be not with child, shall unlawfully administer to her or cause to be taken by her any poison or other noxious thing, or shall unlawfully use any instrument or other means whatsoever with the like intent". Under section 59 it is an offence to unlawfully supply or procure any "poison or

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[819] Bila, K (2004) "A slippery slope: Wrongful birth and wrongful life" [Web:] http://clr.prf.cuni.cz/clanek.php?clanek=94 [Date of access: 20 March 2006].

[820] Slabbert (2000) 102. One other aspect that needs to be mentioned is the question of maternal conduct during pregnancy. Although the English courts are not prepared to go to extremes regarding protective intervention, intervention in the life of a female drug abuser can be Draconian in a fashion differential to that of a man. If a woman continues her habit during her pregnancy, she will run the risk of her child being taken into governmental care at birth and it will be difficult for her to re-establish care of the child. This will be so even if the parenting skills of the woman have never been tested and the effect of drug use by a mother on a child whom she keeps free of drugs has not been the subject of research. While criminal penalties may serve to curb drug abuse to some extent, for a pregnant mother the risk of losing her child may well present the ultimate sanction. See Connors, J (1990) "Woman, drug control, and the law" *Bull Narc* 42(1):41-47. See also the Children and Young Persons Act of 1969.

other noxious thing knowing it is intended to be unlawfully used with intent to procure a miscarriage".[821]

According to the Infant Life Preservation Act it is an offence to destroy the life of a child capable of being born alive, unless it is done in good faith for the purpose only of preserving the life of the mother.[822] Of course this does not mean that illegal abortions did not occur. While there was a steady increase in the use of artificial fertilisation, and women were making determined efforts to limit family size, women did find themselves with unwanted pregnancies. Abortions were discreetly advertised and there were a considerable body of folklore about methods of inducing miscarriages. Violent purgatives were popular among working class women, and penny royal, aloes and turpentine were all used. Other methods to induce miscarriage were very hot baths and gin, extreme exertion, a controlled fall down a flight of stairs, or veterinary medicines. So-called

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821 See in general *R v The Secretary of State for Health, Schering Health Care Limited, Family Planning Association* [2002] EWHC 610. This case concerned the legality of the prescription, supply and use of the morning-after pill. The claimant, John Smeaton, who acted on behalf of the Society for the Protection of Unborn Children (SPUC), said that such prescription or supply amounts, in principle, to a criminal offence under sections 58 and/or 59 of the Offences against the Person Act. In reality, the allegations that SPUC made extends to this: a woman who takes the morning-after pill is herself potentially committing a criminal offence under the 1861 Act. Furthermore, and whatever SPUC may have said, the allegations of serious criminality that it made, extend to cover any form of birth control which may have the effect of discouraging a fertilised egg from implanting in the lining of the womb, that is to say, not merely the morning-after pill but also IUDs, the mini-pill, and even the pill itself. Put shortly, the effect of sections 58 and 59 of the 1861 Act, read together with the relevant parts of the Abortion Act 1967, is that abortifacient substances, substances which cause miscarriage or abortion, may be administered only if two doctors certify that the conditions set out in the 1967 Act are satisfied. Otherwise, the use of such substances is in principle criminal. SPUC's case was that, whatever it may be called, the morning-after pill is not in fact a contraceptive. It is, said SPUC, an "abortifacient"; in other words, it causes miscarriages. Accordingly, said SPUC, unless the procedures laid down by the 1967 Act are complied with, the supply and use the morning-after pill may involve the Commission of Criminal Offences. Compliance with the procedures laid down by the Abortion Act requires the involvement of two doctors. So, if SPUC was right, the use of the morning-after pill would in effect be lawful only if it had been prescribed by two doctors. Evoi said: "There would in my judgment be something very seriously wrong, indeed grievously wrong with our system, by which I mean not just our legal system but the entire system by which our polity is governed, if a judge in 2002 were to be compelled by a statute 141 years old to hold that what thousands, hundreds of thousands, indeed millions, of ordinary honest, decent, law abiding citizens have been doing day in day out for so many years is and always has been criminal. I am glad to be spared so unattractive a duty". He further said: "Decisions on such intensely private and personal matters as whether or not to use contraceptives, or particular types of contraceptives, are surely matters which ought to be left to the free choice of the individual. And, whilst acknowledging that I have had no argument on the point, I cannot help thinking that personal choice in matters of contraception is part of that 'respect for private and family life' protected by Article 8 of the Convention."

822 Section 1 of the Infant Life Preservation Act, 1929 (hereafter referred to as the Infant Life Preservation Act.) According to this Act, a child is capable of being born alive at 28 weeks.

"backstreet" abortionists were fairly common, although their bloody efforts could be fatal. It is not clear how frequently these methods were used – it has been estimated that, in 1914, 100 000 women made efforts to procure a miscarriage, usually by drugs.[823]

The two statutes discussed above, read together, could be used to justify therapeutic abortion, and by 1966 "legal" abortions were readily available to women who could afford them. [824]

In *R v Bourne*,[825] the defendant, a surgeon of the highest skill, openly performed an abortion in a London hospital on a 14-year old girl who was pregnant as a result of being gang-raped by a group of soldiers. He was charged with unlawfully procuring the abortion on the girl under section 58 of the Offences against the Person Act. The defendant presented himself to the authorities in order to challenge the scope of the law, his contention being that the inclusion of the word "unlawfully" in section 58 presupposed that abortion could, in some circumstances, be "lawful". The jury were directed that it was for the prosecution to prove beyond reasonable doubt that the operation was not performed in good faith for the purpose only of preserving the life of the girl. The surgeon had not waited until the patient was in peril of immediate death, but it was his duty to perform the operation if, on reasonable grounds and with adequate knowledge, he was of opinion that the probable consequence of the continuance of the pregnancy would be to make the patient a physical and mental wreck. As the accused was found not guilty, the statement as to the law in this matter was in the form of the direction to the jury. The judge carefully distinguished between danger to life and danger to health, and between the act of the professional abortionist and an operation openly performed by a qualified surgeon. The case was one of first impression, and was, therefore, the only statement of the law as to the duties of a surgeon in such cases.

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[823] Answers.com (2004) "Abortion in the United Kingdom" [Web:] www.teachersparadise.com/ency/en/.../abortion_in_the_united _kingdom.html [Date of access: 11 January 2006].
[824] Jackson, EM (2001) *Regulating reproduction: Law, technology and autonomy* 76.
[825] *R v Bourne* [1938] 3 ALL ER 615.

5 3 2 The Abortion[826] Act of 1967[827]

It is important to note that the Abortion Act did not invalidate the Offences against the Person Act or the Infant Life Preservation Act. However, it replaced the common law.[828] Section 5(2) of the Abortion Act provides that, for the purposes of the law relating to abortion, anything done with the intent to procure a woman's miscarriage is done unlawfully, unless authorised by section 1 of the Act.[829] This Act created statutory defences to the crimes of procuring a miscarriage and destroying a viable fetus. Since 1968, abortion has been lawful in Scotland, England and Wales if two medical practitioners believe in good faith that one of the four grounds as stipulated in section 1(1) of the Act are satisfied. The relevant provision, as amended by section 37(1) of the later Human Fertilisation and Embryology Act of 1990, is section 1, which reads as follows:

> Subject to the provisions of this section a person shall not be guilty of an offence under the law relating to abortion when a pregnancy is terminated by a registered medical practitioner if two registered medical practitioners are of the opinion, formed in good faith:
> (a) That the pregnancy has not exceeded its twenty fourth week and that the continuation of the pregnancy would involve risk, greater than if the pregnancy were terminated, of injury to the physical or mental health of the pregnant woman or any existing children of her family, or

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826 The term "abortion" is not defined in the Act. Section 1(3) provides for the following: "Except as provided by subsection (4) of this section, any treatment for the termination of pregnancy must be carried out in a hospital vested in [the Secretary of State for the purposes of his functions under the National Health Service Act 1977 or the National Health Service (Scotland) Act 1978 [or in a hospital vested in a National Health Service trust] or in a place approved for the purposes of this section by the Secretary of State]."

827 In May 1996, the Termination of Pregnancy Restriction Bill was given its first reading in the House of Lords. The Bill, if passed, would have amended the Abortion Act of 1967 so that to perform terminations on the sole ground of a diagnosis of Down's syndrome would become illegal. The Bill was introduced into the House of Lords by the Conservative Peer Viscount Brentford, but a second reading was not requested and the Bill never became law. Although inconsistent and contradictory in its early legal development, the introduction of the Abortion Act of 1967 clarified the position on abortion and to this day provides the prominent statutory framework on which abortion is based.

828 For a discussion of the Abortion Act see Slabbert (2000) 86-95.

829 It is also important to note the amended section 5(1) of the Abortion Act, which states that no offence under the Infant Life Preservation Act is committed by a registered medical practitioner who terminates a pregnancy in accordance with the provisions of the former Act. According to this section, the only protected people under the Act are "registered medical practitioners", and therefore the other health care professionals whose conduct falls within the provisions as set out in the Abortion Act, are not protected. Slabbert also asks the question of whether the protection afforded by section 5(1) extends to the pregnant woman, to a second certifying doctor who does not perform the operation, and to the nurse who acts upon the instructions of the doctor. See Slabbert (2000) 92.

(b) That the termination is necessary to prevent grave permanent injury to the physical or mental health of the pregnant woman, or
(c) That the continuance of the pregnancy would involve risk to the life of the pregnant woman, greater than if the pregnancy were terminated, or
(d) That there is a substantial risk that if the child were born it would suffer from physical or mental abnormalities as to be seriously handicapped.[830]

According to section 1(2) of the Act, in determining whether the continuance of the pregnancy would involve such risk of injury to health as mentioned under subsections 1(a) and (b), account may be taken of the pregnant woman's actual or reasonably foreseeable environment. Therefore, this section provides for a case in which it can be foreseen that termination will be necessary for the benefit of the woman, although at the time the termination is carried out, it is not immediately necessary to save her life.[831]

It is immediately apparent that the abovementioned grounds for a legal termination of pregnancy are extremely broad. Only section 1(1)(a) includes a time limit and therefore a termination of pregnancy is, in principle, legal at any gestation provided that the requirements of section 1(1)(d) are satisfied – for example, that there is a substantial risk of serious handicap. No guidance is given in the statute on the interpretation of these terms. This omission has the advantage of not fettering the discretion of the medical profession but simultaneously fails to provide the guidance sought by doctors. Furthermore, it is clear from the wording of the statute that a medical opinion formed in good faith is sufficient to satisfy the legal requirements. Hence, a substantial risk of serious handicap need not actually exist, provided that two doctors are willing to certify in good faith that it does in fact exist. It is also important to note that the grounds set out in section 1(1) only provide defences to a death in utero and not to a death ex utero.

[830] The terms "substantial risk" and "seriously handicapped" are not defined in the Abortion Act. These terms will therefore have to be examined by the courts. In addition, the Choice on Termination of Pregnancy Act, as discussed in chapter 4, contains more specific indications for abortion; for example, abortion is available on request in the first 12 weeks of the gestation period, in the first 20 weeks for rape, incest, socio-economic reasons or to protect physical or mental health, and also after 20 weeks if the woman's life is in danger or the fetus is serious malformed. Jackson mentions that the grounds for abortion in terms of the Abortion Act are vague. See Jackson (2001) 77.

[831] Slabbert (2000) 87.

Therefore, the defences would not be applicable to a charge of murder or manslaughter.[832]

According to Plomer, the case of *Vo v France*,[833] although not an English case, is destined to become a landmark decision in the jurisprudence of the European Court of Human Rights, as the court for the first time had the opportunity to consider directly the possible application of Article 2 of the European Convention on Human Rights to the "unborn fetus" in circumstances where the termination of pregnancy was not voluntary. For this reason it is necessary to refer to the case. Mrs Vo was a French national of Vietnamese origin. She was six months pregnant when she visited the Lyons Clinic for a routine pregnancy check. She was seen by a doctor who confused her with another patient, Mrs Thanh Van Vo (a similar name), who was at the clinic to have a coil removed. Mrs Vo's French was not very good. On the basis of medical notes relating to her namesake and without examining Mrs Vo, the doctor proceeded to try and remove the coil and in doing so ruptured the amniotic sac, causing a huge loss of fluid. Mrs Vo had to be hospitalised and lost her baby. Expert evidence showed the baby to have been between 20 and 21 weeks old at the time of the death. Expert reports also concluded that the hospital had been negligent in respect of procedures to avert the risk of confusion between similar names and that the doctor had been negligent in failing to examine the patient before medical intervention. Mrs Vo sought to have the doctor prosecuted for unintentional homicide. He was charged and found not guilty of unintentional homicide

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832 See in general Sheldon, S & Wilkinson, S (2001) "Termination of pregnancy for reason of fetal disability: Are there grounds for a special exception in law?" *Med'l L Rev* 9(2):85-109. The issue of whether there exists a right to abortion under the European Convention on Human Rights was considered in *X v United Kingdom*. In this case, the European Commission on Human Rights decided that, even if the fetus was protected under Article 2 of the European Convention on Human Rights, its right to life would of necessity be subject to an implied limitation in respect of a termination of pregnancy to protect the mother's life or health. A similar point was made in *Paton v United Kingdom* and in *H v Norway*, in which a termination of pregnancy at 14 weeks under a domestic law (which did not require a threat to the mother's life or health) was held not to violate Article 2. It is clearly established in current English law that a fetus does not have any legal rights or interests in domestic law. Neither does the father have any legal right to challenge an abortion that is lawful under the Abortion Act. See *X v United Kingdom* (1980) 19 D&R 244. See also *H v Norway* (1992) 73 D&R 155; *Paton v Trustees of the British Pregnancy Advisory Service and Another* fn 799 *supra*, and *C and Another v S and Others* fn 798 *supra*.

833 *Vo v France* (2005) 40 EHRR 12.

by the Criminal Court of First Instance on 3 June 1996 on the ground that the fetus was not viable at the time and therefore not a "human person" or "another" within the meaning of former Article 319, now Article 221-6, of the French Criminal Code. The judgment was reversed on 13 March 1997 by the Lyons Court of Appeal, which held that the fetus's right to life was protected from the beginning of life and that viability was not a requirement, providing the child was alive when the injury occurred. The judgment of the First-instance Criminal Court was described by the Lyons Court of Appeal as derogation from the right to life protected by regional and international treaties. The French Court of Cassation disagreed and reversed the judgment of the Lyons Court of Appeal on 30 June 1999. It held that the Court of Appeal had misinterpreted domestic and convention law on the right to life of an unborn fetus.

Mrs Vo took her claim to the Strasbourg Court. She alleged that the absence of a criminal remedy within the French legal system to punish the unintentional destruction of a fetus constituted a failure on the part of the state to protect, by law, the right to life within the meaning of Article 2 of the Convention. The chamber of the court to which the case was originally assigned, relinquished jurisdiction under Article 30 of the Convention, in favour of a grand chamber, because the case raised "a serious question affecting the interpretation of the Convention". The Grand Chamber found no breach of Article 2.

Plomer submits that there are two distinct issues raised by the judgment of the Grand Chamber. The first is whether an unborn fetus may be the subject of a right to life under Article 2. The second is whether Article 2 requires that the remedy for unintentional death of an unborn fetus should take the form of a criminal law penalty. The Grand Chamber left open the first of these, but ruled upon the second. It decided by a majority that there had been no violation of Article 2 because, even assuming that Article 2 covers the life of an unborn fetus, there is no corresponding obligation on states to protect such a life through the imposition of criminal penalties for the negligent taking of life. An analysis of the Grand Chamber's reasoning reveals that, on the one hand, this conclusion is consistent with the earlier jurisprudence of the European Commission on Human Rights and the court, in voluntary abortion cases, on the possible applicability of Article 2

to the unborn fetus. On the other hand, the judgment also creates new tensions and uncertainties on the reach of Article 2 and its application to the unborn fetus.[834]

According to Goldman, this case is wholly unconcerned with the states' domestic abortion laws, which have long been the subject of applications to the convention institutions and have been found to be consistent with the convention. He submits that, as with other convention provisions, Article 2 must be interpreted in an evaluative manner so that the great dangers currently facing human life can be confronted. This is made necessary by the potential that exists for genetic manipulation and the risk that scientific results will be used for a purpose that undermines the dignity and identity of the human being. He continuous to say that the court has, moreover, often stated that the convention is a living instrument to be interpreted in light of present-day conditions. He therefore argues that Article 2 of the convention is applicable to that case and had been violated, as the right to life was not protected by the law of the respondent state.[835]

The provisions of the Abortion Act are discussed in further detail below. The Abortion Act allows for medical staff to opt out of providing abortions if they have a moral objection to the procedure: "… [N]o person shall be under any duty … to participate in any treatment authorised by this Act to which he has a conscientious objection."[836]

5 3 3 Interpretation of the Abortion Act

In this Act the following expressions have meanings hereby assigned to them: "The law relating to abortion" means sections 58 and 59 of the Offences against the Person Act, and any rule of law relating to the procurement of abortion.

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[834] For a discussion of the case see Plomer, A (2005) "A fetal right to life? The case of Vo v France" *Hum Rts L Rev* 5:311-338.

[835] See in general Goldman, T (2005) "Vo v France and fetal rights: The Decision Not to Decide" *Recent Development Harv Hum Rts J* 18:277-282.

[836] Section 4(2) excludes the right of conscientious objection if the abortion is "necessary to save the life or to prevent grave permanent injury to the physical or mental health of a pregnant woman".

5 3 4 The role of the father in abortion cases

Under current English law, neither the father nor the fetus has any rights until the child is born. A 24-year old British man went to the High Court in an attempt to prevent his ex-girlfriend from aborting their unborn child. Mr Stephen Hone from Coventry was deeply distressed when his 31-year old girlfriend told him of her decision to obtain an abortion. Mr Hone explained: "I am fighting for my child, but I am also fighting for a father's rights ... I am not asking too much; she is three months pregnant now. I am asking for six months out of her life to save the life of a child." Mr Hone added that, if he lost the case, he would fight to avoid his child's tissue being donated for medical research. He said: "If the worst comes to the worst I want to give my unborn baby a decent burial." Under a legal precedent set in 1978,[837] a father has "no rights whatsoever" under the Abortion Act to prevent his child from being aborted. Mr Hone claimed that the West Midlands Health Clinic, which sanctioned the abortion, acted against the 1967 Abortion Act rules because only one doctor was consulted instead of two. He claimed no questions were asked about the woman's physical and mental state, or why she wanted to terminate the pregnancy. However, the real question was whether a man had a right to control a woman's body. The court did not prevent Mr Hone's ex-girlfriend, Claire Hansell, from having a termination, provided that the correct procedures were followed. The Calthorpe Nursing Home in Edgbaston, Birmingham, gave what the judge of the Family Division, Mr

[837] *Paton v Trustees of the British Pregnancy Advisory Service and Another* fn 799 *supra*. Mr Paton sought to prevent his estranged wife from obtaining a termination of pregnancy. Mrs Paton obtained the two necessary certificates from registered medical practitioners to enable a legal termination under section 1 (1)(a) of the Abortion Act. She did not consult her husband, nor did the doctors contact him. He applied to the court for an injunction. The court refused the injunction on the basis that a husband has no right, enforceable at law or in equity, to stop his wife having, or a registered medical practitioner performing, a legal abortion. The court refused to supervise the discretion of a doctor acting under the Abortion Act where there was no clear indication of bad faith. See also *C and Another v S and Others* fn 798 *supra*. Robert Carver, president of Oxford University Pro-Life Group, applied for an injunction to restrain his pregnant ex-girlfriend from terminating her pregnancy. Carver conceded he had no *locus standi* based on a claim of biological paternity. However, he argued that he had sufficient personal interest to do so as the proposed termination would be a crime concerning the life of his child. In addition, he argued that the fetus was a proper party to the proceedings since it was the subject of a threatened crime. Given the gestational age of the fetus (between 18 and 20 weeks) he argued it was capable of being born alive and the act of aborting it would be an offence of child destruction under section 1(b) of the Infant Life Preservation Act. The Judge at first instance refused to grant an injunction, stating that a fetus had no right to be a party and Carver had failed to establish an offence under the Infant Life Preservation Act. Carver appealed, but the Court of Appeal dismissed the appeal stating that medical evidence suggested that the fetus would not be capable of being born alive within section 1(1) of the Life Preservation Act. The House of Lords upheld the decision by refusing leave to appeal.

Justice Sumner, said was a "highly responsible and helpful" undertaking in that it would not rely on the certificate signed by the doctor who originally saw Ms Hansell. It was also said that if an abortion did take place after the proper procedures had been followed, that they would not dispose of the fetus without first giving seven days' notice to Mr Hone. After the case was decided, Mr Hone said: "It is a victory in one sense but a loss in the sense that it has still not prevented the abortion of my child."[838]

5 3 5 The use of fetal tissue for research purposes

The ethical acceptability of using fetal tissue for the derivation of embryonic germ cells is closely tied to the ethical acceptability of abortion. The first report to regulate this area was *Sir John Peel's* code of practice on the use of fetuses and fetal material for research, published in 1972. Many of the ethical questions posed by the use of cadaveric fetal tissue were considered by the Polkinghorne Committee[839] in 1989. The Polkinghorne Committee's guidelines were accepted by the Department of Health in 1990. In the United Kingdom there are no specific statutory provisions governing the use of tissues from the cadavers of fetuses, although the Abortion Act governs the legality of the abortion that makes fetal tissue available. The uses of fetal tissue contemplated in the review included teaching, therapy and research. The Polkinghorne Review concluded that "ethics committees should examine all proposals for work with fetuses or fetal tissue, whether alive or dead and whether classed as research or therapy, because of the high level of public concern". Research ethics committees in the United Kingdom have already approved research on the technique of transplanting cadaveric fetal tissue into the brains of those affected with Parkinson's disease.[840]

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[838] BBC News (2001) "Decision in abortion fight case" [Web:] www.news.bbc.co.uk/hi/english/health/newsid_1229000/1229473.stm [Date of access: 21 March 2006]. See also BPAS Abortion Care (2001) "Woman in Hone case has abortion" [Web:] www.bpas.org/press-office/archive_2001/30_03_2001.html [Date of access:] 21 March 2006.

[839] The Polkinghorne Committee aimed to review the guidance on the research use of fetuses and fetal material.

[840] United Kingdom. Medical Research Council (2001) "Human tissue and biological samples for use in research. Operational and ethical guidelines" [Web:] www.mrc.ac.uk/pdf-tissue_guide_fin.pdf [Date of access: 24 March 2006].

The potential of embryonic germ cells to create valuable cell lines for transplantation raises the possibility that an abortion could be sought with a view of donating cadaveric fetal tissue in return for possible financial or therapeutic benefits. In the Polkinghorne Review, concerns that knowledge about the uses for fetal tissue might influence a woman's decision to have her pregnancy terminated are discussed. Accordingly, the review recommended that great care should be taken to separate the decisions relating to abortion and to the subsequent use of fetal material. In addition, it was recommended that procedures be implemented that make it impossible for a woman to specify that fetal tissue which she makes available, will be used in a particular way. This was intended to limit the degree to which any morally dubious desires could be implemented, and in particular, any ethically unacceptable use of the fetus.[841]

The Polkinghorne Code of Practice requires written consent to be obtained from women for the use of the fetus or fetal tissue. The process of consent requires the mother to be counselled and given all the information in a way that is comprehensible, enabling her to make a proper judgment of whether or not to allow the fetus to be used for research and therapy. This review recognises that some women may be prepared to consent to some uses of fetal tissue but not to others. In contrast to the regulations under the Human Fertilisation and Embryology Act governing embryo donation, it concludes "that to allow for such preferences would be too great a breach of our principle that a mother should not be able to direct that the fetus be used in a specific way". As a result, it requires that explicit consent for all permissible purposes should be obtained on all occasions.[842]

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[841] Shaw, R (2001) "Responses to 'whose hands on your genes?' consultation" [Web:] www.hgc.gov.uk/Client/redir.asp?Contentid=453 [Date of access: 25 March 2006].

[842] The National Bioethics Advisory Commission Report goes even further. To ensure that inappropriate incentives do not enter into a woman's decision to request an abortion, the National Bioethics Advisory Commission recommends that directed donation of cadaveric fetal tissue for embryonic germ cell derivation be prohibited. It goes on to state that, although potential donors of cadaveric fetal material would not receive a direct therapeutic incentive to produce or abort tissue for research purposes in the same way that such personal interest might arise in a transplant context, a prohibition was thought necessary to ensure that inappropriate incentives, however remote, do not enter into a woman's decision to have an abortion. See Royal College of Pathologists (2005) "Disposal following pregnancy loss before 24 weeks of gestation", Human Tissue Authority Code of Good Practice, 5.

The review states that:

> No specific reference should be made to any particular research or therapy nor any suggestion made that any use will, in fact, take place. It should be confirmed that any use will be strictly controlled and restricted to purposes for which tissue of this kind is necessary for medical benefit. The mother should be assured that appropriate measures will be taken to prevent her being identified by anyone, apart from those attending her … The mother's explicit consent must be obtained to the use of fetal tissue in research, therapy and teaching. The mother should be asked to relinquish any property rights.

There has, however, still been a growing demand by the National Health Service Trust for comprehensive, up-to-date advice on the disposal of fetal tissue from pregnancies that end before the 24th week of gestation. In response to this need, the Department of Health, the Royal College of Obstetricians and Gynaecologists, and others have worked together to produce advice in the form of "question and answers" on this sensitive issue.[843] The advice sets out the different disposal options available to national health service trusts; reminds them of the need to make information available to families; and emphasises the importance of personal choice and decision-making. Representatives from the main professional and voluntary organisations working in this field were involved in the development of this document and have all agreed and endorsed it. The proposed Human Tissue Authority[844] takes on the responsibility for producing a number of codes of

[843] Royal College of Pathologists (2005) "Disposal following pregnancy loss before 24 weeks of gestation", Human Tissue Authority Code of Good Practice, 5. These guidelines do not cover babies born dead after the 24th week of pregnancy. Any baby, irrespective of gestational age, that is born alive and then dies immediately afterwards is a live birth, and neonatal death should be treated as such in terms of registration and disposal. Embryos created in vitro and which have not been transferred into a woman, are covered by the Human Fertilisation and Embryology Act, and disposal of these should be in accordance with the Human Fertilisation and Embryology's Authority's Code of Practice. See Human Fertilisation and Embryology Authority (2003) "6th Code of Practice: Response to consultation" [Web:] www.hfga.gov.uk/AboutHFEA/Constitutions/Code%20response.pdf [Date of access: 20 April 2006]. This advice also does not cover the disposal or collections of fetal tissue and stillbirths that have been retained for teaching or research. These will be subject to different guidance contained in a code of practice (yet to be published), that will specifically deal with disposal of existing holdings. The advice was developed in association with representative from Antenatal Results and Choices, the British Pregnancy Advisory Service, Child Bereavement Trust, Confidential Enquiry into Maternal and Child Health, Department of Health, Marie Stopes International, Miscarriage Association, Nursing and Midwifery Council, Royal College of Midwifes, Royal College of Nursing, Royal College of Obstetricians and Gynaecologists, Royal College of Pathologists, Stillbirth and Neonatal Death Society and the Welsh Assembly Government.

[844] See section 13, 14, and 15 of the Human Tissue Act.

practice,[845] which covers different areas relating to the taking, storage, use and, where appropriate, disposal of human tissue. It was felt that the existing Department of Health advice on the disposal of fetal tissue, which dates from 1991, is inadequate and an interim measure is needed.

Although these questions and answers do not mention the need for consent, national health services trusts' should be aware that parental consent may be needed for some forms of disposal in their locality. It must be acknowledged that this is a very difficult area of policy development, and all detail relating to this area cannot be provided. The aim is to cover the regulation of the main issues.

The following is stated in the Human Tissue Authority's Code of Good Practice:

(a) A woman or couple should be made aware that information on disposal options is available if they wish to have access to it. Any personal, religious or cultural needs relating to the disposal of the fetal tissue should be met wherever possible, and it should be documented in the woman's medical notes. It should be clearly documented in the woman's medical notes whether information has been requested or not, and if so, whether it has been given.
(b) Any woman or couple who wish to make their own arrangements for the disposal of fetal tissue may do so.
(c) All fetal tissue should be stored in accordance with the previous Department of Health guidance prior to disposal.
(d) Fetal tissue can be buried after consultation with the woman or couple. Fetal tissue may also be cremated.
(e) Fetal tissue may be incinerated, although the appropriateness of this may vary depending on the individual circumstances.

[845] These new codes of practice replace the advice given in Executive Letter (91)144, namely the "Executive Letter on Sensitive Disposal on the Dead Fetus and Fetal Tissue", 12 December 1991.

(f) There are two documents addressing issues relating to the disposal of fetal tissue, with the independent sector carrying out abortions on the behalf of national health services trusts.[846]

In addition, in the case of *X*,[847] the application concerned a young girl who had fallen pregnant at the age of 14. She underwent a legal abortion in April 2001. At the request of X's father, the aborted fetus was retained by the Health and Social Security Committee at the hospital where the operation was performed with a view to charging the suspected father of the fetus, a 32-year-old man, with the criminal offence of having sexual intercourse with a girl who is over the age of 13 years but below the age of 16 years. Both of X's parents wished the committee to release tissue from the aborted fetus to the police, although X steadfastly declined to give her consent. The Attorney-General of Jersey applied for a declaration as to the legality of the release of tissue samples from the aborted fetus for the purposes of criminal investigation and/or prosecution. A guardian *ad litem* was appointed on behalf of X. She was 16 years old by the time the hearing started. The application was dismissed owing to the following reasons:

(a) X had an interest in the nature of ownership, although not a true property interest, conferring an authority within the bounds of public decency and the general law to make decisions concerning the disposition of the aborted fetus. Accordingly, her consent was required prior to the release of such tissue to the police.
(b) Parental consent was insufficient to override the absence of consent by X, given statutory provisions in both Jersey and England relating to the position of patients aged 16 and 17 years: Parents do retain the right and duty to be heard as to what is in the best interests of a child, even at the age of 16 of 17, and may properly try to influence the choices of their offspring.

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[846] The Stillbirth and Neonatal Death Society's "Pregnancy loss and the death of a baby: Guidelines for professionals" (currently under revision); and the Royal College of Nursing's "Sensitive disposal of all fetal remains".

[847] The facts of the case are published and discussed in In the matter of X (2003) "Access to fetal material: Property rights and pace" *Med'l L Rev* 11(1):142-146.

(c) The court has the power to override X's refusal to grant consent, although this jurisdiction should be exercised with caution.

(d) It is possible that further evidence could be brought, which would be relevant in determining the best interests of X, but given the significant delay that had already occurred and the inevitable emotional trauma of abortion at such a young age, X's welfare would be best served by dismissing the application and authorising the disposal of the fetus in accordance with normal hospital procedures.

The Jersey Court was asked to make a declaration that it would not be unlawful for the hospital to release the fetal remains to the police. They would then be able to seek to identify the father, who could then be charged with the offence of unlawful sexual intercourse with a girl under 16 years. The court's decision to refuse the declaration was based upon a logic flow: First, who has control over the remains of the fetus and on what basis? (Answer: The mother, who has dispositional authority although the fetus is not subject to a true property interest.) Second, is the mothers consent required? (Answer: "Yes", on the basis of her property-like interest.) Third, can the mother's refusal of consent be overridden? (Answer: "Yes", by the court under its inherent jurisdiction over children, but "no" by the parents, if to do so would be in her best interests). Fourth, would disclosure to the police be in her best interests? (Answer: "No.") A question to ask is how would English law deal with the facts of this novel case?

There is no doubt that a fetus that is delivered dead following an abortion is not a legal person in English law. Only if it were "born alive" would that be the case. What is entirely unclear, however, is whether a mother's consent would be required for its future use or disposition because English law has never addressed the issue of whether a mother has any legal interest in the remains of a fetus following an abortion.

In England, the issue of access to the fetal remains is likely to be resolved through an application under Schedule 1 of the Police and Criminal Evidence Act.[848] This Act provides special protection for sensitive material that is held in confidence by a professional, for example medical or health records and human bodily material. Could the police then obtain the evidence, the fetal remains, or part thereof, under section 9 and Schedule 1 of the Act? This will depend on whether the fetal remains are "excluded material" which falls within section 11 of the Act. If it is, the police may obtain access by seeking an order from a circuit judge under Schedule 1 of the Act; provided that the conditions set out are satisfied. Otherwise, they would only be able to obtain the fetal remains in the unlikely event that they came upon it lawfully while on the premises and they had reasonable grounds to believe it was relevant evidence in relation to an offence and it was necessary to seize it in order to prevent it being concealed, lost, altered or destroyed.[849] Section 11(1) includes in the definition of "excluded material", "human tissue" or "tissue fluid" that has been taken for the purposes of diagnosis or medical treatment and that a person holds in confidence. There are three requirements in section 11(1). First, the subject matter must be "human tissue" or "tissue fluid". Clearly, fetal remains would fall within the former statutory phrase. Second, that tissue must be held "in confidence" by the hospital. Again, there can be no doubt that this would be the case. Third, the tissue must have been taken "for the purposes of diagnosis or medical treatment". If, as is suggested here, the fetal material would be "excluded material", a Circuit Judge could only order access if three conditions are met:

(a) There are reasonable grounds for believing the material is on specified premises.
(b) A search of the premises for that material could have been authorised by a warrant issued to a police officer under an enactment before the Police and Criminal Evidence Act came into force.
(c) The issue of the warrant would have been appropriate under Schedule 1.

[848] The Police and Criminal Evidence Act, 1984 (hereafter referred to as the Police and Criminal Evidence Act).
[849] Section 19(3).

One final aspect that deserves mention is that the Police and Criminal Evidence Act only deals with access by the police to "excluded material". The fact that the police could not obtain an order under Schedule 1 does not prevent the hospital from disclosing confidential information, or its equivalent, in the form of human tissue. When to do so would be justified in the public interest.[850]

5 4 THE HUMAN TISSUE ACT[851]

For modern biomedical businesses and research, human tissue samples are an irreplaceable resource collected in large numbers for transplantation, training, research, drug testing, clinical audit, cell line development, and trade. The 54 000 organs, body parts, stillborns, and fetuses that were retained between 1970 and 2001 are just a small proportion of the total quantity of stored tissue specimens in the United Kingdom. There are about 345 public sector tissue collections for transplantation, five large tissue banks established primarily for research, and a large number of medium-sized tissue collections. Some 150 million tissue specimens are also collected each year for diagnostic pathology tests, most of which are blood samples disposed of within days. This fact indicates that careful differentiation of collection for diagnosis and storage of tissue is needed if laws

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850 In the matter of X (2003) *Med'l L Rev* 142 *at* 142, 143, 144.

851 The Act arose from concerns raised by events at the Bristol Royal Infirmary and the Royal Liverpool Children's Hospital, Alder Hey during 1999 to 2000. The Kennedy and Redfern inquiries at these hospitals established that organs and tissue from children who had died were often removed, stored and used without proper consent. A subsequent census by the Chief Medical Officer for England (2000) and the Isaacs Report (2003) showed that storage and use of organs and tissue from both adults and children without proper consent has been widespread in the past. It also became clear that the current law in this area was not comprehensive, nor as clear and consistent as it might be for professionals or for the families involved. In Northern Ireland, the report of the Human Organs Inquiry (June 2002) had reached a similar conclusion. In advice to the government, in *The Removal, Retention and Use of Human Organs and Tissue from Post-mortem Examination*, published in 2001, the Chief Medical Officer for England recommended that there should be a fundamental and broad revision of the law on human organs and tissue taken from adults and children either during surgery or after death. A consultation document, *Human Bodies, Human Choices*, was introduced in July 2002, setting out proposals to review the current law in England and Wales. The broad approach to changing the law outlined in the consultation document drew a large degree of consensus and formed the basis of the proposals for the Act. In May 2001, the Department of Culture, Media and Sport set up a working group on human remains, which recommended in November 2003 that the laws preventing repatriation of human remains by certain national museums should be relaxed. See United Kingdom. Department of Health (2004a) "Explanatory notes to the Human Tissue Act 2004" [Web:] www.opsi.gov.uk/acts/en2004/2004en30.htm [Date of access: 21 March 2006].

are to be realistically operable. Precise estimates for tissue retention in the private sector are difficult to obtain in view of commercial secrecy.[852]

5 4 1 Part 1: Removal, use and storage of human tissue for scheduled purposes[853]

Part 1 regulates consent. It sets out the requirement to obtain appropriate consent to carry out activities regulated under the Act, namely storage and use of whole bodies; removal, storage and use of human material, organs, tissues and cells from the bodies of deceased persons; and storage and use of material from living people for purposes set out in Schedule 1. It defines appropriate consent by reference to who may give it, and provides for a "nominated representative" who may make decisions about regulated activities after a person's death. Part 1 makes it an offence to carry out regulated activities without appropriate consent; makes it unlawful to use bodies or human material, once donated, for purposes other than those set out in Schedule 1; and establishes penalties. Part 1 also sets out what should happen to "existing holdings" of human material obtained before the consent provisions take effect. This part also exempts coroners from the requirements of Part 1 of the Act, and allows for the storage and use of human material obtained from living persons for specified purposes without consent. Part 1 does not apply to the removal, as opposed to the storage and use, of human material from living persons. The current law will continue to apply to that. Nor does Part 1 affect the existing law on storage and use of human material for purposes other than those mentioned in Part 1.

Section 1 is the foundation of the Act. It establishes that consent from an appropriate person is required before certain activities can be undertaken for particular purposes. The purposes to be regulated are listed in Schedule 1, and are referred to in these notes as "scheduled purposes". Relevant material from a human body is defined in section 53 as any material consisting of or including human cells, with the exception of gametes, embryos outside the body (as defined in and separately regulated by the Human Fertilisation and Embryology Act), and hair and nails from a living person. Cell lines are

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[852] Liddell & Hall (2005) *Med'l L Rev* 170.

[853] In this part "excepted material" means material which has – (a) come from the body of a living person, or (b) come from the body of a deceased person otherwise than in the course of use of the body for the purpose of anatomical examination. See section 12 of Part 1.

also excluded by virtue of section 54(7), as is any other human material created outside the human body.[854]

Subsection (10) makes it lawful for relevant material, which has been obtained from a living person, to be stored and used for the limited purposes set out in Schedule 1 Part 2 without any consent. These purposes are ones considered intrinsic to the proper conduct of a patient's treatment, clinical audit, quality assurance and performance assessment – which could include evaluations of in vitro diagnostic devices, or necessary for the public health of the nation.

Subsection (11) provides that the Secretary of State may vary, omit, or add to the purposes set out in Schedule 1, by means of a statutory instrument, subject to affirmative resolution in both the House of Commons and the House of Lords. Subsection (12) excludes from the consent requirements of section 1 the storage and use of relevant material in in vitro diagnostic medical device testing where this is already regulated by Directive 98/79/EC. Subsection (13) is aimed at ensuring that bodies and relevant material are not exported and re-imported simply to get around the consent requirements.

5 4 1 1 Section 2: Appropriate consent: Children

Section 2 sets out the meaning of "appropriate consent" in relation to activities regarding the body of a deceased child, or relevant material from living or deceased children.[855] Living children who are competent to do so may give their own consent. If they are not competent or choose not to decide, appropriate consent will be that of a person with

[854] Subsections (2) and (3) deal with the special requirements for the lawful storage and use of a body for anatomical examination. These provisions are carried over from the Anatomy Act, 1984. Subsections (4) to (9) allow activities of the kind mentioned in subsections (1) to (3) to be done in certain cases without meeting the conditions for which those subsections provide. The exceptions relate to imported bodies and material and to bodies and material from bodies, of persons who died before the coming into force of the new regime, where there is a gap of more than 100 years between the date of death and the activity concerned. This allows continued import of tissue for research and excludes archaeological specimens from the consent provisions. There is also an exception for health-related research on material from living people where the material is not linked to an identifiable individual and the research has been ethically approved in accordance with regulations. It is anticipated that this ethical approval will be given by existing research ethics committees.

[855] For the purposes of this section, children are people under the age of 18 years.

parental responsibility for them. Competence is not defined in the Act, but is established according to common law principles, namely the "Gillick test".[856]

5 4 1 2 Section 3: Appropriate consent: Adults

Section 3 sets out the meaning of "appropriate consent" in relation to activities concerning the body of a deceased adult or relevant material from a person who is, at the time of the activity, a living or deceased adult. If the adult is alive, his own consent is required.[857]

5 4 1 3 Section 6: Activities involving material from adults who lack capacity

This section enables the Secretary of State to specify in regulations the circumstances in which there is to be deemed to be consent to activities regulated by the Act in relation to adults who lack capacity to consent for themselves, where a decision of theirs about such matters is not already in force. It is envisaged that the regulations will provide for consent to be deemed in place where the activity would be in the adult's best interests; for example, it could be in their best interests to donate tissue to a close relative for transplantation. The regulations will also be able to provide that, where consent has been given by a proxy in accordance with Schedule 1 to the Medicines For Human Use (Clinical Trials) Regulations 2004/1031, storage and use of material from the adult lacking capacity as part of the trial should be treated as done with consent. The regulations will also be able to take account of the Mental Capacity Bill, introduced in the House of Commons on 17 June 2004, in particular in relation to research involving those who lack capacity to consent, which will be regulated by that Bill.

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856 In *Gillick*, it was held that a young girl is competent to consent to contraceptive advice and treatment if she has a sufficient understanding and intelligence to enable her to understand fully what is proposed. See *Gillick v West Norfolk and Wisbech Area Health Authority* [1986] AC.

857 Section 5 regulates the prohibition of activities without consent. Subsection (1) penalises the carrying out of any of the activities to which sections 1(1), 1(2) or 1(3) applies if done without appropriate consent. This means that where there is consent to use material for one purpose, it may not be used for another. However, a person does not commit an offence if he reasonably believed that the appropriate consent was in place, or that the activity was not one in relation to which consent was required. Subsection (2) penalises a person who knowingly makes a false representation to another person that appropriate consent has been given or is not needed. Subsections (3) to (6) relate to offences and penalties in connection with anatomical examination that have been transferred from the Anatomy Act of 1984.

5 4 1 4 Section 7: Powers of a court to dispense with the need for consent

Subsections (1) to (3) of this section allow the Human Tissue Authority to give direction, deeming consent to be in place, in relation to relevant material from a living person who is either untraceable, or who has not responded to requests for consent to use of his material, but where the material could be used to provide information which may be relevant to another person. These are expected to be rarely used powers, but they may be important where valuable information could be obtained about the treatment and diagnosis of the applicant for the direction. Subsection (4) enables the Secretary of State to make regulations that would provide a similar power for a court to deem consent to be in place where relevant material or a body could be used for health-related research. It is envisaged that this power would be exercised only in rare and unusual cases where the research would be in the overwhelming public interest, for example, where a person has died of an unknown virus that has the potential to spread among the general population.[858]

5 4 1 5 Section 10: Existing anatomical specimens

This section provides for what should be done, once the consent provisions of the Act take effect, about bodies and parts of bodies already donated for dissection under the Anatomy Act of 1984, but where the anatomical examination of them has not been concluded. This Act provides that bodies might be kept for up to three years with the donor's or his next of kin's authority and body parts might be kept for longer. This section provides that the terms of the authority given under the Act are to be treated as "appropriate consent" to anatomical examination. In addition, if the existing authority allowed parts of the body to be held after conclusion of the examination and the examination was not in fact concluded before the consent provisions in the Act came into

[858] Section 8 deals with the restriction of activities in relation to donated material. This section provides that, where the body of a deceased person or relevant material from a human body is the subject of any consent under section 1, it may not be used, or stored for use, for purposes other than the following: (a) a purpose listed in Schedule 1, (b) medical diagnosis or treatment, (c) disposal, or (d) another purpose excepted by regulations. It will be an offence to use such material for any other purpose. The offence does not apply where a person believes on reasonable grounds that the body or material is not relevant material that is the subject of appropriate consent. The regulatory power is intended to be used in ensuring that legitimate uses of tissue that may come to light in future will not be criminalised.

force, the authority is to be treated as "appropriate consent" to storage for the purposes of education and research. Subsection (6) is intended to ensure that, where authority under the Anatomy Act has been given on terms, the authority under the Act that is based on that authority is also subject to those terms.

5 4 2 Part 2: The regulation of activities involving human tissue

Section 13 of the Act establishes the Human Tissue Authority. The Authority has the following general functions:

(a) Maintaining a statement of the general principles that it considers should be followed;
(b) Providing, in relation to activities within its remit, such general oversight and guidance as it considers appropriate;
(c) Superintending, in relation to activities within its remit, compliance with requirements imposed by or under Part 1 or this part, and codes of practice under this Act;
(d) Providing to the public, and to persons carrying on activities within its remit, such information and advice as it considers appropriate about the nature and purpose of such activities;
(e) Monitoring developments relating to activities within its remit and advising the Secretary of State, the National Assembly for Wales and the relevant Northern Ireland department on issues relating to such developments; and
(f) Advising the Secretary of State, the National Assembly for Wales or the relevant Northern Ireland department on such other issues relating to activities within its remit as he, the assembly or the department may require.[859]

5 4 2 1 Section 14: Activities

Subsection (1) lists the activities within the Human Tissue Authority's remit. The activities include disposal of bodies and relevant material stored or used for scheduled

[859] Section 15(a)-(f).

purposes. Subsection (3) excludes from the remit of the Human Tissue Authority activities done in relation to material from bodies, or bodies of persons who died before the Act came into force and has been dead for at least 100 years. Subsection (4) provides that the Secretary of State may, by order, add to the activities within the remit of the Human Tissue Authority. Subsection (5) defines "relevant material" in this section as excluding blood or anything derived from blood for the purpose of transplantation. Blood and blood products for transfusion will be regulated upon implementation of Directive 2002/98/EC, setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components.[860]

5 4 2 2 Section 27: Provision with regard to consent

Subsection (1) provides that in a code of practice dealing with consent, the Human Tissue Authority must lay down standards relating to obtaining consent from a person in a qualifying relationship. Subsection (3) provides that the Human Tissue Authority may lay down different standards for obtaining consent in exceptional cases; for example, a blood relative lower down the hierarchy than a partner or spouse may have a greater interest in obtaining information about their deceased relative's health where this may be relevant to their own health. Subsection (4) sets out the hierarchy of people close to a deceased person who are eligible to give "appropriate consent" to the activities listed in section 1(1) to (3), other than for the purposes of anatomical examinations or public display. If there is more than one person in an eligible class who is competent to give consent, the consent of any one of them would suffice. Subsection (9) provides that the Secretary of State may amend the hierarchy by order.

5 4 2 3 Section 32: Prohibition of commercial dealings in human material

This section transposes the existing prohibition on buying or selling organs from the Human Organ Transplants Act of 1989, and extends the prohibition to cover all human

[860] See also section 16, which is applicable to licence requirements. Section 17 defines who is permitted to act under the authority conferred by a licence: The individual designated in the licence as the person under whose supervision the licensed activity is authorised to be carried out, the "designated individual", any other person notified to the Human Tissue Authority by the designated individual as a person to whom the licence applies, and any person acting under the direction of either of the first two.

material, subject to certain exceptions, intended to be used for transplantation. Advertising for suppliers of material for reward is also prohibited. Subsection (3) allows the Human Tissue Authority to designate a person who may lawfully engage in trade in human material. (For example, the National Blood Service will continue to be allowed to purchase blood from abroad.) Subsection (6) allows for the possibility of commercial tissue banks by allowing licence holders to receive more than just expenses in relation to these activities. Subsection (7) provides that reimbursement for expenses connected with transporting, removing, preparing, preserving or storing the body of a deceased person or relevant human material is not prohibited. Subsection (7) also provides that it is not an offence to provide expenses or recompense for loss of earnings given to an individual supplying human material, and allows for costs incurred by others to be passed along a chain of suppliers. Subsection (9) makes clear that the material covered by the prohibition excludes gametes and embryos, as defined in and regulated by the Human Fertilisation and Embryology Act of 1990, and material that has become property by reason of the application of human skill. Cell lines are excluded from the section by virtue of section 54(7).[861]

5 4 2 4 Section 34: Information about transplant operations

These sections are transposed from the Human Organ Transplants Act of 1989. Section 33 sets out the offence and penalties related to the removal and transplantation of organs and other material from living donors in circumstances other than those provided for in regulations made under this section. These include circumstances where the Human Tissue Authority is satisfied that no reward has been given in relation to the transplant. Section 34 replicates the existing requirement for information about organ transplants to be supplied to the specified authority, the United Kingdom Transplant Authority. Failure to supply information, or the supply of false information, is an offence under this section.

[861] Kaye, J (2006) "A guide to the Human Tissue Act 2004" [Web:] www.ethox.org.uk/ education/teach/HTAguide.htm [Date of access: 24 March 2006].

5 4 3 Part 3: Miscellaneous and general provisions

5 4 3 1 Section 44: Surplus tissue

This section allows any human material that comes from a body during medical treatment, diagnostic testing or research, or "relevant material," as defined in section 53, which is no longer required for scheduled purposes, to be disposed of. Subsection (4) makes it clear that the reference to lawful disposals in the section is not intended to affect the lawfulness of disposals of human material.

5 4 3 2 Section 45: Non-consensual analysis of DNA

It is an offence under section 45(1) to have any bodily material; that is, any material that has come from a human body and that consists of or contains human cells, intending to analyse the DNA in it without qualifying consent, subject to certain exceptions. This offence applies to the whole of the United Kingdom. The offence does not apply if the results of the analysis are to be used for excepted purposes listed in Part 2 of Schedule 4. These include general purposes such as medical treatment and criminal justice purposes, as well as more specific matters, which largely reflect what may be done without consent under Part 1 of the Act, with modifications for Scotland where necessary. Paragraph 11 of Schedule 4 also has the effect that if consent to use material has been obtained under section 1(1) of the Act, it is not necessary to obtain a separate consent where that use involves DNA analysis.

Part 1 of Schedule 4 sets out what constitutes qualifying consent. It can be given to analysis of DNA for any purpose. It can also be given by the person from whose body the material came, or someone with parental responsibility if the person is a child. Once the person has died, consent may be given by anyone who stood in a qualifying relationship with the deceased (as listed in section 54(9)) immediately before he died. The hierarchy referred to in section 27(4) does not apply to this list.

Certain material is outside the scope of the offence altogether, and this includes material from a person who died more than 100 years ago and embryos outside the body, as these are subject to separate regulation by the Human Fertilisation and Embryology Act.

5 4 3 3 Section 47: Power to give effect to community obligations

This section contains a power to amend the Act at a later date by regulations subject to the affirmative procedure in order to implement community obligations in relation to human material. This section has in view Directive 2004/23/EC of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells, which was due to be implemented by 7 April 2006. The power in this section will allow any necessary amendments to be made to the Act by regulations.[862]

5 4 3 4 Section 50: Prosecutions

This section specifies that proceedings regarding offences relating to appropriate consent, commercial dealing in tissue and payment for transplants will be instituted only with the consent of the Director of Public Prosecutions.

5 4 3 5 Section 58: Transition

This section provides for the fact that the maximum penalties in the Act reflect the provisions of the Criminal Justice Act of 2003. Until such time as the relevant provisions of the Act are in force, the maximum penalties are to be read as those that apply under the law currently in force.

5 5 THE HUMAN FERTILISATION AND EMBRYOLOGY ACT

The Human Fertilisation and Embryology Act governs the regulation of research on human embryos. This legislation was enacted primarily to regulate the practice of in vitro fertilisation, and the creation, use, storage and disposal of embryos formed by this means.[863] The regulatory authority established under the Act is the Human Fertilisation

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[862] See United Kingdom: Department of Health (2006) "Human Tissue Act 2004 information" [Web:] www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/Tissue/TissueGeneralInformation/TissueGeneralArticle/fs/en?CONTENT_ID=4102169&chk=7yP5JQ [Date of access: 24 March 2006].

[863] According to section 1(2) of the Human Fertilisation and Embryology Act, the Act, so far as it governs bringing about the creation of an embryo, applies only to bringing about the creation of an embryo outside the human body, and references to embryos, the creation of which was brought about in vitro, in their application to those where fertilisation is complete, are to those where fertilisation began outside the human body, whether or not it was completed there. References to embryos taken from a woman do not include embryos whose creation was brought about in vitro. The Act, so far as it governs the keeping or use of an embryo, applies only to keeping or using an embryo outside the human body.

and Embryology Authority,[864] which is also empowered to issue licences, under strict conditions, for research on human embryos. The Act followed widespread discussion, both inside and outside Parliament, stimulated by the report of the Warnock Committee.[865]

According to section 3, research on embryos older than 14 days, or earlier if the primitive streak has appeared, is prohibited.[866] Research may not be undertaken except under a licence issued by the Human Fertilisation and Embryology Authority. The placement of an embryo in an animal, or a live embryo other than a human embryo in a woman, or any live gametes other than those in a woman, is also prohibited. Furthermore, the replacement of the nucleus of an embryonic cell with the nucleus taken from a cell of any person or embryo and the subsequent development of such an embryo is prohibited.

Section 4 regulates the prohibition in connection with gametes. No person may store any gametes; or in the course of providing treatment services[867] for any woman, use the sperm of any man unless the services are being provided for the woman and the man together; or use the eggs of any other woman.[868] The mixing of gametes with the live gametes of any animal is also prohibited.[869] Furthermore, a licence cannot authorise the storing or using of gametes in any circumstances in which regulations prohibit their

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References to gametes, eggs or sperm, except where otherwise stated, are to live human gametes, eggs or sperm; but references to gametes or eggs do not include eggs in the process of fertilisation.

[864] Section 2(1). See also sections 5, 6, 7, and 8 for the functions of and procedures followed by the Human Fertilisation and Embryology Authority.

[865] The United Kingdom Parliament: House of Lords (2002) www.parliament.the-stationery-office.co.uk/pa/Id200102/dselect/Idstem/83/8301.htm-14k.

[866] Section 3 of the Act read as follows: "Prohibitions in connection with embryos. (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 authorise – (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 use, or (d) replacing a nucleus of a cell of an embryo with a nucleus taken from a cell of any person, embryo or subsequent development of an embryo. (4) For the purpose of subsection 3(a) above, the primitive streak is to have appeared in an embryo not later than the end of the period of 14 days, beginning with the day when the gametes are mixed, not counting any time during which the embryo is stored."

[867] Treatment services is defined in section 2 of the Act as medical, surgical or obstetric services provided to the public or a section of the public for the purpose of assisting women to carry children.

[868] Section 4(1)(a) and (b).

[869] Section 4(1)(c).

storage or use.[870] No person may place sperm and eggs in a woman in any circumstances specified in regulations except in pursuance of a licence.[871]

Section 9 of the Act makes provision for licence and other committees.[872] According to section 11 of the Act, the Human Fertilisation and Embryology Authority may grant the following, and no other, licences:

(a) Licences under paragraph 1 of Schedule 2 of the Act that authorise the activities in the course of providing treatment services.
(b) Licences under Schedule 2 of the Act, authorising the storage of gametes and embryos.
(c) Licences under paragraph 3 of Schedule 2, authorising activities for the purpose of a project of research.

Section 12 of the Act lists the general conditions pertaining to every licence granted under the Act.[873] Section 13 provides the following conditions for every licence issued under paragraph 1 of Schedule 2 of the Act.

Section 13(2) states that information must be recorded about the following:

(a) The persons for who services are provided in pursuance of the licence;
(b) The services provided for them;

[870] Section 4(2).
[871] Section 4(3).
[872] See also section 10 for the licensing procedure.
[873] Some of the conditions include: (a) That the activities authorised by the licence shall be carried out only on the premises to which the licence relates and under the supervision of the person responsible. See section 12(a). (b) That proper records be maintained in such form as the Human Fertilisation and Embryology Authority may specify in directions. See section 12(d). (c) That no money or other benefit shall be given or received in respect of any supply of gametes or embryos unless authorised by directions. See section 12(e). (d) That where gametes or embryos are supplied to a person to whom another licence applies, that person also be provided with such information as the Human Fertilisation and Embryology Authority may specify in directions. See section 12(f).

(c) The person whose gametes are kept or used for the purposes of services provided in pursuance of the licence, or whose gametes have been used in bringing about the creation of embryos so kept or used;
(d) Any child appearing to the person responsible to have been born as a result of treatment in pursuance of the licence;
(e) Any mixing of egg and sperm and any taking of an embryo from a woman or other acquisition of an embryo; and
(f) Such other matters as the Human Fertilisation and Embryology Authority may specify in directives.[874]

Section 14 of the Act set out conditions for every licence authorising the storage of gametes or embryos, and provides for the following:

(a) That gametes of a person or an embryo taken from a woman shall be placed in storage only if received from that person or woman or acquired from a person to whom a licence applies and that an embryo, the creation of which has been brought about in vitro, otherwise than in pursuance of that licence, shall be placed in storage only if acquired from a person to whom a licence applies;
(b) That gametes or embryos that are or have been stored shall not be supplied to a person otherwise than in the course of providing treatment services, unless that person is a person to whom a licence applies; and
(c) That no gametes or embryos shall be kept in storage for longer than the statutory storage period, and if stored at the end of the period, shall be allowed to perish[875]

There are also certain specified conditions pertaining to research licences. These conditions pertain to paragraph 3 of Schedule 2 to the Act. The records maintained in pursuance of the licence shall include such information as the Human Fertilisation and Embryology Authority may specify in directions about such matters. No information may

[874] Section 13(2)(a)-(f). See also section 13(3)-(7).
[875] Section 14(a)-(c). See also section 14(2), (3), and (4). The statutory storage period in respect of gametes is such period not exceeding ten years, as the licence may specify. The statutory storage period in respect of embryos is a period not exceeding five years, as the licence may specify. See also section 14(5).

be removed from any records maintained in pursuance of the licence before the expiry of such period, as may be specified in directives for records of the class in question. No embryo appropriated for the purposes of any project of research may be kept or used otherwise than for the purposes of such a project.[876]

Under Schedule 2 to the Act, a licence may not be granted "unless the Authority is satisfied that any proposed use of embryos is necessary for the purposes of the research", and it cannot authorise any activity unless it appears to the Authority to be necessary or desirable for the purposes of –

(a) promoting advances in the treatment of infertility;
(b) increasing knowledge about the causes of congenital disease;
(c) increasing knowledge about the causes of miscarriages;
(d) developing more effective techniques for contraception; or
(e) developing methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation, or for such other purposes as may be specified in regulations.

The Act limits these "other purposes" to projects of research "which increase knowledge about the creation and development of embryos, or about disease, or enable such knowledge to be applied".[877] Licence applications therefore have to be subjected to two tests: First, that the use of embryos is necessary for the purposes of the research and they cannot be achieved by other means, such as work on animals; and second (and only if the first test is satisfied) that the research is necessary or desirable for one of the specified purposes.

Since the Act was passed, there have been a number of important developments. The most significant was the cloning of Dolly the sheep in 1996, which led to widespread concern that the same technique might be used to produce a baby. At the same time, the cloning of Dolly enhanced interest in the feasibility of using cell nuclear replacement to

[876] Section 15(1)-(4). See also sections 16-22 for further provisions pertaining to licences.
[877] Schedule 2, paragraph 3(3).

develop treatment therapies. The issues arising from these developments were looked at in 1998, jointly by the Human Fertilisation and Embryology Authority and the Human Genetics Advisory Commission, which undertook a public consultation on human cloning. Their report recommended, among other things, that the Secretary of State for Health should consider specifying in regulations two further purposes for which the Human Fertilisation and Embryology Authority might issue licences for research, namely –

(a) the development of methods of therapy for mitochondrial disease; and
(b) the development of therapeutic treatments for diseased or damaged tissues or organs.

In September 1999, following this report, the government set up an expert group under the chairmanship of the Chief Medical Officer, Professor Sir Liam Donaldson, to undertake an assessment of the anticipated benefits of new areas of research using human embryos; the risks and the alternatives; and to advise whether these new areas of research should be permitted and whether regulations should be made under the 1990 Act to extend the purposes for which the Human Fertilisation and Embryology Act might issue licences for research involving human embryos. In its report, the expert group reviewed the scientific evidence. Its principal recommendation was that research using embryos, whether created by in vitro fertilisation or cell nuclear replacement to increase understanding about human disease and disorders and their cell-based treatments, should be permitted subject to the controls under the 1990 Act.[878]

In light of the expert group's report, the government brought forward draft regulations extending the purposes for which research on human embryos could be lawfully undertaken, subject to the Human Fertilisation and Embryology Act. What were to become the Human Fertilisation and Embryology (Research Purposes) Regulations of 2001 were debated and passed by the House of Commons on 19 December 2000 and by

[878] The United Kingdom Parliament: House of Lords (2002) www.parliament.the-stationery-office.co.uk/pa/Id200102/dselect/Idstem/83/8301.htm-14k.

the House of Lords on 22 January 2001. These regulations provides for further purposes for which research licences may be authorised. The Human Fertilisation and Embryology Authority may issue a licence for research under paragraph 3 of Schedule 2 to the Act for any of the following purposes:

(a) Increasing knowledge about the development of embryos;
(b) Increasing knowledge about serious disease; and
(c) Enabling any such knowledge to be applied in developing treatments for serious disease.[879]

The regulations refer to "serious" disease, whereas the Act itself refers simply to disease, and there is no definition of what constitutes serious disease. They do not include among the purposes increasing knowledge about the creation of embryos, even though the Act invites an extension of the purposes in these terms. In the debates on the regulations, particular concern was expressed about the prospect of the use of the cell nuclear replacement procedure to produce cloned human embryos, albeit for research rather than reproductive purposes. Lord Walton of Detchant proposed an amendment, calling on the government to support the appointment of a select committee to undertake to review the regulations following the report of that committee. This amendment was passed without a division, and the regulations duly came into effect on 31 January 2001.

Before the regulations were made, the Pro-Life Alliance applied for judicial review of them on two grounds. It was submitted that they were *ultra vires* the 1990 Act, and it sought a declaration that an embryo created by cell nuclear replacement does not fall within the definition of embryo in the Act. In the Quintavalle case,[880] the question of

[879] Statutory Instrument 2001 No 188. The Human Fertilisation and Embryology (Research Purposes) Regulations 2001.

[880] Zain Hashmi, a little boy, suffered from a serious genetic disorder called beta thalassaemia major. His bone marrow did not produce enough red blood cells and, in consequence, he was often very weak and needed daily drugs and regular blood transfusions to keep him alive. However, his health could be restored to normal by a transplant of stem cells from a tissue-compatible donor. The problem was to find compatible tissue that Zain's immune system would not reject. The chances of finding a compatible donor who was not a sibling were extremely low. Even with siblings, the chances were only one in four. None of Zain's three elder siblings were compatible. In addition, the donor had to be free of the same disorder. That increased the odds even more. Zain's mother, Mrs Hashmi, had twice conceived in the

whether embryos created by cell nuclear replacement are equivalent to embryos created by in vitro fertilisation was examined. The core issue was whether static legislation would prove flexible enough to deal with rapid advances in technology that, while having the same or similar outcomes to traditional methods, achieved those outcomes by novel means.

As previously discussed, the process of cell nuclear replacement involves the removal of the nucleus of an egg that 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. Pro-Life argued that the Human Fertilisation and Embryology Authority regime did not cover a cell nuclear replacement embryo. Section 1(1) of the Human Fertilisation and Embryology Act provides that "(i)n this Act, except where otherwise stated – (a) Embryo means a live human embryo where fertilisation is complete, and (b) references to any embryo include an egg in the process of fertilisation and, for this purpose, fertilisation is not complete until the appearance of a two cell zygote".

It was submitted that, although an embryo created by somatic cell nuclear transfer resembles a zygote, it does not have the same properties, namely the combination of haploid cells,[881] and does not go through the process of "fertilisation". At first instance,

hope of giving birth to a child whose umbilical blood could provide stem cells for Zain. At one time, the fetus was found to have beta thalassaemia major, and she had an abortion. On the second occasion, she gave birth to a child whose tissue turned out not to be compatible. There was a way to save the Hashmi family from having to take risks with conception. For 30 years it has been possible to produce a human embryo by fertilising egg and sperm outside the body and then implanting that embryo in the womb. In vitro fertilisation has enabled many couples that could not be fertilised naturally to have children. More recently, it has become possible to perform a biopsy upon the newly fertilised in vitro-fertilised embryo and remove a single cell to test it for genetic disorders. (This is called pre-implantation genetic diagnosis, as already discussed in chapter 1.) It provides a woman with information about the embryo proposed to be implanted in her body, so that she may decide whether or not to proceed. Mrs Hashmi, for example, would have been spared having to have a fetus carrying beta thalassaemia major aborted if the embryo had been created by in vitro fertilisation and the disorder was diagnosed with pre-implantation genetic diagnosis. See *The Queen on the application of Bruno Quintavalle on behalf of Pro-Life Alliance v Secretary of State for Health* fn 553 *supra*. The decision was overturned in *R (on the application of Quintavalle on behalf of Pro-Life Alliance) v Secretary of State for Health* fn 553 *supra*. See also McVeigh, K (2002) "Judge closes cloning loophole" *The Scotsman*, January 19 [Available on internet:] thescotsman.scotsman.com/uk.cfm?id=68372002 [Date of access: 18 March 2006]; Sheldon, S (2005) "Saviour siblings and the discretionary power of the HFEA" *Med'l L Rev* 13(3):403-411.

881 A cell is haploid if it contains exactly half of a species' typical full set of genetic material. Haploid cells are often used in sexual reproduction. See International Society for Complexity, Information and

Justice Crane adopted a literal approach in interpreting the relevant provisions of the Human Fertilisation and Embryology Act, finding the restrictive wording precluded him from including what Parliament had not foreseen or intended.[882] The High Court ruled that the Human Fertilisation and Embryology Act of 1990 did not protect such an embryo. The ruling left human cloning unregulated until the government was forced to rush through emergency legislation to close the legal loophole. However, the government won the legal battle when the High Court's ruling was overturned. The appeal judges ruled that an embryo is an embryo, whether created by fertilising an egg with sperm, or by cloning. In allowing the government's appeal, Lord Phillips, the senior civil judge in England, said: "I hold that an organism produced by cell nuclear replacement falls within the definition in the Act." Lord Phillips also said he believed Parliament would have intended to cover the cell nuclear replacement technique in the 1990 law if it had been known at the time. The technique had not been developed when the Act was passed, and it only came to prominence in 1997 when Edinburgh's Roslin Institute created Dolly.[883] Before the appeal was heard, the government immediately announced that it would introduce legislation to prohibit reproductive cloning. The Human Reproductive Cloning Bill was introduced on 21 November, and became law on 4 December 2001. The Human Reproductive Cloning Act of 2001 prohibits reproductive cloning. It is an offence for a person to place a human embryo which has been created otherwise than by fertilisation in a woman.[884] A person who is guilty of this offence is liable on conviction on indictment to imprisonment for a term not exceeding ten years, or a fine, or both.[885]

5 5 1 The welfare of a child born as a result of the treatment

Section 13(5) of the Act provides that a woman shall not be provided with treatment services unless account has been taken of the welfare of any child who may be born as a

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Design (2005) "Haploid cells" [Web:] www.iscid.org/encyclopedia/Haploid_Cells [Date of access: 18 March 2006].

[882] See in general Mason, K (2003) "Clones and cell nuclear replacements: A Quintavalle saga" *Edinb L Rev* 7:379-387.

[883] *R (on the application of Quintavalle on behalf of Pro-Life Alliance) v Secretary of State for Health* fn 553 *supra*.

[884] Section 1(1).

[885] Section 1(2).

result of the treatment, including the need of that child for a father, and of any other child who may be affected by the birth.

The welfare principle is rarely subjected to legal or political scrutiny. Jackson argues that its application to fertility treatment is problematic, and it should be deleted from the legislation. According to her, there are three main problems with this version of the welfare principle:

(a) It is *unfair*, because we do not expect fertile people to prove their parental adequacy prior to conception.
(b) It is *disingenuous*, because we do not give the clinicians who are responsible for making this welfare assessment enough information with which to make this complex judgment.
(c) It is *incoherent*, because in other contexts the law insists that existence must almost always be judged preferable to non-existence.

She firmly states that the welfare of children who do not yet exist is, in simple and crude terms, none of the law's business.[886]

5 5 2 Status provisions

Until the advent of assisted reproductive technology in the latter years of the 20th century, a child could say with certainty that they had two biological parents despite the fact that they may have been living in entirely different legal and social families; for example, on adoption or private fostering arrangement. In vitro fertilisation techniques and donor insemination and surrogacy arrangements changed that. The consequence of assisted reproduction techniques are that a child's biological mother is not necessarily either its

[886] For a discussion of the "welfare principle" see, Jackson, EM (2003) "Fertility treatment: Abolish the welfare principle" [Web:] www.prochoiceforum.org.uk/irl_rep_tech_1.asp [Date of access: 2 March 2006]. See also Slabbert (2000) 76-79, where she refers to another concern relating to the anonymity of the identity of gamete donors. Children born as a result of "treatment services" are denied the opportunity to determine their genetic roots by the maintaining of donor secrecy. Slabbert submits that this is not always in the bests interest of these children, nor does it "take account" of the welfare of the child born as a result of treatment services.

genetic or legal mother. This is because section 27 defines a biological mother as the woman giving birth to the baby.[887] Therefore, in a surrogacy arrangement with a donor egg, the child would have three mothers: its genetic mother, the egg donor; its biological mother as defined by section 27; and its legal mother, the person(s) commissioning the birth.[888] This section allows married commissioning parents to apply for a parental order severing a child's legal relationship with their biological parents, provided a number of prerequisites are met. In such a situation the surrogate's name will appear on the birth certificate.

Section 28 of the Act details a child's legal father: If a couple are married and, at the time the embryo is implanted, the husband consented to be the child's legal father irrespective of whether the sperm is his or from a donor. For an unmarried couple the criteria for legal paternity is that the couple are undergoing treatment together. So, if the criteria under sections 28(2) and 28(3) are met, the legal father and the name registered on the birth certificate is the husband or partner. A child will be legally fatherless if a single woman undergoes treatment alone.

The legislation sometimes creates surprising outcomes and there has been some judicial criticism of it, as can be seen in two recent cases. In *Re D*,[889] an unmarried couple received in vitro fertilisation treatment together within the meaning of section 28(3). Although they subsequently separated, the woman continued with the treatment without informing the clinic of the separation, and she fell pregnant. Following the birth, the man applied for parental responsibility and visiting rights. At the Court of First Instance, the mother, father and court accepted that by virtue of section 28(3) the man was the legal father even though there was no biological relationship. The court made an order for indirect contact and adjourned the parental responsibility application. The father appealed

887 Section 27 reads as follows: "(1) The woman who is carrying or has carried a child as a result of the placing in her of an embryo or of sperm and eggs, and no other woman, is to be treated as the mother of the child. (2) Subsection (1) above does not apply to any child to the extent that the child is treated by virtue of adoption as not being the child of any person other than the adopter or adopters. (3) Subsection (1) above applies whether the woman was in the United Kingdom or elsewhere at the time of the placing in her of the embryo or the sperm and eggs."

888 Section 30.

889 *Re D* [2001] 1 FLR 972.

and Butler's Sloss P expressed: "… [I]t was highly undesirable that a novel and difficult set of circumstances such as these were allowed to determine an important issue of jurisdiction and fact, which will have implication for this child, for the mother, for the father, for all their families, for many years to come."

The father subsequently made an application for a declaration of parentage relying on section 28(3). The court made a declaration that the man was the legal father and the mother appealed.[890] The Court of Appeal properly considered the meaning of section 28(3) for the first time in the case and found that its natural and ordinary meaning should be adopted. Therefore, at the time of the successful implantation of the embryo into the mother's uterus, the parties were not being treated together and the original order was set aside.

An even more complex case was *Leeds Teaching Hospitals NHS Trust v Mr A, Mrs A & 5 ORS*.[891] This case concerned two married couples receiving in vitro fertilisation treatment. A syringe needle was not properly cleaned, resulting in sperm from the first father (Mr B) being used to fertilise an egg from the second mother. The resultant embryo was successfully implanted in the second mother, who gave birth to twins. The mistake may not have been discovered if Mr B had not been black and the second couple (Couple A) both white and the children therefore mixed race. Both couples agreed that the second couple would bring up the twins; however, their parentage under the Human Fertilisation and Embryology Act was confused. Their biological father was obviously the first husband, while the identity of their legal father remained uncertain. Under section 28(2), the second husband would have to have consented to the treatment to be the father and Butler Sloss P found that he would not have so consented. The second husband then argued that section 28(3) could apply on the basis that he and his wife were receiving treatment together. However, the court held that the "mistake" vitiated the concept of "treatment together". Accordingly, the court felt that, to recognise what had been agreed,

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[890] *Re R* [2003] 1 FLR 1183.

[891] *Leeds Teaching Hospitals NHS Trust v Mr A, Mrs A & 5 ORS* [2003] ECWA 259, as quoted in Willmott (2004) "Does a child have a right to know who their parents are?" [Web:] www.clarkewillmott.com/ services/individuals/family_mat. html?bulletin=707 [Date of access: 19 March 2006].

a residence order should be made in favour of the second couple and for them to later apply to adopt the twins. This made the second husband their legal father, although it meant that the mother lost her right to be their "natural" mother.[892] The verdict of the judge performed a "legal acrobatic" in that she upheld both the primacy of the nuclear family as the privileged child-rearing sight, and the importance of children's rights and necessity to know both of their biological parents. She decided that the twins in question should remain living with couple A, but nevertheless Mr B was granted legal rights, since he was the biological father.[893]

5 6 CONSENT REQUIREMENTS

5 6 1 Introductory remarks

As previously discussed, informed consent is especially important in all research on tissues of human origin. The Human Fertilisation and Embryology Authority and researchers take consent requirements very seriously. According to English legal principles, failure by a medical practitioner to obtain his patient's lawful consent to medical interventions may result in the practitioner incurring civil and/or criminal liability. Such practitioner may be convicted of criminal assault and battery, and the non-consenting and uninformed patient also has two private law remedies at his/her disposal. These remedies include an action for damages based on assault and battery, as well as an action for damages based on negligence.[894]

In *Chatterton v Gerson*,[895] Bristow stated the following: "In my judgment what the court has to do in each case is to look at all the circumstances and say, 'Was there real consent?' Equally, to avoid a claim of negligence, the information disclosed to patients, when obtaining consent, about risks must be 'reasonable' in the eyes of the court. Leaving aside breaches of professional duty so obvious that they 'speak for themselves', has traditionally

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[892] Gill'ard, C (2004) "Law and morality in assisted reproductive technology case study on the Leeds Teaching Hospitals NHS Trust v Mr & Mrs A & Others" [Web:] www.psljournal.com/archives/all/lawandmorality.cfm [Date of access: 20 February 2006].

[893] See in general Harris, J (2003) "Assisted Reproductive Technological Blunders (ARTBs)" *J Med'l Eth Cur Cont* 29(4):205-206.

[894] Van Oosten (1989) 70-71.

[895] *Chatterton v Gerson* [1981] 1 ALL ER 257 (QB).

been determined by the Bolam test." The Bolam test applies where expert witnesses, nearly always from within the medical profession, are asked to confirm the appropriateness of a particular aspect of medical care. The care is regarded as appropriate if the experts convince the court that a relevant, reasonable body of professional opinion would endorse the course of action that was actually taken. In the case of consent, the issue would be the amount and accuracy of information disclosed by a doctor and contested by a patient. The appropriateness of this will be irrespective of –

(a) the degree that claimants believe that they were morally entitled to specific information they were not given;
(b) the degree of harm they suffered as a result; and
(c) the extent to which the patient's claim for a financial remedy may be supported by the public's opinion.[896]

Therefore, consent assessed as appropriate by the Bolam test is judged by a "professional standard", which may be inappropriate outside the profession if it disregards the patient and is based solely on the views of clinicians.[897]

5 6 2 The Human Fertilisation and Embryology Act: Consent

Section 13(6) of the Act reads as follows:

> A woman shall not be provided with any treatment services involving –
> - the use of any gametes of any person, if that person's consent is required under paragraph 5 of Schedule 3 to this Act for the use in question,
> - the use of any embryo the creation of which was brought about in vitro, or
> - the use of any embryo taken from a woman, if the consent of the woman from whom it was taken is required under paragraph 7 of that Schedule for the use in question,
>
> unless the woman being treated and, where she is being treated together with a man, the man have been given a suitable opportunity to receive proper counselling about the implications of taking the proposed steps, and have been provided with such relevant information as is proper.

[896] *Bolam v Friern Hospital Management Committee* [1957] 2 ALL ER 118 (QB).
[897] For a discussion of the judicial position of the doctrine of informed consent, and the doctor's duty to disclose in the English law see Van Oosten (1989) 70-189 and the cases discussed therein.

Section 14(d) of the Act reads as follows:

> The following shall be conditions of every licence authorising the storage of gametes or embryos –
> ... that such information as the Authority may specify in directions as to the persons whose consent is required under Schedule 3 to this Act, the terms of their consent and the circumstances of the storage and as to such other matters as the Authority may specify in directions shall be included in the records maintained in pursuance of the licence.

Section 14(2) of the Act states that no information shall be removed from any records maintained in pursuance of such a licence before the expiry of such period as may be specified in directions for records of the class in question.

5 6 2 1 Schedule 3: Consent to the use of gametes or embryos

Consent under Schedule 3 must be given in writing, and "effective consent" under this schedule means consent that has not been withdrawn. According to paragraph 2 of this schedule, consent to the use of any embryo must specify one or more of the following purposes:

(a) Use in providing treatment services to the person giving consent, or that person and another specified person together;
(b) Use in providing treatment services to persons not including the person giving consent; and
(c) Use for the purposes of any project of research, and may specify conditions subject to which the embryo may be so used.

Consent given to the storage of any gametes or any embryo must specify the maximum period of storage, and state what is to be done with the gametes or embryo if the person who gave consent dies or is unable because of incapacity to vary the terms of the consent or to revoke it,[898] and may specify conditions subject to which the gametes or embryo may remain in storage.[899] Consent specified under paragraph 4 may apply to the use or storage of a particular embryo, or in the case of a person providing gametes, to the use or

[898] Slabbert submits that this paragraph does not provide a clear answer. In this respect, the Act fails to provide what should happen, and requires only that the consent-giver addresses it. See Slabbert (2000) 72.
[899] Schedule 3, paragraph 2.

storage of any embryo whose creation may be brought about using those gametes. Consent may also be withdrawn, in accordance with this schedule, either generally or in relation to a particular embryo or particular embryos.

Before a person consents, he/she must be given a suitable opportunity to receive proper counselling about the implications of taking the proposed steps, and must be provided with proper information.[900]

5 6 2 2 In vitro fertilisation and the use of subsequent embryos

A person's gametes may not be used to bring about the creation of any embryo in vitro unless there is effective consent by that person to any embryo, the creation of which may be brought about with the use of those gametes, being used for one or more of the purposes mentioned in paragraph 2(1) of Schedule 3. An embryo created through this technique may not be received by any person unless there is effective consent by each person whose gametes were used to bring about the creation of the embryo to the use for one or more of the purposes stipulated in paragraph 2(1) of Schedule 3.[901]

The consent requirements for embryos obtained by lavage differ from the above provisions. An embryo taken from a woman may not be used for any purpose unless there is an effective consent by her to the use of the embryo. An embryo taken from a woman may not be received by any person for use for any purpose unless there is an effective consent by her to the use of the embryo for that purpose.[902]

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[900] Schedule 3, paragraph 3. According to paragraph 4, the terms of any consent may from time to time be varied, and the consent may be withdrawn by notice given by the person who gave the consent to the person keeping the gametes or embryo to which the consent is relevant. This paragraph applies to the provision of treatment services, as well as for the purposes of any research project.

[901] Schedule 3, paragraph 6. See also paragraph 5, which reads as follows: "A person's gametes must not be used for the purposes of treatment services unless there is an effective consent by that person to their being so used, and they are used in accordance with the terms of the consent. A person's gametes must not be received for use for those purposes unless there is an effective consent by that person to their being so used."

[902] Schedule 3, paragraph 7. This paragraph does not apply to the use, for the purpose of providing a woman with treatment services, of an embryo taken from her.

Similar provisions pertain to the storage of gametes and embryos. A person's gametes, and in vitro-fertilised embryos, may not be kept in storage unless there is an effective consent by that person to their storage and they are stored in accordance with the consent.[903]

The case of Diane Blood and her wish to conceive her dead husband's child is well known. The decision by the Court of Appeal[904] resulted in the clarification of certain areas of The Human Fertilisation and Embryology Act. It has also left other issues unresolved, which no doubt will result in future litigation.

The Blood's married in 1991. The couple decided to start a family late in 1994. Mr Blood contracted meningitis in 1995, and died on 2 March, before there being successful conception. During Mr Blood's illness, Mrs Blood raised the question with the medical practitioners of taking a sample of sperm by electro ejaculation. Two such samples were taken, and the sperm preserved, while her husband was in a coma, and shortly before he was pronounced clinically dead. Mrs Blood sought to receive treatment to conceive using the samples. The Human Fertilisation and Embryology Authority refused consent, deeming it contrary to the Act. On judicial review, the President of the Family Division, Sir Stephen Brown, upheld the authority's decision. Mrs Blood appealed successfully. While the authority's decision was correct that treatment in the United Kingdom could not take place without Mr Blood's written consent, the authority had not been advised as to the importance of the European Convention[905] regarding Mrs Blood's rights to treatment in other member states. Mrs Blood had the right to be treated in Belgium with her husband's sperm, unless there were good public policy reasons for not allowing this to happen.

The authority also appeared not to have had sufficient regard for the fact that in future it would not be possible for this problem to arise, because under United Kingdom law Mr Blood's sperm should not have been preserved since he had not given his written consent.

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[903] Schedule 3, paragraph 8.
[904] *R v Human Fertilisation and Embryology Authority, ex parte Blood* [1997] 2 All ER 687.
[905] European Convention for the Protection of Human Rights and Fundamental Freedoms, 1950.

If the sperm had not been preserved, it could not have been exported. The court did not criticise the fact of preservation of the sperm in the circumstances of this case, since the storage had taken place in close consultation with the authority in a *bona fide* manner and in an unexplored legal situation. The authority had the option to reconsider the question of export of the sperm and, if the matter were subject to fresh consideration, the authority would have to decide whether to allow the export or to refuse it on grounds that were acceptable according to the European Convention.[906]

According to Rodgers, it is a little paradoxical that the Court of Appeal can declare the keeping of Mr Blood's sperm without his consent to be unlawful, and also that the treatment of Mrs Blood is unlawful under United Kingdom legislation, and yet pave the way for Mrs Blood's treatment in the European Union. The Human Fertilisation and Embryology Authority subsequently authorised the exportation of Mr Blood's sperm to Belgium, where she could receive the necessary treatment. The court's decision in the case was based on two main areas of law, namely the interpretation of the Human Fertilisation and Embryology Act and the impact of European legislation permitting citizens to obtain services, including medical services, in other member states. In considering the first issue, the court upheld the view of the High Court, that the preservation and use of the stored sperm was not permitted under the 1990 Act. This was the line taken by the Human Fertilisation and Embryology Authority.[907]

Rodgers also makes reference to future possibilities to address the above issues. If the Law Commission's proposals as to the best interests test, Law Commission No 231,[908] were to be implemented, the wife would have a greater chance of legitimately authorising removal of sperm. The commission suggested that, in assessing what is in a patient's best interests, regard should be held for the following:

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[906] See in general *Centre for Reproductive Medicine v Mrs U* [2002] EWCA Civ 565. See also *Paton v Trustees of the British Pregnancy Advisory Service and Another* fn 799 *supra*; *C and Another v S and Others* fn 798 *supra*; *R v Secretary of State for the Home Department, ex parte Mellor* [2001] EWCA Civ. 472. This case concerned a long-term prisoner's application to have his wife artificially inseminated with his sperm.

[907] Rodgers, ME (1997) "Gametes: Storage, consent and treatment" *Web J Cur Leg Issues* [Available on internet:] http://webjcli.ncl.ac.uk/1997/issue3/rodgers3.html [Date of access: 19 March [2006].

[908] Law Commission No 231 (1995) Mental Incapacity (London: HMSO) HC 189 of 1994-5.

(a) Insofar as is ascertainable, his past and present wishes and feelings and the factors which he would consider if he were able to do so.
(b) If it is practicable ... the views as to that person's wishes and feelings and as to what would be in his best interests.
(c) Anyone, whether his spouse, a relative, friend or other person, engaged in caring for him or interested in his welfare.[909]

Under these proposals, consideration should be given to the wishes of the patient to conceive a child with his wife prior to his incapacity. Clearly, some cogent evidence would be required. Mrs Blood would have benefited from this proposal, as the court did discuss the evidence produced that highlighted Mr Blood's desire to have children. Unfortunately, these proposals are unlikely to be implemented in the near future; therefore, for the spouses who find themselves in this situation today, removal of sperm, regardless of evidence to indicate that it would be consented to, must fall foul of the common law provisions, and removal would be deemed unlawful.

Slabbert submits that although these provisions are understandable in order to discourage posthumous pregnancies, they seem inconsistent with the general legislative tendency of recent years to minimise or mitigate the differential status of children based solely on the conduct of their parents, and are strongly criticised by the European Court of Human Rights. The common law presumptions pertaining to legitimacy and paternity would also not apply in respect of the resulting children.[910]

In a similar case[911] pertaining to consent, a woman, Natalie Evans (35) from Wiltshire, was receiving fertility treatment in October 2001 when doctors discovered pre-cancerous cells on her ovaries. She immediately underwent a course of in vitro fertilisation, which produced six embryos fertilised by the sperm of her fiancé, before having her ovaries

[909] Draft Mental Incapacity Bill (2003) clause 3(2)(a) and 3(2)(c).
[910] Slabbert (2000) 74.
[911] *Evans v Amicus Healthcare Ltd and Others (Secretary of State for Health and Another intervening)* [2003] 2161. See also *Natalie Evans v Amicus Healthcare Ltd & Others* [2004] 727; *Human Fertilisation and Embryology Authority v Amicus Healthcare Limited, Royal United Hospital Bath NHS, Natalie Evans, Howard Johnston, Secretary of State Health, Director of Public Prosecutions* [2005]. See Alexander Harris Solicitors (2005) "Save my embryos: A plea to the European Court of Human Rights" [Web:] alexanderharris.co.uk/article/Save_my_embryos_a_plea_to_the_European_Court_of_Human_Rights [Date of access: 19 March 2006]. See also Alghrani, A (2005) "Deciding the fate of frozen embryos: Natalie Evans v Amicus Healthcare Ltd and Others [2004] WL 1174355" *Med'l L Rev* 13(1):244-256.

removed to treat the disease. The next year, however, the couple split and Mr Johnston wrote to the fertility clinic asking it to destroy the spare embryos. Ms Evans tried to gain permission to use her frozen embryos anyway, but both the High Court and the Court of Appeal rejected her legal challenge. They pointing out that the 1990 Human Fertilisation and Embryology Act governing in vitro fertilisation treatment stipulates that consent from both man and woman is vital at every stage of the process. She also made an emotional plea to her former fiancé, Howard Johnston, to change his mind and let her use the embryos, which could not be implanted without his consent.

It was ordered that the embryos be destroyed, and the clinic storing them informed Ms Evans that the date had been set to destroy the embryos. But, with less than 24 hours to go, the European Court of Human Rights stepped in on 7 March 2006 and requested the British Government to halt the destruction while a last legal plea was heard. In its ruling, the Strasbourg Court, which polices the European Convention on Human Rights, rejected all three grounds to Ms Evans's challenge and ruled that –

(a) the embryos in question did not enjoy any right to life;
(b) there had been no violation of her "right to a family life"; and
(c) there had been no discrimination in her treatment.

But, crucially, two of the seven judges who heard the case dissented from the judgment, arguing that the "bright line" nature of the United Kingdom Act, which spells out the need for consent from both partners right until the implantation of the ovaries, did not properly balance the rights of the individual with the need for clear public policy. In their dissenting opinion appended to the ruling, the two also argued that United Kingdom authorities should have done more to safeguard the rights of Ms Evans to have a child.

Although that opinion carries no more than moral weight, the court effectively invited Ms Evans to appeal to the Court's Grand Chamber, where 17 judges would hear her final appeal. At a press conference in London, Ms Evans said she had been buoyed by the dissenting judges and confirmed that she would make one more appeal. She faced a race

against time, however, because the embryos held at a clinic in Bath would be destroyed in October 2006 under a five-year storage limit. If the embryos were to be destroyed, it would end her chance of having a baby naturally. Ms Evans also said she would prefer not to take the legal route and appealed one more time to Mr Johnston, who consistently argued that he did not want the emotional and legal burden of a child with his former partner by allowing her to use the embryos.

Only a few years ago, a debate over the rights to use frozen embryos would have seemed purely academic and speculative. However, as technological advances increase our control over human fertility, we must be prepared for more cases such as that of Natalie Evans to come to the courts, and to challenge ideas about the boundaries of ethical acceptability.

The latter provisions are apparently aimed at avoiding litigation in respect of cryopreserved embryos in divorce proceedings. With the advent of in vitro fertilisation procedures and cryopreservation of excess embryos, it is inevitable that the disposition of frozen embryos would become a litigated issue during divorce proceedings. In addition, as scientists recognise the value of these excess embryos, it is inevitable that in vitro fertilisation clinics would vie for ownership rights over these embryos. The questions that face the state are –

(a) whether the embryos should be treated as property or as people; and
(b) whether embryo disposition agreements signed by the progenitors should be enforced.

Case law has primarily developed during divorce proceedings when the divorcing parties express differing intents regarding the disposition of their frozen embryos. One of the first state supreme courts to address a custody dispute over frozen embryos was Tennessee, in the case of *Davis v Davis*.[912] In this case, custody of seven embryos was at

[912] *Davis v Davis* fn 123 *supra*. Evidence was led on behalf of the applicant, Mr Davis, that the position of the frozen embryos was that of a group of undifferentiated cells that had no organs or nervous system,

issue. The court declared that Mrs Davis should be allowed the opportunity to bring these children to term through implantation. It was submitted that, at that stage of the embryo's development, the respective contributors of the gametes should be the sole arbiters over the fate of the pre-embryos, and if the contributors of the gametes could not agree on the fate of such pre-embryos, they should be allowed to die a passive death.

On appeal, the judgment was overturned and joint control was vested in the former husband and wife, giving them equal say over the disposition of these gametes. Awarding sole custody to the former Mrs Davis was regarded as impermissible state action, as such an award would infringe Mr Davis's constitutionally protected right in respect of procreation, forcing him to become a parent against his will. Prior to the in vitro fertilisation procedure, the couple did not sign an embryo disposition agreement. The court concluded that the embryos are neither "persons" nor "property", but occupy an interim category that entitles them to special respect because of their potential for human life. *In dicta*, the court noted, as a guideline of the in vitro fertilisation world, that an agreement regarding disposition should be presumed valid and should be enforced as between the progenitors. However, in this case there was no agreement, so embryo disposition turned on the parties' constitutional rights to privacy, specifically the decision whether to bear or beget a child. Therefore, the court avoided characterising the embryos as persons, which would inevitably prohibit their destruction or donation to medical research.[913] In this respect, the Human Fertilisation and Embryology Act attempts to avoid the consent problems that arose in the Davis case. As mentioned above, where the embryo is created in vitro, the woman's partner can effectively require that the embryo be perished by withdrawing his consent as is required in terms of the Act, whereas in the case of an embryo recovered by lavage he cannot do this.[914]

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and that life only commenced after development of the primitive streak, and that despite the fact that fertilisation had occurred, no unique individual had yet been created.

913 Enmon (2002) *Utah L Rev* 621 *at* 633.

914 Slabbert (2000) 76.

5 6 3 The welfare of any child born as a result of the treatment: Some concerns

Section 13(5) of the Act provides that a woman shall not be provided with treatment services unless account has been taken of the welfare of any child that may be born as a result of the treatment, including the need of that child for a father, as well as the welfare of any other child who may be affected by the birth.

5 6 4 Conclusive remarks

The Human Fertilisation and Embryology Act has succeeded in providing a clear framework for many issues involving the human embryo, including questions involving the intricacy of its status. The Act only grants full protection to the embryo extra uterum from 14 days. The fate of the embryo is closely tied to the decisions of gamete or embryo providers through the effect of their consent in respect of the following:

(a) The creation of embryos;
(b) The use of embryos in treatment; and
(c) The storage of embryos.

The criminal provisions contained in the 1990 Act prohibiting certain practices, such as practices in respect of embryo research, are balanced and justified, particularly in view of the rather free hand that researchers are allowed under the Act.[915]

5 7 THE UNITED KINGDOM STEM CELL BANK

5 7 1 Introductory remarks

The United Kingdom recently officially opened the world's first stem cell bank. The United Kingdom Stem Cell Bank will store both new and existing adult and embryonic stem cell lines, as well as stem cells derived from fetal tissue. Researchers in the United Kingdom and possibly other countries will be able to apply for access to the stem cells, and applications are reviewed by a "high-level steering committee" that will develop regulations regarding the stem cell bank and the use of its cell lines. Inglis said that the

[915] Slabbert (2000) 80.

cost of access to the lines will vary depending on the applicants – academic researchers will be charged "only a nominal fee", while private companies will "pay the full economic cost".[916]

5 7 2 Code of practice for the use of human stem cell lines[917]

The framework and content of this code of practice are based on the principles of good research practice as applied to the use of human stem cell lines for basic and clinical research leading to the development of therapeutic interventions. These principles should be followed if the work is to be conducted within a transparent, regulated and ethical framework. The code has been developed by the Steering Committee for the United Kingdom Stem Cell Bank and for the use of human stem cell lines.

A route map outlining the steps for the accession of stem cell lines from the stem cell bank is annexed to the code. In order to provide the Steering Committee with the information needed to oversee research involving stem lines, researcher are requested to complete the relevant application form following the guidance in section 9. The ownership of any intellectual property embodied in stem cell lines curated by the bank will remain with the originator. Therefore, the bank can only release stem cell lines if there is a material use licence between the depositor and accessor, setting out the rights of exploitation and ownership of any intellectual property arising from the research conducted by the user. Researchers from academia and industry in the United Kingdom and abroad can access the bank. It is expected that this bank will become the first port of call for researcher wishing to work with human embryonic stem cell lines. The bank will make available standardised, quality-controlled aliquots of stem cell lines and will allow researchers to work with well-defined material so that direct comparisons can be made between studies.

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[916] Gajewski, KA (2004) "The United Kingdom officially opened the world's first stem cell bank" *The Humanist*, July 1 [Available on internet:] highbeam.com/library/doc0.asp?docid=1G1:119072936&refid=ink_tptd_mag [Date of access: 20 March 2006].

[917] Medical Research Council (2005) "Code of practice for the use of human stem cell lines" [Web:] http://www.mrc.ac.uk/public-use_of_stem_cell_lines [Date of access: 26 March 2006].

Researchers wishing to export human embryonic stem cell lines should apply to the Steering Committee as outlined in section 9. Free and informed consent[918] are key principles of the Human Tissue Act and the Human Fertilisation and Embryology Act. Comprehensive information must be given in a form that is readily accessible and allows a free and informed decision to be made by potential donors. All written information and consent forms have to be approved by local ethics committees, and for research involving embryos also by the Human Fertilisation and Embryology Authority.[919]

Each gamete provider must consent in writing –

(a) to the use of embryos created using their gametes in the research project for the derivation of stem cell lines;
(b) that they understand that a sample of any stem cell line will be deposited in the bank and that the derived stem cell lines may be used in other research projects;
(c) that they are under no obligation to take part in the study and that a decision not to participate will not alter the treatment that they would normally receive;
(d) that they understand that they have a right to withdraw their consent without giving any reason;
(e) that they understand that any cell line derived from their donated gametes or embryos may eventually be used for treatment purposes in the future;
(f) that they understand that cell lines or discoveries made using them may be patented and used for commercial purposes, but that the donor will not benefit financially from this; and
(g) whether they agree to be contacted in the future in the unlikely event that that the Stem Cell Steering Committee considers that they should be contacted in relation

[918] Informed consent is defined in the code as "the voluntary consent given by a patient to participate in a study after being informed of its purpose, method of treatment, procedure for assignment to treatment, benefits, and risks associated with participation, and required data collection procedures and schedule".

[919] Before patients consent to donate their embryos for use in research projects to derive stem cell lines, they must be given verbal information supported by relevant written material.

to confirm test results performed on stem cell lines that are of direct relevance to their own, their family's or public health.[920]

Those working with stem cell lines are expected to follow the general principles of good research practice. The European Union's directive on setting standards of quality and safety for the donation, procurement, testing, procession, storage and distribution of human tissues and cells will govern all tissues and cells intended for human application. The directive covers haematopoietic, umbilical cord and bone marrow stem cells, reproductive cells (namely eggs and sperm), fetal tissue, and adult and embryonic stem cells. The directive does not cover research for purposes other that application in the human body, for example in vitro research, or in animal models. A key principle of the European Union's Tissue Directive is the requirement of traceability of human tissues and cells from donor to recipient and vice versa, in order to make it possible to verify the compliance with quality and safety standards.[921]

5 8 CONCLUSION

In summary, the United Kingdom Abortion Act of 1967 legalises the termination of pregnancies where there is a substantial risk that if the child were born it would suffer from such physical or mental abnormalities as to be seriously handicapped. Following amendments to this Act there is no time limit on such terminations. In 2000, 1 760 abortions were performed solely on those grounds, while another 73 were performed on a combination of grounds including risk of serious handicap. The abnormalities identified included spina bifida, Down's syndrome and a family history of heritable disorder. 94 of

[920] A gamete is defined in the code as "a male sperm or female egg". Fetus is defined as "a developing human from eight weeks after conception to birth". Embryo is defined as "the first stage in the development of a human being, usually the result of fertilising an egg with sperm; from the eight week of fertilisation the embryo if referred to as a fetus".

[921] It is likely that this directive will build on current United Kingdom guidance, including the Code of Practice for Tissue Banks (2001), Guidance on the Microbiological Safety of Human Organs, Tissues, and Cells used in Transplantation (2000), and the Code of Practice for the Production of Human-derived Therapeutic Product (2002). A further directive is currently under negotiation in relation to tissue engineering. Stem cells and stem cell lines intended for human use must be derived and processed in clinical grade facilities that meet the requirements set out in the Code of Practice for Tissue Banks (2001), and have been inspected by the Medical Health Research Authority and other appropriate accreditation agencies. This guidance is all available as an annexure to the Code of Practice for the Use of Human Stem Cell Lines.

the terminations took place after 24 weeks' gestation.[922] Research and innovation involving fetuses or fetal material in England, Wales and Northern Ireland is covered by the Human Tissue Act, which will come into effect in April 2006. Guidance to replace the Polkinghorne Report is provided in codes of practice published by the Human Tissue Authority. In 2005, draft codes were published in the United Kingdom for public consultation. The Human Tissue Act will also cover research using tissue left over from surgical or diagnostic procedures.[923]

The derivation of human embryonic stem cells in the United Kingdom is regulated by the Human Fertilisation and Embryology Act, which gave effect to the majority of the recommendations made by the Warnock Committee. In concluding that embryo research could be morally justified in certain circumstances. The committee stated that although "the embryo is entitled to some added measure of respect beyond that accorded to other animal studies that respect cannot be absolute, and may be weighed against the benefits arising from research".

According to the Human Fertilisation and Embryology Act, embryo research may only be conducted in accordance with a licence up to the formation of the primitive streak, which is taken to occur no later than fourteen days after the mixing of the gametes. Embryo research will only be licensed if the Human Fertilisation and Embryology Authority is satisfied that the use of embryos is necessary for the purposes of the research and considers the proposed research to be necessary or desirable for one of the purposes set out in Schedule 2, paragraph 3 to the Act. Moreover, after being "offered such relevant information as is proper", embryo and gamete donors must give written consent to the use of the embryo for research, and may specify conditions subject to which the embryo may be used. One of the key features of embryo research in the United Kingdom, including research involving the derivation of embryonic stem cells, is that the Human Fertilisation

[922] Morris & Saintier (2003) *Med'l L Rev* 167 *at* 171.
[923] United Kingdom. Department of Health (2005) "Code of practice for tissue banks" [Web:] www.dh.gov.uk/assetRoot/04/03/42/63/04034263.pdf [Date of access: 10 April 2006].

and Embryology Act allows research to be conducted upon embryos created specifically for research as well as supernumerary embryos.[924]

The issue of research involving embryos and fetuses has been a matter of serious social concern for the past three decades. As each new scientific and medical development is introduced that affects embryos and fetuses, new state laws are proposed to deal with them. Bills on cloning and stem cell research are the subjects of vast media attention and public debate. As technologies develop that focus increasingly on the human embryo, lawmakers are having difficulty coming to agreement on legislative policy in the absence of societal accord about the moral and legal status of the embryo. Although state legislatures have addressed regulation of research on the unborn for 30 years, the more recent technologies are being debated within a new context. Both the legislative frameworks in South Africa and the United Kingdom as it currently stands have been discussed. In the next chapter some recommendations are made, specifically pertaining to South Africa, to address the shortcomings in current legislation.

[924] Halliday (2004) *Med'l L Rev* 40.

CHAPTER 6 EMBRYONIC STEM CELL RESEARCH AND CLONING: A PROPOSED LEGISLATIVE FRAMEWORK IN CONTEXT OF LEGAL STATUS AND PERSONHOOD

6 1 INTRODUCTION

In *The Enforcement of Morals* Lord Patrick Devlin asked: "To what extent should society use the law to enforce its moral judgments?"[925] Fifty years later, in an era of stem cell research, pre-implantation genetic diagnosis and the prospect of human cloning, this has emerged as one of the dominant questions for those struggling to develop regulatory policy. Most would agree with the claims that the law often reflects public morality, that what is ethical ought to be permitted, and what is unethical ought to be prohibited. Few other areas of social activity highlight this challenge more than reproductive genetics, where diverse moral values and proposed health benefits require such careful balancing. Finding this balance can be a tremendous challenge.[926]

The variation in how different jurisdictions address the regulation of embryonic stem cell research, and especially cloning techniques, highlights the difficulty of regulating an area so permeated with moral ambiguity.[927] One can certainly sympathise with governments throughout the world as they seek ways to face the unique challenges associated with this controversial research. But given the lack of social consensus about the technology, as

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925 Devlin, P (1957) *The enforcement of morals* Oxford: Oxford University Press, as quoted in Caulfield, TC & Knowles, L (2004) "Law and policy in the era of reproductive genetics" *J Med'l Eth* 30(4):414.

926 Caulfield & Knowles (2004) *J Med'l Eth* 414 *at* 415.

927 A number of countries already have laws that create a very restrictive or prohibitive approach towards research involving human embryos. For example, Ireland and Austria have laws that limit research on and the creation of human embryos. A more "middle ground" approach is however emerging in a number of jurisdictions. For example, some countries are considering or have already adopted what has been called a "cautious approach". In general, these schemes allow research on "surplus embryos" left over from in vitro fertilisation. However, the creation of embryos for the sole purpose of research and all forms of somatic cell nuclear transfer involving human embryos, including "therapeutic cloning", are banned. Canada is a good example of such an approach. At the other end of the regulatory spectrum lie the jurisdictions that either explicitly allow or have not explicitly excluded the possibility of a full range of research activities, including therapeutic cloning and the creation of embryos for research purposes. The regulatory framework present in the United Kingdom is the best example of such an approach. See Pattinson, SD (2002) "Reproductive cloning: Can cloning harm the clone?" *Med'l L Rev* 10(3):295. See in general Regnier, ME & Knoppers, BM (2002) "International initiatives" *Health L Rev* 11(1):67-71; Caulfield, TC (2003) "The regulation of embryonic stem cell research: A few observations on the international scene" *Health LJ (Sp Ed)*, 87 *at* 88, 89.

the moral ambiguity seems to be intensifying with the passing of time, the use of statutory prohibitions is surely a mistake. Whether one favours a more restrictive research environment or one that leaves room for activities like therapeutic cloning, a more responsive regulatory framework seems only logical. Given the speed of scientific advance, the legal framework should be developed in a manner that allows a reasonably quick response to both new social concerns, and scientific advances. It is important to realise that legislative prohibitions can quickly become dated.[928] Whatever scheme is adopted, it should be crafted to meet the realities of stem cell research and cloning. There will never be moral consensus, science will move forward and create unique regulatory challenges, and new social concerns are going to emerge.[929]

South Africa does not have specific laws to deal with stem cell research, although the Human Tissue Act forbids any experimentation with fetal tissue without consent from the Minister. There is currently an urgent need in South Africa for a more coherent and uniform approach in respect of matters concerning embryonic stem cell research.[930] Even when chapter 8 of the National Health Act comes into force, South Africa will still not have a comprehensive statute to regulate the legal consequences of matters pertaining to the human embryo and fetus, ranging from in vitro fertilisation, embryo research, artificial insemination and genetic manipulation, the use of fetal tissue for therapeutic purposes, surrogacy, and cloning. Slabbert points out that matters involving the embryo extra uterum are regulated by a few fragmented sections contained in, for example, the

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928 When in vitro fertilisation was accomplished in the United Kingdom, at least one state in the United States of America passed a law attempting to discourage the procedure. After Dolly the sheep was born, nine states adopted laws restricting human reproductive cloning. When researchers began creating and using human embryos for stem cell research, states began introducing laws to deal with that technology as well. In 2002 and 2003, dozens of bills were introduced in state legislatures on cloning and stem cell research. In total, 38 states considered such bills. Some states considered multiple and conflicting bills. In all, 133 separate bills were introduced on these subjects. See Lori, B & Andrews, JD (2004) "Monitoring stem cell research: Appendix E: Legislators as lobbyists: Proposed state regulation of embryonic stem cell research, therapeutic cloning and reproductive cloning" [Web:] http://www.bioethics.gov/reports/stemcell/appendix_e.html [Date of access: 22 February 2006].

929 Caulfield (2003) *Health LJ (Sp Ed)* 87. See also Pattinson (2002) *Med'l L Rev* 295.

930 Statute law is an indispensable source of law and a *sine qua non* for the regulation of modern state. Unfortunately, acts of parliament are often in skeleton form, and flesh has to be added by delegated legislation. This, however, sometimes leaves the regulation of certain areas in law, for example biotechnology, unclear. For a discussion of the interpretation of statutes, which falls outside the scope of this dissertation, see Du Plessis, L (2002) *Re-interpretation of statutes* 20, 37. See in general Botha, CJ (2005) *Statutory interpretation: An introduction for students*.

Human Tissue Act, and guidelines issued by the South African Medical Research Council. These diverse provisions have to be read in conjunction with one another to determine the scope of protection offered to the embryo and fetus, as well as to determine the legality of practices involving the extra uterum embryo. The question therefore arises whether the embryo and fetus are adequately protected in this manner.[931]

A brief proposed regulatory framework for stem cell research and cloning is provided in the paragraphs below. The scope of this dissertation does not allow for the provision of a detailed, in-depth regulatory framework. While this framework attempts to highlight some of the relevant issues in the fields of ethics, law and social science, these issues – and additional topics – would need to be addressed in a fully comprehensive survey. It is therefore not meant as an extensive analysis of the complex social factors at play in the regulation of the research. Rather, it merely seeks to provide the reader with a sense of how certain policy-makers, especially in South Africa, have reacted to this controversial area of research. A few recommendations are also made on how the current legislative measures can be adapted in order to ensure the well-balanced regulation. (The existing legal framework in South Africa has already been discussed in chapter 4; therefore it is not discussed in detail again.)

6 2 THE EXISTING LEGAL FRAMEWORK IN SOUTH AFRICA

6 2 1 The Human Tissue Act

As discussed in chapter 4, only a few of the provisions of the Human Tissue Act relate to the embryo and fetus directly. For example, section 19 of the Act prohibits the use of placentas, fetal tissue and umbilical cord for medical and dental purposes, their transplantation into the body of another living person or their use for the production of a therapeutic diagnostic or prophylactic substance, except with ministerial consent. However, no reference is made to fetal gametes, which means that the removal and use of fetal oocytes are not prohibited in terms of this provision. In South Africa, the Human Tissue Act currently prohibits both therapeutic and reproductive cloning of humans. This

[931] Slabbert, MN (2001) "Are the human embryo and the foetus *extra uterum* sufficiently protected in terms of South African law?" *TSAR* 3:495 *at* 496.

situation will change when chapters 8 of the National Health Act is promulgated, and therapeutic cloning will then be allowed under strict conditions, requiring ministerial permission. Reproductive cloning on humans will however remain strictly prohibited.

It is clear from the definition of "artificial fertilisation" in section 1 of the Human Tissue Act that the creation of embryos for the sole purpose of being used for research purposes is not addressed. The definition provides for the creation of an embryo outside the human body, but stipulates that such an embryo has to be placed into the womb of a female person. The regulations[932] to this Act do not provide any guidance on the regulation of such a procedure either. Recommendations to address this problem are made in the paragraphs below.

6 2 2 The National Health Act

It seems as if the National Health Act potentially undermines the right to academic freedom and freedom of scientific research largely in the manner in which it regulates the use of tissue, and gametes removed or withdrawn from living persons, as well as in its regulation of health research ethics. In addition, the National Health Act potentially has a negative impact on the integrity, independence and efficacy of the Medical Research Council. While South Africa recognises the importance of regulating the use of tissue or gametes removed or withdrawn from living persons, section 56 of the National Health Act raises many concerns about academic freedom and the freedom of scientific research, both entrenched in section 16(1)(d) of the Constitution. While there may be justification for limiting such forms of research, it is submitted that constitutional guarantees cannot be limited in the manner proposed by The National Health Act.[933] Concerns with regard to the National Health Act include the following:

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[932] Artificial Insemination of Persons, and Related Matters fn 683 *supra*.

[933] University of Witwatersrand. Centre for Applied Legal Studies (2003) "Public hearings on the National Health Bill: Oral submissions of the AIDS Law Project and the Treatment Action Campaign" [Web:] www.law.wits.ac.za/cals/docs-2003/ALP-TAC-oral-National-Health-Bill-18-Aug-2003.pdf [Date of access: 1 April 2006]. Although referring to the National Health Bill, these submissions are applicable to the National Health Act as well.

(a) Tissue and gametes may only be used for "medical or dental purposes" as may be prescribed. The Act does not define "medical or dental purposes", and prescribed is defined in section 1 of the Act as "prescribed by regulation made under section 90". Currently, there are no regulations, which leave the regulation of tissue and gametes from living persons unclear. It is submitted that a definition of "medical and dental purposes" be inserted in section 1 of the Act, or that such a definition be included in the unpublished regulations. It is also submitted that "scientific and medical research or experimentation" be included in the definition of "medical and dental purposes" or that a definition be provided for "scientific and medical research" and "experimentation". Furthermore, the National Health Act does not define "stem cells" or "stem cell research" in section 1, and it is recommended that these cells be defined in the Act.[934]

(b) Certain types of tissue and gametes may not be "removed or withdrawn … for any purpose contemplated in subsection (1)", unless ministerial authorisation has been obtained, however without any guidance in the Act as to how such power is to be exercised. This raises considerations relating to Parliament's obligations to provide a framework for the exercise of such power. Insofar as "tissue and gametes from a person who is mentally ill" and "tissue which is not replaceable by natural processes from a person younger than 18 years" are concerned, this is not problematic. However, concerns arise particularly in respect of section 56(2)(a)(iv), which deals with "placenta, embryonic or fetal tissue, stem cells, and umbilical cord".[935]

(c) The Minister's authority to permit such conduct is granted largely in the absence of sufficient guidance as to how such a power is to be exercised. In terms of section 36(1) of the Constitution, rights may only be limited if the limitation takes place by law of general application and "the limitation is reasonable and justifiable in an open and democratic society based on human dignity, equality and freedom, taking into account all relevant factors". In terms of section 36(2), if these conditions are not satisfied, a constitutionally entrenched right may not be

[934] It is also recommended that "blastocyst" be defined in section 1 the National Health Act for the reason that the "blastocyst" is the primary source of embryonic stem cells.
[935] Strydom (2003) *TSAR* 37 *at* 54, 55.

limited. It is questionable whether the manner in which the National Health Act limits freedom of scientific research satisfies these requirements. According to the Constitutional Court, a limitation of rights will be justified only if the purpose of the limitation is proportional to its impact. In assessing proportionality, a court will consider the nature and importance of the right concerned; the extent of the limitation, as well as the availability of less restrictive means to achieve the same purpose.[936] While it is clear that the use of tissue and gametes removed or withdrawn from living persons for the purposes of scientific research raises complex ethical issues, it is difficult to understand why this particular form of limitation is required. In particular, it is difficult to understand why their use for research purposes requires ministerial permission, and not the permission of health research ethics committees registered with the National Health Research Ethics Council. Section 73 of the National Health Act empowers health research ethics committees to review research proposals and protocols to ensure that research conducted at all health establishments promotes certain goals. Alongside the promotion of health as one of these goals, this section expressly mentions "the prevention of communicable or non-communicable diseases or disability" and "cures for communicable or non-communicable diseases". The omission of "treatments for communicable or non-communicable diseases" from the expressly mentioned list of health goals is cause for concern. As the provision currently reads, it unjustifiably violates the right of access to health care services, as well as the right to academic freedom and freedom of scientific research. Furthermore, health research ethics committees are not required or even empowered to receive the results, whether complete or partial, of research conducted on human subjects. This severely limits the efficient and effective functioning of both health ethics committees and the National Health Research Ethics Council, for without information relating to these results, there is no mechanism for updating, re-evaluating and setting appropriate ethical guidelines, norms and standards.

[936] For a discussion of section 36 of the Constitution see paragraph 3.2.

The introduction of a comprehensive regulatory framework within which health research will be conducted will be welcomed, particularly given the inadequacies of the current regulatory framework. Yet, in dealing with national health research and information, the National Health Act potentially affects the integrity, independence and efficacy of the Medical Research Council in three ways:

(a) In terms of the South African Medical Research Council Act[937], the Medical Research Council is expressly empowered to "undertake research of its own accord", to "undertake research on behalf of the State or any other authority, or on behalf of any person or institution, or support such research financially", and to "regulate and control research on or experimentation with humans, animals or human or animal material performed by … employees of the Medical Research Council; or … persons performing such research or experimentation for or on behalf of the Medical Research Council, or with research aid by the Medical Research Council". In terms of section 69(3) of the National Health Act, however, the National Health Research Committee is tasked with determining what health research is to be carried out by public health authorities, as well as developing "an integrated national strategy for health research". Clearly, the scope of the Medical Research Council's research will be affected by decisions of the National Health Research Committee, a body whose membership does not necessarily include any representation from the Medical Research Council.

(b) Section 72 of the National Health Act sets up the National Health Research Ethics Council, whose functions include setting "norms and standards for conducting research on humans and animals, including norms and standards for conducting clinical trials". This potentially conflicts with section 17(2) of the Medical Research Council Act, which empowers the Medical Research Council to "determine ethical directives which shall be followed in … research on or experimentation [with humans and animals]". In addition, the National Health Act potentially has an impact on all health-related research conducted by, or on behalf

[937] The Medical Research Council Act, 1991 (Act 58 of 1991) (hereafter referred to as the Medical Research Council Act).

of, or supported by the Human Sciences Research Council.[938] As is the case with the National Health Research Committee, membership of the National Health Research Ethics Council does not necessarily include a representative from the Medical Research Council.

(c) The National Health Act is silent on the nature of the relationships between the Medical Research Council and the National Health Research Committee and the National Health Research Ethics Council. This potentially creates unnecessary tension and uncertainty. The objects of the Medical Research Council, as set out in section 3 of the Medical Research Council Act, are primarily "through research, development and technology transfer, to promote the improvement of the health and the quality of life of the population of the Republic". Placing certain of its key functions subject to vague and unclear lines of control, while simultaneously creating the potential for the exclusion of the Medical Research Council from the decision-making authorities tasked with exercising control over such functions, severely compromises its independence as well as its ability to realise its objectives.[939]

6 3 FIRST SOUTH AFRICAN ETHICAL AND LEGAL GUIDELINES FOR BIOTECHNOLOGY RESEARCH

With modern biotechnology presenting legal, ethical and social challenges in medical science, Durban-based LIFElab has initiated South Africa's first comprehensive ethical and legal guidelines documents. The Health Professions Council will incorporate the information into an ethical guidelines booklet for health professionals.[940] The legal guidelines are nearing completion and it is hoped to incorporate both guidelines into a manual. A large part of the South African population consists of vulnerable and poor

[938] In this regard see section 3(1)(a) of the Human Sciences Research Act, 1968 (Act 23 of 1968) (hereafter referred to as the Human Sciences Research Act), which empowers the Human Sciences Research Council "to undertake, cause to be undertaken or aid financially research on behalf of the State or any person or authority". The National Health Act's silence on its relationship with the Human Sciences Research Act creates unnecessary uncertainty and potentially undermines the Human Science Research Council's integrity, independence, and efficacy.

[939] University of Witwatersrand. Centre for Applied Legal Studies (2003) www.law.wits.ac.za/cals/docs-2003/ALP-TAC-oral-National-Health-Bill-18-Aug-2003.pdf.

[940] Lifelab EcoBio Innovation Centre (2006) "Start of a new chapter for research" [Web:] www.lifelab.co.za/media.asp [Date of access: 2 April 2006]

groups with low levels of education that may be easily influenced and exploited. The ethical guidelines aim to ensure that research conducted on potentially vulnerable participants is done ethically. The legal guidelines aim to consolidate and simplify applicable legislation by providing guidelines incorporating and explaining relevant provisions from the various laws impacting on biotechnology. The guidelines aim to simplify matters such as proper permit application procedures for activities involving genetic modification, understanding which activities are permitted or prohibited by law and how to initiate the process of setting up a biotechnology plant or laboratory. Both the ethical and legal guidelines will be a first of its kind in South Africa.[941]

The ethical and legal guidelines will provide guidance on contentious issues such as cloning, human genetic research, informed consent and confidentiality. Globally, there is a mad rush to support research in this nascent field, as it offers the best prospects of finding cures for a lot of currently incurable diseases. The guidelines will clarify some common misconceptions of what are permissible and non-permissible activities in relation to cloning, for example.[942] The guidelines will not only address concerns in relation to medical biotechnology, but also deal with the much-debated issue of the use and production of genetically modified organisms. The legal and ethical guidelines will emphasise the proper assessment of the risks posed by activities involving genetically modified organisms, and make it clear that the law does not permit any activity involving genetically modified organisms where a potential risk to the environment, human or

[941] The project was headed up for LIFElab by professor Ames Dhai, Head of Medical Bioethics at the University of KwaZulu-Natal; professor David McQuoid-Mason; Mr James Scott Wylie, Professor of Law at University KwaZulu-Natal; Dr Nhlanhla Msomi, CEO of LIFElab/EcoBio; and two researchers, Mrs Hannelie van der Merwe and Ms Nelia van Wyk. LIFElab, which is a consortium of stakeholders in the biotechnology sector of the East Coast region, stimulates and promotes the creation of a biotechnology economy in the region.

[942] The following activities, among others, discussed in the guidelines ethics project are unethical and/or unlawful: (a) Research on embryonic stem cells exceeding 14 days of the development of the embryo. (b) The manipulation of any genetic material, including genetic material of human gametes, zygotes or embryos, which includes nuclear transfer or embryo splitting, for the purpose of the reproductive cloning of a human being. (c) Placing a cloned human embryo into the body of a human or animal. (d) Creating or developing a human embryo which contains the genetic material of more than two persons. (e) The intentional alteration of the genome of a human cell in a manner that makes the alteration heritable by descendants of the human whose cell was altered (so-called germ-line gene therapy). (f) Collecting a viable human embryo from the body of a woman. (g) Placing an animal embryo into the body of a human; placing a cloned human embryo into the body of a woman, commercial trading in eggs, sperm or embryos of humans. (h) Research involving totipotent stem cells.

animal health exists. The procedures and safeguards should ensure that each application for activities with genetically modified organisms is adequately and comprehensively scrutinised for potential risks, and conflicts with other South African legislation are properly explained.[943]

Although guidelines or policy statements pertaining to research and biotechnology do not constitute law, they are still legally relevant. In the absence of express legislation on a specific subject, the courts of law will have recourse to common law, characterised by a set of principles or a "beginselstruktuur", which may assist in finding the answers to unanswered questions. Therefore, in determining what would be legally permissible or impermissible, the courts should take into account the views of reputable members of a profession as to what activities in the field of their discipline are proper or improper.[944] At the time of writing, the abovementioned guidelines are still unpublished.

6 4 GENERAL REGULATORY RECOMMENDATIONS

6 4 1 Germ-line therapy

It is submitted that germ-line therapy be directed to alleviate disease in individual patients, although wider applications may soon need attention. There is, at present, insufficient knowledge to evaluate the risks to future generations of gene modification of germ lines. There are no simple solutions to the dilemmas presented by the practice of germ-line therapy. On the one hand, germ-line therapy may lead to the eradication of genetic disorders in the human genome; on the other hand, the line between the elimination of genetic disorders and the genetic enhancement of normal human traits become blurred. At present, no human germ-line manipulation is possible and none, as far as known, is contemplated in any part of the world. The question in future will be whether the possible benefits might outweigh the disadvantages sufficiently to justify removing the current prohibition on research. It is therefore recommended by the Medical Research Council that gene modification of the human germ line should not yet be

[943] Lifelab EcoBio Innovation Centre (2005) "First South African ethical and legal guidelines for biotechnology research nears completion: Ensuring high standards of research" *Lifelab Newsletter* 1(3). [Available on internet:] www.lifelab.co.za/PDFs/December%2520Newletter%25202005.pdf [Date of access: 2 April 2006].

[944] Slabbert (2001) *TSAR* 495 *at* 498.

attempted, but once sufficient knowledge has been attained to evaluate the risks to future generations, the question of limitations must become central, and ethics become paramount.[945]

6 4 2 Fetal tissue

When examining the Choice on Termination of Pregnancy Act, together with its regulations,[946] it is clear that no reference is made to the donation of aborted fetal tissue for research and therapeutic purposes. As mentioned earlier, neither the Human Tissue Act, nor the National Health Act, makes provision for it. It is recommended that a definition of "fetal tissue" and "embryonic tissue" be inserted in section 1 of the National Health Act, or that these terms be included in the definition of "tissue" as provided in section 1 of the said Act. It is further recommended that a definition of "fetus" be inserted in section 1 of the Act.

It is further recommended that England's approach be followed, by drafting a code of good practice. Such a code could provide guidance on best practices for those working with fetal tissue and embryonic stem cells. The code should provide confidence and reassurance to professionals and the public alike that fetal tissue research is performed according to best practices and is conducted within a transparent and ethical framework.[947]

It is advisable that the following conditions be observed:

(a) The fetus should be available for research only as a result of separation by natural processes or by lawful means.
(b) Dissection of the fetus should not be carried out while a heartbeat is still apparent or there are other obvious signs of life.

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[945] Du Toit *et al* (1999) www.sahealthinfo.org/ethics/book2.htm.
[946] The regulations are published in Government Notice R168 in *GG* 17746, 31 January 1997.
[947] United Kingdom. Department of Health (2005) www.dh.gov.uk/assetRoot/04/03/42/63/04034263.pdf. See also chapter 4 for a discussion of the Department of Health's Guidelines for good practice in the conduct of clinical trials in human participants in South Africa.

(c) Research procedures should not be performed in the immediate area in which clinical procedures are carried out.
(d) Those concerned with research involving the use of tissue from a fetus should have no part in the management of either the mother or the fetus, or in deciding if the fetus is pre-viable.
(e) The research must be conducted only in institutions that have a properly constituted ethics committee, and only according to written protocols approved by the ethics committees of all institutions involved.
(f) The consent of the mother and, whenever possible in practise, that of the father should be obtained before research is undertaken. If fetal cells, including cells from fetal membranes, placenta, umbilical cord and amniotic fluid, are to be stored or propagated in tissue culture, or tissues or cells are to be transplanted into a recipient human, consent for this should be obtained specifically.
(g) The decisions whether it is appropriate in a particular instance to approach the mother about the possible use of fetal tissue for research and whether a fetus or its tissues fall in a category that may be used for research, must rest with the attending clinician and not with the intending research worker.[948]

The attending clinician should also obtain consent for research. When an ethics committee reviews a proposal for research, it should also take particular account of the following:

(a) The required information should not be obtainable by other means or by using other species.
(b) The investigators should have the necessary special facilities and skills.
(c) There should be no element of commerce involved in the transfer of human fetal tissue.

[948] United Kingdom. Department of Health (2000) "Stem cell research: Medical progress with responsibility" [Web:] www.embrios.org/celulasmadre/informe_donaldson.htm [Date of access: 12 April 2006]. See also Bernstein, A (2001) "Human stem cell research: Opportunities for health and ethical perspectives: A discussion paper" [Web:] www.cihr-irsc.gc.ca/e/documents/stem_cell_e.pdf [Date of access: 12 April 2006].

(d) The separation of clinical and research responsibilities that is crucial to the ethical basis for research in this area should be clear.
(e) A record of all attempts to transplant human fetal tissue, including a description of the outcome, should be maintained by the institution.

In this field of health, as in other experimental fields, those who conscientiously object to research projects or therapeutic programmes conducted by institutions that employ them, should not be obliged to participate in those projects or programmes to which they object, nor should they be put at a disadvantage because of their objection.

In addition, a problem that needs to be solved with regard to minors and the termination of pregnancies is whether a minor would be capable of giving informed consent for the donation of her fetal tissue for research purposes. It should be taken into account that, in terms of the common law offence of rape, women under the age of 12 are irrebuttably presumed incapable of giving consent to sexual intercourse and that, in terms of the Sexual Offences Act, the consent of women under the age of 16 is presumed invalid. Also in terms of the Child Care Act, minors under the age of 18 need parental consent to undergo any operation, and parental consent under the age of 14 for medical treatment. Bekink submits that the question can rightly be asked whether they are then capable of giving informed consent to the termination of a pregnancy resulting from the above offences. It is therefore also questionable whether a minor is capable of giving informed consent to the donation of her fetal tissue for research purposes. It is submitted that this be regulated by either the Choice on Termination of Pregnancy Act or the National Health Act.[949] The Choice on Termination of Pregnancy Act also provides no indication of how to deal with criminal backgrounds that lead to particular pregnancies, and whether fetal tissue must be kept for future proof in a criminal case. It is submitted that a provision be inserted in the Choice on Termination of Pregnancy Act to regulate this issue. It is recommended that the issue be regulated similarly as in the United Kingdom (by means of their Police and Criminal Evidence Act).[950]

[949] Bekink (2006) *THRHR* 14 *at* 21.
[950] For a discussion of the relevant provisions of the Police and Criminal Evidence Act see chapter 5.

6 4 3 Research on selection of fetal sex

It is recommended, as stipulated in the Medical Research Council's guidelines, that research into the selection of the fetal sex is inappropriate if it may result in a request for an abortion because the sex of the fetus is unacceptable to the parents. On the other hand, gender selection may be beneficial in sex-linked genetic diseases and may be justified under exceptional circumstances.

6 4 4 The creation of embryos for stem cell research

The National Health Act makes no reference to either the prohibition or allowance of techniques where embryos are created for the sole purpose for being used in stem cell research. According to the Medical Research Council's guidelines, the production of excess embryos for the sole purpose of research should be discouraged. Also, the guidelines acknowledge that pre-embryo manipulation may yield valuable medical information. However, it can be regarded as ethical only if the embryos are not specifically produced for the purpose of research. In addition, the embryos should not be transferred to the uterus unless there is reasonable certainty that the manipulation carries no potential risks for the fetus. It is recommended that a provision be inserted in the National Health Act regulating such practice.

As previously discussed in chapter 5, the United Kingdom has a specific law that permits the creation of human embryos by fertilisation of an egg with a sperm or by somatic cell nuclear transfer. The 1990 Act and the 2001 regulations allow for the isolation of stem cells for any of the research purposes set out in the law. It is recommended that South Africa follow a similar approach.[951]

6 4 5 In vitro fertilisation

The National Health Act does not provide a definition for either artificial fertilisation or artificial insemination and the regulation thereof. It is submitted that these definitions be

[951] See in general Clemmens (2005) *Ind Health L Rev* 95. See also Knoppers, BM (2004) "Legal and ethical approaches to stem cell and cloning research: A comparative analysis of policies in Latin America, Asia and Africa" *JL Med & Eth* 32(4):626-640.

inserted in section 1 of the Act, and that the techniques be regulated under chapter 8 of the said Act. It is further recommended that in vitro fertilisation be included in the definition of artificial fertilisation, or that a specific definition of in vitro fertilisation be provided. With regard to in vitro fertilisation, it is recommended that a definition of "embryo transfer or zygote transfer" be provided as well. It is also recommended that a meaning of "surplus assisted reproduction technology embryos" be provided in the Act or unpublished regulations. The current legislative framework in South Africa addresses neither the question of the fate of frozen embryos at the end of the freezing period, nor the issue of "surplus embryos". Likewise, the currently proposed law for the regulation of the donation of eggs for purposes of in vitro fertilisation does not address the possibilities of embryo stem cell research.

It is further recommended that a human embryo should be classified as a "surplus embryo" if it is excess to the needs of the woman for whom it was created and her spouse at the time it was created. It is recommended that each person give written authority for the use of the "surplus embryos" for a purpose other than a purpose relating to the assisted reproductive technology treatment of the woman concerned, and that each person determines in writing that the embryo is excess to their needs. According to the Medical Research Council's guidelines, more research is necessary to improve results in the practice of in vitro fertilisation, since its current application is only effective in about 15 to 20% of cases. The guidelines also stipulate that maintaining embryos in vitro beyond the gestational age of two weeks is not ethically acceptable.[952]

It is submitted that it should be permissible to donate human "surplus embryos" no longer destined for implantation for research under certain conditions, for example with free and informed consent – no buying or selling of embryos, no in vitro culturing of human embryos beyond 14 days – and separation of the medical teams involved in the in vitro fertilisation treatment and in the stem cell research. The idea is that if embryos are definitely not going to be implanted, "nothing is lost" by their being used for embryonic stem cell research. Such a claim implies that it might be acceptable to use spare embryos

[952] Du Toit *et al* (1999) www.sahealthinfo.org/ethics/book2.htm

for embryonic stem cell research even if they have the moral status of persons. Another suggested solution to the problem of destroying viable embryos is to create embryos that cannot develop to term. As discussed previously, this can be done for example by inducing unfertilised eggs to develop as if fertilisation had occurred, producing "parthenogenetic"[953] embryos that can go through the early cleavage divisions to the blastocyst stage, but cannot develop into a fetus. Unfortunately, these ideas run the risk of trying to please everyone but pleasing no one. Those with absolutist religious views are likely to regard the creation of such embryos as unnatural and immoral, while scientists can object that embryonic stem cells created in this way are likely to have abnormalities that will seriously limit their usefulness.[954]

6 4 5 1 Informed consent

As previously discussed, informed consent is especially important in all research on tissues of human origin, and should be taken very seriously by researchers and by the relevant ethics committees. Every effort should be made to ensure that people undergoing in vitro fertilisation treatment and who are invited to donate surplus eggs or embryos for research understand fully what is involved, and that they are given relevant information and time to consider it. Wherever possible, steps should be taken to ensure that the person providing the in vitro fertilisation treatment is not the same as the prospective researcher in order to avoid the risk, real or perceived, of moral pressure being borne on potential donors. It is recommended that the separation of clinical and research roles be standard practice for the donation of eggs or embryos. The prohibition of payment to donors for gametes has been an important element in preventing undesirable commercialisation of this aspect of assisted reproduction and should be strictly maintained.[955]

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953 For a discussion of the technique of parthenogenesis see paragraph 2.4.5.1.

954 Corrigan, OP *et al* (2005) "Ethical, legal and social issues in stem cell research and therapy. A briefing paper: Cambridge Genetics Knowledge Park" [Web:] www.cgkp.org.uk/resources/pdf/stem_cell_paper.pdf [Date of access: 23 March 2006].

955 Similar recommendations were made in the United Kingdom. See The United Kingdom Parliament: House of Lords (2002) www.parliament.the-stationery-office.co.uk/pa/Id200102/dselect/Idstem/83/8301.htm-14k.

6 4 5 2 Sperm placed in storage prior to medical intervention: In vitro *fertilisation*

Options on consent forms for what should happen upon the death of a sperm provider have not been addressed in South Africa. The following recommendations can be taken into consideration:

(a) Sperm should be disposed of in a culturally appropriate and respectful manner as specified in the consent form. Sperm should be available for use only by a specified person within a specified timeframe.
(b) If the option selected in the consent form leads to a request for insemination by the partner of the deceased, clinics must provide appropriate counselling, which would include, for example, the advisability of a suitable time lapse before making use of the sperm to allow for considered decision-making.
(c) When consent has not been and could not be obtained or when there is a request for a variation to these requirements, an application for ethical review must be submitted. A counselling report should be included as part of this application.
(d) Clinics should undertake an annual review of the storage arrangements, either with the person whose sperm is being stored or, in the event of his death, a designated person. When renewing the consent for storage, the clinic should also ask the person to renew consent for the use and disposal of the sperm. It is recommended that sperm collected in these circumstances be stored for a maximum period specified by the clinics.[956]

6 4 6 Cloning[957]

6 4 6 1 Therapeutic cloning

Section 57(6) of the National Health Act regulates and defines reproductive and therapeutic cloning. Reference is made to "genetic manipulation". It is submitted that a

[956] National Ethics Committee on Assisted Human Reproduction (2002) "Guidelines for the storage, use and disposal of sperm from a deceased man" [Web:] www.newhealth.govt.nz/acart/documents/deceased.pdf [Date of access: 14 May 2006].
[957] See in general Lori, P (2005) "Stem cell research and human cloning: Where do we draw the lines?" *New Eng L Rev* 39(3):623-634.

definition of "genetic manipulation" be inserted in section 1 of the Act to provide a clear interpretation of the scope of both reproductive and therapeutic cloning. It is further advisable that a "somatic cell" be defined in section 1 of the Act, as well as "somatic cell nuclear transfer". It is also submitted that the following principles, drawn from the United States National Bioethics Advisory Committee, could be helpful in the regulation of the donation of human embryos for stem cell research:

(a) Prospective donors should be given timely, relevant and appropriate information to make informed and voluntary decisions regarding the donation of the embryos.
(b) Embryos and cadaveric fetal tissue should under no circumstances be bought or sold. With regard to the growth of entire organs, it is recommended that this technique should be more thoroughly investigated in animal systems before experimentation with human tissue is permitted.

6 4 6 2 Reproductive cloning

The South African Medical Research Council's guidelines stipulate that, in the use of nuclear transfer, the reproductive needs of an individual should not override the best interests of the child produced. The risk attached to the use of the technique on humans carries the possibility of hormonal manipulation for the egg donor, multiple miscarriages for the birth mother, and severe developmental abnormalities in any resulting child. The potential harms outweigh the potential benefits, and until studies in animal systems prove otherwise, they recommend that the use of human nuclear transfer cloning to create a new life should be prohibited.

However, a specific way to justify a ban on many reproductive genetic practices is to base them on particular health and safety concerns.[958] Few disagree with the conclusion that

[958] Some of these safety considerations include: (a) Tumours: Embryonic stem cells are unstable and difficult to control. They have a tendency to divide uncontrollably, leading to tumours/cancer. (b) Genetic defects: Although the original DNA from an embryo is removed and replaced with the nucleus from the person to be cloned, some DNA from the original embryo remains in the form of mitochondrial DNA. This can lead to genetic defects that are not fully understood and which are only seen in later life. (c) Overgrowth syndrome: Clones of animals are larger than average at birth, which can be risky for the mother. (d) Premature ageing: The age of a clone is calculated by taking its birth

reproductive cloning is unsafe, a conclusion used to support a continued moratorium on the use of federal funds to conduct embryo research. Relying on health and safety concerns alone as the basis for a prohibition is problematic, however, for two reasons:

(a) While a number of new reproductive genetic practices are clearly unsafe, the most obvious of which is human reproductive cloning (which presents risks to the developing fetus, the mother and potentially to the born offspring), many controversial practices such as sex selection and therapeutic cloning are not associated with easily defined or specific health risks.

(b) Since many of the identified health and safety concerns are a function of the state of contemporary scientific knowledge, it is possible that some of the concerns will be resolved in the future. If restrictions on various applications of reproductive genetics are based on outdated scientific concerns, their relevance will undoubtedly fade as the science moves forward and social attitudes shift. Therefore, if the technologies are believed to be unsafe and are prohibited on this basis, the research that may one day resolve the safety issues cannot proceed. If the prohibitions are in reality a reflection of both safety and deeper ethical concerns, these must be part of the background policy conversation.[959]

This leaves, as a reason for legislation, only the claim that reproductive cloning will remain wrong even if it becomes safe. Of course it is hard to imagine how this procedure could become safe without first producing many deformed babies. But if at some point, convincing evidence compels us to recognise that reproductive cloning has become safe and effective, legislative prohibition would not be superfluous. The reason for prohibition would then have to be something other than safety, whereupon an infringement of liberty

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age and then adding the age of the original from which it was cloned. Although Dolly was born in 1996, she originates from the udder of a six-year-old ewe, and so her total genetic age is almost 13. (e) Reduction in adaptability: Since, by nature, a clone is a copy of another person, there would be no unique genetic combinations introduced into the human gene pool if human cloning was undertaken on a large scale. Therefore, if a contagious disease struck for which there was no cure; all the clones would be wiped out. See Public Understanding of Biotechnology (2006) "Cloning and genetic engineering" [Web: www.pub.ac.za/factfile/cloning.html [Date of access: 14 May 2006].

959 National Bioethics Advisory Commission (1997) "Cloning human beings" [Web:] http://www.georgetown.edu/research/nrcbl/nbac/pubs.html [Date of access: 6 April 2006]

would loom for those for whom cloning might be the sole or most effective means of treating infertility, or of preventing the transmission of hereditary disease. It would then give us pause that the quintessential liberty protected by the constitutional right of privacy from governmental intrusion is the liberty to beget a child. The proponent of a categorical ban on reproductive cloning implies that, even if other instances of impregnation are private, this one is not. Assisted asexual reproduction does not seem any less private, in the constitutionally inviolable sense, than assisted sexual reproduction.

A considerable argument would be required to establish otherwise. So far, mostly speculations have been heard about how the lives of clones might go. Of course no one has ever met a clone. Many people have known happy monozygotic twins. Even though we often have trouble telling such twins apart, no amount of speculation about identity crises would lead us to question whether monozygotic twins should have been born. There is arguably less cause for concern about clones, because in most instances a clone's age would differ by decades from that of its nuclear genome source. The source and clone would also differ by the societies by which and places where they are reared. The closer one looks at such speculations, the more contrived they seem. Most seem to betray an overdose of genetic determinism. We would best acknowledge that, as a society, we have not fully considered the merits of reproductive cloning when safe. As and when the procedure becomes safe, we shall surely revisit the question of its propriety. That is, however, a topic for another decade.

One of the most obvious problems with legal prohibitions is that they do not have the flexibility needed to regulate an area as rapidly evolving and scientifically complex as reproductive genetics. This problem is well demonstrated by the debates in the United Kingdom regarding the definition of "embryo". The Human Fertilisation and Embryology Act was thought to cover all aspects of embryo research, storage and creation. In fact, the question has arisen whether the Act can be said to apply to embryos created by cloning rather than by fertilisation. In other situations the rapid advances in science, such as in the area of human embryonic stem cell research, has caused countries to revisit existing rigid

prohibitions. In the end, the obsolescence of some legislated bans seems inevitable. Consequently, what is needed is not a technology-by-technology list of prohibitions. Such an approach will only create a chaotic, inconsistent patchwork of laws with little relation to each other. Caulfield and Knowles submit that a flexible, scientifically informed, and responsive oversight scheme is needed.[960]

Jordaan proposes that new legislation be enacted in South Africa to give effect to the following:

(a) A moratorium, which must be subject to a subset clause of three to five years, must be placed on human reproductive cloning.
(b) In order to foster informed public opinion, efforts must be made to educate the public regarding the facts about human reproductive cloning.
(c) If the issue of safety is resolved, human reproductive cloning must be permitted, provided that the number of individuals who are created by cloning a specific genome be limited to a very small number (two to five); the donor(s) must consent to the use of their genetic material; and the donation of the genetic material must be non-commercial.[961]

It is recommended that statutory prohibitions not be enacted to prohibit reproductive cloning and it is agreed with Jordaan that a moratorium be placed on reproductive cloning rather than prohibiting it.

6 4 6 3 Regulation of cloning research

As stipulated in the Medical Research Council's guidelines, it is recommended that continuing supervision of research into and related to cloning is necessary. At present there is no single body constituted for this. Therefore, it is submitted that a new expert

[960] Caulfield & Knowles (2004) *J Med'l Eth* 414 *at* 416. See in general Knowles, LP (2000) "Science policy and the law: Reproductive and therapeutic cloning" *NYUJ Legis & Pub Pol'y* 4(1):13-22. See also Caulfield, TC (2001) "Clones, controversy and criminal law: A comment on the proposal for legislation governing assisted human reproduction" *Alta L Rev* 39(2):335-346.
[961] Jordaan (2002) *SALJ* 119 (2) 294 *at* 304.

supervisory body be established to regulate cloning practices. It is further submitted that this supervisory body should be of sufficient standing to command the confidence of existing research ethics committees, of the public, the professions and of Parliament. It should be responsible for advising on the content of proposals, including the details of protocols, for therapeutic research; advising on the design and conduct of research; and advising on the facilities and service arrangements necessary for the proper conduct of research. It is further submitted in the guidelines that in light of this assessment, the expert supervisory body should make a recommendation on whether the proposal should be approved, and on what conditions. The supervisory body should also be responsible for acting in co-ordination with existing research ethics committees; acting as a repository of up to date information on research in human cloning internationally; overseeing and monitoring the research; and providing advice to health ministers on scientific and medical developments that bear on the safety and efficacy of cloning. It is recommended that any proposal for research related to cloning be approved by this body as well as by a properly constituted research ethics committee.[962]

6 4 7 Stem cell research and the rights of women

Women who undergo infertility treatment are subject to high psychological and physical strain. It is submitted that it is necessary to ensure that the demand for spare embryos and oocyte donation does not increase the burden on women.

6 4 8 Custody and regulation of stem cell lines

As discussed in chapter 2, embryonic stem cell lines can, in principle, be grown in culture indefinitely. It is recommended that there should be considerable urgency in deciding how these lines should be maintained and what degree of regulation, if any, they require.[963] A distinction should be made between embryonic stem cell lines to be used for

[962] Du Toit *et al* (1999) www.sahealthinfo.org/ethics/book2.htm.

[963] While many of the demonstrations of the potential of stem cell research have arisen from academia, the development of this potential, for example, into therapeutic products requires industrial and commercial inputs. For example, industrial involvement will be needed for a large-scale production of cell lines, to support multicentre clinical trials, for marketing, and for distribution. Although considerable funds are available for investment in stem cell research, commercial returns on such investments are for the moment modest. This reflects the fact that most of this work is still at the basic research stage.

research and embryonic stem cell lines that may ultimately be used for therapeutic purposes. Therapeutic application of embryonic stem cells or tissues derived from them is not likely to happen in the near future. If and when it does happen, controls will have to come into operation. It is submitted that a regulatory body be established to oversee clinical studies involving stem cells, and to further oversee such studies from scientific, medical, safety and ethical viewpoint.[964]

A more pressing question is what, if any, arrangements are necessary for the oversight of embryonic stem cell lines used for research purposes once they have been derived from the embryo. The starting point of an analysis is, as with human embryos themselves, the status of the embryonic stem cell lines. These are "human tissue" and need to be treated on a similar basis as other human tissue used for research. The sensitivity of using different human tissues varies according to their nature and source. Certain types of tissue are particularly sensitive, for example human fetal and embryonic material. However, embryonic stem cells, once established as a line, are not embryos. Therefore it is submitted that there is no need for special arrangements to be made beyond those applying to the use of other human material, such as informed consent. The logic of this analysis is that the use of established embryonic stem cell lines does not require the sort of regulation to which human embryo research is currently subject to.

Therefore, commercial interests are trying to position themselves for major profits in the future, but still face uncertain research prospects, therapeutic possibilities and the development of a regulatory environment, the latter largely influenced by ethical issues and public concerns. One of the current framework conditions affecting stem cell research and commercialisation of stem cell therapies is the patenting of human embryonic stem cells and their derivatives. On the one hand, patent rights are necessary to protect and secure industry's huge investments and support innovative research and development. On the other hand, having free and open access to these cell lines stimulates academic research, as they are essential starting materials for their research. The debate on this issue is intense and includes the ethical dimension of this research. A detailed examination of industrial and commercial aspects, however, falls outside the scope of this dissertation. See in general Cloete, R (2003) "Eiendom in die menslike liggaam: Klop Frankenstein aan die voordeur?" *Obt* 24(2):412-430. See also Cloete, R (2003) "Die plek en die rol van onstoflike sake in die Suid-Afrikaanse sakereg: 'n Kritiese oorsig" *Obt* 24(1):65-86. Kincaid (2003) *Pepp L Rev* 553; McDonald, ES (2003) "Patenting human life and the rebirth of the thirteenth amendment" *Notre Dame L Rev* 78(4):1359-1388.

964 When the prospect of clinical studies involving gene therapy emerged, the Gene Therapy Advisory Committee was established by the Department of Health in England to provide further oversight of such studies from scientific, medical, safety and ethical viewpoints. It is submitted that a similar committee be established in South Africa.

Since embryonic stem cell lines are potentially "immortal", obtaining informed consent from those who donate the embryos raises distinctive problems. The principle of respect for persons clearly requires that no human tissue should be taken or used without the informed consent of the donor, or where the tissue is obtained post mortem, of the next of kin. The culturing of cells and stem cell lines means that a person's genetic identity may be reproduced indefinitely. It has been suggested that those who donate an embryo for stem cell research might subsequently expect a share in any benefits accruing from the commercial exploitation of research on stem cell lines derived from it. Currently in the United Kingdom, it is undesirable for legislation to permit such claims. It is submitted that the position be the same for South Africa: Any commercial benefits will have to come about as a result of the research and subsequent developments rather than any intrinsic quality of a particular embryo donated. However, it makes it even more important that potential donors fully understand the implications of embryos being donating used for the production of stem cell lines; and in particular, that the material being donated may be used for a purpose other than the immediate one. It is recommended that the implications arising from the "immortality" of stem cell lines are fully covered in obtaining informed consent from donors giving embryos for the potential establishment of embryonic stem cell lines for research.[965]

6 4 9 Approval of the research by an authority

It is recommended that human embryonic stem cell research should be placed under strict public control by a centralised authority, following for instance the pattern of the United Kingdom licensing body, the Human Fertilisation and Embryology Authority. Authorisations given to such research are highly selective and based on a case by case approach, while ensuring maximum transparency. This must apply whether either the public or the private sector carries out the research in question.

[965] The United Kingdom Parliament: House of Lords (2002) www.parliament.the-stationery-office.co.uk/pa/Id200102/dselect/Idstem/83/8301.htm-14k). See section 28 of the Human Tissue Act, and section 60 of the National Health Act, as discussed in chapter 4, for the regulation of financial gain for the donation of tissue and gametes.

6 4 10 No financial gain for donation

Measures should be taken to prevent commercialisation, and the potential for coercive pressure should not be underestimated when there are financial incentives. Embryos and cadaveric fetal tissue should not be bought or sold, and not even offered for sale. Article 21 of the Council of Europe's Convention on Human Rights and Biomedicine specifically prohibits financial gain from any part of the human body.[966]

6 4 11 Anonymity of the donors and protection of the confidentiality of personal information of the donors

It is submitted that steps must be taken to protect and preserve the identity of both the donor and the recipient in stem cell research and use. It should be prohibited to disclose information that could identify the donor or the recipient. In general, the donor should not know the identity of the recipient, nor should the recipient know the identity of the donor. Although the identity of the donor should normally be protected through coding and other measures to ensure confidentiality, there would still be safety and quality requirements for clinical research demanding that the link to the donors are not completely removed. Anonymity will then not be possible.[967]

6 4 12 Public education

Human embryonic stem cell research has recently provoked intense public and political debate. The general public is increasingly concerned about the social and ethical consequences of these advances in knowledge and techniques, as well as about the conditions forming the choices made in these fields. There is a need for continuing dialogue and education to promote the participation of citizens, including patients, in scientific governance, namely in social choices created by new scientific developments. As with any new potential treatment, the promises of stem cell research may create high and sometimes unrealistic expectations from science among patients suffering from

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[966] The Charter of Fundamental Rights of the European Union recognises in article 3(2) that "(i)n the fields of medicine and biology the following must be respected in particular … the prohibition on making the human body and its parts as such a source of financial gain".

[967] See section 33 of the Human Tissue Act, and section 14 of the National Health Act, as discussed in chapter 4.

incurable diseases and their families, and the imperative of treatment for whatever disease. Many negative research results are not published and may lead to an unbalanced presentation in the media and ultimately affect the dialogue in society. Since failure to deliver the promised cures will have a very negative impact on the perception of science by the public, it is vital to communicate the state of the art technologies and future possibilities in honest and realistic ways. The more science is able to keep its promises, the more it will receive the public recognition needed to reconcile the expansion of knowledge with social progress.[968]

6 4 13 Stem cell bank

The need for a stem cell bank is quite clear. A stem cell bank intends not only to provide high-quality starting materials to facilitate the development of stem cell therapy, but, in providing a centralised resource for researchers, it will optimise the use of existing human embryonic stem cell lines and may reduce the use of human embryos for the development of new stem cell lines by individual teams. It will also offer the opportunity to collect stem cell lines with different immuno-phenotypes. Cell lines with the best matching phenotypes can later be selected for cell or tissue transplantation.

6 4 13 1 Stem cell banks and safety

Procurement and storage of stem cells in stem cell banks lead to the collection and storage of a growing number of personal and familial data. Cell banks should be regulated to facilitate the implementation of a precautionary approach. If unsatisfactory side effects occur, it should be possible to trace the donor and recipient, and to reach their medical files. It is submitted that traceability should be one of the conditions required for the authorisation of cell banks at a national level.

[968] Dhai *et al* (2004) *SAMJ* 906.

6 4 13 2 Stem cell banks and confidentiality

In order to reconcile the traceability requirement and the need to protect the donor's rights, medical confidentiality and privacy, cell banks must take the necessary steps to protect confidentiality of the data.[969]

It is recommended that a regulatory authority should also take responsibility for establishing codes of conduct for the use of embryonic stem cells, whether obtained from a stem cell bank or imported from elsewhere. It could also facilitate the distribution of embryonic stem cell lines to foreign scientists operating under approved ethical guidelines. It should facilitate research and minimise the need both to import embryonic stem cells from abroad and to derive new embryonic stem cell lines. Above and beyond the proposed regulatory authority for the stem cell bank, there is no need for additional levels of regulation.

If in the future it becomes possible to develop adult stem cell lines, it would be desirable for those lines to be placed in such a bank. In that way, stem cell lines could be made available to the widest possible range of reputable researchers and an overview of their use be maintained. However, no special consideration needs to be given to regulations for adult stem cells beyond those of informed consent.

6 4 14 Export and import of stem cell products

It is recommended that public authorities should license stem cell imports and exports. Authorisation should be subject to ethical and safety rules.

6 4 15 Risk-benefit assessment

Risk-benefit assessment is crucial in stem cell research, as in any research, but is more difficult as the uncertainties are considerable given the gaps in our knowledge. Attempts to minimise the risks and increase the benefits should include optimising the strategies

[969] Sax (2006) *Annals Health L* 1. See also United Kingdom. Parliamentary Office of Science and Technology (2004) "Regulating stem cell therapies" [Web:] www.parliament.uk/documents/upload/POSTpn221.pdf.

for safety. It is not enough to test the cultured stem cells or tissues derived from them for bacteria, viruses or toxicity. Safety and security aspects are of utmost importance in the transplantation of genetically modified cells and when stem cells are derived from somatic cells. It is important that the potential benefits for the patients should be taken into account but not exaggerated. The grounds of a precautionary approach need to be taken into account as well.[970]

6 4 16 Protection of the health of persons involved in clinical trials

The possibility of irreversible and potentially harmful changes being introduced in the clinical applications of stem cell research should be minimised. Techniques enhancing the possibilities of reversibility should be used whenever possible. If, for example, genetically modified cells are encapsulated when they are transplanted to stimulate neural cell growth, it should be possible for the procedure to be reversed if something goes wrong.

6 4 17 Basic principles for all medical research

It is strongly recommended that the following principles, as envisaged in the Declaration of Helsinki, be followed in South Africa's regulatory framework pertaining to research on human subjects:

(a) It should be the duty of the physician in medical research to protect the life, health, privacy and dignity of the human subject.
(b) The primary purpose of medical research involving human subjects is to improve prophylactic, diagnostic and therapeutic procedures, and the understanding of the aetiology and pathogenesis of disease. Even the best-proven prophylactic, diagnostic and therapeutic methods must continuously be challenged through research for their effectiveness, efficiency, accessibility and quality.
(c) Medical research should be subject to ethical standards that promote respect for all human beings and protect their health and rights. The particular needs of the economically and medically disadvantaged must be recognised. Special attention

[970] McLaren, A (2001) "Ethical and social considerations of stem cell research" *Nat* 414(6859):129-131.

is also required for those who cannot give or refuse to give consent for themselves, for those who may be subject to giving consent under duress, for those who will not benefit personally from the research and for those for whom the research is combined with care.

(d) Research investigators should be aware of the ethical, legal and regulatory requirements for research on human subjects in their own country as well as applicable international requirements.

(e) The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol. This protocol should be submitted for consideration, comment, guidance, and where appropriate, approval to a specially appointed ethical review committee, which must be independent of the investigator, the sponsor or any other kind of undue influence.

6 5 A PROPOSED MODEL FOR EMBRYONIC STEM CELL RESEARCH AND CLONING: CHARACTERISTICS

Though extensive details of such a regulatory framework are beyond the scope of this dissertation, Caulfield and Knowles submit that any future regulatory framework should strive to incorporate at least the following characteristics:

(a) The people responsible for creating a regulatory framework must be knowledgeable and informed in the scientific, technological and ethical issues.

(b) Recommendations for governance should be broadly and generally framed to allow the regulatory framework to adapt to changes in science and social mores. The enabling legislation should set the framework, articulate the relevant values and guiding principles, and set the standards for analysis; but the details of regulation, including the handling of the relevant definitions, should be left to a regulatory body.

(c) The regulatory body should facilitate and encourage an ongoing public and interdisciplinary discussion.

(d) Any regulatory body created should have oversight powers with respect to reproductive genetics in both the public and private sectors. It makes little sense to carefully regulate only publicly funded research while leaving all other activities under the control of the private sector.

(e) The enabling legislation should be framed to permit regulators to develop familiarity with science and technology so that they can develop an expertise in reproductive genetics. Such expertise will permit foresight and a deep understanding of not only the science, but also the social implications that a particular application of reproductive genetics brings to bear. It will be important, for example, for those involved in regulating reproductive genetics to identify when protocols or techniques involve modification of the human germ line, or where issues of human dignity may be implicated.[971]

In addition, there are problems with the above flexible, regulatory approach. It can certainly be argued that unambiguous prohibitions may have more symbolic weight than the framework they propose. Caulfield and Knowles question, however, whether strong symbolic censure should be a key feature of a framework built on an unclear and shifting public and ethical mandate. Furthermore, as noted about the approach of the United Kingdom, regulatory bodies need not be low-profile bureaucratic entities. On the contrary, the regulatory framework should be structured to be an ongoing focal point of public discussion and, as such, to represent a commitment to open and thoughtful dialogue.

6 6 THE FRAMEWORK FOR REGULATION

6 6 1 Elements of the framework

A first element of this framework should be the assertion that, in principle, embryonic stem cell research should be permitted. This analysis is mainly devoted to assessing the interest of such research, and the existence of such interest is viewed as the main justification to allow the research. The report of the United Kingdom Chief Medical

[971] Caulfield & Knowles (2004) *J Med'l Eth* 414 *at* 416.

Officer's Expert Group on therapeutic cloning[972] is a good example of this approach when it states that "as the Expert Group addressed its task it became clear that it was the potential benefits of research involving stem cells that should be the initial focus of its attention". The assertion holds two important arguments: Research is possible now, and there are no better sources at present than embryonic stem cells. These points are clearly mentioned in the report when it observes that "this potential benefit has been demonstrated in principle in research in animals and in limited work involving adult derived stem cells" and "stem cells derived from embryos currently appear to offer the greatest potential in their ability to self-renew and the range of tissues it should be possible to develop from them". The consequence of this analysis, that some would qualify as utilitarist, is "that the potential benefits of the research justify the use of embryos at a very early stage of their development" and the conclusions incidentally complete this by adding the brief but important sentence: "Including embryos created by cell nuclear replacement." The approach regarding the lawfulness of embryonic stem cell research then appears to be very contextual. It is deeply related to the potential benefit of this research and to the "technical" facilities offered by embryonic cells as sources. This explains why changes in legislation are under consideration in those countries that presently prohibit embryo research. It is also the reason why other countries that have already permitted such research have, in principle, no problem to extend this permission to stem cell research.

The second characteristic of the framework regulation should be setting up, as a counterpart of the legal permission, "rigorous safeguards", which usually concern four areas:

(a) A licensing system to control research activities. It is necessary to ensure the qualifications of the researchers, the safety of the process and the delivery of the legal authorisation.

[972] United Kingdom. Chief Medical Officer's Expert Group on Therapeutic Cloning (2000) "Stem cell research: Medical progress with responsibility" [Web:] www.doh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/fs/en?CONTENT_ID=4065084&chk=IgquYC [Date of access: 25 April 2006].

(b) Specific consent should also be required from those who donate sperm, eggs or embryos. This is, of course, the application of a fundamental principle in bioethics.

(c) The programme should be kept under review, among other reasons to ensure that its potential benefits are still relevant. An appropriate body should monitor research protocols.

(d) Some categories of research should not be permitted, such as the mixing of human adult cells with the live eggs of any animal species. These "safeguards" will lead to setting a standing evaluation process for the research that would allow a confrontation between applied ethical principles and proposed research objectives. Although not simply procedural, the regulation will focus on the construction of contextual ethics. It is therefore more difficult to deduce guiding principles, vision and strategy from such regulation, in particular regarding the status of the human embryo.[973]

6 6 2 Guiding principles

Although guiding principles can be found by examining the commonalities in the existing regulation on embryo research and in the proposed framework for stem cell research, such principles cannot clarify the issue of the status of the human embryo. Many national commissions articulated guiding principles and values that informed their policy decisions and provided a framework for their recommendations on embryo research. Some of these principles include:

(a) Respect for human life and dignity;

(b) The quality, including safety, of medical treatment;

(c) Respect for free and informed consent;

(d) Minimising harm and maximising benefit;

(e) The relief of human suffering;

[973] The framework was proposed by Judge Ch Byk in Byk, C (2004) "Stem cell research" [Web:] www.med.osaka-u.ac.jp/pub/eth/English/ PJ3.htm [Date of access: 2 April 2006].

(f) Freedom of research; and

(g) Non-commercialisation of reproduction.

Although these principles can serve to establish basic standards of practice, particularly when the standards are drafted in general terms and allow for flexibility and adaptability in the face of future developments, they are not very meaningful in drawing a clear possible status for the human embryo. The first reason for this is that, faced with the diversity of opinion on the moral status of the embryo, most reports and derived regulations prefer to state that no definitive answer can yet be given.[974] After highlighting the unsolvable nature of the problem, most adopted a pragmatic approach, seeking to balance the scientific and medical cost of not pursuing embryo research with the ethical cost of permitting such research. A common solution is then to provide some protection to human embryos in the form of certain limits – time limits; limits on the categories of embryos to be used; limits on the significance of research, protocol review and regulatory oversight; and certain prohibitions. Implicitly this approach, which finally permits embryo research, reflects the view of the policy-maker and the legislator on what an embryo is. Although it could not strictly be qualified as moral status or opinion, it is more than a compromise between the two opposed positions on the moral status of the embryo, namely that the embryo either has the same moral status as a human person, or it does not. According to the Warnock Report, it is a choice – political, legal or social – that reflects the view of a society on "how … to treat the human embryo".

6 7 CONCLUSION

Bills on cloning and stem cell research are the subjects of vast media attention and public debate. As technologies develop that focus increasingly on the human embryo, law-makers are having difficulty coming to agreement on a legislative policy in the absence of societal accord about the moral and legal status of the embryo.

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[974] To prevent any further confusion on the moral status of the embryo, it could be advisable to define the term "human embryo" to include any organism not protected as a human subject under the Constitution of the Republic of South Africa, which is derived by fertilisation, parthenogenesis, cloning or any other means from one or more human gametes or human diploid cells.

There are no definite legislation or research guidelines in South Africa to regulate either stem cell research or the cloning of human cells. The Human Tissue Act is the only piece of legislation that can currently be applied to regulate genetic manipulation. However, the new National Health Act does make provision for certain aspects of human cloning and stem cell research. The extent to which society utilises the law to enforce its moral judgments remains a dominant issue in this era of embryonic stem cell research, pre-implantation genetic diagnosis and human reproductive cloning. Balancing the potential health benefits and diverse moral values of society can be a tremendous challenge. In this context, governments often adopt legislative bans and prohibitions and rely on the inflexible and often inappropriate tool of criminal law.[975] Legal prohibitions in the field of reproductive genetics are not likely to reflect adequately the depth and diversity of competing stakeholder positions. Rather, a comprehensive and readily responsive regulatory policy is required. Such a policy must attend to evolving scientific developments and ethical considerations.[976]

Legislation as a means of confining the ambit of scientific research is an imperfect instrument of control. Changes in science are often rapid, while changes in public opinion, which legislation is supposed to reflect, are less rapid by comparison. Therefore the balance between promoting and stifling useful scientific research within a legislative framework is delicate. However, legislation does not need to be inflexible and should respond to the assurances of new knowledge, provided there is appropriate expert review and public debate. In practice, however, legislation is hard to change and political expediency often preserves the status quo. A greater challenge lies ahead, and those

[975] Campbell argues that, while reproductive technologies are characterised by rapid development and change, this does not oust the possibility of regulating them through the use of criminal law. First, criminal prohibitions are subject to change and can be amended by Parliament where it is deemed necessary to meet the ends of justice. Some have argued that such amendments will take too long. Therefore it would be preferable to subject reproductive technologies to the control of an administrative agency that could implement change more swiftly. However, she argues, given the importance of the issues raised by this area of science, in particular the extent to which we are able to create or manipulate human life, its regulation should be left to Parliament to ensure that legislative changes affecting reproductive technologies are subject to public scrutiny and accountability. Furthermore, the significance of issue warrants a legislative amendment process premised on ensuring caution and alertness over quick, reflexive changes. For a discussion of the criminal regulation of reproductive technologies, which falls outside the scope of this dissertation, see Campbell, A (2003) "Defining a policy rationale for the criminal regulation of reproductive technologies" *Health L Rev* 11(3):26-31.

[976] Caulfield & Knowles (2004) *J Med'l Eth* 414.

associated with the regulation of reproductive genetics will have to endure it. No law or policy will or should aim to bring closure. We need to develop a regulatory regime that can work within this reality. Steps must be taken now to move towards a flexible regulatory scheme that promotes ongoing public and professional dialogue, sets limits that respect the ethical commitments we hold as a society, and fosters a climate that will promote valid scientific and clinical endeavour. Prohibitory bans seem to be the least appropriate tool in this context.

It is submitted that legislated bans and prohibitions often amount to little more than ad hoc and short-term solutions to complex social and ethical issues. It can be expected that science will continue to move forward, that social attitudes will continue to evolve, and that policy-makers will continue to struggle with finding the right balance between encouraging scientific progresses and limiting this progress in the face of uncertainty, risk and social opinions. What can be done in such an environment? It is recommend that a flexible and adaptive regulatory model be adopted, not unlike that which currently exists in the United Kingdom to regulate the conduct of research on reproductive biology; namely a model that uses licensing methods to ensure strict compliance with a set of publicly accessible guidelines.

Whether or not South African law is able to meet new challenges, based on its existing principles and policies, and its provisions and legislation, is a question that will have to be answered in due course. The prevalence of health care litigation, whether it is in the arena of private health care funding or constitutional rights, is increasing. Rights and obligations pertaining fundamentally to one's health and ability to live are of primary importance and fundamental to a person's existence on the planet; as well as in the context of a country's health care legislation, and continued litigation in this arena must be guaranteed.[977]

[977] Kirby, N (2004) "Pharmaceutical law conference: Law Society of South Africa" [Web:] http://72.14.203.104/search?q=cache:SUt4q2xk81YJ:www.Issalead.org.za/cgi-bin/Le... [Date of access: 20 March 2006]

CHAPTER 7 CONCLUSION AND RECOMMENDATIONS

7 1 CONCLUSION

7 1 1 Scope and purpose

This research established that there is, understandably, excitement in the world of biomedical research about the potential of stem cells to offer therapies for some of the most intractable diseases suffered by humans. Like all new genetic technologies, however, stem cell research and technology has aroused deep-seated fears and worries in many people, particularly with regard to the issues of embryo research and cell nuclear replacement. Therefore, this research sought to investigate the legal position of the human embryo and fetus in South Africa, which has always been a controversial issue. In particular, the aim of this dissertation was to examine the need for legal direction in respect of the regulation of embryonic stem cell research and cloning in South Africa.

The first issue related to when human life begins, and whether the embryo and fetus deserve the same legal protection as born human beings. A further purpose of the dissertation was to establish and explore the legal and ethical issues that impact on the legal protection of the human embryo and fetus, and whether or not embryo research, as well as fetal tissue research, should be allowed to continue. In order to establish this, the provisions of the Constitution, domestic legislation, the Medical Research Council's guidelines, as well as the regulatory framework of the United Kingdom, were analysed and discussed. The research was conducted in the context of medical law, human rights and the law of persons.

This research further endeavoured to highlight the controversies of embryonic stem cell research and cloning, and drew attention in chapter 6 to some of the less thoroughly studied issues to be faced "further down the line", if and when stem cell-derived therapies become a reality. It was put forward that these issues should not be underestimated and many are deserving of further social science and legal research. It is hoped, however, that the approach to policy development for stem cell research and therapy in South Africa

would be broadly permissive, but with provision for rigorous ethical and legal oversight, and that it will enable policy to evolve in a way that is rational and commands broad public support. The research therefore attempted to identify several ethical, social and legal issues that deserve closer scrutiny.

7 1 2 Summary: Overview of chapters

The legal study of embryonic stem cell research and cloning required an analysis of the ethical and legal issues associated with it. Briefly, chapter one stated the problem, methodology and purpose of the research undertaken.

The clinical aspects surrounding embryonic stem cell research were explained in chapter 2. In summary, stem cells could launch a new era of medicine, curing deadly diseases with custom-made tissues and organs. Most embryonic stem cells used for research are extracted from embryos created by in vitro fertilisation. Scientists are also working on subtracting cells from embryos produced by way of therapeutic cloning, in which the nucleus of for example a skin cell is inserted into an egg whose nucleus has been removed. This is in contrast with reproductive cloning, in which the blastocyst would be implanted in a woman's uterus to produce a baby. Therefore, the distinction between therapeutic and reproductive cloning is based on the steps following cell nuclear replacement and reflects the purpose for which it is undertaken. The initial process, to the blastocyst stage, is identical.

Embryonic stem cells' ability to develop into any type of cell, called pluripotency, is both a benefit and a bane to scientists, who must keep harvested cells from manufacturing and then mould their identities to suit patients' needs. One of the greatest challenges in this work is to harness and direct cell differentiation – telling one stem cell to form blood, another skin, and another liver. Unlike embryonic stem cells, adult stem cells have not proved able to morph into any kind of cell and may be limited to becoming cell types within their tissue of origin. Similarly, stem cells from a newborn's cord blood produce only blood cells. Recently though, cord tissue has been found to contain mesenchymal

cells capable of generating bone and cartilage. Stem cells are one of the most fascinating areas of biology today.[978]

With reference to the advances in medicine, particularly embryonic stem cell research and cloning, the time has come to carefully investigate the legal position of the embryo and fetus against the background of the Constitution and the South African common law. As was stated in chapter 3, the Constitution is considered to be the supreme law in South Africa, and any legislation that is irreconcilable with it is invalid to the extent of the conflict. Secondly, according to section 39 of the Constitution, the Bill of Rights applies to all law and binds the executive, legislature, judiciary and all organs of state. It was also established that, in terms of section 36 of the Constitution, rights may be limited in terms of the Bill of Rights under specific circumstances and in a particular manner for the protection of some public interest or the rights of others.

The first question related to the legal status of the embryo and fetus, which is difficult to determine. It was established that legal personality begins at birth.[979] It was further established that the *nasciturus* fiction, although applicable to the discussion, cannot protect the embryo and fetus when being used in research, because the embryo is destructed and would therefore not be born alive. Actions that could arise from prenatal injuries were also discussed. To summarise, the action for "wrongful birth" is one instituted by the parents of a disabled child against the doctor on the basis that the latter's failure to properly inform them of the risk of birth defects deprived them of their choice to terminate the pregnancy. The action for "wrongful pregnancy" or "wrongful conception" is one brought by the parents of a healthy but unwanted child. The action for "wrongful life" is one brought by the disabled child against the doctor, on the basis that the doctor's failure to inform the parents of the increased risk caused his birth in a deformed state. Our existing case law shows that the actions for "wrongful birth" and

[978] For a clinical explanation of what stem cell research entails see chapter 2.
[979] Boberg (1999) 28. See also Slabbert (1997) *TSAR* 234 *at* 238.

"wrongful pregnancy" have evolved and can now rightfully be accommodated in the law of delict.[980]

It was further found that the fetus is not a constitutional bearer of rights, and therefore has no "right to life" as envisaged in section 11.[981] However, the state has a constitutional duty to respect, protect and promote both fetal and maternal life and health arising from sections 7(1) and 7(2) of the Constitution. The constitutional values of human life and dignity are objective value norms constituting an objective value order, giving rise to a constitutional duty on the state. The state has a positive duty to take steps to ensure that human life and dignity are respected, promoted and valued. It may regulate embryonic stem cell research, fetal tissue research and cloning techniques. A balance also needs to be struck between maternal and fetal interests.

Scientists have long recognised the promise of research involving human fetuses for the advancement of basic science, as well as for the development of life-saving vaccines and therapies. Such research continues to this day as scientists seek new treatments for a variety of diseases, such as Alzheimer's disease, Parkinson's disease, diabetes, heart disease, and kidney failure. This research, however, raised a further concern, one that as a political issue is inextricably linked to the controversy over abortion. It was put forward that, in South Africa, a woman's right to terminate her pregnancy is constitutionally protected, emerging from a value-orientated interpretation of the rights to security of the person,[982] life,[983] privacy,[984] equality[985] and human dignity.[986] The state therefore has a constitutional duty to protect and promote the values of human life and human dignity, by regulating access to abortion.[987] It was also submitted that a women's right to reproduce includes a right to terminate her pregnancy. Although the protection of a fetus is a

[980] Strauss (1991) 197.
[981] *Christian Lawyers Association of South Africa and Others v Minister of Health and Others* fn 269 *supra*.
[982] Section 12 of the Constitution.
[983] Section 11 of the Constitution.
[984] Section 14 of the Constitution.
[985] Section 9 of the Constitution.
[986] Section 11 of the Constitution.
[987] Slabbert (2000) 209, 341.

superior value, this does not mean that it eliminates all the woman's rights, such as her right to self-determination. It was further put forward that because neither the Choice on Termination of Pregnancy Act, nor the Human Tissue Act, nor the National Health Act makes provision for the regulation of fetal tissue, a provision should be inserted in either the Choice on Termination of Pregnancy Act or the National Health Act to regulate the situation. It was further recommended that fetal tissue be used in research only with the explicit consent of the woman who chooses to terminate her pregnancy. In the case of fetal tissue research, the use of the fetal tissue does not result in intentional destruction of a live fetus, and the fetus is not created solely for the purposes of research. The Medical Research Council of South Africa recommends that, for the present, fetal tissue from cadavers and embryos remaining after completion of infertility treatments should be the only source of embryonic stem cells for the purposes of research. It was submitted that these recommendations are too restrictive and may stifle scientific progress, whose objective is to benefit patients with irreversible and debilitating diseases.

Therefore, in summary, the development of the fetus is regarded as a basis for increasing the state's protection over the fetus, whereas the woman's opportunity to choose an abortion in the early stage of her pregnancy should be seen as accommodating sufficiently her dignity and autonomy in order to justify restrictions at later stages of the pregnancy. Therefore, the state's duty to protect developing human life does not imply that there is a legal duty on a woman to carry a pregnancy to term.

The right to human dignity, which protects the intrinsic worth of human beings, was also examined. Intrinsic worth is based on our inborn human qualities. Therefore, nobody may be treated as something less than human or as a mere object. The normative premise, upon which the new constitutional dispensation as a system of limited government is based, is the protection of human dignity. It was established that because the Constitution cherishes the value of human dignity, the state has a positive duty to protect fetal life. It is also stated in the Universal Declaration on the Human Genome and Human Rights that research on the human genome "should fully respect human dignity, freedom, and human rights". Therefore, the promotion of the constitutional values of human life and dignity

oblige the state to regulate abortion, embryonic stem cell research and cloning in order to protect developing human life. However, the state also has an interest in maternal health, which cannot be dissociated from the abortion decision.

The wording of section 14 of the Constitution indicates that the right to privacy is essential for the preservation of an individual's dignity, including his or her physical, psychological and spiritual wellbeing. This right also allows individuals to make personal decisions about their lives, free from interference by the state, and usually refers to control over matters such as marriage, reproductive freedom, contraception and family relationships. There can be no doubt then that the decision of a woman whether or not to abort her fetus and to donate it for research purposes, or to donate "surplus" embryos for research purposes, also falls within the scope of personal and intimate decisions that must be exercised without interference from the state. The prohibition on discrimination based on sex and gender, as envisaged in section 9 of the Constitution, also relates to reproductive autonomy, and specifically the issue of abortion and fetal tissue research. Therefore, a woman's entitlement to equality and equal protection in terms of the law is an important element in the assertion of reproductive self-determination.

It was further argued that the freedom of scientific enquiry must allow and encourage research and scientific advances. However, although the freedom of scientific research and academic freedom are enshrined in section 16(1)(d) of the Constitution, the right itself must be balanced against the other rights in the Constitution. Therefore, constraints on the freedom of scientific enquiry may be imposed to protect the safety of the community and individuals and the rights and interests of the subjects of scientific enquiry. It was submitted that embryo research and cloning fall into this category. It was established that research on human embryos raises concerns. Such research is almost instinctively opposed by some on the grounds that it may reach a stage where it is regarded as tampering with the creation of human life. However, research may have distinct advantages about which there appears to be worldwide consensus.[988] Therefore, the advantages of the research were contrasted with the arguments against the research.

[988] Slabbert (2001) *TSAR* 495 *at* 502.

Several organisations are working to institute a worldwide ban on reproductive cloning, but many countries oppose such a ban, based on the belief that all cloning techniques should be available in medical research. While many favour research on therapeutic cloning for treating human disease and illness, reproductive cloning for producing offspring has always been far more controversial. Embryonic stem cell research, fetal tissue research and therapeutic cloning relate to the right of access to health care services as envisaged in section 27 of the Constitution, especially if they were the only treatments available and widely recognised as being appropriate for the purpose of curing an incurable disease. Health care is generally considered to be a basic need. Section 27(1)(a) of the Constitution specifically provides that everyone has the right to have access to health care, including reproductive health care. This right is however limited internally by section 27(2), which mentions that the state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of these rights.[989] It was established that the Constitution does not guarantee a right to health, but only the qualified right of access to health care services.

It was further submitted that if reproductive cloning was to be permitted, the research would have to be justified and argued on the basis of a limitation of rights in terms of section 36 of the Constitution. It would also have to be established whether reproductive cloning falls within the scope of the right to reproduce. It was also agreed with Jordaan that a moratorium be placed on reproductive cloning, rather than a statutory prohibition.

This research further revealed that informed consent is of utmost importance with regard to medical treatment. Section 12(2)(c) of the Constitution provides that "everyone has the right to bodily and psychological integrity, which include the right not to be subjected to medical or scientific experiments without their informed consent". The doctrine of informed consent in the context of medical law was discussed. In principle, consent should be given by the patients themselves. Only in exceptional cases may consent for medical treatment or operations be given on behalf of such a person. The patient must

[989] See *Soobramoney v The Minister of Health* fn 534 *supra*.

have knowledge of all the true and essential facts relating to the treatment he/she is consenting to.[990] The National Health Act, as well as the Choice on Termination of Pregnancy Act, also includes provisions pertaining to consent. These legislative provisions were discussed in detail in chapters 3 and 4.

It was further established that the right to freedom of religion and thought is contained in most human rights treaties. However, members of religious communities may seek to use the freedom of religion as a shield to fend off attacks on constitutionally offensive group practices.[991] Important in the context of reproductive rights is the freedom to express religious, philosophical and social convictions regarding reproductive self-determination. According to Slabbert, this means that on the one hand individuals may enjoy the human rights of reproductive choice, and on the other hand that health professionals must be free not to participate in practices that they find offensive on religious grounds (for example, performing abortions or sterilisations or assisted reproduction procedures and embryo research).

Domestic legislation was analysed and examined in chapter 4. The first was the Choice on Termination of Pregnancy Act. It was established that the morality of abortion is widely associated with the legal status of the fetus, and also with the use of fetal tissue for research purposes. There has already been a constitutional challenge to this health-related Act.

The Choice on Termination of Pregnancy Act was enacted on 1 February 1997. This Act allows a girl or woman to access termination of pregnancy services upon request during the first 12 weeks of her pregnancy.[992] The Act explicitly promotes the provision of "non-mandatory and non-directive counselling"[993] before and after the termination of a pregnancy. A termination of pregnancy may only take place with the informed consent of

[990] Claassen & Verschoor (1992) 62.
[991] *Christian Education South Africa v Minister of Education* fn 448 *supra*.
[992] Section 2(1)(a).
[993] Section 4.

the pregnant woman.[994] In the case of a pregnant minor, however, a doctor or midwife must advise the minor to consult with her parents, guardian or friends before the pregnancy is terminated.[995] The Act defines a minor as a person under the age of 18 years.[996] The Act explicitly provides that no termination of pregnancy may be denied simply because a minor chooses not to consult her parents or guardians. In July 1997 three Christian groups, including the Christian Lawyers Association, challenged the Act. They argued that the Act violates the right to life of the fetus and is accordingly unconstitutional. The government opposed the action on the basis that since the right to life does not extend to a fetus, the groups had no legal basis for their claim. Four years later, the Christian Lawyers Association launched a new challenge to the Act concerning a minor's right to exercise her choice to terminate a pregnancy. The government objected to the case on the grounds of it being vague and embarrassing and not disclosing a cause of action. Therefore, the Choice on Termination of Pregnancy Act was not declared unconstitutional.

The Human Tissue Act, which is at the time of writing still applicable law, was examined. It was established that only a few provisions relate to the embryo and fetus. The Act makes provision for the use of tissue and gametes removed or excised from a living donor. The Act prohibits the use of placentas, fetal tissue and umbilical cords for medical and dental purposes, their transplantation into the body of another living person or their use for the production of a therapeutic, diagnostic or prophylactic substance, except with the consent of the Minister or his nominee.[997] The Act further prohibits the genetic manipulation of gametes or zygotes outside the human body.[998] This research revealed the inadequate way embryology is currently regulated in terms of this Act. Slabbert also submits that the potential abuse of assisted reproduction techniques, together with outdated guidelines and statutory provisions regulating activities involving the embryo, definitely threatens the dignity of human life and consequently the public welfare. The enactment of legislation protecting the embryo would not only provide for

[994] Section 5.
[995] Section 5(3).
[996] Section 1.
[997] Section 18 and 19.
[998] Section 39A.

more comprehensive supervision, but would also reflect contemporary opinion more accurately and facilitate legal certainty. Legal protection for the embryo and fetus can be provided in the form of a legal duty towards research entities. This would not create any rights for the embryo and the fetus, but would rather place obligations on third parties in relation to the treatment of the embryo.[999]

The Human Tissue Act governing genetic manipulation is, in South Africa at any rate, about to change. Currently, neither reproductive nor therapeutic cloning is allowed, but the National Health Act is due to be passed. Embryonic stem cell research and therapeutic cloning will not be prohibited, but reproductive cloning will remain prohibited.[1000] Very strict regulatory criteria will have to be complied with for therapeutic cloning, including authorisation by the Minister for work in this field. Section 57(4) affirms that the Minister may permit research on stem cells and zygotes that are not more than 14 days old. The National Health Act will therefore provide for a whole new set of principles focusing on stem cell research and cloning. Concern has been expressed about the high degree of control entitled by the National Health Act to the Minister over the National Health Research Committee.[1001] For example, the Act makes it possible for a Minister of Health to appoint members to the National Health Research Committee who are sympathetic to his or her own ideology and also to remove any dissenting voices. It does not provide explicit safeguards for researchers in the public sector who risk their careers by speaking out against government policy. There is, therefore, the danger that misguided decision-makers who are driven by ideology rather than scientific evidence could hijack the national research agenda.

It was concluded that much would depend on the content of the regulations. The same could be said for the Act. On the positive side, the chapters on research do have many redeeming features. Section 71(1) reinforces the sentiment espoused in section 12(2) of the Constitution, which affirms everyone's right to bodily and psychological integrity, including the right to security in and control over their body; and not to be subjected to

[999] Slabbert (2001) *TSAR* 495 *at* 510.
[1000] Section 57(6) of the National Health Act.
[1001] Section 69.

medical or scientific experiments without their informed consent. The National Health Act clarifies the legality in South Africa of human reproductive and therapeutic cloning, as well as stem cell research (in section 57). It empowers the National Health Research Ethics Council to issue national research ethics guidelines.[1002] It also offers unprecedented and novel protections for researchers. It allows the National Health Research Ethics Council to adjudicate complaints about the functioning of health research ethics committees and to hear any complaint by a researcher who believes that he or she has been discriminated against by a health research ethics committee. This will hopefully encourage thorough and considered protocol reviews by such committees.

The Act provides that every institution, agency or health facility at which health research is conducted will have to either have, or have access to, a registered health research ethics committee.[1003] One of the health legislation tasks of the council will be to "set norms and standards for conducting research on humans and animals, including norms and standards for conducting clinical trials". This task has already been addressed by the Medical Research Council, the National Department of Health and, to an extent, by the Medicines Control Council. Coordination, rather than *ab initio* development of guidelines, would therefore be necessary. The provisions for a national health information system are, by contrast, rather less prescriptive. The national department is tasked with facilitating and coordinating the development of a national system that includes data from all spheres, as well as the private sector.

The Medical Research Council's guidelines were also discussed. Van Wyk submits that these guidelines should be considered as "law of general application". However, when these guidelines are regarded, it is clear that they need thorough revision to bring them in line with the provisions of section 36 of the Constitution and with international guidelines.[1004]

[1002] Section 72.
[1003] Section 73.
[1004] Van Wyk (2001) *THRHR* 3 *at* 22.

The regulatory process for stem cell research and cloning in the United Kingdom, as was discussed in chapter 5, began with the Committee of Inquiry into Human Fertilisation and Embryology, which led to the Warnock Report. Controversially, Warnock took the view that research on human embryos was morally permissible, and some members of the committee (in fact a just majority) were prepared even then to sanction the creation of embryos for research. However, as a counterweight, it was emphasised that the human embryo has a special status and should not be regarded simply as a ball of cells. The government took forward the main thrust of Warnock's recommendations by enacting the Human Fertilisation and Embryology Act. The governing policy and the key regulatory principles underlying the legislation are reasonably clear. In short, the policy states that if embryos are to be available for research, it is better to regulate such research openly and effectively. This demanded that the legislation declared quite explicitly what is lawful and what is not. It also called for a dedicated regulatory body, namely the Human Fertilisation and Embryology Authority, to licence and monitor such research. As far as research on embryos is concerned, the three main principles are as follows:

(a) The Human Fertilisation and Embryology Authority should licence such work only if it is necessary, which is referred to as the necessity principle.[1005]
(b) If the Human Fertilisation and Embryology Authority is satisfied that such research is necessary, a licence should be granted only if the particular activity is judged to be necessary or desirable in relation to one of the approved statutory purposes.[1006]
(c) Research on embryos should under no circumstances continue beyond 14 days or after the appearance of the primitive streak.[1007]

The Act also provides that research may be licensed "for such other purposes as may be specified in regulations".[1008] This provision is, however, limited the increased knowledge about the creation and development of embryos or about disease, or enables such

[1005] Schedule 2, paragraph 3(6).
[1006] Schedule 2, paragraph 3(2).
[1007] Section 3(3)(a) and 3(4).
[1008] Schedule 2, paragraph 3(2).

knowledge to be applied.[1009] At a later stage government decided to extend the purposes, opening the way for stem cell research to deliver on its apparent potential. When the Human Fertilisation and Embryology (Research Purposes) Regulations were enforced, three new purposes were added to the original five.

The Human Tissue Act received Royal Assent on 15 November 2004. It is a framework for regulating the storage and use of human organs and tissue from the living, and the removal, storage and use of tissue and organs from the deceased, for specified health-related purposes and public display. The Act applies to England, Wales and Northern Ireland. The Act makes consent the fundamental principle underpinning the lawful retention and use of body parts, organs and tissue from the living or the deceased for specific health-related purposes and public display.

The Act repealed and replaced the Human Tissue Act of 1961, the Anatomy Act of 1984 and the Human Organ Transplants Act of 1989 as they related to England and Wales. It also repealed and replaced the Human Tissue Act (Northern Ireland) of 1962, the Human Organ Transplants (Northern Ireland) Order of 1989 and the Anatomy (Northern Ireland) Order of 1992. On 12 December 2005, the newly established Human Tissue Authority announced two key dates in 2006 when it will start operating under the Human Tissue Act.

Baroness Hayman, the chair of the Human Tissue Authority, said: "Our aim is to provide an environment that will increase the confidence of the public and professionals alike. We hope that we can help foster an environment of trust in which patients are able to have confidence that their wishes will be respected, and that scientific and medical research can flourish on that basis."

Adrian McNeil, Chief Executive, said: "Since we were established in 2005, we have made substantial progress. Our timetable is designed to allow the research and medical communities enough time to prepare for the licensing requirements from next year. We

[1009] Schedule 2, paragraph 3(3).

will operate a regulatory system that is proportionate to risk, and we are working with professionals, regulators, and public bodies to ensure best practice and avoid duplication."[1010]

The European Union's Tissues and Cells Directive were to be implemented on 7 April 2006, and tissue banks storing tissue and cells for human application would be licensed under the directive from that date. Also in April, the authority was to publish its revised codes of practice guidelines and the licensing framework for all other activities. To allow time for further consultation with professionals and piloting of the framework for regulation, licences for these activities are to be granted from 1 September 2006.

It is strongly recommended that a statutory framework similar to the one adopted in the United Kingdom be considered in South Africa to provide for the statutory regulation of all practices involving human artificial insemination and embryology. Such an authority should also be established to control a scheme for the granting, revocation, variation or suspension of licences in respect of the storage of embryos and gametes, the performance of assisted reproduction techniques, and research involving embryo.

7 2 RECOMMENDATIONS

7 2 1 Summary of regulatory recommendations

In chapter 6, a brief proposed regulatory framework for stem cell research and cloning was provided. In the debate surrounding embryo research, including stem cell research and cloning, it has been established that the moral status of the embryo is not the sole ethical consideration. There is also an obligation to do everything possible to alleviate the suffering of existing human beings. If stem cell research has the potential to achieve that end, it is proposed that there is a moral duty to pursue it. It is then of the utmost importance to achieve a balance between all competing legal and ethical principles. It was put forward that, in deciding where this balance should lie, various considerations

[1010] United Kingdom. Department of Health (2004a) www.opsi.gov.uk/acts/en2004/2004en30.htm

should be taken into account, including the likelihood that the research will be successful and the possibility of achieving the goal, namely a cure for incurable diseases. Some opponents of embryo research suggest that it is unjustified because better prospects are offered by adult stem cell therapy. The difficulty, however, is that it is not possible to know whether it is true unless the research is done and if other lines of research prove unsuccessful. Valuable time would then have been lost and many people would have suffered and died in the meantime. Policy-makers in the United Kingdom have accepted the view held by most scientists in the field, namely that research on both embryonic and adult stem cells should be pursued.

It was proposed that South Africa follows a similar approach by providing a liberal regulatory framework that guarantees the highest ethical standards. It was also submitted that research in South Africa not be too restrictive.

It was further recommended that we be reminded of the fundamental concepts of beneficence and non-maleficence applicable to human embryonic stem cell research. Beneficial research should be carried out by weighing risks against benefits, as it is beneficence to do well; and harms and risks should be avoided.[1011] It was put forward that there should be regulations on the development and use of human stem cells that will be used as biological product or medical devices to treat or cure diseases. These would end the current debate and monitor the conduct of clinical trials involving human experimentations closely. Progress should be made as the research would be ethically supported if a reasonable approach is used where benefits outweigh the risks and even unreasonable objections. However, the regulations need to ensure responsible and professional social control of stem cell research in South Africa. For an effective legal framework, the human stem cell research should be regulated and monitored in accordance with relevant ethical considerations.

[1011] See Edelstein, I (1943) www.pbs.org/wgbh/nova/doctors/oath_classical.html.

In addition, any proposed laws and regulations must be sufficiently flexible to allow for an adequate response to the scientific and biotechnological advances currently being developed at a very fast pace. It was submitted that it is of utmost importance to facilitate and not hinder worthy and deserving embryonic stem cell research and therapeutic cloning techniques where there are tremendous potential curative cell-therapy treatments. Although there is no current evidence regarding which source of stem cells is the best for curing diseases, we should continue to strive in research using all sources to discover the truth. However, it may be prudent to set policies and institute measures to accelerate adult stem cell research over embryonic stem cells, so that in areas where adult stem cells are successful, the controversial embryonic stem cells may not be necessary. There should then be a strict overview of human stem cell research with adequate rules and guidelines relating to privacy, confidentiality, adequate counselling, and the securing of informed consent in order to prevent abuses and sufferings.

A further ethical debate surrounds the use of cell nuclear replacement to create embryos for the derivation of stem cells. Some opponents feel an instinctive distaste for what they regard as an "unnatural" process. It was submitted that it is difficult to find a logical defence for this view, as many long-accepted technological developments are similarly "unnatural". Another frequently heard argument is that of the "slippery slope": That perfecting techniques for cell nuclear replacement will make it more likely for reproductive cloning to eventually happen. However, the distinction between reproductive and therapeutic cloning is quite clear, and this argument should not be upheld. A further criticism of cell nuclear replacement research is that it is, as some have claimed with embryonic stem cell research in general, unnecessary and unlikely to lead to successful therapies for disease. Again, this cannot be resolved unless the research is done. It was submitted that even if a low change of success exist, it does not constitute an ethical reason for giving priority to other types of embryonic stem cell research.

It is also imperative at a legal level that donors be protected by requirements for informed consent. As stipulated in the Human Fertilisation and Embryology Act, donors of embryos for research should be given appropriate counselling and "such relevant

information as is proper" to make a decision whether to donate or not. Participants should also be informed that prior to the embryo being used in research, they may vary or withdraw the terms on which they gave consent. It is advisable that a detailed donor information and consent form be prepared for this research in South Africa. Donors must be given thorough and appropriate information, including that any stem cell lines may continue indefinitely and may be used in different research projects. In addition, in vitro fertilisation clinics should ask couples to designate in advance how they want their surplus embryos to be managed, and this should include the position if one of the donors was to die.

In light of the above considerations, it seems clear that rather than using the law to react in an ad hoc manner to specific scientific innovations, we should attain a more comprehensive understanding of new developments, and draft laws that reflect that understanding. It is possible to develop a broadly framed legislative mandate and to structure regulatory bodies that are responsive to change. In doing so we could use the law to promote flexibility and continued conversations regarding the issues involved, and make transparent the ethical commitments implicit in our governing policies. Public discourse is needed so that the law may move forward in a way that complements not only these ethical commitments, but also the scientific commitments.

It was recommended that providing compensation for research injuries be considered and incorporated into the consent forms. It would only be fair and ethical to follow the argument through, to provide for research injuries compensation that may occur in human stem cell research. Otherwise it is not displaying responsibility, but is a case of reaping the tremendous benefits of human stem cell research, and not wanting to bear the predictive and unexpected risks associated with it. But, on the other hand, compensation for research injuries should not be too prohibitive so as to discourage research or put undue financial strain on the research grants. This is, however, an area that would have to be deliberated on by different ethics committees. It was further recommended that the possibility of an international convention on bioethics and human stem cell research be

established so that international consensus can be reached with minimum standards and safeguards to be placed at national levels.[1012]

7 2 2 Conclusive remarks

Debate about the ethics of embryonic stem cell research and cloning will surely continue to reverberate around the world as one legal system after another, as well as regional and international legal communities, seek to clarify their regulatory positions. The scientific progress associated with stem cell therapy does not enter a regulatory vacuum, and social policy should be designed to adapt to changing social circumstances. Nevertheless, as was pointed out, there are quite a few social, ethical and legal issues that need to be resolved. These difficult issues raise the question of whether the existing regulatory framework in South Africa is adequate. Perhaps, it could be argued, a special regulatory regime is needed for stem cell research or therapy or both in order to maintain public confidence. On the other hand, one must be wary of suggesting yet another regulatory body; perhaps all that is needed is better co-ordination of the existing regulation and regulators and more accessible descriptions of current ethical and legal standards.

Well-monitored clinical trials are the best anyone in any country can hope for, and promising medical advancements should not be forgone in the face of minimal danger. Adopting a research policy for South Africa with no risks attached will mean accepting a research policy with no future of improvement and success. As a result of the United Kingdom's liberal stem cell research policy they will likely become an international leader in embryonic stem cell research, simply because they didn't say "no". South Africa shouldn't say "no" either. With many countries adopting obtuse stem cell research policies motivated by religious naysayers, South Africa has the opportunity to join the United Kingdom and be among the few nations possessing enough foresight to endorse this initiative. The payoff will not only be an influx of eager scientists and research

[1012] See the Council for International Organisations of Medical Sciences' International Ethical Guidelines for Biomedical Research Involving Human Subjects on compensation for research injuries, which is not found in other international guidelines or documents, as quoted in Kian, CT & Leng, TS (2005) "The Singapore approach to human stem cell research, therapeutic and reproductive cloning" *Bioeth* 19(3):290-303. See also Lori, B & Annas, GJ (2002) "Protecting the endangered human: Toward an international treaty prohibiting cloning and inheritable alterations" *Am JL & Med* 28(2):151-178.

money, but also the chance to become a global leader in stem cell therapies, thrusting South Africa to the forefront of the medical community, and helping its people live healthier lives.[1013] Even though the research is still violently opposed and even ridiculed by some, the implementation of a structured, well-balanced regulatory framework – subject to strict ethical guidelines – would ensure that embryonic stem cell research and therapeutic cloning be accepted as self-evident in future.

[1013] See in general Schuklenk & Lott (2002) *SA J Obstetr & Gyn* 57 *at* 60.

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Explanatory notes on formatting

(a) In the main body of this dissertation, the initials of the authors are provided only in the first occurrence of the reference. Thereafter only their surnames are used in indicating the reference in the remainder of the dissertation. Their initials are also reflected in the bibliography below.

(b) With regard to journal articles, books, and internet sources, the full reference is given in the first occurrence in the main body of the text, and thereafter the abbreviated reference is used. The full references are reflected in the bibliography below.

(c) With regard to journal references, their abbreviated names are used in the main body of the text and also in the bibliography below, since the full names can be found in the table of abbreviations.

(d) References to case names appear in the main body of the text in italics except when they are intended as references to the people themselves in which case they appear as regular text, for example the *Friedman* case means the case of *Friedman v Glicksman*, while Mrs Friedman means the applicant in the case.

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Declaration of Helsinki

Department of Health's Guidelines for good practice in the conduct of clinical trials in human participants in South Africa

European Convention for the Protection of Human Rights and Fundamental Freedoms

Health Services Guidelines for the disposal of fetal tissue, 12 November 1991

Human Genome Diversity Project

International Convention on Civil and Political Rights

International Covenant on Economic, Social and Cultural Rights

Law Commission No 231 (1995) Mental Incapacity (London: HMSO) HC 189 of 1994-5.

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Human Tissue Act, 2004

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REGULATIONS

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TABLE OF ABBREVIATIONS

AJ	Acta Juridica
Alb LJ Sci & Tech	Albany Law Journal of Science & Technoglogy
Alta L Rev	Alta Law Review
Am JL & Med	American Journal of Law and Medicine
Am UL Rev	American University Law Review
Annals Health L	Annals of Health Law
Austl J Hum Rts	Australian Journal of Human Rights
Austl LJ	Australian Law Journal
Bioeth	Bioethics
Bio Sci L Rev	Bio-Science Law Review
Bost BJ	Boston Bar Journal
Bull Narc	Bulletin on Narcotics
Cam LJ	Cambridge Law Journal
Cam U Press	Cambridge University Press
Cap UL Rev	Capital University Law Review
Col U Press	Columbia University Press
Conn L Rev	Connecticut Law Review
Consult	Consultus
Crim L Forum Int'l J	Criminal Law Forum: An International Journal
DJ	De Jure
DR	De Rebus

De Paul J Health Care L	DePaul Journal of Health Care Law
Edinb L Rev	Edinburgh Law Review
Eur Int Prop Rev	European Intellectual Property Review
Flo Coast L Rev	Florida Coastal Law Review
GG	Government Gazette
Harv Hum Rts J	Harvard Human Rights Journal
Hast LJ	Hasting Law Journal
Health LJ (Sp Ed)	Health Law Journal (Special Edition)
Health L Rev	Health Law Review
Hous J Int'l L	Houston Journal of International Law
Hum Rts L Rev	Human Rights Law Review
Hum Rts Sum	Human Rights Summer
Ind Health L Rev	Indiana Health Law Review
Issues L & Med	Issues in Law and Medicine
J Contemp Heatlh L & Pol'y	Journal of Contemporary Health Law and Policy
J Fac Phar Teh Un Med'l Sci	Journal of Faculty of Pharmacy, Tehran University of Medical Sciences
J Int'l Biotech L	Journal of International Biotechnology Law
JL Med & Eth	Journal of Law, Medicine and Ethics
JLM	Journal of Law and Medicine
J Mars L Rev	John Marshall Law Review
J Med'l Eth	Journal of Medical Ethics

J Med'l Eth & Cur Cont	Journal of Medical Ethics and Current Controversies
Loy Los An Int'l & Comp L Rev	Loyola of Los Angeles International and Comparative Law Review
Med & L	Medicine and Law
Med'l L Rev	Medical Law Review
Minn JL Sci & Tech	Minnesota Journal of Law, Science & Technology
Monash Bio Rev	Monash Bioethics Review
Mur U Elec JL	Murdoch University Electronic Journal of Law
Nat	Nature
Nat Geogr Mag	National Geographic Magazine
New Eng J Med	New England Journal of Medicine
New Eng L Rev	New England Law Review
Notre Dame L Rev	Notre Dame Law Review
NYUJ Legis & Pub Pol'y	New York University Journal of Legislation and Public Policy
Obt	Obiter
Pac LJ	Pacific Law Journal
Pepp L Rev	Pepperdine Law Review
Persp	Perspektief
Pop Mech Mag	Popular Mechanics Magazine
Pta News	Pretoria News
Rutgers LJ	Rutgers Law Journal
S-B	Sake-Beeld
S Cal L Rev	Southern California Law Review

SA J Obstetr & Gyn	South African Journal of Obstetrics and Gynaecology
SAJHR	South African Journal on Human Rights
SALJ	South African Law Journal
SAMJ	South African Medical Journal
St Louis ULJ	Saint Louis University Law Journal
Stell L Rev	Stellenbosch Law Review
Stetson L Rev	Stetson Law Review
THRHR	Tydskrif vir die Hedendaagse Romeins-Hollandse Reg
TSAR	Tydskrif vir die Suid-Afrikaanse Reg
Tul J Comp & Int'l L	Tulsa Journal of Comparative and International Law
U Chi L Rev	University of Chicago Law Review
U Miami L Rev	University of Miami Law Review
U Mich JL Ref	University of Michigan Journal of Law Reform
U Penn L Rev	University of Pennsylvania Law Review
UCLA Women's LJ	UCLA Women's Law Journal
Utah L Rev	Utah Law Review
Wash & Lee L Rev	Washington & Lee Law Review
Web J Cur Leg Issues	Web Journal of Current Legal Issues
Women's Rts L Rep	Women's Rights Law Reporter
Yale LJ	Yale Law Journal