

**THE MORAL STATUS
OF
EMBRYONIC STEM CELL
RESEARCH
IN THE
SOUTH AFRICAN CONTEXT**

NICO NORTJÉ



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Promoter: Prof. A. A. van Niekerk

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I, the undersigned

Nico Nortjé,

hereby declare that the work contained in this dissertation is my own original work and that I have not previously, in its entirety or in part, submitted it at any university for a degree.

Signature

Date

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Summary

Should surplus embryos which are destined to be discarded be protected at all cost, to the extent that they cannot contribute to medical knowledge - knowledge which could benefit society at large? Are embryos people or merely items of property? Different moral theories address these questions in different ways. Deontologists argue that the end never justifies the means and that the right not to be killed is more fundamental than the obligation to save. Utilitarians, on the other hand, argue that certain criteria should be met before moral significance can be contributed to an entity.

The question of the moral status of the embryo is, as my discussion will show, one of the most widely discussed issues in the history of bioethics. Extensive literature exists on the topic. This study holds that an *Ethics of Responsibility* (ER) should be applied when answering the questions posed above as it encourages one to accept responsibility for the choices or decisions made and to defend them accordingly. I have endeavoured to answer the question of the personhood and rights of the embryo within the framework of the *Ethics of Responsibility*. Although these concepts overlap in many ways they remain central to the debate surrounding the sanctioning or prevention of the use of human embryonic stem cells in research.

After identifying the micro-issues surrounding the human embryonic stem cell debate and explaining why both the deontologist and utilitarians fail to provide any adequate answers in this respect, I turn my attention to macro-issues such as safety concerns surrounding the usages and storage of stem cells. Commercialization, power issues, accessibility and the allocation of limited resources are also examined. Living in a society such as South Africa one cannot be blind to the inequalities of our health system. On a macro level I cannot but conclude that stem cell research does not seem to be a viable exercise within the South African context. South Africa faces a health care crisis far greater than the benefits stem cell research currently has to offer. However, the need still exists for a policy to guide future lawmakers who might need to address stem cell research and to guide decisions and actions. This brings me to my final chapter, namely proposing a morally justified policy for South Africa.

I propose a policy which respects and values the autonomy of the progenitors' choices (provided they have not been coerced) and which focuses on the beneficence of the greater

society. Furthermore, it is paramount that the goal of any stem cell research should be for therapeutic use ONLY. Before commencing with the extraction of the stem cells, scientists should be obligated first to present convincing evidence that they have tried alternative ways to reach the same result. Once this has been proven, a regulatory body could issue the scientist/team with a license to undertake the specific research with a specific therapy as goal in order to prevent abuse. If they are found guilty of any unethical conduct their licenses should be revoked and an investigation launched.

Opsomming

Moet embryo's wat bestem is om weggegooi te word ten alle koste beskerm word, tot so 'n mate dat hulle geen bydrae kan lewer tot mediese kennis nie – kennis wat tot voordeel van die samelewing in die breë kan strek? Is embryo's mense of bloot eiendom? Verskillende morele teorieë spreek hierdie vraagstuk op verskillende wyses aan. Deontoloë voer aan dat die doel nooit die middele heilig nie, en dat die reg om nie doodgemaak te word nie meer fundamenteel is as die verpligting om te red. Utilitariste daarteenoor voer aan dat daar aan bepaalde kriteria voldoen moet word voordat morele betekenis aan 'n entiteit toegeken kan word.

Die vraag rakende die morele status van die embryo is, soos my bespreking sal toon, een van die mees besproke onderwerpe in die geskiedenis van die bio-etiek. Uitgebreide literatuur bestaan oor die onderwerp. Hierdie studie voer aan dat 'n *Etik van Verantwoordelikheid* toegepas behoort te word in die beantwoording van bogenoemde vrae, aangesien dit 'n persoon aanmoedig om verantwoordelikheid te aanvaar vir sy of haar keuses of besluite, en om dit dienooreenkomstig te verdedig. Ek het gepoog om die vraag rakende die mensheid en regte van die embryo binne die raamwerk van die *Etik van Verantwoordelikheid* te beantwoord. Hoewel hierdie konsepte in verskeie opsigte oorvleuel, bly hulle belangrike vraagstukke in die debat rakende die gebruik al dan nie van menslike embrionale stamselle in navorsing.

Na die identifisering van die mikrovraagstukke rakende die menslike embrioniese stamseldebate, skenk ek aandag aan makrovraagstukke soos veiligheidsaangeleenthede rakende die gebruik en stoor van stamselle. Kommersialisasie, magiskwessies, toeganklikheid, en toewysing van beperkte hulpbronne word ook ondersoek. In 'n samelewing soos Suid-Afrika kan 'n mens nie blind staan teenoor die ongelykhede van ons gesondheidstelsel nie. Op makrovlak kan ek nie anders as om tot die slotsom te kom dat stamselnavorsing nie haalbaar binne die Suid-Afrikaanse konteks is nie. Suid-Afrika staar 'n gesondheidskrisis in die gesig wat by verre erger is as die voordele wat stamselnavorsing tans kan bied. Ten spyte hiervan is dit steeds nodig om 'n beleid daar te stel wat wetgewers wat dit in die toekoms nodig mag vind om stamselnavorsing aan te spreek, sal lei, en wat besluite en aksies sal rig. Dit lei my finale hoofstuk in, naamlik, 'n voorstel vir 'n moreel-verantwoorde beleid vir Suid-Afrika.

My voorstel is 'n beleid wat die outonomie van die voorsate se keuses respekteer en waardeer (met dien verstande dat hulle keuse nie afgedwing is nie), en wat fokus op die weldadigheid

van die breë samelewing. Dit is verder van uiterste belang dat die doel van enige stamselnavorsing SLEGS vir terapeutiese gebruik moet wees. Alvorens stamselle onttrek word, moet wetenskaplikes verplig word om oortuigende bewyse te lewer dat alternatiewe metodes aangewend is ten einde te poog om dieselfde resultaat te behaal. Indien sodanige bewys gelewer is, moet 'n regulerende liggaam 'n lisensie vir spesifieke navorsing met 'n spesifieke terapie as doelwit aan die wetenskaplike/span uitreik ten einde misbruik te voorkom. Sou hulle skuldig bevind word aan enige onetiese gedrag, moet hulle lisense herroep word en 'n ondersoek geloods word.

A well instructed people alone can be permanently a free people.

James Madison

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Chapter 1: Orientation and problem statement

“For even the mind is so dependent on the temperament and on the disposition of the organs of the body, that if it is possible to find some means that generally renders men more wise and more capable than they have been up to now, I believe that we must seek for it in medicine... [W]e could be spared an infinity of diseases, of the body as well as of the mind, and even also perhaps the enfeeblement of old Age, if we had enough knowledge of their causes and all the remedies which Nature has provided us.”

(Descartes, R. Discourse on the Method of Conducting One’s Reason well and seeing Truth in the Sciences, Part VI Paragraph 2, Private translation by Richard Kennington.)

The research which is currently being done on human stem cells holds, if medical researchers are to be believed, some of the most exciting and revolutionary promises in the history of medicine. The *Cartesian dream* has seemingly become possible due to the relatively recent discovery of stem cells in the human body by James Thomson and his team in 1998 (Thomson *et al.* 1998:1145). These cells have the unique quality of being not yet fully differentiated and are therefore able to develop (if the process can be duly managed) into a variety of tissues. For the first time, there seems to be a good prospect that the loss of somatic function induced by diseases such as diabetes, paralysis and myocardial infarction, to name but a few, may in future be ameliorated by injecting patients with cells which have differentiated into precursor cells, to cure or treat the symptoms of their degenerative diseases (Fischbach and Ruth 2004:1364-1370; Gurdon and Colman 1999:743).

Research shows that human stem cells have in the past been differentiated *in vitro* into neural (neurons, astrocytes and oligodendrocytes), cardiac (synchronously contracting

cardiomyocytes), endothelial (blood vessels), hematopoietic (multiple blood cell lineages), hepatocyte (liver cell), and trophoblast (placenta) lineages (Ludwig & Thomson 2004:285-289).

Stem cells can be obtained from three sources, e.g. from umbilical cord blood (immediately after birth), adult cells (i.e. the liver, bone marrow, the lining of the digestive track), and from human embryos before the 14th day after conception. This discussion will, however, concentrate only on the moral problems generated by stem cells derived from human embryos – those cells which are generally regarded as having the best therapeutic potential.

The treatments that are foreseen on the basis of human embryonic stem cell research are expected to work in fundamentally different ways from normal drugs and to have a different effect on the body. Medicinal drugs are often successful because of their ability to alter aspects of a cell's metabolism. However, drugs cannot cause the growth of new, healthy cells that will actually replace damaged cells (Okarma 2001:4). It is in this respect that stem cell research holds revolutionary promise, as stem cells “can both renew themselves in their undifferentiated state as well as differentiate into descendant cells that have a specific function.” (Okarma 2001:4). In a recent article Rick Weiss (2005:6) refers to stem cell therapies as “one of the holy grails of modern biology”.

Human embryonic stem cells are *pluripotent* (able to develop into many types of tissues); *immortal* (able to continue dividing indefinitely without losing their genetic structure); *malleable* (can be manipulated without losing their function); and they express the enzyme *telomerase* (which allows cells to grow and divide) (Holland *et al.* 2001:xviii). Because of these unique qualities, research on the topic can lead to a better understanding of foetal developmental abnormalities, the way in which specific tissues and organs develop, and how tissue differentiation takes place. It is foreseen that stem cells can be used to help detect foetal genetic abnormalities; to reduce infertility, pregnancy loss, and birth defects; to aid the development of cardiomyocytes for therapy of congenital heart failure and myocardial infarctions; to find cures for insulin dependent diabetes mellitus; to assist in treatment of neurological diseases such as Parkinson's disease, strokes and Alzheimer's disease; to restore the haematopoietic systems of cancer patients; to treat arteriosclerosis; to aid in wound healing; to develop cartilage forming cells which help those with osteoarthritis and rheumatoid arthritis; and so the list continues (Okarma 2001:6-10).

However, the exciting potential of this research has not meant that it was instantly welcomed as an indication of scientific progress. The research has, on the contrary, from the outset been submerged in Faustian moral controversy. The overwhelmingly serious moral objection that many commentators – from bioethicists to politicians, policymakers and even scientists - have raised against the research on embryonic stem cells is that their “harvesting” (an unfortunate term) implies the wilful “killing” of human embryos that have the potential to grow into fully-fledged human beings. In the USA, objections to this research have caused the Bush administration to prohibit federal funding for research on embryonic stem cell lines derived after August 9, 2001 (Sandel 2004:208), bar about 60 lines which existed before the ban. This position was confirmed when a challenge from liberal senators to implement the Stem Cell Research Enhancement Act of 2005, on the 19th of July 2006, was rejected due to a lack of a two-third majority (GovTrack 2006). The Bill’s purpose was to amend the Public Health Service Act and to provide for human embryonic stem cell research.

In the light of the moral controversy surrounding embryonic stem cells, one may ask why the cells are not simply derived from other available sources or even from animals. The answer is that research has clearly shown (Chapter 2) that the therapeutic potential of non-embryonic stem cells (adult stem cells) is significantly inferior to that of embryonic stem cells. The levels of pluripotency are, for example, not the same. Non-embryonic stem cell lines also do not last as long as their embryonic counterparts and, while non-embryonic stem cells from, for example, the liver can possibly reproduce already differentiated liver cells, they cannot yet be manipulated to develop into *other* tissues. Finally, stem cells cannot be harvested from tissue such as the heart muscle which, as a result of serious heart attacks, may be permanently damaged. Stem cell research for the repair of this kind of tissue only has therapeutic potential if embryonic stem cells can be utilised for that purpose.

In South Africa, the newly promulgated National Health Act (no. 61 of 2003) for the first time makes statutory provision for stem cell research. Article 57 of the Act states that:

(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 utilizing adult or umbilical cord stem cells.
- (3) No person may import or export human zygotes or embryos without the prior written approval of the Minister.
- (4) The Minister may permit research on stem cells and zygotes which are not more than 14 days old on written application 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.

Because of the hugely beneficial potential of the outcomes of stem cell research and against aforementioned dilemmas, there exists a great need for a morally justified, well-researched and responsible outline for public policy in order to help provide a positive arena for public debate. McLean (2001:205) points out that stem cell research holds the promise of not only changing human life, but of also changing the power structures and fundamental notions about human personhood, moral status and morality. The moral problem underlying the decision to either allow or ban research on human embryonic stem cells funded by public resources will be investigated. This study will not only deal with the general moral problems raised by the research on embryonic stem cells, but will also discuss which public policy for research on embryonic stem cells is, morally speaking, the best motivated, given the moral judgment on stem cell research that a rigorous philosophical-ethical analysis yields. Lastly, this research will focus on the specific circumstances of South Africa, bearing in mind the intricacies and idiosyncrasies of the complex and diverse texture of the moral make-up of South African public opinion. A morally justified public policy for tax-funded embryonic stem cell research will be proposed in the light of the complexities of South Africa's public opinion on morally related matters.

In order to systemize the discussion, Shannon's distinction (2001:177) between "micro" and "macro" issues will be drawn upon. "Micro" will refer to the moral issues pertaining to the status of embryonic life and the way in which stem cell research might or might not impact on the respect that we owe (or do not owe) to that life form. "Macro", in turn, will refer to the issues pertaining to public policy, and how such a policy is morally grounded.

Chapter 2 will discuss the nature of stem cell research, as well as the question why embryonic stem cell research is regarded as preferable to research on stem cells derived from other sources.

My aim with chapter 3 will be to focus on the legal applications, both nationally and internationally, which are all relevant to embryonic stem cell research. After taking an in-depth look at the legal applications I will turn my attention in more detail to the field of moral reasoning. Chapter 4 will be concerned with a more philosophical discourse where I will critically discuss and evaluate the two main, and most documented, schools of thought in philosophy namely deontology and utilitarianism.

After critically evaluating both streams I will deal with the core of my dissertation and address “micro” issues. I will raise matters such as the possible abuses of stem cell research and the applications thereof in the practice of medicine. One cannot ignore that medicine is driven by market economies and that, sadly, body parts are commercialised – issues I will address. I will also try and attempt to answer whether stem cell research is appropriate for the health needs of Africa before turning my attention to the moral status of the embryo. A critical discussion will be given on issues such as: Is the embryo a person?; Does the embryo have any rights? Is there any consensus from the debate about the moral status of the embryo? In conclusion I will argue that stem cell research is morally defensible from an ethics of responsibility.

Chapter 6 will deal with “macro” issues. The general moral position argued for in chapter 5 will be advocated in terms of policy suggestions for the public domain. In this regard possible constraints on the acceptance of stem cell research funded with public resources, particularly in the South African context, will be critically analysed. Amongst these are issues such as concerns about the safety of these technologies, power issues (i.e. what effect this research might have on power relations in society, particularly the sensitivities surrounding power in South Africa’s historical context), the role of markets and the complexities included in importing these technologies into a situation, such as that in South Africa, where there exist serious questions regarding the morality of globalisation, the accessibility of the technologies for all strata of the population, as well as, lastly, the desirability of this research in a context of severely limited resources and other financial and scientific priorities.

The problems identified under the different chapters represent the more specific goals that are to be addressed in this dissertation.

Chapter 7 will be a summative discussion in which policy recommendations on the issue of embryonic stem cell research in South Africa will be made and defended against possible rejoinders.

Benatar writes:

Given the pervasiveness of a deeply spiritual and communal world-view in Africa, and the fact that many Africans perceive most sources of modern power to be used against them (or not for their benefit) by those lacking spiritual awe for life, and by those whose political and economic decisions are focused on individualism and materialism, it is not difficult to imagine why Africans should lack confidence that the ability to alter genetic structures will suddenly be used for the benefit of all humans – including them (1999:171-172).

This study will argue for the morality of stem cell research under the discipline of clear-cut guidelines that will ensure its beneficence for (South) Africans. Although there may, rightly, be scepticism about the possible advantages of these new technologies in the African context, (South) Africa is part of the larger world and suffers, on a large scale, from diseases upon which stem cell research can have a significant impact. The dissertation will, in particular, concern itself with the moral basis for a practice about which there are wide-ranging moral concerns - concerns often born from ignorance and an unhealthy anti-science mentality. The research will hopefully contribute – if only modestly – to the rectification of this unhappy situation.

With this study I hope to show the ineffective way in which human embryonic stem cell research in South Africa is regulated. I will furthermore point out the shortcomings in current legislation with regards to stem cell research.

One of the main challenges of this study is guaranteeing an inclusive and comprehensive study of embryonic stem cell research in South Africa, whilst proposing a regulatory policy outline within the context of the legal and ethical status of the embryo. A disadvantage of undertaking this particular study is the lack of local research in the particular field; while substantial

research relating to human embryonic stem cells exists in the international context, the field is still in an “embryonic” stage in South Africa. This study resolves the problem by undertaking a study comparative to work done in the United Kingdom, currently a leader in the field of embryonic research. I will attempt to clarify the intricate issues inherent in the field through an investigation of not only the legislative, but also the ethical and clinical aspects of embryonic stem cell research. It is important to note that this study will be inter-disciplinary, covering a wide range of disciplines in an attempt to ensure an up-to-date, comprehensive and inclusive investigation of the subject at hand.

Chapter 2: The nature and possible advantages of stem cell research

The final stage is come when Man by eugenics, by prenatal conditioning, and by an education and propaganda based on perfect applied psychology, has obtained full control over himself. Human nature will be the last part of Nature to surrender to Man.
(C.S. Lewis - *The Abolition of Man* - 1987:37)

The discovery of the laws of heredity by the Augustinian monk, Gregor Mendel, in 1865, foretold the advent of the Genetic Age. With the publication of James Watson and Francis Crick's paper on their discovery together with Rosalind Franklin and the New Zealander Maurice Wilkins of the double-helical structure of the DNA molecule on April 25, 1953, a new era commenced. The 1990s saw the field of genetics developing at a tremendous pace.

One of the major achievements of the 1990s was the research published in 1993 by two American scientists, Jerry Hall and Robert Stillman, who managed to multiply 17 human embryos, ranging from the 2-cell to the 8-cell stage, to 48 embryos (Adler 1993:60). Since then many scientific news-breaking stories have contributed to ambivalent cultures of hope and mistrust. Arguably the most controversial news was a report on the birth of the first cloned mammal, Dolly the sheep, by the journal *Nature* on 27 February 1997 (Wilmut *et al.* 1997:810-813). Another historic event took place in 1998, when a team from the University of Wisconsin in Madison announced the creation of an immortal line of embryonic stem cells taken from discarded embryos donated by IVF clinics (Thomson, *et al.* 1998:1145-1157). At the same time, another group of scientists from Johns Hopkins, led by John Gearhart, reportedly isolated stem cells from embryonic germ (EG) cells taken from primordial aborted foetal tissue and cultured them (Gearhart, 1998:1061-1062).

According to The President's Council on Bioethics (PCB) (2004:109), research using human and animal stem cells is an extremely active area of current biomedical inquiry. It is contributing new knowledge about the pathways of normal and abnormal cell differentiation and organismal development, and creating the possibility of new cell transplantation therapies

for human diseases. However, as Fischbach and Ruth explain, before one can accurately evaluate the value of stem cell research; it is important to have an overview of stem cell biology (2004:1365).

“Stem cells” refer to a diverse group of remarkable multipotent precursor cells that occur in animals at all stages of their development.

“...cells that can proliferate with almost unlimited potential, maintaining a pool of growing and dividing cells, with the added ability that some of the daughter cells can differentiate into specific cell types.”

(Dr David A. Prentice (2000), Professor of Medical and Molecular Genetics, Indiana State University)

Stem cells have different properties and abilities, depending on the age of the organism and the location of the stem cells within the organism. (Chapman *et al.* 1999:1; PCB 2002:65; PCB 2004:2). Embryonic stem cells are undifferentiated and *unspecialised* (have no specific function yet), they can and do give rise to the more than 200 kinds of differentiated and *specialised* cells (muscle cells, nerve cells, skin cells, blood cells, bone cells and cartilage cells) of the body (House of Lords 2002:15; NIH 2001:1). All *specialised* cells originally arise from stem cells.

Depending on their developmental potential, cells may be called *pluripotent*, *totipotent* or *unipotent*. Cells that can produce most of the cell types of the developing body are said to be *pluripotent* (Latin: *plures* - several or many). The somewhat more *specialised* stem cells are called *totipotent* (Latin: *totus* - entire) cells and have the capacity to differentiate into embryo and into extra-embryonic membranes and tissues. *Unipotent* stem cells (Latin: *unus* - one) produce only one differentiated tissue cell type (Slack 2000:1431; PCB 2004:188).

Regardless of the fact that stem cells can be obtained from a variety of sources (which will be discussed hereafter), they all share some basic characteristics. They all have the potential of unlimited self-renewal, that is, they are able to continue dividing indefinitely without losing their genetic structure. Furthermore, they can also produce non-permanent progenitor cells with limited capacity for proliferation, from which a variety of lineages of highly differentiated cells can be derived (neural cells, muscle cells, blood cells, etc.). This is achieved by the cell

undergoing an asymmetric division which produce two dissimilar daughter cells. One is identical to the parent and continues to contribute to the original stem cell line. The other varies in some way. This latter cell contains a different set of genetic instructions (resulting in an alternative pattern of gene expression) and is characterized by a reduced proliferative capacity and more restricted developmental potential than its parent. Eventually a stem cell becomes known as a progenitor or precursor cell, committed to producing one or a few terminally differentiated cells such as neurons or muscle cells (Chapman *et al.*, 1999:1; Holland *et al.*, 2001:xviii; NIH 2001:1-3; Pontificia Academia Pro Vita 2000:1; PCB, 2004:2-5).

Stem cells will grow “indefinitely” *in vivo* (in the body). However, embryonic and some adult stem cell preparations are capable of prolonged growth beyond 50 population doublings *in vitro* (in an artificial environment outside the body) while retaining their characteristic stem cell properties and initially with no change in the chromosome numbers and structure (PCB 2004:115).

When stem cells have been extracted from the donor, they can be preserved in a laboratory setting. The practical advantages of preserving stem cell preparations by freezing are numerous. Such preservation makes it possible to repeat an experiment many times with a very similar stem cell preparation. It would also make it possible, should stem cell based therapies be developed in the future, to treat multiple patients with a common, well-characterized cell preparation derived from a single initial stem cell sample. The stem cells are preserved in liquid nitrogen at -322°F , a process known as cryopreservation, where they remain until the patient is ready/needs therapy (PCB 2004:188). Stem cells from cord blood are of special importance as they can be cryopreserved for over 15 years while retaining significant functional potency (Broxmeyer *et al.*, 2003:645).

Most specialised cells do not divide themselves but are replenished from populations of stem cells, often via intermediate less specialised cell types. Stem cells are also a potential source of new cells for the regeneration of diseased or damaged tissue and are thus central to normal human growth and development (House of Lords 2002:15).

Types / Sources of stem cells

Stem cells first arise during embryonic development and exist at all developmental stages and in many systems of the body throughout life. The human body is a stem cell “factory”, supplying an almost unlimited source of stem cells. However, the challenge lies not in locating these cells, but in isolating them from their source. Sources include adult tissues, foetal remains, placentas, umbilical cord blood and human embryos (PCB 2004:3). Due to the scope of the field, this study will focus on embryonic stem cells and adult stem cells (including umbilical cord stem cells).

a) Human embryonic stem cells

Human embryonic stem cells are special cells found in the early embryo before it begins to differentiate. Human embryonic stem cells are derived from the inner cell mass of embryos at the blastocyst stage, roughly five to nine days after fertilization—after the zygote has divided enough times to result in about 200 cells, but before it has undergone gastrulation, differentiation into the three primary germ layers and implantation into the uterine wall (Fischbach and Ruth 2004:1364; Landry and Zucker 2004:1184). At this point, human embryonic stem cells can turn into any type of cell in the human body. The sources for these ‘building blocks’ come either from human embryos, usually those from fertility clinics who are in excess of clinical need (Thomson *et al.* 1995:7844), or aborted foetal tissue (Holland 2001:77-78). It is important to notice that these human embryos were created *in vitro* in an assisted reproduction procedure; remained in storage after completion of all intra-uterine transfers requested by the mother; and have departed parental control according to instructions to the attending physician that the embryos shall be given to research and that there shall not occur any transfer to a uterus, or *ex vivo* nurture beyond a number of weeks specified in the instructions, of either the embryos or any totipotent cells taken from the embryos (Guenin 2001:1659).

The vast volume of experimental data reported in the literature with regards to human embryonic stem cells is the result of experiments done on mice and rhesus monkeys (Thomson 1995:7844-7848). Embryonic stem cells from the mouse have been studied intensively since their discovery almost 25 years ago (Evans 1981:154-156). Discussions on human embryonic

stem cells therefore assume in part that their fundamental properties will resemble those of mouse and primate embryonic stem cells (Chapman *et al.*, 1999:2). It is important to note that embryonic-like stem cells, called embryonic germ (EG) cells, can also be derived from primordial germ cells (the cells of the developing foetus from which eggs and sperm are formed), but this study will focus on human embryonic stem cells only.

Knowledge gained from human embryonic stem cells is important because they combine characteristics not found in other cell lines. Human embryonic stem cells are *pluripotent* (able to develop into many types of tissues); *immortal* (able to continue dividing indefinitely without losing their genetic structure); *malleable* (can be manipulated without losing their function); and they express the enzyme *telomerase* (which allows cells to grow and divide) (Holland *et al.* 2001:xviii).

Many opponents of embryonic stem cell research argue that the cells are not truly pluripotent. However, laboratory-based norms for testing the pluripotent nature of embryonic stem cells have reported differently. In one test, embryonic stem cells derived from the inner cell mass of one blastocyst were injected into the cavity of another blastocyst. The result was the formation of chimeras (a mixture of tissues and organs of cells) (Martin 1981:7634-7638). Research shows that human embryonic stem cells *in vitro* are capable of durable self-renewal, while maintaining a normal karyotype (normal complement of chromosomes) (Shamblott *et al.* 1998:13728; Shamblott *et al.* 2001:116). To date, several laboratories have demonstrated that human embryonic stem cells *in vitro* are pluripotent; they can produce cell types derived from all three embryonic germ layers (Amit *et al.*, 2000:275).

Because of the unique qualities mentioned, research on stem cells can lead to a better understanding of foetal developmental abnormalities and the way in which specific organs develop. It is foreseen that it will become possible to use stem cells to help detect foetal genetic abnormalities; to reduce infertility, pregnancy loss and birth defects; to aid the development of cardiomyocytes for therapy of congenital heart failure and myocardial infarctions; to find cures for insulin dependent diabetes mellitus; to assist in the treatment of neurological diseases such as Parkinson's disease, strokes and Alzheimer's disease; to repair the haematopoietic systems of cancer patients; to treat arteriosclerosis; to aid in wound healing; to develop cartilage forming cells which help those with osteoarthritis and rheumatoid arthritis; and so the list continues (Okarma 2001:6-10).

“The isolation and subsequent growth of embryonic stem cells in culture allow scientists to obtain millions of these cells in a single tissue culture flask, making something once rare and precious now readily available to researchers. It is worth noting here the striking parallel to recombinant DNA and monoclonal antibody technologies, both of which have amplified rare and precious biological entities. Like those technologies, embryonic stem cell technology may well be transformative in opening scientific arenas that to date have been closed.”

(Chapman *et al.*, 1999:2)

Securing stem cells for research, must however, be done under conditions of the most thorough truthfulness in order to defend the safety of the donors, to assure the community that significant restrictions are not being violated, to enable those who are ethically uncomfortable with elements of this research to participate to the greatest extent possible, and to assure the highest quality of research and outcomes. The President’s Council on Bioethics (2004:189) suggests guidelines for human embryonic stem cell research. For example, stem cells must have been derived from an embryo that was created for reproductive purposes; must no longer be needed for these purposes or non-viable (afflicted with a serious genetic disorder); informed consent must be obtained for the donation of the embryo and no financial inducements may be provided for donation of the embryo. Chapman *et al.* (1999:17) elaborate on these norms and suggest that (1) women should not undergo extra cycles of ovulation and retrieval in order to produce more “spare” embryos in the hope that some of them might eventually be donated for research, and (2) there should be a solid “wall” between personnel working with the woman or couple who hopes to become pregnant and personnel requesting embryos for stem cell purposes.

Before one can objectively evaluate the case of human embryonic stem cells, it is necessary to look at both the advantages and disadvantages. Vogel (2000:1674) points out that the claims of human embryonic stem cells for transplantation therapy assume that it will be possible to cultivate such cells on a large scale. However, according to Vogel, present systems fall short of this goal, since a lot is required for minimal results. For example, in a clinical trial for Parkinson's disease, foetal brain tissue from six aborted fetuses was required in order to treat a single individual (Vogel 2000:1674).

Destroying embryos is a common practice in fertility clinics and a main point of concern for opponents to embryonic stem cell research, who argue that the frequency of an activity does not in itself establish its moral permissibility (Baylis 2001:55). Opponents believe that life begins at conception, and that doing research on human embryos is unethical even where donors give their consent.

Another point of criticism is the possibility that women may be exploited by IV-attending doctors with ulterior motives who might over-stimulate a patient's ovulation cycle in order to ensure multiple embryos.

A fourth point relates to the debate about a patient's immune system. It is argued by the members of the House of Lords (2002:27) that it is possible that transplanted cells would differ in their immune profile from that of the recipient and so would be rejected. Because embryonic stem cells will not normally have been derived from the patient to be treated, there exists the risk of rejection by the patient's immune system.

Yet another point of concern, raised by the House of Lords (2002:27) is that, since embryonic stem cells have the potential to differentiate into all cell types, it might be difficult to ensure that, when used therapeutically, they do not differentiate into unwanted cell types or undergo chromosomal alterations which generate tumours.

Another potential disadvantage of the use of human embryonic stem cells for transplant therapy may be the inclination of undifferentiated human embryonic stem cells to induce the formation of tumours (*teratomas*), which are typically benign (NIH 2001:17).

Finally, James Thomson, who discovered embryo stem cells, states in his paper (Odorico *et al.* 2001:201) that "...the long population-doubling time of human embryonic stem cells makes it difficult to envision this becoming a routine clinical procedure..."

Proponents of human embryonic stem cells identify the advantages of using human embryonic stem cells in therapy as flexibility, immortality and ease of availability. Human embryonic stem cells are also pluripotent. Haematopoietic adult stem cells, for example, can be removed from bone marrow or blood and cultured in a laboratory; however, the cells eventually cease dividing and no longer self-renew under these conditions. In contrast, human embryonic stem

cells have been grown continuously in laboratory conditions for over two years without losing their ability to self-renew or to form all cells and tissues of the body (Okarma 2001:5).

Since they are pluripotent, human embryonic stem cells can be produced in large quantities in the laboratory under standard conditions. This is an important advantage over adult progenitor cells extracted from an individual, which are present in very low quantities. Human embryonic stem cells can be cultured and multiplied, in principle indefinitely, and can be induced to differentiate into a wide range of different cell types - skin, heart muscle, nerve cells, etc. - using special chemical treatments. This opens up a possibility to create replacement cells to inject into patients suffering from a wide range of diseases which cause irreversible cell degeneration, like Parkinson's, some heart conditions and diabetes. Although in its earliest phases, research with human embryonic stem cells is proving to be important in developing innovative cell replacement strategies to rebuild tissues and restore critical functions of the diseased or damaged human body.

One in every six couples in America suffer from infertility problems, 15% of pregnancies are premature, 3% of live births are characterised by birth defects (Okarma 2001:6), 58 million Americans suffer from cardiovascular disease, 30 million from auto-immune diseases, 16 million have diabetes and 5.5 million Parkinson's disease (Perry 2000:1423). A thorough knowledge of developmental biology and developmental events is critical if one looks at these statistics, and a study of human embryonic stem cells will serve to facilitate understanding of the diseases involved and will advance possible cures. It would be possible to obtain an understanding of how specific tissues and organs develop without conducting direct research on human embryos or foetuses.

Okarma (2001:6) also points out that genes that fundamentally control tissue differentiation may be identified by applying genomic technologies to cultured human embryonic stem cells as they differentiate "and grow into a variety of cell types". Identification of genes that control normal tissue differentiation could lead to sensitive and comprehensive prenatal diagnostic approaches with which to detect foetal genetic abnormalities, reducing infertility, pregnancy loss and birth defects.

More evidence of the usefulness of research on human embryonic stem cells can be found in various studies. Foetal neural stem cells, isolated in the foetal brain, have been effectively

applied in rat models of Parkinson's disease (Sawamoto *et al.* 2001:3895-3903; Studer *et al.* 1998:290). Tissue derived from the foetal pancreas has been found to stimulate insulin production when transferred into diabetic mice (Beattie *et al.* 1997:247). Similarly, research also suggests that embryonic stem cells from mice can be transplanted into animals that have spinal cord injuries and to a degree restore neural function (McDonald *et al.*, 1999:1410). In yet another experiment by Schuldiner and his team (2000:11307), cells arising from human embryonic stem cells expressed genes related to liver and pancreas function. *In vitro* studies of human embryonic stem cells also present the possibility (Schuldiner *et al.*, 2000:11309) of investigating the role of biochemicals created in the normal cellular milieu in provoking stem cells to differentiate, to migrate to a location needing repair and to assimilate into tissues. These findings underwrite the promises of regenerative medicine.

Although adult stem cells may be less controversial and entangled with fewer ethical concerns, strong evidence suggests that the prospect of adult stem cell research and its therapeutic application is unlikely to be realised without research on human embryonic stem cells, which can be studied for their ability to differentiate and dedifferentiate. These qualities have been illustrated by research done on the embryonic stem cells of mice (as mentioned earlier). Most future studies probably can and will be undertaken using embryonic stem cells from mice (or other animals). Nevertheless, if safe and reliable therapies are to be developed, a comparison with human embryonic stem cells must eventually be made (House of Lords 2002:30).

As the members of the House of Lords (2002:31) conclude in their report:

To date, it is impossible to predict which stem cells—those derived from the embryo, the foetus or the adult—will best meet the needs of basic research and clinical applications. The answers clearly lie in conducting more research.

It is important to take note of recent developments in laboratories (such as Advanced Cell Technology, where research is headed by Dr Robert Lanza) where biologists have seemingly developed a technique for establishing colonies of human embryonic stem cells from an early human embryo without destroying it, as reported on the website of the journal *Nature* (Wade 2006:1).

The latest technique, according to Wade (2006:1), would be performed on a two-day-old embryo, after the fertilized egg has divided into eight cells, known as blastomeres. The embryo,

now with seven cells, can be implanted in the woman if no defect is found. Many such embryos have grown into apparently healthy babies over the 10 years or so the diagnostic tests have been used.

The above only became public knowledge a few weeks ago, and I am therefore not in a position to give a well researched opinion thereon. As such I will hold that the embryos will still be destroyed when their stem cells are harvested, which will form the basis of all discussions to follow.

b) Adult stem cells

An adult stem cell is an undifferentiated cell found amid differentiated cells in a tissue or organ, throughout the mature animal, which can restore itself, and can differentiate to generate the main *specialised* cell types of the tissue or organ. The prime function of adult stem cells in a living organism is to sustain and repair the tissue in which they are found (Prentice 2004:309), or to maintain a state of homeostasis. For example, haematopoietic stem cells are constantly being generated in the bone marrow where they differentiate into mature types of blood cells which can replace blood cells (Domen and Weissman 1999:201-208). Another example is the well-known therapy of stem cell transplant (a form of a bone marrow transplant) for cancer patients. In this therapy, stem cells that can give rise to blood cells (red and white cells, and platelets) are given to patients to restore tissue destroyed by high quantities of chemotherapy or radiation therapy.

Stem cells are thought to reside in a specific area of each tissue where they may remain quiescent (non-dividing) for many years until they are activated by disease or tissue injury. The adult tissues reported to contain stem cells include the brain, bone marrow, peripheral blood, blood vessels, skeletal muscle, skin and liver. Prentice (2004:309) states that the possibility that the human body contains cells that can repair and regenerate damaged and diseased tissue has gone from an unlikely possibility to an almost certainty within just a few years.

The phrase “adult stem cell” is to some extent unsuitable, because the cells are present even in infants and similar cells can be found in the umbilical cord and the placenta. More accurate terms have been proposed, such as “tissue stem cells”, “somatic stem cells”, or “post-natal stem

cells” (PCB 2004:10). However, because of common usage of this terminology this study will continue to use the term “adult stem cell”.

As with embryonic stem cells, most of the knowledge about adult stem cells comes from studies on mice. Scientific reports on stem cells in the organs of adult mice - including brain, muscle, skin, digestive system, cornea, retina, liver and pancreas - have cast a new light on the body’s own capability to replenish its tissues. The record of adult tissues reported to contain stem cells is growing (it seems almost by the day) and includes bone marrow, peripheral blood, brain, spinal cord, dental pulp, blood vessels, skeletal muscle, epithelia of the skin and digestive system, cornea, retina, liver and pancreas. However, it is important to keep in mind that, when comparing mouse and human haematopoietic stem cells (HSC), only about half of the genes expressed in mouse haematopoietic stem cells match genes expressed in human haematopoietic stem cells (Phillips *et al.* 2000:1635-40). Even the genetic predisposition that directs the differentiation of human foetal liver stem cells and human haematopoietic stem cells, both of which develop into the components of blood, appear to be quite diverse (Phillips *et al.* 2000:1638). A more in-depth study of the differences between mouse and human stem cells is therefore necessary.

There are numerous reasons for using adult stem cells as opposed to human embryonic stem cells. Apart from the moral justification mentioned earlier (the alleged sanctity of the human embryo), adult stem cells are naturally located to produce a specific tissue. Some adult stem cells are also known to secrete growth factors that activate or defend other cells existing in the tissue that could enhance the beneficial effects of the transplant (Noble 2000:12393). Thirdly, some stem cells are able to migrate to damaged tissue. This was illustrated by Aboody and his team (2000:12847), who demonstrated the migration of neural stem cells to tumour sites in the brain of a rat.

The belief that countless diseases may in the future be treated with stem cell therapy is motivated by the success of bone marrow transplants in the treatment of patients with leukaemia and other cancers, inherited blood disorders, and diseases of the immune system (Thomas and Blume 1999:341).

However, it is frequently difficult - if not impossible - to differentiate adult, tissue-specific stem cells from progenitor cells (cells which give rise to other cells, but are not able to develop

into all the cell types of a tissue). It is, in fact, one of the main points of criticism against adult stem cells that they are hard to isolate (only one in 10,000 bone marrow cells are successfully isolated). Other points of criticism include their limited proliferation potential and limited range of cells they can be differentiated into (McKay 2000:361).

In order to fully comprehend the usage and viability of adult stem cells as a source for research material, it is important to understand the concepts of differentiation and plasticity more clearly.

Adult stem cells are present in many tissues and can differentiate and form particular cell types of the tissue in which they exist. When stem cells start to differentiate, they begin by first giving rise to a more specialised kind of stem cell - the “precursor cells” or “progenitor cells”, which are partly differentiated. These precursor cells in turn either proliferate through self-renewal or produce fully specialised or differentiated cells (Robey 2000:1489, PCB 2004:112).

Once an adult stem cell has fully differentiated into “daughter” cells, these daughter cells contain mature phenotypes (all the observable characteristics of a cell - its morphology; interactions with other cells and the non-cellular environment; proteins that appear on the cell surface; and the cell’s behaviour) which are fully incorporated into the tissue, and are capable of specialised functions that are suitable for the tissue (NIH 2001:25).

The bulk of research has been done on the “normal” differentiation patterns of specifically located adult stem cells. Examples include *haematopoietic stem cells* which give rise to all the kinds of blood cells; *bone marrow cells* which can turn into a variety of cell types such as bone cells, fat cells, cartilage cells and other kinds of connective tissue cells; *neural stem cells* which give rise to nerve cells (neurons) and two categories of non-neuronal cells (astrocytes and oligodendrocytes); *epithelial stem cells* (in the lining of the digestive tract) which give rise to numerous cell types, such as absorptive cells, goblet cells, Paneth cells and enteroendocrine cells; and lastly, *skin stem cells* which give rise to keratinocytes.

Adult stem cells were initially thought to be limited to the generation of differentiated cells which were specific to the organ from which they were isolated. Research conducted by Galli and his team (2000:986-991) shows, however, that adult stem cells can be motivated to form other cell types in specific situations. Adult stem cells demonstrate the ability, known as

plasticity, to form specialised cell types of other tissues. Many plasticity experiments involve stem cells which originate from bone marrow (Brazelton *et al.*, 2000:1775-1779; Lagasse *et al.* 2000:1229-1234; Petersen *et al.* 1999:1168-1170) and the brain (Bjornson *et al.* 1999:534-537; Clarke *et al.* 2000:1660-1663). Bone marrow stem cells can also differentiate into other tissue, such as skeletal muscle (Ferrari *et al.* 1998:15230), cardiac muscle (Orlic *et al.* 2001:705) or liver tissue (Alison *et al.* 2000:257).

The differentiated cell types which are the products of plasticity usually share the morphological characteristics of the differentiated cells and display their characteristic surface markers. A few studies (Brazelton *et al.* 2000:1778; Mezey *et al.* 2000:1779) show that transplanted adult stem cells demonstrate plasticity *in vivo*. However, there is inadequate proof that adult stem cells can restore lost function *in vivo* (Lagasse *et al.* 2000:1234). This study intends to gain a better understanding of the process which allows adult stem cells to have plasticity. If the process can be recognised and controlled, existing stem cells from healthy tissue might be induced to repopulate and repair diseased tissue.

Growing evidence suggests that reservoirs of stem cells may reside in several types of adult tissue. These cells may retain the potential to differentiate from one phenotype into another, and may exhibit the characteristic of plasticity, thereby presenting exciting possibilities for cellular based therapies (Safford and Rice 2005:57).

Prentice (2004:314-328) lists over twenty possible types of adult stem cells. However, for the purpose of this study only the major possible sources will be discussed.

The most common and widely studied adult stem cells are located in the bone marrow. Bone marrow contains at least two (Jiang *et al.* 2002:41; Pittenger *et al.* 1999:143) stem cell sources, namely haematopoietic stem cells (which produce blood and related cells) and mesenchymal cells (which form connective tissue lineages, such as bone, cartilage and adipose tissues). Mesenchymal cells have been identified as having tissue repairing cells characteristics (Bianco *et al.* 2001:180). These cells contribute to numerous tissues after transplantation into a new host (Palermo *et al.* 2005:336).

Many studies (Ferrari *et al.* 1998:1528; Lange *et al.* 2005:71; Long *et al.* 2005:65; Mezey *et al.* 2000:1779; Pittenger *et al.* 1999:143; Sanchez-Ramos *et al.* 2000:247; Woodbury *et al.*

2000:364) have shown that mesenchymal stem cells have the ability to differentiate *in vitro* into a range of cell lineages, including neuronal tissue, bone, cartilage, muscle tissue and fat lineages, and have the ability to repair damaged renal tubules in the kidneys (Kale *et al.* 2003:42). Recent description of mesenchymal stem cells and their role in haematopoiesis and immune modulation suggest that their potential for cell therapy extends beyond their traditional accessory function in haematopoietic stem cell engraftment (El-Badri *et al.* 2004:463). Mesenchymal stem cells contribute significantly to tissue restructuring and immune functioning, in addition to facilitating durable, long-lasting stem cell engraftment. They are also relatively easy to obtain and expand in *in vitro* cultures, rendering them a prime candidate for genetic manipulations for stem cell therapy. They have the potential to differentiate into multiple lineages such as osteoblasts, adipose tissue, cartilage, tendon and stromal cells (El-Badri *et al.* 2004:463).

Recent studies (Gulbins *et al.* 2002:E28; Leone *et al.* 2005:1196) suggest that the administration of bone marrow-derived stem cells might improve myocardial perfusion and left ventricular (LV) function after acute myocardial infarction, since myocardium cells cannot be regenerate because cardiac muscle cells do not re-enter the cell cycle. Spontaneous mobilisation of bone marrow stem cells occur, following a primary percutaneous intervention. Therefore, a reduced myocardial function can be improved by cell transfer therapy (Schwartz and Kornowski 2003:237). Stem cell-derived cardiomyocytes in particular, of bone marrow cell origin, would allow for selective replacement of pacemaker cells or arterial or ventricular cardiomyocytes (Gulbins *et al.* 2002:E34).

Rare bone marrow stem cells have been isolated in the peripheral blood system (Kessinger and Sharp 2003:319), making it possible to have more bone marrow stem cell therapies, for example for treating stroke and cardiac victims (Orlic *et al.* 2001:10344; Willing *et al.* 2003:449).

Three more main categories of stem cells can also be found in the nervous system namely nerve cells proper (neurons), and two kinds of supporting cells (oligodendrocyte and astrocyte). Stem cells, especially from the olfactory bulb, lining of the ventricles and the spinal cord (Shihabuddin *et al.* 2000:8727; Zhu *et al.* 2005:97), are able to differentiate into one or more neural cell lineages (Pagano *et al.* 2000:295). Many authors (Bjornson *et al.* 1999:534, Galli *et*

al. 2000:986, Galli *et al.* 2003:598) also found that neural stem cells can differentiate into other tissue - for example blood and muscle tissue - when stimulated to divide.

A team from South Korea (Chu *et al.* 2003:129) also recently demonstrated that transplanted human neural stem cells differentiate into mature neurons to replace lost neural cells in the adult hippocampus. This can dramatically influence the therapies devised for the treatment of Parkinson's disease, Alzheimer's and other degenerative neurological diseases (Safford and Rice 2005:57). However, the usage and possible potentiality of human neural stem cells are still not fully comprehended and earnest studies around the globe aim for better understanding and application.

However, the success of the Edmonton Protocol for islet transplantation has provided new hope in the treatment of type 1 diabetes - a debilitating condition which affects millions world-wide, and which is characterised by the auto-immune destruction of insulin-producing pancreatic islets of Langerhans (Ryan *et al.* 2004:710; Street *et al.* 2004:667). Ryan and his team (2001:710) transplanted cadaveric pancreatic islets into patients, offering the prospect of good glycaemic control without major surgical risks. It is important to note (Street *et al.* 2004:3107) that a significant positive correlation was observed between the number of islet progenitor cells transplanted in the Edmonton study and long-term metabolic success as assessed at 2 years post-transplant assessments.

However, in order for islet transplantation to become a widely used technique, an alternative source of cells must be identified to supplement the limited supply currently available from cadaveric donor organs (Street *et al.* 2004:667).

Muscle tissue contains satellite cells (Brzoska *et al.* 2004:723) which normally participate in the replacement of myoblasts (undifferentiated cells capable of giving rise to muscle cells) and myofibers. The formation of bone and the repair of bone defects require a source of pluripotential mesenchymal stem cells. However, the capacity of the human body to generate bone components is limited. Sun and his colleagues (2005:3953) demonstrate that myogenic cells, on the other hand, have the capacity to differentiate into osteogenic (bone-forming tissue) lineage *in vitro*.

There are also indications (Tsuboi *et al.* 2005:317) that muscle may contain other stem cells - either haematopoietic migrants from bone marrow, or intrinsic stem cells from muscle tissue. Although haematopoietic stem cells are rare in muscle, they nonetheless occur approximately four times more often in muscle than in peripheral blood. (Tsuboi *et al.* 2005:317). This could contribute to therapies used in repairing cardiac damage (Gulbins *et al.* 2002:E28; Leone *et al.* 2005:1196; Schwartz and Kornowski 2003:237; Schwartz and Kornowski 2003:237). Another characteristic of stem cells derived from muscle tissue which make them useful in therapies, is their ability to renew muscle tissue suffering from physiological stresses (Palermo *et al.* 2005:336; Poleskaya *et al.* 2003:841).

Corneal limbal stem cells are present in the cornea which provides the eye with protection and the refractive properties essential for visual acuity (Daniels *et al.* 2001:483). The past two decades have witnessed remarkable progress in limbal stem cell transplantation. In addition to harvesting stem cells from a cadaver or a live related donor, it is now possible to cultivate limbal stem cells *in vitro* and then transplant them onto the recipient bed (Fernandes *et al.* 2004:5). The importance of limbal stem cells in the maintenance of the corneal epithelium has long been recognised, and such cells are now used clinically in the repair of a severely damaged cornea (Boulton and Albon 2004:643).

Limbal stem cell deficiency through ocular trauma or diseases causes corneal opacification and visual loss (Nishida *et al.* 2004:379). Ocular surface disease arising from limbal stem cell deficiency is characterised by persistent epithelial defects, corneal vascularisation, chronic inflammation, scarring and conjunctivalisation, resulting in visual loss. Limbal stem cell transplantation replaces the corneal stem cell population in these eyes with the hope of restoring vision (Ang and Tan 2004:576).

Tissue engineering of the cornea represents a paradigm shift in medical treatment to overcome the present disadvantages of corneal transplantation, primarily immune rejection and the shortage of donor corneas. Transplantation of cultivated corneal epithelial cells expanded *ex vivo* from corneal epithelial stem cells, has been developed and already forms part of the clinical sphere (Nishida 2003:S28). Recent studies indicate that corneal epithelial stem cells reside preferentially in the basal layer of peripheral cornea in the limbal zone, rather than uniformly in the entire corneal epithelium (Nagasaki and Zhao 2005:126; Sun and Lavker 2004:202).

In recent years there has been increasing progress in identifying stem cells from adult tissues and their potential application in tissue engineering. With the recent isolation of stem cells from human adult dental pulp (Shi and Gronthos 2003:696), these advances provide a promising future for tooth replacement / regeneration. Essential for this approach is the identification of donor stem cells for various components of the teeth (Mina 2004:120).

Miura and colleagues (2003:5807) were the first to identify a population of highly proliferative, clonogenic cells capable of differentiating into a variety of cell types, including neural cells, adipocytes and odontoblasts. They called these multipotent cells SHED (stem cells from human exfoliated deciduous teeth). It was found that SHED are able to induce bone formation and generate dentin after *in vivo* transplantation (Miura *et al.* 2003:5807). SHED are not only derived from a very accessible tissue resource but are also capable of providing enough cells for potential clinical application. Thus, exfoliated teeth may, as Miura *et al.* (2003:5807) and Kamata (2004:417) explain, be an unexpected unique resource for stem cell therapies, including autologous stem cell transplantation, tissue engineering, regeneration of dental and periodontal tissues and various diseases such as odontogenic tumours.

In the words of Chai and Slavkin (2003:469), “The prospects for tooth regeneration in the 21st century are compelling.”

While most of the work conducted on adult stem cells has focused on mesenchymal stem cells found within the bone marrow, one of the more exciting discoveries identified adipose (fat) tissue as a great source for human stem cells. There is some debate as to whether the cells originate in the fat tissue or are perhaps mesenchymal or peripheral blood stem cells passing through the fat tissue. Whatever the answer, these cells represent a readily available source for isolation of potentially useful stem cells (Prentice 2004:326; Zuk *et al.* 2002:4279).

In addition to mesodermal (adipose, cartilage, muscle and bone tissue) capacity, adipose derived stem cells differentiate into putative neurogenic cells, exhibiting a neuronal-like morphology and expressing several proteins consistent with the neuronal phenotype (Zuk *et al.* 2002:4279). Since these stem cells are readily available, they have great potential for cellular therapies (Safford *et al.* 2002:371).

Recent research has reported that adipose tissue contains a population of cells with the ability to differentiate into different cell types, including adipocytes, osteoblasts, myoblasts, chondroblasts and even cardiomyocyte progenitors (revealing the presence of ventricle- and atrial-like cells) (Miranville *et al.* 2004:349; Planat-Bénard *et al.* 2004:223). Furthermore, stem cells with multi-lineage potential at the single cell level have been isolated from human adipose tissue. These cells have been cultivated in culture and, interestingly, maintain their characteristics with long-term passaging (Rodriguez *et al.* 2005:125; Safford and Rice 2005:57).

Adipose derived stem cells from adipose tissue is also an additional source of unique, pluripotent stem cells with multi-germline potential (Zuk *et al.* 2002:4280). Just one of the many success stories which resulted from the application of adipose stem cells, is the case of a 7-year-old girl suffering from widespread calvarial (an incomplete skull; especially the portion of a skull including the braincase and excluding the lower jaw or lower jaw and facial portion) defects after severe head injury (Lendeckel *et al.* 2004:370). Chronic infection resulted in an unstable skull with marked bony defects. Two years after the initial injury the calvarial defects were repaired. Autologous adipose derived stem cells were processed and applied to the calvarial defects in a single operative procedure. The stem cells were kept in place using autologous fibrin glue. The postoperative course was uneventful and CT-scans showed new bone formation and near complete calvarial continuity three months after the reconstruction (Lendeckel *et al.* 2004:370).

A special group of cells that needs a special mentioning is umbilical cord blood stem cells, a type of non-embryonic stem cell. Previously considered a waste product, umbilical cord blood stem cells / cord stem cells can be collected from both vaginal deliveries and caesarean sections, either *in utero* or *ex utero*, at no risk to the donor; processed to remove excess plasma and red cells; cryopreserved (for over 15 years); tested; and stored to provide an 'off-the-shelf' product (Broxmeyer *et al.* 2003:645; Wagner 1997:187; Warwick and Armitage 2004:995).

The first known attempt at cord blood stem cell transplant occurred over 30 years ago when a 16-year-old boy with acute lymphoblastic leukaemia received cord blood units from 8 different donors. Umbilical cord blood is now accepted as an alternative source of haematopoietic stem cells for transplantation in children (Chao *et al.* 2004:354; Dhot *et al.* 2003:989). Interest in

umbilical cord blood as an alternate source of haematopoietic stem cells is growing rapidly. Umbilical cord blood offers the clinician a rich source of haematopoietic stem cells that is readily available and rarely contaminated by latent viruses (Gluckman 1995:413; Gluckman 1996:166; Lee *et al.* 2004:273; Rogers and Casper 2004:893; Romanov *et al.* 2003:105; Wagner 1997:187).

Cord blood stem cells are a unique product, used in the transplantation setting to restore haemopoiesis. It restores haematopoietic stem cell function in patients suffering from malignancies and non-malignant diseases, bone marrow failure disorders, inherited metabolic and immunological disorders, acute leukaemia and post-traumatic and hereditary diseases of the central nervous system (Chao *et al.* 2004:354; Gluckman 1995:413; Gluckman 1996:66; Sanchez-Ramos 2002:880; Rocha *et al.* 2004:375; Rocha *et al.* 2004:2276; Warwick and Armitage 2004:995). Related and unrelated cord blood stem cell donations have been successfully transplanted in both the paediatric and adult settings (Warwick and Armitage 2004:995).

Cord blood stem cell transplants present a multitude of advantages. Not only do they have a lower risk of some important viral infections (particularly cytomegalovirus) and a lower incidence and severity of acute and chronic graft versus host disease (GvHD), but they are easily available, involve a non-invasive collection procedure and carry no risk for mothers and donors (Chao *et al.* 2004:354; Dhot *et al.* 2003:989; Gluckman 1995:413; Gluckman 1996:166; Laughlin *et al.* 2004:2265; Warwick and Armitage 2004:995).

Cord stem cells are a population of multipotential cells that can proliferate and differentiate into multiple mesodermal tissues, including bone, cartilage, muscle, ligament, tendon, fat and stroma (Kim *et al.* 2004:733). Furthermore, research shows (Kakinuma 2003:217; Rogers and Casper 2003:25; Rogers and Casper 2004:893; Sanchez-Ramos 2002:880) that cord stem cells also have the potential to generate non-haematopoietic cells, such as neural, hepatic and endothelial cells.

Cord blood stem cell banks have been established world-wide to supply haematopoietic stem cells for related and unrelated donors. Currently, more than 65,000 units are available and more than 2500 patients have received transplants of cord blood (Dhot *et al.* 2003:989; Rogers and Casper 2004:893; Warwick and Armitage 2004:995). It has been proposed that individually

banked cord blood cells may, at some later time, offer a good match for a patient needing stem cell-based treatments, whether the individual cord-blood-donor himself or a close relative, and in unrelated recipients may require a less exact genetic match than adult bone marrow (Chao *et al.* 2004:354).

Adult stem cells present a resourceful means for gene therapy claims through their proliferative abilities. Adult stem cells have been successfully used in the treatment of patients with genetic diseases. One example is where bone marrow stem cells from newborns with a range of severe combined immunodeficiency (SCID) syndromes were isolated from the patients. A functional gene was introduced and the newly engineered cells were implanted into the same patients, with great success (Aiuti *et al.* 2002:2410-2413; Cavazzana-Calvo *et al.* 2000:669–672).

The use of adult stem cells not only side-steps legal and ethical issues, but also solves the problem of immunological rejection. A patient's body is more likely to accept newly introduced adult stem cells which are taken from the patient and cultivated. Viral or bacterial infections are also limited. The use of adult stem cells, for example the isolation of haematopoietic stem cells from bone marrow, is already commonly used. Another positive attribute of adult stem cells is the fact that they are already specialised and therefore it may be easier to stimulate them into becoming other tissue.

Woodbury and his team (2000:364) discovered that bone marrow stromal cells have the ability to develop into liver or nerve tissue, and that adult stem cells by and large contain “indiscriminate potential”. Several articles in respected journals share similar success stories with regard to the use adult stem cells. Examples include the usage of adult stem cells, chemotherapy, surgery and irradiation in the successful treatment of patients with advanced neuroblastoma (Kawa *et al.* 1999:3216); the usage of a combination of adult stem cells and chemotherapy in the successful treatment of breast cancer (Stiff *et al.* 2000:2169); and the usage of chemotherapy and adult stem cells in the successful treatment of patients with solid tumours (Aghajanian *et al.*, 1999:2198).

The study field of stem cell research has seen progressive development and results. Great advances were announced in 2000 (Magavi *et al.* 2000:951; Woodbury *et al.* 2000:364) when it was established that brain cells can be re-grown *in vivo* without any surgery. Another achievement in 2000 was the discovery that by motivating production and differentiation of

endogenous neuronal mice stem cells, mice with Parkinson's were doing well (Fallon *et al.* 2000:14690). Three years later similar results were established in human subjects (Gill *et al.* 2003:589).

The existing data on adult stem cells is increasing daily and the potential of adult stem cells to influence medicine is vast. However, obtaining large numbers of stem cells for research purposes is much more difficult with adult stem cells - as opposed to embryonic stem cells - as source. It seems highly unlikely that adult stem cells alone can supply all of the cell types necessary for most clinical research. Adult stem cells can by large only complement, but not replace, therapies that may be achieved from embryonic stem cells.

Additionally, isolating homogeneous adult stem cells presents a challenge, not only because of their location, e.g. neural stem cells in the brain, but also because they appear in low quantities throughout tissue. Adult stem cells are also finite (i.e. they can't live as long in a culture *ex vivo*), which influences their ability to proliferate.

Further points of criticism, raised by proponents of embryonic stem cells, is that adult stem cells may actually be carriers for damaging genetic mutation or alteration for disease, or that they may become defective during experimentation (House of Lords 2002:28). Lastly, it is argued that the control and safety of dedifferentiation presents a major challenge about which little is yet known.

Usage of stem cells

With more than 4,000 registered diseases linked to genetic abnormalities, it is only fitting to elaborate on some of the achievements the isolation of human embryonic stem cells and adult stem cells has had in medicine.

Many human diseases, such as Parkinson's, some heart failure conditions, leukaemia and diabetes, involve irreversible cell degeneration. However, a few medical disorders are caused by a mutation of one gene alone (e.g. Huntington's disease). The vast majority of medical conditions with some genetic link involve either the complex interaction of a number of genes or the interaction of genes and environment (called multi-factorial conditions). Common medical problems that are multi-factorial include heart disease, hypertension, psychiatric

illness, dementia, diabetes and cancer – in these cases the genes may indicate a predisposition to the medical problem but environmental factors will influence if and when the problem will emerge, and how serious it will be (Legal Information Access Centre 2002).

To make more concrete the advantages and developments in the treatment of the above-mentioned diseases, the next section will focus on neurodegenerative diseases, auto-immune diseases and cardiovascular diseases in general. Numerous advances have been made in various fields of research, including areas related to cancer, spinal cord injuries, cystic fibrosis and even neurological disorders. This study will, however, focus only on the three categories mentioned.

a) Neurodegenerative diseases

Damage to the central nervous system was once considered irreparable. However, there now exists growing optimism that neural transplant therapies (such as the transplantation of cells and tissues to the mammalian brain and central nervous system) may one day enable complete circuit reconstruction and thus functional benefit for patients with neurodegenerative conditions (Sayles *et al.* 2004:321). Clinical cell transplant trials have already been performed for Parkinson's disease, Huntington's disease, demyelinating diseases, retinal disorders, stroke, epilepsy and even deafness (Barker and Widner 2004:472). This discussion will review some of the neurodegenerative diseases investigated and treated by stem cell therapy, focusing particularly on Parkinson's disease (PD), Huntington's disease (HD) and Amyotrophic lateral sclerosis (motor neuron disease)(ALS).

Many nervous system diseases result from loss of nerve cells. Mature nerve cells cannot divide to replace those that are lost. Thus, without a “new” source of functioning nerve tissue, no therapeutic possibilities exist. In Parkinson's disease, the neurons, which connect the substantia nigra to the striatum (composed of the caudate nucleus and the putamen) and produce the chemical transmitter dopamine, die. Cerebral dopamine depletion is therefore the hallmark of Parkinson's disease (Hermann *et al.* 2004:131; Hoglinger *et al.* 2004:726; Roitberg *et al.* 2004:355; Roybon *et al.* 2004:261).

One of dopamine's major roles is to regulate the nerves that control body movement. As Parkinson's disease progresses, less dopamine is produced, leading to movement difficulties

(NIH 2001:81) characterised by motor symptoms such as bradykinesia, rigidity and tremors (Roybon *et al.* 2004:261).

Since the late 1980s hundreds of patients with Parkinson's disease have received allografts of dopamine-rich foetal tissue. The grafted tissue has been shown to survive and ameliorate many of the symptoms of the disease, both in the clinical setting and in animal models of the disease (NIH 2001:81).

The motivation behind the use of cells as therapeutic modalities for neurodegenerative diseases in general, and in Parkinson's disease in particular, is that they advance patient functioning by restoring the damaged cell population. It is argued that these cells will survive, grow neurites, establish functional synapses, integrate best and durably with the host tissue mainly in the striatum, renew the impaired wiring, and lead to meaningful clinical improvement. To increase the generation of dopamine, researchers have already transplanted non-neuronal cells. Recent studies on embryonic and adult stem cells have demonstrated that these cells are able to both self-renew and produce differentiated tissues, including dopaminergic neurons (Freed *et al.* 2001:710; Kim *et al.* 2002:50; Levy *et al.* 2004:353; Takagi *et al.* 2005:102; Zhao *et al.* 2003:7925).

However, the logistical, technical and ethical problems involved in recovering enough developing dopamine neurons from foetal tissue are great and have limited the application of this therapy (NIH 2001:82; Takagi *et al.* 2005:102).

Embryonic stem cells can be kept in culture in a completely undifferentiated state. They are still capable of becoming not just nervous system cells but every cell type in the body. If researchers want to be able to implant cells derived from undifferentiated embryonic stem cells, they must take care that no cells in the mix give rise to unwanted cell types, such as muscle or bone, within the nervous system. Stem cells from other tissues - including umbilical cord blood and human bone marrow (Chen *et al.* 2001:2682) - can also be coaxed to display many of the surface-protein "markers" characteristic of nervous system cells. It is not yet clear, however, whether these cells are capable of giving rise to fully functional neurons. A great deal of basic research remains to be done to find which of these cells provide the best means to obtain a workable therapy for Parkinson's disease (NIH 2001:83).

Another neurodegenerative disease namely motor neuron disease or amyotrophic lateral sclerosis (ALS) (known as Lou Gehrig's disease in the United States and Charcot's disease in Europe) affects nerve cells found in the brain and spinal cord (Veldink *et al.* 2004:491). The tissue in the motor tracts of the lateral columns and anterior horns of the spinal cord thickens, resulting in progressive muscle atrophy (decrease in size of tissue due to a disease) that starts in the limbs and eventually results in total muscle paralysis.

Amyotrophic lateral sclerosis (ALS) is the most frequent paralytic disease of adults. It is untreatable and invariably fatal, with almost 20% of all cases inherited (Grieb 2004:239). With the lack of effective drug treatments for ALS, and compelling preclinical data, stem cell research has highlighted this disease as a candidate for stem cell treatment. Stem cell transplantation is an attractive strategy, especially in the light of early successes in animal models of neurodegenerative disease (Kerr *et al.* 2003:5131; Silani *et al.* 2004:200).

It has recently been shown in animal models of ALS that stem cells significantly slow the progression of the disease and prolong survival. Mesenchymal stem cells transplanted into the spinal cord of humans have been found safe and the research furthermore showed that it was well tolerated by ALS patients (Mazzini *et al.* 2003:158). Liu and Martin (2004:1479) found that the adult mammalian olfactory bulb is a source of pluripotent neural stem cells and progenitor cells that have the potential to become, in a context-dependent manner, specific types of cells for regeneration of tissues in brain, spinal cord and muscle. It is therefore an ideal source of stem cells for the treatment of ALS.

b) Cardiovascular diseases

Cardiovascular disease is the leading cause of death in the United States, taking the lives of more people each year than the next five leading causes of death combined (Ludwig and Thomson 2004:285). Although not the leading cause of death in South Africa (Statistics South Africa 2005:27), cardiovascular disease is on the rise in South Africa (Schutte *et al.* 2004:161), especially hypertension, which commonly leads to stroke. Vorster (2002:239) states that the mortality rate from cardiovascular disease in South Africa confirms that stroke is a major public health problem amongst black South Africans, possibly because of an increase in hypertension, obesity and smoking habits. However, authors such as Bovet (2002:717) and Kahn and Tollman (1999:63) point out that the population of rural South Africa is undergoing a

health transition from predominantly infectious diseases to non-communicable diseases, particularly vascular disease.

For the purpose of this study the focus will fall specifically on the advances made in the field of cardiovascular disease by utilising stem cells in the treatment of cardiac diseases and acute cerebral infarctions. Myocardial infarction is the leading cause of heart failure in developed countries (Davani *et al.* 2005:305; Lee and Makkar 2004:729). The heart is perceived as an incurably differentiated organ, which is incapable of regeneration (Kh and Ashraf 2005:99). Furthermore, adult heart tissue cannot be expanded in culture and thus there are no human heart cell lines available for research. The limited amount of physiological research done directly on human heart cells has generally relied on biopsy samples, which are small, available erratically and usually obtained from diseased hearts (Ludwig and Thomson 2004:285).

When heart cells die in a heart attack, it is not because the heart cells themselves are flawed, but because the blood supply is cut off. Thus, for new heart cells to be successful, they need to integrate functionally with the surrounding heart cells, obtain a new blood supply and avoid immune rejection (Itescu *et al.* 2003:288; Ludwig and Thomson 2004:286).

Because of their ability both to replace and/or repair damaged tissue, stem cell therapy provides an ideal means to improve therapy for cardiac disorders associated with heart muscle injury (Semsarian 2002:259). Since the heart is a mesodermally-derived organ, it is a likely contender for regeneration with bone marrow derived stem cells. Numerous studies have mentioned the capacity of bone marrow derived adult stem cells to contribute to regeneration of cardiac tissue after an infarction (Jain *et al.* 2005:93; Itescu *et al.* 2003:288; Kh and Ashraf 2005:99). As Timmermans *et al.* (2003:176) points out, bone marrow stem cells could hold the answer to restoring myocardial infarctions and preventing post-infarct congenital heart failure, since they are able to produce new cardiomyocytes in animals and humans.

Many other different stem cell types, including embryonic stem cells (Davani *et al.* 2005:305; Kumar *et al.* 2005:111; Nir *et al.* 2003:313) and skeletal myoblast cells (Fraser *et al.* 2004:658; Menasche 2005:105; Yeo 2004:396), have been studied and have been shown to have various successes in restoring damaged myocardial tissue.

Acute cerebral infarction, commonly known as stroke, is another type of cardiovascular disease which affects the arteries leading to and within the brain. A stroke causes irreversible locally restricted loss of the neuronal circuitry and supporting glial cells with consecutive functional deficits and disabilities (Haas *et al.* 2005:59; Peterson 2004:312). It is noteworthy that stroke prevalence in rural South Africa is higher than previously documented in Africa, but lower than in high-income countries (Connor *et al.* 2004:627).

Clinical trials have investigated the effects of a human immortalized neuronal cell line and foetal neurons in stroke victims with persistent and stable deficits (Haas *et al.* 2005:59; Savitz *et al.* 2004:406; Tang *et al.* 2004:1342). Preclinical studies have focused on the effects of human stem cells from various sources such as the brain, bone marrow, umbilical cord, foetal tissue and adipose tissue (Savitz *et al.* 2004:406).

Transplantation of mesenchymal stem cells have been shown to improve neurological deficits after stroke in rats (Hanabusa *et al.* 2005:853). Mesenchymal stem cells can secrete a series of growth factors and neurotrophic factors. They also have the potential ability to differentiate to the neural cells *in vitro* and *in vivo*. Therefore mesenchymal stem cell transplantation can be employed as a source of progenitor cells for cell therapy in patients with acute cerebral infarction in order to encourage recovery of brain functioning.

c) Auto-immune diseases

The immune system is an intricate system of cells which, as a rule, work to protect the body. However, if a person suffers from an auto-immune disease, the immune system wrongfully attacks itself, a process generally referred to as inflammation. Inflammation can appear in the body in different ways. For example, in the brain it is defined as multiple sclerosis; in the joints as rheumatism; in the gut as Crohn's disease; and in the pancreas as Type 1 diabetes mellitus.

Auto-immune diseases, according to Drachman and Brodsky (2005:83), are increasingly recognised and treated with conventional immunosuppressive agents such as anti-inflammatory drugs and immunomodulatory agents (i.e. steroids and inhibitor proteins) (NIH 2001:62). Patients with intractable conditions have been treated with high-dose therapy and with or without autologous (own donated) stem cell transplants. The results have been highly

encouraging in many but not all cases, with durable responses in the limited time they have been followed up (Drachman and Brodsky 2005:83).

This section will give detailed consideration to three kinds of auto-immune diseases, namely multiple sclerosis, rheumatism and diabetes.

Multiple sclerosis (MS) is a relatively common and seriously disabling disease of the central nervous system, for which there is currently no cure (Fassas and Kazis 2003:701). Available therapies include immunomodulating agents and standard-dose immunosuppressants, which may be helpful but are not curative. Recently, studies in animal models (Gratwohl *et al.* 2001:755) have indicated that control of auto-immune disease can be obtained by high-dose immunosuppression followed by haematopoietic stem cell transplantation (rescue). The use of haematopoietic stem cell transplants aims to time-shift the clinical autoimmunity to an earlier period, therefore attempting to restore self-tolerance (Openshaw *et al.* 2002:233). Autologous transplants for severe and refractory multiple sclerosis was proposed in 1997 and has been performed ever since in selected patients. To date, more than 200 patients have been treated world-wide, and similar results have been obtained in other centres (Fassas *et al.* 2004:53; Fassas and Kazis 2003:701). Ample evidence exists that human stem cell transplant is a technically feasible approach to multiple sclerosis (Comi *et al.* 2000:376; Fassas *et al.* 2002:1088; Hintzen 2002:155).

The authors of a report on the outcome of 14 patients with severe multiple sclerosis treated with autologous transplantation after a median follow-up period of 3 years, reported that the progression-free survival was 85.7%, while disease activity-free survival was 46.4% (Saiz 2004:282).

A better understanding of how adult stem cells affect development and foster treatment of auto-immune pathologies, and of better ways to manipulate the host immune responses, require broader application of stem cell therapy (El-Badri 2004:463). Autologous haematopoietic stem cells therefore deserve further study through randomised controlled trials (Blanco 2005:54).

Another auto-immune disease is rheumatism, which causes inflammation of the joints. This inflammation is marked with deformities, which is the cause of an attack on the synovium.

There is evidence that mature dendritic cells (DCs) present in the rheumatoid joint mediate immunopathology in rheumatism (Santiago-Schwarz *et al.* 2001:1758; Thomas and Quinn 1996:3074). Dendritic cells are the most effective of antigen (forming antibodies) presenting cells. They are derived from bone marrow stem cells and reside in peripheral tissues or blood (Sarkar and Fox 2005:656). Santiago-Schwarz and his team (2001:1758) reveal that early myeloid progenitors for DCs and DC growth factors existing in rheumatoid synovial fluid (SF) are also likely participants in the rheumatoid disease process. Dendritic cells may therefore be central to the pathogenesis of rheumatism and could also be logical targets for treatment (Thomas *et al.* 1994:2613). DCs themselves could be used to deliver therapeutic gene products in auto-immune disease. DCs have been used to treat or prevent collagen arthritis in mice (Sarker and Fox 2005:656).

Other data also suggests that high doses of chemotherapy and autologous stem cell transplantation on joint damage in patients with rheumatism could potentially be beneficial. The results of a study by Verburg and colleagues (2005:421) show major beneficial slow-down effects on the rate of joint destruction during the first 2 years of follow-up after treatment.

Another challenge in medical science as far as auto-immune disease go is Type 1 diabetes. Diabetes is believed to occur in 10% to 16% of South Africans (Katz 2005:14). The destruction of pancreatic islet β -cells results in type 1 diabetes. β -cells produce insulin, and as their numbers dwindle the ability to appropriately control blood glucose levels is lost. Even with current insulin therapies, type 1 diabetes reduces a patient's life expectancy by 10 to 15 years, and these patients often develop serious complications such as blindness and kidney failure (Tenneille and Thomson 2004:288).

Recently, the transplantation of β -cells from cadavers has proven to be an effective treatment for some forms of uncontrollable diabetes, but the source of tissue for transplantation is severely limited and will never come close to meeting the demands of people with type 1 diabetes (Ramiya *et al.* 2004:45; Street *et al.* 2004:667; Tenneille and Thomson 2004:288). According to Trucco (2005:9), regenerative β -cells are rare - about one in 3,000 to 9,000 cells.

Ramiya and colleagues (2004:45) point out that diabetic patients are in dire need of a regenerative cure, thanks to the shortage of pancreatic tissue and a lifetime requirement of immunosuppressive drugs to prevent rejection and recurrent disease. Recent advances in the

directed differentiation of embryonic and adult stem cells have heightened interest in the possible application of stem cell therapy in the treatment of diabetes (Holland *et al.* 2004:13). However, the field of generating new β -cells from stem cells, either embryonic or adult, is still in its infancy (Bonner-Weir 2003:10; Ramiya *et al.* 2004:45). Therefore, procedures that reduce *in vitro* manipulation of cells and allow stem cells to develop into islets *in vivo* are crucial.

In 2004, Tian *et al.* (2004:969) announced that type 1 diabetes could be successfully prevented in individuals through the genetic engineering of haematopoietic stem cells. This view is supported by Banerjee *et al.* (2005:318) who demonstrated that diabetic bone marrow retains its stemness and potential to induce pancreatic regeneration on transplantation.

Another source of adult stem cells improving diabetes has been shown to exist in the spleen. Stem cells of the spleen have illustrated the capacity to mature into cell types other than islet cells, including neurons and bone cells. These findings call for reappraisal of the lowly spleen for treating diabetes. Stem cells of the spleen have been shown to home in on the pancreas, where they mature into fully functional islet cells (Kodama *et al.* 2005:2; Kodama *et al.* 2004:38).

The gut also contains one of the largest stem cell populations in the body; yet it has been largely disregarded as a source of potentially therapeutic cells. The stem cells reside in the crypts located at the base of the projecting villi, reproduce themselves and repopulate the gut lining. Making use of a patient's own gut cells could represent an attractive approach to ultimately cure diabetes (Fujita *et al.* 2004:57).

From an embryonic stem cell point of view, authors like Okarma (2001:9), Doss, *et al.* (2004:465) and Heit and Kim (2004:5) have shown that cell therapy with insulin-producing cells derived from human embryonic stem cells could render a permanent cure of insulin-dependent diabetes. Insulin-producing cells derived from embryonic stem cells have been shown to reverse experimentally induced diabetes in animal models (Blyszczuk and Wobus 2004:3).

Montanya (2004:435), however, is of the opinion that some of the results are questionable, and that the generated cells lack many characteristics of differentiated β -cells. According to

Montanya, a much better understanding of the processes that govern the expansion and differentiation of stem cells are needed.

Conclusion

Both embryonic and adult stem cells can contribute to the improvement of new therapies and cures for many degenerative illnesses. Human embryonic stem cells have the advantage of being multipotent and are easily cultivable in the laboratory. The degree of plasticity of adult stem cells is still indefinite and there are a number of difficulties in purifying and culturing them. The only proven stem cell-based medical therapies that are presently to be had, rely on adult-derived stem cells from bone marrow and skin, and adult stem cells from other tissues which might someday provide therapies that stimulate the body's own regenerative potential. Because of the misinterpretation of knowledge and speculative hope, there might be an unjustifiable notion that extensive clinical application of new therapies is definite and pending. In fact, stem cell research is in its formative years and there are significant gaps in knowledge that pose barriers to the realisation of new therapies from either adult or embryo-derived stem cells (Committee on the Biological and Biomedical Applications of Stem Cell Research *et al.* 2004:41).

As knowledge of stem cells grows, investigators will be able to answer meaningful questions regarding therapeutic approaches. However, all these matters will have to await the establishment of a more definite scientific underpinning. Access to human embryonic stem cells is likely to, in the end, decide the tempo at which scientists make progress in this field. Human embryonic stem cells, in fact, demonstrate numerous properties of which an enhanced understanding could assist researchers in modifying adult stem cells to attain better development in culture and better controlled differentiation.

The next chapter will focus on the legal positions nationally as well as internationally with regards to stem cell research. Since much of contemporary debate focuses on whether the embryo should be allocated rights or whether it is merely a form of property which could be applied in a commercial venture to make profit for the investor, I will take a critical look at the development of our own legal system and what kind of protection (if any) is afforded the embryos.

Chapter 3: The legality of stem cell research

Defining human life as starting at the moment of conception is undoubtedly a convenient starting point for many. However, for others the implantation of the embryo into the uterine wall is a better marker for the beginning of life. This developmental stage for individual life has indeed been accepted not only in the United Kingdom, but also in many other countries throughout the world (Fischbach and Fischbach 2004:1364). It stands to reason that those involved in the debate would most likely look towards the law to define under which conditions the use of embryonic stem cells is morally justifiable, and when not.

From a legal point of view, the use of stem cells derived from an embryonic entity would not be in opposition to any existing law and would therefore be morally permissible in legal terms. However, this does not make the issue clear cut. For a more in-depth look at the subject, I will discuss the Human Tissue Act, the Choice on Termination of Pregnancy Act, the Constitution and the National Health Act. The Human Tissue Act and its regulations shall first be discussed to address a particular stem cell related problem. Thereafter the other Acts and legal frameworks will be discussed – keeping in mind that all of the Acts are interconnected and need to be dealt with in particular order to reach an educated conclusion. I am indebted to the excellent work of de Vries (2005) and Swanepoel (2006), upon which I have drawn extensively.

The Human Tissue Act

The Human Tissue Act (Act 65 of 1983), which originated with the first successful heart transplant by Dr Chris Barnard and which regulates tissue and organ transplantations, makes provision for the use of tissue and gametes which are removed from a living donor for medical and dental purposes. The Act furthermore bans the usage of placentas, foetal 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. Hence the Human Tissue Act also prohibits the genetic manipulation of gametes or zygotes outside the human body.

Even though the Human Tissue Act was annulled by the National Health Act (Act 61 of 2003), which greatly influences the field of stem cell research, it is necessary to take note of the former act in order to fully address any legitimacy issues which transpire from the stem cell debate.

The embryo is formed through the bringing together of male and female gametes. In the case of stem cell research, this mostly occurs in a test tube outside the human body. The Human Tissue Act excludes gametes from the definition of tissue. However, "tissue" does include "any flesh, bone, organ, gland or body fluid"; an embryo thus falls within this definition. The resultant effect is that researchers do not have to satisfy the requirements with regard to tissue until they fertilise an egg cell to create an embryo.

Also of relevance is the definition of "artificial fertilization of a person" in section 1 of the Human Tissue Act:

“[A]rtificial fertilization 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 - 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 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.”

Part A of the definition provides for the creation of an embryo outside the human body, similar to the procedure performed in the creation of embryos for the sole purpose of being used in research. Part B, however, stipulates that such an embryo has to be placed back into the womb of a female person. It is clear that this does not directly address the needs of researchers attempting to create embryos solely for the derivation of stem cells (De Vries 2005:61).

Section 19 of the Human Tissue Act states that *tissue, blood or gametes shall only be used for medical and dental purposes including, in the case of gametes, the artificial fertilisation of another person.* The term "including" leaves room for the interpretation that a person is not

bound to using gametes for the sole purpose of *artificial fertilisation*, but could also utilise them for other medical purposes, for example stem cell related endeavours. It is important to note that according to subsections 19 (i-iii), the Act prohibits the use of gametes obtained from mentally ill persons, minors or habitual criminals so declared in terms of the Criminal Procedure Act. Hence, the proscription is only applicable to the acts specified in sections 19 (a-c), with the result that gametes obtained from the abovementioned excluded groups could be utilised for purposes of creating embryos for the derivation of stem cells. There is therefore no regulatory ban on the use of stem cells according to the Human Tissue Act.

While the Human Tissue Act is flawed due to the above-mentioned loopholes, it also provides some important guidelines. The Act states that research performed on spare IVF embryos may only be conducted in approved institutions and with the written permission of the donors of the gamete or the embryo. These guidelines have been accepted by the Medical Research Council of South Africa under the guidance of Prof du Toit. The scope of this dissertation, however, does not allow for an in-depth analysis of the workings of the research council; still, it is encouraging to know that there exists a body which guides researchers at ground level.

The Abortion and Sterilization Act *and* The Choice on Termination of Pregnancy Act

Although the Human Tissue Act addresses the legitimacy of conducting research, the position of the South African law regarding the legal status and personhood of embryos still needs to be addressed, as it forms an significant part of my discussion. In this regard I will next discuss two of the most important pieces of legislation relating to the issue, namely The Abortion and Sterilisation Act (Act 2 of 1975) and The Choice on Termination of Pregnancy Act (Act 92 of 1996).

Swanepoel (2006:23) points out that, before 1975, abortion was a common-law crime with only one recognised ground of justification, namely necessity. The Abortion and Sterilisation Act criminalised abortion that did not fall within certain defined circumstances, giving embryos and fetuses rights. However, the Choice on Termination of Pregnancy Act was promulgated on 1 February 1997 after a watershed case in 1995 in which a certain Ms Brown challenged the Minister of Health by arguing that the Abortion and Sterilisation Act 2 of 1975 unreasonably and unjustifiably infringed the applicant's constitutionally protected rights of privacy and

dignity and right to equality. The Choice on Termination of Pregnancy Act repealed the Abortion and Sterilisation Act of 1975.

McGregor and Moore (1995:4) point out that both the general prohibition on abortions and the listed grounds for a permissible abortion amounts to a *prima facie* infringement on fundamental rights, namely that:

- (a) the provisions are an infringement of the applicant's right to personal privacy and dignity.
- (b) the provisions amount to an impairment of equality, in particular, they amount to unfair discrimination on the basis of disability.
- (c) the infringement of personal privacy and equality is not saved by the limitations clause.

They conclude that the foetus or embryo does not qualify as a “person” in terms of section 10 of the Bill of Rights, since the abortion of a “person” would be murder. This conclusion is drawn by applying the South African Common Law which deals with the problem of killing an innocent person to protect another. If the foetus or embryo were indeed a person, any act of abortion (even using the morning-after pill) would constitute a criminal act. The embryo can only attain legal personhood (and protection) after birth. In view of this argument, the embryo or foetus cannot qualify as a constitutional person and consequently does not enjoy the protection of section 10 and 11 of the Bill of Rights (Chapter two of the Constitution of South Africa) which states that:

10. Human dignity – Everyone has inherent dignity and the right to have their dignity respected and protected.

11. Life – Everyone has the right to life.

The Choice on Termination of Pregnancy Act which repealed the Abortion and Sterilization Act shows a change in society's attitude toward abortion and the respect owed to embryos and fetuses. Our society had to accept the reality that many people were suffering from illegal abortion practices (40-50 percent of women who had an abortion will have a miscarriage with their next pregnancies) and that dangerous abortions were performed purely out of social constraints.

Swanepoel (2006:166) points out that the preamble of the Choice on Termination of Pregnancy 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 have 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. Furthermore, the termination of pregnancy is not regarded as a form of contraception or "population control," and the Act promotes reproductive rights and extends freedom of choice by affording every woman the right to choose whether to have an early, safe and legal termination of pregnancy according to her individual beliefs. With reference to the above, the foetus therefore is seen as a non-human or non-person for legal purposes. It is furthermore evidently not entitled to any protection afforded to humans by the criminal law.

The Choice on Termination of Pregnancy Act only regulates abortion of an *in utero* embryo; the destruction of *extra uterum* embryos (cryopreserved embryos) falls outside the scope of the Act. It was not until recently that the law addressed these special measures in the form of the National Health Act of 2003, most likely because the Abortion and Sterilisation Act was promulgated before *in vitro* fertilisation was even a consideration and because of the limitations of the Choice on Termination of Pregnancy Act (stem cells were only discovered in the human body in 1998). It is evident that the law had not – until the promulgation of the National Health Act, which I will discuss next - kept up with scientific advances.

National Health Act

In the previous section it was argued that stem cell research would not violate any legislation and that the protection of the embryo (before the 14th day) is not governed by any law.

However, clear guidance with regards to the way in which, by whom, under which circumstances and where stem cell research should be affected in “the-world-after-1998’s-stem-cell-discovery” remained lacking.

South Africa’s approach to the issues surrounding the regulation of stem cell research is combined in new legislation, namely the National Health Act (Act 61 of 2003). Although the National Health Act is better equipped to answer the challenges presented by this new technology, it still requires extensive refinement by means of regulations (the lack of which at this stage creates loopholes which would be difficult to defend) in order to deal with current and future difficulties.

The National Health Act is the first legislation ever to define embryos and zygotes:

“**embryo**” means a human offspring in the first eight weeks from conception;

“**zygote**” means the product of the union of a male and a female gamete.

In addition, the terms “organ” and “tissue” are defined in such a way that it does not include stem cells and blood or blood products from which such cells can be derived. Although the definition of tissue does refer to body fluid, it is submitted that this does not include stem cells derived from any type of bodily fluid. The National Health Act has thus become a keystone in the stem cell debate, providing the bulk of the provisions needed to facilitate its implementation into the South African legal system.

Sections 56(2)(a)(iv) and 56(2)(b) are of paramount importance in the legal argument I wish to make:

(2) (a) Subject to paragraph (b), the following tissue, blood, blood products or gametes may not be removed or withdrawn from a living person for any purpose contemplated subsection (1):

(iv) placenta, embryonic or foetal tissue, stem cells and umbilical cord, excluding umbilical cord progenitor cells.

(b) The Minister may authorise the removal or withdrawal of tissue, blood, a blood product or gametes contemplated in paragraph (a) and may impose any condition which may be necessary in respect of such removal or withdrawal.

Section 56(2)(a)(iv) of the National Health Act places a prohibition on the removal of stem cells and the tissue from which stem cells can be derived. The only way in which to proceed with such research is to obtain ministerial authorisation in terms of section 56(2)(b) of the Act. The fact that power is granted to the Health Minister may very well become subject to Constitutional scrutiny. The decision-making powers vested in the Minister in terms of the National Health Act are unnervingly legislative in nature.

Section 60 furthermore governs stem cell research by providing that only an authorised institution may receive remuneration for the import or export of blood or blood products. Section 60(4), however, adds the following:

(4) It is an offence for a person - who has donated tissue, a gamete, blood or a bio-product to receive any form of financial or other reward such donation, except for the reimbursement of reasonable costs incurred by him or her to provide such donation; and to sell or trade in tissue, gametes, blood or blood products, except as provided for in this Chapter.

The National Health Act also provides that institutions be awarded licences and permits to conduct stem cell research. In addition, research oversight committees have been put in place: each institution desiring to conduct stem cell research is required to have a health research ethics committee which is registered with and under the supervision of the National Health Research Ethics Council.

In accordance with most international acts, section 57(4) allows for the Minister of Health to approve research on stem cells and zygotes which are not more than fourteen days old. It is important, however, as De Vries (2005:519) points out, that there appears to be no ban on the use of zygotes which are created solely for research purposes. Providing the researcher has ministerial and donor consent, it does not matter whether the source of the stem cells are left-over embryos following IVF procedures or embryos created solely for research purposes. This may present difficulties once the National Health Act comes into force. Given the large number of religious groups and even certain international documents which supports a prohibition on the use of embryos created solely for research purposes on the basis that it instrumentalizes

human life, the possibility of a public outcry against stem cell research in general cannot be ignored. Should the public focus exclusively on this method of stem cell derivation, it could hamper progress in all areas of stem cell advancement.

The National Health Act makes it very clear that no person may manipulate any embryo or foetus. The law also unambiguously states that no experimentation on any stem cell and/or zygote might be done without the written consent of the Minister of Health. However, some wording in the Act is unclear and rather unfortunate. Chapter 8, subsection 57, clause 2 notes that:

The Minister may, under such conditions as may be prescribed, permit therapeutic cloning utilising adult or umbilical cord stem cells.

The use of the words “therapeutic cloning” carries far too many negative connotations in light of the general (uninformed) public view that the process involves cloning of entire individual beings. Furthermore, it is unclear which conditions the Act is referring to and who would be responsible for determining these conditions. Although the present health needs of the country are radically removed from anything stem cell research can provide the answer to, the whole issue relating to when and by whom research should be allowed needs to be addressed so as to prevent unnecessary exploitation by those with ulterior motives.

The free hand the Minister has in granting permission leaves the National Health Act open to abuse and emphasizes the need for a sound and well debated policy. As this study has set out from the beginning to propose a morally justified policy for stem cell research in South Africa, I will next take an in-depth look at the Constitution of South Africa in order to evaluate the above-mentioned issues and to prove that, even set against the background of such a progressive constitution, embryos cannot be afforded any legal rights.

Constitution of South Africa

South Africa has one of the most progressive constitutions in the world. Many people and entities which previously had no voice were given one, and many actions previously considered illegal (i.e. terminating a pregnancy under the Choice on Termination of Pregnancy Act) were legalized. All ethical considerations are inextricably intertwined with the constitutional

principles that have been promulgated in the Constitution of the Republic of South Africa. Ethics cannot function outside the realm of the legal framework of any society and according to this principle the Bill of Rights (chapter two of the Constitution) establishes certain measures which protect the human rights of all subjects.

The Constitution impacts in a threefold way on embryonic stem cell research:

- a) The Constitution is seen as the most important law in South Africa and any legislation which opposes it is invalid to the extent of the conflict.
- b) The Bill of Rights gives the state the mandate to use the powers the Constitution provides for in ways which do not violate fundamental human rights.
- c) According to section 39 of the Constitution, 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.

Before discussing the constitutional application to the stem cell debate, it is important to mention that not all the sections of the Bill of Rights are related to private persons. The Bill of Rights has both a horizontal and a vertical application, with the horizontal application subject to the nature of the right as well as the nature of the duty imposed by the right (De Vries 2005:115).

The Bill of Rights will be the main focus of my discussion and will aid my argument that embryonic tissue does not qualify for person status. I will focus on a few clauses of the Bill of Rights.

The Right to Life (Section 11)

The right to life as protected in section 11 of the Bill of Rights is the most basic human right on which all other rights are premised. This explains why issues of social policy, such as that which this discussion focuses on, are readily associated with the right to life. With the likely

exclusion of human dignity, life itself is the most fundamental right protected by the Constitution.

Abortion is quite often associated with embryonic stem cell research and many examples from legislation are used to prove a legal point. From a constitutional position, the issues of abortion and embryonic stem cell research both point to the conflict between the right to freedom and physical integrity and the state's duty to protect life, which, in the case of abortion and embryonic stem cell research, refers to developing life. 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 (Swanepoel 2006:78).

The issue of whether the human embryo is or is not a person seems to be one of the most important issues in the current debate on the morality of embryonic stem cell research. Even *in vitro* fertilisation, as Swanepoel (2006:78) points out, involves the death of some embryos which do not implant and develop into fetuses. Those who oppose abortion 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 therefore any embryo's destruction is a form of homicide. Embryonic stem cell research also involves the destruction of human embryos.

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. To ascertain the position of our legal system on this question, I would like to turn to the South African Law of Persons and National Health Act, both of which are helpful in establishing the status of the legal personality in the South African context. According to Cronjé and Heaton (1999:9), the beginning of legal personality occurs only at birth, provided that:(a) the birth has been fully completed (a complete separation between mother and foetus); (b) the child – even for a short time – must have been alive (must have breathed, open their eyes and/or cried); and (c) must have existed independently of its mother's body. Consequently, in the South African Law of Persons a foetus does not hold any legal status.

However, the same authors (1999:12) show that the conceived but unborn foetus (the *nasciturus*) can obtain legal status *in vitro* by applying the fiction of *nasciturus pro iam nato*

habetur, quotiens de commodo eius agitur (one about to be born will be held already to have been born whenever that is to his advantage). For the *nasciturus* fiction to come into action the foetus must have been conceived at the time that the benefit would have accrued to him and the child must subsequently be born alive. Attention has to be drawn to the fact that this fiction applies only to the *nasciturus*. The status of the embryo, and even the embryonic organism, cannot be based on the *nasciturus* fiction, which is underwritten by the Choice on Termination of Pregnancy Act 92 of 1996. This Act legalised abortion on the basis that a woman's right to her own body weighs heavier than the rights of the embryo or foetus.

Two very different meanings of the word "life", as it is used in connection with humanness, can be distinguished. 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 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 South African law, namely in the case of *Clarke vs. Hurst*. 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.

Medical and scientific experiments (Section 12)

Section 12(2) of the Bill of Rights reads as follows:

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;
- (c) and not to be subjected to medical or scientific experiments without their informed consent.

Section 12(2) provides the basis for autonomy and the rights of the individual by protecting against unwarranted intrusion by external parties. Section 12(2)(c) discusses the principle of "*medical or scientific experiments*", an important element to my argument.

Quite often this section of the Bill of Rights is used by pro-lifers to suggest that all experimentation has a Frankensteinian undertone and that it should not be allowed at any cost. The medical sciences are not an exact science and the distinction between day-to-day care and experimental medicine often becomes blurred (De Vries 2005:117). While it may be fair to argue that stem cell based applications could still be deemed experimental in nature, the same applies to the first heart surgery. The fact remains that the more often the procedure is applied, the more likely it becomes that it loses its experimental quality and is condoned by the general public.

Section 12(2)(a) also has bearing on the stem cell debate. The section allows an individual to make his or her own decisions with regards to reproduction. This decision would necessarily include both the method of becoming pregnant and the method for the termination of the pregnancy, and would thus include the decision to donate cryopreserved embryonic tissue or not.

Privacy (Section 14)

The right to privacy, as stated in section 14 of the Bill of Rights, reads as follows:

Everyone has the right to privacy, which includes the right not to have-

- their person or home searched;
- their property searched;
- their possessions seized; or
- the privacy of their communications infringed.

In section 7(5) of the Choice on Termination of Pregnancy Act the privacy of a woman undergoing a termination of pregnancy is ensured, and in section 33 of the Human Tissue Act the publication of certain facts about a donor is prohibited (De Vries 2005:123). The publication of genetic information through a system of informed consent will address most issues of privacy (a point I will return to later in my discussion).

Socio-economic rights (section 27)

Section 27 of the Bill of Rights reads as follows:

- (1) Everyone has the right to have access to - health care services, including reproductive health care, sufficient food and water; and social security, including, if they are unable to support themselves and their dependents, 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.

This section focuses on the role of the public sector in medical intervention to help take care of all those who need help and are marginalised. However, it is important to note that the rights provided for in section 27(1) are conditional on the availability of resources by the state. This raises the issue whether the state should be responsible for funding stem cell research when the money might be better spent on other medical interventions. The issue of scarce resources will be discussed at length later on in my discussion, with particular attention to the Soobramoney case, one of the most important court cases in South Africa relating to this matter.

In summary, I have attempted in this section to examine the constitutional principles pertaining to embryonic stem cell research. When making a decision as to whether a person (or even the progenitors) has a right to destroy a cryopreserved embryo, one of the first questions should be whether the embryo constitutes "life". The issue of whether the embryo is a bearer of constitutional rights and whether it constitutes life was addressed. According to my interpretation of the Constitution, the foetus is not a bearer of constitutional rights. The Constitution makes it clear that, while the embryo should be given more respect than mere property, it should not be afforded the status of life. Thus, if an embryo does not constitute "life", a couple should have the right to destroy the embryo, unless there is a state interest that is deemed more important than that right.

International comparative analysis

While the legislation detailed above affords fairly comprehensive protection to embryos, it does not grasp the importance of the issue of the embryo's status; instead statutes take an

arbitrary point in the embryo's development, namely the formation of the primitive streak, as the cut-off point for experimentation.

The proposed impact and promises of stem cell research has taken on global proportions, particularly because of its close ties to other fields of genetic advancement. Although each country takes a different approach based on its legal and cultural background, as well as its assessment of other areas of healthcare, there is still a level of consensus amongst most of the countries. Without examining the legislative position in too much detail, a number of European developments are discussed below, with particular emphasis on the United States of America and the United Kingdom's frameworks. I have included the United Kingdom in specific since its pro-active legislative position has proved to be extremely effective in addressing both public and private interests. Thereafter the regulatory frameworks within the United States of America will be discussed.

Even though most of this discussion on the legislation of stem cell research reflects the South African legal position (with the United States arguably being the leader in world genetic advancement at present) the scope of stem cell research justifies an examination of the methods used by other countries in addressing the issues.

International legislation on human embryonic stem cell research

At the international level, there is intense debate in many countries regarding the potential of stem cell research and therapy. The variation in outlook between different countries regarding stem cell research and its regulation thereof is striking. These differences principally echo differences in cultural and religious traditions.

Many countries usually refer somewhere in their policy to the right to life as defined by the International Covenant on Civil and Political Rights of 1966 (Article 1), as well as by the Universal Declaration of Human Rights of 1948, Article 3 (See addendum C), which states that:

Article 3

Everyone has the right to life, liberty and security of person.

For the purpose of understanding present trends in policy forming internationally, it is important to have a look at a few countries' policies.

Germany

According to the Stem Cell Act (Stammzellgesetz) of 2002, in reflection of the State's responsibility to revere and defend the right to life and human dignity and to promise the independence of research, the rationale behind the Act is:

1. to ban, as a matter of principle, the importation and utilization of embryonic stem cells,
2. to prevent demand in Germany from causing the derivation of embryonic stem cells or the production of embryos with the aim of deriving embryonic stem cells,
and
3. to determine the requirements for permitting, as an exception, the importation and utilization of embryonic stem cells for research purposes.

The Act therefore prohibits the derivation and use of human embryonic stem cells from embryos. However, the Act (Heinemann and Honnefelder 2002:534) also states that research concerning embryonic stem cells shall not be carried out unless it has been shown by giving scientific reasons that:

such research serves eminent research aims to generate scientific knowledge in basic research or to increase medical knowledge for the development of diagnostic, preventative or therapeutic methods to be applied to humans.

France

According to a survey conducted by the Directorate of Biotechnology, Agriculture and Food, of the European Commission (2004), France permits the use of human embryonic stem cells and their derivation from surplus embryos which are not required by the genetic parents for reproduction. The amendment of the Bioethics law of 1994 was adopted in June 2004 – it prohibits human embryo research but includes the curtailment of the application thereof for five years permitting research on “spare” human embryos under the following conditions:

- The research should have the potential to lead to major therapeutic advances and only be undertaken if there is no alternative method of comparable effectiveness available;
- The embryos must derive from an *in vitro* fertilisation, in the context of medically assisted reproduction (spare embryos);
- Written consent of the couple from whom the embryos are issued must be obtained;
- Authorisation by a central body (to be created).

Israel

Presently there is no specific law regulating or guiding stem cell research in Israel and embryo destruction for stem cell research is allowed. The Public Health Regulations of 1997 still stipulate terms and conditions for the permission of harvesting, fertilizing, freezing and implanting fertilized eggs for reproductive purposes (Directorate of Biotechnology, Agriculture and Food 2004b:7). However, the Regulations deal with neither the issue of the destiny of frozen embryos nor the issue of “spare” embryos.

According to the Directorate (2004b:7) in 1999, the Knesset (Israeli Parliament) passed the Prohibition of Genetic Intervention (Human Cloning and Genetic Modification of Reproductive Cells) Act. The reason behind this Act is the recommendation of a five-year period during which certain genetic interventions in humans may not be performed, thereby aiding an appraisal of the ethical, legal, societal and scientific undertones of such therapies and their burden on human dignity.

China (People’s Republic of China)

Research on embryonic tissue is in general forbidden in China. However, according to the Ethical Guiding Principles on Human Embryonic Stem Cell Research of 2003, human embryonic stem cells used for research purposes can only be derived from the following means with voluntary agreement:

- Spare gamete or embryos after *in vitro* fertilization (IVF);

- Foetal cells from accidental spontaneous or voluntarily selected abortions;
- Embryos obtained by somatic cell nuclear transfer technology or parthenogenetic split embryos; and
- Germ cells voluntarily donated.

Any donated or created embryo, according to these Guidelines, is not allowed to exceed 14 days starting from the day when fertilization or nuclear transfer was performed.

European Union

The member States of the Council of Europe and the other States and the European Community, signed the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine in 1997 in Oviedo, Spain.

Article 18 of the Convention (1997) stipulates that it is the responsibility of each country to come to a decision on whether or not to authorise embryo research (Romeo-Casabona 2002:559). However:

Article 18 – Research on embryos *in vitro*

1. Where the law allows research on embryos *in vitro*, it shall ensure adequate protection of the embryo.
2. The creation of human embryos for research purposes is prohibited.

Furthermore, according to the Charter on Fundamental Rights of the European Union which was approved by the European Council on October 14th 2000, different types of practices relating to embryo research are banned (Article 3 - Right to the integrity of the person), namely eugenic practices, in particular those aimed at the selection of persons and the reproductive cloning of human beings.

It is important to point out that there is no legislative competence to regulate research by the European Union structures, however, forms of governing are proposed in the outline of the

Directives. One such a Directive, for example, is Directive 98/44/EC which deals with the legal protection of biotechnological inventions (patenting on life). Article five, subsection one, of this Directive, stipulates that:

The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.

Australia

Presently three of Australia's six states have banned human cloning and another two are in the process of considering legislation. However, no two states hold similar positions on stem cell research. The Research Involving Human Embryos Act of 2002 and the ethical guidelines on the use of assisted reproductive technology in clinical practice and research by the Australian Health Ethics Committee (2004) tried to rectify this by addressing concerns about scientific developments in relation to human reproduction and the utilisation of human embryos by regulating activities that involve the use of certain human embryos created by assisted reproductive technology.

Other than the Irish Constitution's loophole, the Research Involving Human Embryos Act of 2002 is quite specific about what is viewed as a human embryo. According to the Act, a human embryo refers to:

a live embryo that has a human genome or an altered human genome and that has been developing for less than 8 weeks since the appearance of 2 pro-nuclei or the initiation of its development by other means.

Research relating to the destruction of existing surplus assisted reproductive technology embryos (IVF created embryos) are permitted under a strict regulatory regime, whereby the researcher has to obtain a licence. Any violation of the 2002 Act could result in a maximum imprisonment of five years.

United Kingdom

The utilization of human embryonic stem cells and their source from surplus embryos not used or needed by the genetic parents for reproduction is permitted in the United Kingdom. This grant is, however, limited to embryos created for research intentions by *in vitro* fertilization and embryos created with the somatic-cell nuclear transfer technique.

In 1984 the Warnock Committee was the first committee ever established in the *United Kingdom* (UK) to explore ethical questions relating to fertility treatment. The committee agreed that the embryo has a “special status”, although not one that justifies its being attributed “absolute protection” (House of Lords 2002:36). According to this view, an embryo in its earliest stages is not accorded the full moral standing of a human person, but it is nonetheless regarded as deserving some degree of respect and is treated as more than a mere object or collection of somatic cells in tissue culture (PCB 2004:82). This view, which has influenced many policies henceforth, was enacted in the Human Fertilisation and Embryology Act of 1990.

The question arose: what in practice would validate medically valuable research? It is important to ascertain this as it will guide us in forming a policy in chapter seven.

The House of Lord’s report (2002:41-42) on the 1990 Act states:

When living tissue is involved, a further degree of sensitivity is necessary. The 1990 Act requires this to be demonstrated in the following ways:

- (a) through the extensive restrictions that are rightly placed on the use of embryos - the 1990 Act permits research on embryos to be carried out only if there is no alternative available and it is necessary or desirable to achieve one of the permitted purposes;
- (b) through strict adherence to the rules governing the informed consent of the donors;

- (c) through restrictions on export where restrictions on use after export could not be overseen or enforced;
- (d) through restrictions on mixing with non-human material; and
- (e) through meticulous record-keeping of the creation and disposal of early embryos for research so that every embryo is accounted for.

The Act also prohibits research on embryos older than fourteen days (the significance of which lies in the onset of the development of the primitive streak, which is the first sign of the nervous system as discussed earlier and when individuality has been laid down since twinning cannot take place anymore). This limit seems to have been widely accepted. However, since the passing of the Act there have been a number of important developments which were not and could not have been anticipated at the time. The Human Fertilisation and Embryology (Research Purposes) Regulations 2001 were consequently adopted in 2001 and made a few amendments to the original 1990 Act (House of Lords 2002:7). These amendments extend the grounds for research on embryonic organisms, for example for the treatment of infertility and the development of more effective contraceptive techniques.

The regulation of research on human embryos is therefore primarily directed by the Human Fertilisation and Embryology Act 1990 (Amended in 2000), which also regulates the practice of *in vitro* fertilisation and the formation, use, storage and discarding of embryos formed by this means. The Human Fertilisation and Embryology Authority (HFEA) is in charge of licensing and regulating any research involving the creation or use of human embryos (House of Lords 2002:1). According to the Act, the HFEA should see to it that embryos used in research may not be kept after 14 days (excluding storage) and only if the genetic parents of the embryo have given their consent.

The Act approved research using above-mentioned embryos, under strict conditions, with the aim to better understand the reasons for infertility and miscarriage, to develop more successful means of contraception and to derive means to identify genes that may cause congenital birth defects. This was all before the major turn in genetic history, namely the creation of Dolly the sheep.

In January 2001, policies were put in place to expand the reasons for which embryo research could be licensed. The further purposes were to increase knowledge about the development of

embryos, to increase knowledge about serious disease and to enable such knowledge to be applied in developing treatments for serious disease.

United States of America

In the *United States of America* Fletcher (2001:27) explains that the entire debate around stem cells was initiated by the Roe versus Wade case in 1973, where the Supreme Court ruled that a foetus is not a person in the context of constitutionally protected rights. The discourse regarding the rights of the foetus has been raging since, and almost two and a half decades later in 1999, the National Bioethics Advisory Commission (NBAC) took a stand on the moral status of the embryo. The NBAC agreed with the 1979 Ethics Advisory Board (EAB) and the 1994 Human Embryo Research Panel (HERP) views that an embryo merits respect as a **form** of human life, but not at the same level of respect as would be accorded to persons (Fletcher 2001:32).

In view of the fact that they are neither persons (not having human form) nor property (being owned in terms of intellectual rights – patents – by someone else), the HERP suggested that embryos should be allocated “special respect” by limiting the time frame in which research may be done on them and by limiting the purposes for which they may be used (Parens 2001:40). It is interesting to note that the legal explanation of “human life” differs from state to state in the United States of America. In most states, life commences at the moment the zygote is formed (fusion of male and female gametes), and consequently the destruction of a human foetus is seen as an abortion. However, should an embryo be prevented from implantation into the uterus, it is not be seen as an abortion but rather as a “contraceptive” device (an inconsistency I will examine later).

The public policy with regards to stem cell research is furthermore also fundamentally connected to the priorities of public funding. Since government is the biggest contributor to any research in the USA, they also consequently have the biggest influence on policy forming. However, what is paramount is what research is sanctioned. As with public bodies, the assumption is that if government sanctions specific kinds of research, it inevitably agrees with the research and the moral restraints or consequences connected to it. Therefore, before the tax dollar can be spent or approved, public policy would have to comply with certain standards that are not only legally, but also morally justifiable.

i) Policy on foetal research during the pre-Clinton administration

The development of public policy with regards to stem cell research has a long history. According to Doerflinger (2001:136), the U.S. Supreme Court's 1973 abortion decisions (Roe vs. Wade) set the stage for policy debates on foetal research. Treating the child in the womb as a disposable non-person opened the door for some hideous experiments. The issue was addressed in 1974 in a bill (Public Law 93-348) which instituted a task group (the National Commission for the Protection of Human Subjects) to put guidelines in place for federally funded research concerning human subjects (*in utero* and *ex utero*).

In 1975 the task group's recommendations were incorporated into federal regulations (Doerflinger 2001:136), generally prohibiting federally funded foetal research unless the research would directly benefit the unborn child or his or her mother. However, as with all laws there were inevitable loopholes. The guidelines focused only on live foetuses in the womb (and those who have just left the womb). "Foetus" had been defined to include the product of conception from implantation onwards. The question arose whether research was then allowed on dead unborn foetuses and the human embryo in the laboratory that has not yet been implanted into a womb. The answer to this will open up the possibility of accepting the usage of them in research.

Moratoriums were instituted and in 1975 research using the remains of dead unborn foetuses (spontaneous or induced abortions) was allowed. Doerflinger (2001:138) points out that, given the ambivalent outcome and the amount of public disagreement surrounding suggestions for federally funded experiments on human embryos, the Carter administration (1977-1981) never proposed funding for any research involving human embryos. This was the trend followed by subsequent administrations until 1993.

ii) The Clinton administration

Encouraged by Clinton's election, congress once again started to debate foetal tissue research. Consequently the National Institute of Health (NIH) appointed an *ad hoc* advisory panel to review new proposals for funding human embryonic experiments. The proposal of the NIH's Human Embryo Research Panel approved funding of a wide range of research in which live human embryos would be destroyed during the first two weeks of their existence, explicitly

allowing for the possibility of extending the timeline at a later stage. Experiments in which live embryos would be destroyed for their stem cells and where embryos would be created and destroyed solely for research purposes, were among the recommendations (Doerflinger, 2001:138).

However, these recommendations were rejected by President Clinton, who issued an order restricting the proposal to cases where "spare" or unwanted embryos from fertility clinics would be used.

Once again Congress intervened in 1996 by means of the Dickey amendment. A proviso of the Department of Health and Human Services (DHHS) Appropriations Bill unequivocally banned federal funding of any research in which human embryos are harmed or placed at risk. According to this very influential amendment (SEC. 510):

- (a) None of the funds made available in this Act may be used for
 - (1) the creation of a human embryo or embryos for research purposes; **or**
 - (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on foetuses *in utero* under 45 CFR 46.208(a)(2) and section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)).
- (b) For purposes of this section, the term human embryo or embryos includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

In 1999 and 2000, the Clinton administration instructed that funded research could utilize only those human embryos that had been left over from IVF procedures, which had been donated in accordance with the standards of informed consent and in circumstances free of financial inducements. Provided that these fundamental conditions were met, the administration argued that the potential benefits of stem cell research were so great that publicly funded research could be ethically justified and should be supported (PCB, 2004:30).

iii) The Bush administration

The 9th of August 2001 saw yet another historical moment in the stem cell research debate. The Bush administration announced that no more surplus embryos from IVF treatment clinics were allowed to be used to derive stem cell lines from. From the 9th onwards, federal funding was only reserved for research using cells from approximately 60 stem cell lines identified by the National Institutes of Health as having been derived from excess human embryos prior to the announcement. Bush justified his position to fund these pre-existing lines by stating that the embryos from which they were derived had already been destroyed and could no longer develop further. In his words: “the life and death decision had already been made” (The White House, 2001).

The administration’s policy made it feasible to use public funding for research performed on those pre-existing lines, but it rejected in advance the support of research on any lines created after the date of the statement. Additionally, to qualify for funding, those pre-existing lines must have been derived from excess embryos created exclusively for reproductive reasons, must have been made available with the informed consent of the donors and without any financial inducements to the donors (PCB 2004:29).

The ban on using federal funding for research on embryonic stem cell lines derived after August 9, 2001 (Sandel 2004:208) was confirmed when a challenge from liberal senators to implement the Stem Cell Research Enhancement Act of 2005, on the 19th of July 2006, was rejected when they failed to obtain a two-third majority (GovTrack 2006). This Bill’s purpose was to amend the Public Health Service Act to provide for human embryonic stem cell research. The government of the United States of America therefore still control and enforce stem cell research.

iv) The Bush policy

The policy’s central feature - the announcement date separating qualified from disqualified stem cell lines - holds to the opinion that public funds should not be used to promote or support the destruction of embryos.

In addition to the ethical aspect of the policy, public debate has centred on the balance of benefits and harms resulting from the combination of the administration's policy and the state of the relevant science. It has focused on whether there are "enough" cell lines and on whether the science is advancing as quickly as it could. The present policy aims therefore to support stem cell research while insisting that federal funds should not be used to support or promote the future destruction of human embryos (PCB 2004:36).

However, some criticisms (PCB 2004:63-71) have been raised against the policy, namely:

a) Arbitrariness

The present funding policy is seen as fundamentally arbitrary, since it relies on a specific cut-off date. Cell lines derived from embryos destroyed on August 9, 2001 are eligible for federal funding, but those obtained from embryos destroyed the next day are not.

b) Unsustainability

A general point of critique is that the policy cannot be expected to hold over time and that it will eventually prove unsustainable as scientists make progress using existing stem cell lines. However, once they have depleted the usefulness of the present lines, they would be prohibited from capitalizing on what they have learned and progress further using stem cell lines not now eligible for federal funds.

c) Inconsistencies

Critics of the policy have charged that the policy is morally contradictory, or at least inconsistent, in its own terms. One common aspect of the charge of inconsistency concern the distinction the policy draws between public and private funding. The current policy addresses only federal funding of embryo research and is silent on the conduct of such research in the private sector.

In reaction to the criticism of inconsistency, advocates of the policy argue that although it is a free market democracy, federal government should not offer support or incentives for the destruction of nascent human life for research.

v) NIH guidelines for embryonic stem cell funding

The NIH suggests a few guidelines (PCB 2004:191-194) which would apply to pluripotent stem cells derived from human foetal tissue and excess IVF embryos before the 14th day of development.

- a. To ensure that the donation of human embryos in excess of the clinical need is voluntary, no inducements, monetary or otherwise, should have been offered for the donation of human embryos for research purposes. Fertility clinics and/or their affiliated laboratories should have implemented specific written policies and practices to ensure that no such inducements are made available.
- b. There should have been a clear separation between the decision to create embryos for fertility treatment and the decision to donate human embryos in excess of clinical need for research purposes to derive pluripotent stem cells. Decisions related to the creation of embryos for fertility treatment should have been made free from the influence of researchers or investigators proposing to derive or utilize human pluripotent stem cells in research. To this end, the attending physician responsible for the fertility treatment and the researcher or investigator deriving and/or proposing to utilize human pluripotent stem cells should not have been one and the same person.
- c. To ensure that human embryos donated for research were in excess of the clinical need of the individuals seeking fertility treatment and to allow potential donors time between the creation of the embryos for fertility treatment and the decision to donate for research purposes, only frozen human embryos should have been used to derive human pluripotent stem cells. In addition, individuals undergoing fertility treatment should have been approached about consent for donation of human embryos to derive

pluripotent stem cells only at the time of deciding the disposition of embryos in excess of the clinical need.

- d. Donation of human embryos should have been made without any restriction or direction regarding the individual(s) who may be the recipients of transplantation of the cells derived from the human pluripotent stem cells.
- e. Informed consent should have been obtained from individuals who have sought fertility treatment and who elect to donate human embryos in excess of clinical need for human pluripotent stem cell research purposes. The informed consent process should have included discussion of the following information with potential donors, pertinent to making the decision whether or not to donate their embryos for research purposes. Informed consent should have included:
 - (i) A statement that the embryos will be used to derive human pluripotent stem cells for research that may include human transplantation research;
 - (ii) A statement that the donation is made without any restriction or direction regarding the individual(s) who may be the recipient(s) of transplantation of the cells derived from the embryo;
 - (iii) A statement as to whether or not information that could identify the donors of the embryos, directly or through identifiers linked to the donors, will be removed prior to the derivation or the use of human pluripotent stem cells;
 - (iv) A statement that derived cells and/or cell lines may be kept for many years;
 - (v) Disclosure of the possibility that the results of research on the human pluripotent stem cells may have commercial potential, and a statement that the donor will not receive financial or any other benefits from any such future commercial development;
 - (vi) A statement that the research is not intended to provide direct medical benefit to the donor; and

- (vii) A statement that embryos donated will not be transferred to a woman's uterus and will not survive the human pluripotent stem cell derivation process.

The ethical-legal rationale behind the stem cell policy is that it seeks those benefits of embryonic stem cell research that might be possible without encouraging any potential destruction of human embryos.

Conclusion

Summarising all the mentioned international legislation, one is either faced with a total ban or by one where the embryonic tissue is viewed to be suitable for research up to the fourteenth day after conception (appearance of the primitive streak).

Furthermore, the research should aim to generate scientific knowledge in basic research or to increase medical knowledge for the development of diagnostic, preventative or therapeutic methods to be applied to humans. The agreement also exists that no embryo may be created especially and solely for research purposes and that the only embryos to be used are those which are the surplus from *in vitro* fertilization. Furthermore, written consent of the couple from whom the embryos are issued must be obtained, and the whole process must be managed and controlled by a central body.

Seen against the above-mentioned the National Health Act of 2003 is very much in line with international standards and policies.

Chapter 4: A critique of traditional moral approaches for reflecting on the ethics of stem cell research

Before turning to the specific arguments in favour of stem cell research as well as the broad moral framework in terms of which I would like to develop and defend them (*viz* the ethics of responsibility) in chapter 5, I now pay some critical attention to the two traditional frameworks of moral reasoning, *viz* deontology and utilitarianism, and the way in which stem cell research is broadly assessed by each. I find this necessary in order to, in chapter 5, argue that the approach that I there propagate, seems to me to be considerably preferable to these more traditional approaches.

The deontological framework for the moral assessment of stem cell research

Deontology's, (Immanuel Kant), answer to the question *what makes a right act right*, is quite simple. The end *never* justifies the means and one must do his/her duty regardless of the consequences. Pojman (2000:44-46) writes: “You must do your duty disinterestedly, as though it were the last act of your life, simply because it is your duty... It is not the consequences that determine the rightness of an act but certain features in the act itself... Acting unjustly is wrong even if it maxims expected utility...Moral duty must be done solely for its own sake”.

According to the deontological theory, the issue concerning killing/destroying centres around the rights of the party whose “life” is at stake – moral obligations which are absolute irrespective of the consequences produced. According to Brody (1983:144), the central question posed by this theory is: When are the rights of the threatened party to be respected and when may those rights be overridden? Deontologists suggest that the right not to be killed is more fundamental than the right to save (Brody 1983:146) and that the people’s rights cannot be weighed by assessing the value of a human life.

Kant’s view is that human beings have an exceptional place in the moral order of the world. In his view, human beings have a fundamental importance (dignity) (Gaylin 1984:18). Man's fundamental importance or dignity, Kant believed, is derived from his ability to be an independent, rational agent,

competent of making his own decisions and setting his own goals. These clearly are attributes that embryonic tissue cannot display; therefore an embryo would not fit the fundamental importance that Kant bestows on rational humanity.

The Kantian postulation on the topic of personhood states that a person should always be treated as an end and not merely as a means to some end, by virtue of their dignity (Beck 1960; Hare 1997:11; Peters 2001:128). This dignity is conferred upon persons by virtue of their autonomy. It cannot be denied that embryos lack rational will or autonomy, since they are unable to engage in any such acts. They may, as Lebacqz (2001:152) explains, have the potential to develop reason, but one cannot speak of respecting their reason, for it is not yet developed. Therefore, embryos do not fit Kant's criteria for personhood.

To respect the embryo, therefore is to affirm that the value of the embryo is not dependent on its value for us or its usefulness to us, since respect regards a value in itself beyond usefulness (Lebacqz 2001:159). Even Kant's formulation of respect for persons, according to Lebacqz (2001:159), does not prohibit persons from being used as means to others' ends, but from being used merely as a means.

Kant's moral vision (Landman 1985:73) is articulated in his examination of the reflection on duty. Moral agents, according to Kant, have a duty to obey the commands of the moral law. As mentioned earlier, the duty not to kill overrides the duty to save. This translates into a moral law, and it forms an important part of my argument that the life of the living should dutifully be revered and protected in preference over saving the cryopreserved condition of the unviable embryonic tissue, which will be discarded regardless. As Kant pointed out, the reflection on duty is unconditional, pursued for its own sake and may never be disregarded.

According to Kant, respect for persons is a categorical imperative. Landman (1985:75) aptly explains: "If there were goals or ends that were sought not for their tendency to satisfy individual human desires or needs, but for their independent and intrinsic worth, then, according to Kant, these independently subsisting ends, ends in themselves or objective ends, would provide the basis for categorical imperatives, for imperatives or commands that are objective in the sense of being unconditional."

These categorical imperatives – which enable us to stand outside our personal maxims (general rules) and impartially and impersonally estimate whether they are suitable as principles for all of us to live by

(Pojman 2000:47) - become the objective moral law which imposes moral duties, which no good person can deviate from, on all moral agents (Landman 1985:75). Therefore the moral law referred to becomes a collective rule which binds all rational beings uniformly. An action is moral only if it manifests respect for persons or for human personality (Landman 1985:79). However, this raises the following question: since Kant only assigned moral standing to rational beings, what about non-rational entities (i.e. embryos)? The answer seems to be straightforward: since the embryonic tissue does not have rationality, it cannot be assigned moral worth. Furthermore, since it lacks human personality, it cannot be assigned moral respect. From the deontological perspective it would thus not be a crime against humanity to utilize the cryopreserved embryonic tissue; in fact, it would be a crime against humanity if it were not.

The utilitarian framework for the moral assessment of stem cell research

I would now like to turn my discussion to *utilitarianism*, the theory developed by Hutcheson and refined by Bentham and Mill (Pojman 2000:37). “Utilitarianism begins with one of the most important moral insights of modern times and couples it with a powerful metaphor which underlies our moral life. The insight is that consequences count; indeed, it goes one step further than this and claims that only consequences count. This puts it in sharp contrast to Kant's moral philosophy, which - as we have seen - places almost exclusive emphasis on the intentions behind an action. Utilitarianism goes to the other extreme, maintaining that the morality of an action is to be determined solely through an assessment of its consequences” (Hinman 2003:136).

The theory, which accepts *utility* or the *Greatest Happiness Principle* as the foundation of morals, holds that actions are right if they promote happiness in greater proportion than unhappiness, and wrong if they tend to produce the reverse of happiness (Mill 1863:4).

Hinman (2003:136) explains that utilitarians believe that the consequences that are significant to the morality of actions are consequences that increase or reduce the welfare of all those affected, therefore considering all involved impartially. Welfare in the utilitarian definition can thus be seen as attaining a reasonable degree of the quality of life a person wants or prefers to have.

It is important to stress that the utilitarian holds that the right act in any situation is the one which produces the best overall result, as determined from an impersonal view which gives equal weight to the welfare of every involved party (Beauchamp and Childress 2001:340-341). The notion of impartiality is taken even further by some utilitarians who declare that all other people's interests should become one's own. This notion should not, however, overshadow what Beauchamp and Childress (2001:341) describe as the one and only basic principle of ethics which utilitarians accept, namely that of utility. This principle follows that we *ought always to produce the maximal balance of positive value over disvalue (or the least possible disvalue, if only undesirable results can be achieved)*.

Brody (1983:10), in his work *Ethics and its Applications*, explains utilitarian ethics as follows: "The basic thesis of this approach is that the rightness or wrongness of an action is based solely on the consequences of performing it; the right action is that which leads to the best consequences... First, they seek to determine all the available alternatives. Next, from a list of these alternatives, they try to foresee the consequences of performing each of them. Finally, they evaluate the consequences in terms of which are best. The action that is most likely to have the best consequences is the one judged to be the right thing to do."

The utilitarian maxim, *those results that produce maximal utility are best*, is achieved only by evaluating all consequences over the long term. In other words, something is morally right and permissible if the good is maximized by comparing all options for action and then choosing the maximum amount of aggregate happiness. I think this is a perspective that should be accommodated in our thinking about the morality of stem cell research although, as will be shown later, the argument requires a broader motivational framework than that provided by utilitarianism. Although conferring individual rights to embryos and attempting to give each one a *face* is admirable, the reality of the society we live in is such that we are already battling to find sufficient natural fuel and food resources and over-population poses a serious problem. My argument will support the idea that cryopreserved *in vitro* created embryos cannot be granted moral status, and their cell-masses should thus be utilized for the greater good of society as a whole before they are destroyed as permitted (and required) by law. My argument is based on the examination of society at large as well as an evaluation of every person's "welfare" or happiness in an unbiased way so as to maximise the general aggregate good, and as such supporting public policy which is beneficial for at least the majority of individuals involved, and also by taking responsibility for one's actions.

This brings me to the concept in utilitarian theory which states that taking the life of a human “being” is not fundamentally wrong, but saving/enhancing the life of human “beings” is preferable. Singer (1994:182) takes the idea a step further by adding that the fact that a being is a human being, in the sense of a member of the species *homo sapiens*, is not relevant to the wrongness of killing it; it is, rather the question of whether the entity killed is a person or not. Personhood is then characterised by traits such as rationality, autonomy and self-consciousness that make a difference. Brody (1983:132) summarises the position as follows: “...killing is wrong only when it leads to bad consequences. Saving lives is right only when it leads to good consequences ... consequences are good when they result in the satisfaction of desires and bad when they result in the frustration of desires.”

It is important to remember that these desires represent the majority’s needs. For example, where there is a clash between self-interest and the interests of the community, the self is obliged to sacrifice its interests for the good of the community. Accordingly, only the consequences and not the means should be taken into account when reasoning (Brody 1983:137). Embryonic stem cell research will therefore be morally permissible if it leads to a maximisation of the satisfaction of desires (maximising pleasure or minimising pain); otherwise it will not be morally permissible.

However, in determining the consequences of deriving stem cells, one should not take into account what the embryo’s life would have been like had it continued since, if the embryo is destroyed it will not have had desires, and nothing will have been satisfied or frustrated. From the utilitarian point of view, the only concern should be the maximisation of the satisfaction of desires and the minimisation of the frustration of desires. Focusing only on the *in vitro* fertilized cryopreserved embryo population, the majority of them from which stem cells would be derived are products that will be discarded in *in vitro* clinics. The latter argument would therefore apply more aptly, and it would thus be better to minimise the frustration and maximise the satisfaction, thereby allowing the derivation of stem cells from the said embryos. Quoting Lockwood, Devolder (2005:178) explains in her article that the potential of the embryo cannot ‘unfold’ or diminish, it can only be frustrated. However, if one takes into account the bigger picture, the satisfaction of developing medical treatments would outweigh the frustration of keeping the embryo cryopreserved and not destroying them by deriving their stem cells, and in the utilitarian equation grant the harvesting of the cells. As Hare (2002:82)

points out, “[i]n utilitarianism one cannot get emotionally involved in making a decision. In making moral judgements one has to be impartial to the interests of the parties affected by the judgement.”

The question which should be asked, however, is how these consequences we refer to so often are measured/evaluated, in order to ascertain whether they carry any weight. What defines utility? Hinman (2003:136) suggests three “*characteristics*” which define utility, namely pleasure, happiness and preference satisfaction. Utilitarians at times measure pleasure or happiness in units of hedons (the Greek word for pleasure) and displeasure or suffering or unhappiness in units of dolors (the Greek word for pain). Therefore, what types of things are to be judged in terms of their consequences? The three most common things are acts (which gives rise to act utilitarianism), rules (rule utilitarianism), and social policies (practice utilitarianism) (Hinman 2003:141-3).

For the act utilitarian, moral rules are useful in guiding human actions, but are also expendable if they do not promote utility in a particular context. The act utilitarian contends that when breaking rules justifiably clashes with our traditional moral convictions, we need to revise our convictions rather than discard act utilitarianism (Beauchamp and Childress 2001:344-345). In other words, we should always perform the action which will maximize utility and produce the greatest overall utility.

Peter Singer as prototype utilitarian thinker on the moral status of prenatal life

As an example of radical utilitarian thinking, and because his views have been so influential in bioethical reflection on the status of prenatal life (so directly relevant for the issue in this dissertation) I now turn to the views of Peter Singer, one of the best known but also most controversial bioethicists alive today.¹

For Singer, as for most utilitarians, moral standing is not determined by our ability to *reason* (as it is with Kant), or to *talk/communicate*. It is determined by our ability to *suffer*. In this, he draws directly on the famous statement by Jeremy Bentham. Bentham writes: “The day may come when the rest of the animal creation may acquire those rights which never could have

¹ I shall draw heavily on the exposition of Singer’s views by WA Landman (1990).

been withheld from them but by the hand of tyranny. The French have already discovered that the blackness of the skin is no reason why a human being should be abandoned without redress to the caprice of a tormentor. It may one day come to be recognized that the number of the legs, the villosity of the skin, or the termination of the *os sacrum* are reasons equally insufficient for abandoning a sensitive being to the same fate. What else is it that should trace the insuperable line? Is it the faculty of reason, or perhaps the faculty of discourse? But a full-grown horse or dog is beyond comparison a more rational, as well as a more conversable animal, than an infant of a day or a week or even a month old. But suppose they were otherwise, what would it avail? The question is not, Can they *reason*? Nor Can they *talk*? But, Can they *suffer*?" (Bentham 1948:311, his italics) *Sentience* – the ability to feel and to experience pain - rather than rationality or linguisticity, confers moral standing

Singer is indeed an *act-utilitarian*, one who claims that the best action is the one that produces the most good for all concerned. That raises the question: What good consequences are to be maximized? To answer, he draws on classical utilitarianism (CU) and its hedonist view: The good is reducible to pleasure or happiness. Pleasure (enjoyment) must be maximized, and pain (suffering) ought to be minimized.

With CU, Singer also espouses the Principle of Equality. By that he means that the sufferings of all sentient beings have equal weight. Differences of sex, race, status, religion, age, species and intelligence are irrelevant.

Wherein, then, according to Singer, lies the moral wrongness of killing? He first refers to the *side-effects of killing*: killing has bad effects on others (friends, relatives, etc.). It is an unsavoury activity to observe, and it might foster a culture of killing that is undesirable for society. This reason does indeed not reveal why killing is inherently wrong, and cannot show why it would be wrong to secretly kill a hermit. A better reason is the reason motivated by the utilitarian calculus itself: *killing reduces the amount of pleasure in the world*. Since only sentient beings can experience pleasure, which constitutes the highest good, the result of killing is a reduction of the amount of pleasure-experiencing entities. That is bad.

Singer, in addition, espouses the so-called "replaceability thesis" which he explains as follows: "When the death of a disabled infant will lead to the birth of another infant with better prospects of a happy life, the total amount of happiness will be greater if the disabled infant is

killed. The loss of happy life for the first infant is outweighed by the gain of a happier life for the second. Therefore, if killing [a] haemophiliac infant has no adverse effect on others, it would, according to the total view, be right to kill him. The total view treats infants as replaceable, in much the same way as it treats non-self-conscious animals” (Singer 1993:186).

The foetus, for Singer, is a sentient being, but not a person, and its life has less value than a dog, a whale or an elephant – all animals on whom the epithet of “person” might, quite probably, be bestowed (more about that in the next chapter). Also, the *potential* of a foetus to become a person does not confer any additional moral status to it, just as little as the potential of an acorn to become an oak tree, morally compels us to now already treat the acorn as an oak tree.²

From this follows Singer’s infamous argument regarding the moral acceptability of infanticide. Infants, according to him, have moral standing as sentient beings, but they have no more moral standing than foetuses; they have moral standing on the basis of sentience, but there are no more “personal traits” present in an infant than in a 25 weeks or 35 weeks old foetus. All infants are also replaceable. If parents do not want a new (normal) baby, adoption is an option. Since adoption is not normally an option in the case of disabled newborns, their painless killing and replacement is morally in order.

Note that Singer is not so much in favour of infanticide across the board, but rather of infanticide in cases where newborns are suffering from intractable congenital malformations – cases where, as stated, adoption is not really an option. For example, Singer writes as follows about the lectures that he was supposed to deliver in Germany in 1991, and which were eventually cancelled because of public outcry as a result of his position: “My intention in these lectures was to defend a view which I have argued in several previously published works: that the parents of severely disabled newborns should be able to decide, together with their physician, whether their infant should live or die. If the parents and their medical adviser are in agreement that the infant’s life will be so miserable or so devoid of minimal satisfactions that it would be inhumane or futile to prolong life, then they should be allowed to ensure that death comes about speedily and without suffering” (Singer 1993:342).

² For a comprehensive analysis of the “argument from potentiality”, see Reichlin 1997; Van Niekerk & Van Zyl 1996; De Roubaix 2005; Warren 2001; Wennberg 1985.

Note, in this passage, the clear utilitarian approach: what is important in such a decision, are the consequences and not some inherent characteristic(s) of the act itself. Should those consequences serve optimal utility and should they optimally prevent suffering, they are in order. Little account is taken of the force of traditional moral intuitions, particularly the strong societal intuition that killing in general, and the killing of vulnerable, defenceless infants in particular, is morally abhorrent. The only guideline for moral action is the question as to the maximal utility of consequences. It is self-evident that, in terms of such a view, there can hardly be any doubt about the moral acceptability of stem cell research. In such research, we are dealing with a living entity that is part of the species *homo sapiens sapiens*, but that is not yet sentient, cannot suffer any pain, has absolutely no trait of personhood yet, and can therefore be killed at will, particularly in view of the promise of the indubitable benefits that experimenting with embryos can bring about.

To summarize Singer's brand of utilitarianism in this respect: the only moral objections relevant to killing non-personal sentient beings (certain animals, human foetuses and human infants) are:

- (a) the indirect objection from side-effects;
- (b) the direct objection from decreasing happiness.

Therefore, the painless killing of these non-sentient beings is morally justifiable.

One of the main appeals of act utilitarianism is that it deals with individual decisions on a case-by-case basis. There is no such thing as an exception since every case is judged on its individual merits (Hinman 2003:149). Notwithstanding its sensitivity to individual cases, act utilitarianism is also subject to a number of objections, namely (1) that it is too time-consuming to calculate the consequences of each individual's actions (act utilitarians, however, maintain that we can live most of our lives on the basis of rules of thumb, rules that summarize past experience in such situations.); (2) a parallel objection that it is too difficult to predict the consequences of individual actions, especially the long-term consequences (act utilitarians concede that predictive powers are limited, but that this is a difficulty with life, not with act utilitarianism.); and (3) that act utilitarianism is not always compatible with the demands of justice (Rachels 2007:103-104). Another well-known objection to act utilitarianism is that it is not compatible with the idea of human rights, since it seeks the greatest good for the most people, and the latter is exactly what can be trumped by an appeal to human rights (Brody

1983:19). Act utilitarianism is also criticised because of its disregard of the value of special relationships (Brody 1983:18-19)

It is objections like these, springing forth from act utilitarianism's complete disregard for rules, integrity and the moral import that the past has on us, that fed into the revision of this theory that is known as *rule utilitarianism*. Rule utilitarianism looks at the overall consequences of adopting a rule which would guide everyone's actions in a specific way under certain types of conditions. Rules are acceptable to rule utilitarianism, and the rules that are accepted are those one that can be motivated on the basis that adherence to them would maximise utility. Or, put differently, rule utilitarianism argues that we should act in unison with those rules that will create the greatest overall total of utility for society as a whole. These rules in turn should then determine which kinds of acts are morally right and morally wrong (Wellman 1975:40-42).

Evaluation of the traditional moral frameworks

In the next chapter, I am going to formulate my own moral arguments in support of stem cell research. I am also going to develop the broad moral approach or framework in terms of which those arguments will be couched. I shall call that framework, following the ideas of thinkers such as Hans Jonas, Emil Levinas, Zygmunt Bauman and Anton van Niekerk, the "ethics of responsibility". This approach or framework takes as its point of departure the untenability of the traditional approaches (deontology and utilitarianism) to moral reasoning, particularly in so far as those approaches are applicable to the moral problematic of stem cell research. I shall conclude this chapter with a few remarks about the latter untenability.

The first remark to be made is that the deontological and utilitarian approaches to moral reasoning were developed in cultural-historical contexts that were entirely oblivious to the remarkable developments in medical science and technology generally and reproductive and genetic technologies in particular. In that sense there is a striking resemblance to the problems that arise when moral theologians assert that "biblical" or "Christian" ethics are entirely appropriate for the moral assessment of what we are currently seeing in terms of new medical technologies. Scientists are in these times alerting us to realities on the molecular and genetic levels of human and other organisms that would have been entirely incomprehensible, not only to any biblical author such as St Paul, but most certainly also to Kant, Bentham and Mill.

Of course, it could be argued that broad moral frameworks or approaches to moral reasoning need not concern itself with the details of scientific developments. The argument could be that such frameworks at most provide basic normative precepts as well as broadly orientating argumentative strategies that could be applied to most moral problems, provided that the nature of the moral dilemmas in those alleged problems are, in every case, clear. However, I am not convinced that this rebuttal will fly consistently.

The trouble with deontology

Let's firstly remind ourselves of the standard objections to the deontological and utilitarian frameworks that have been developed in much literature in contemporary times. Deontology accepts the moral authority of fundamental moral rules. In the case of Kant, the best known of the deontologists, these rules (e.g. the rule that claims that lying is always wrong, even in a situation where telling the truth would have the direst conceivable consequences for another human being)³ are derived from the claim of the categorical imperative, viz. that a human subject should always be treated as an end, and not a means, and that the respect for other human beings implied by that dictum make the rule against lying absolute. In the same vein, Kant defends capital punishment as a form of necessary moral retribution, but then also on the basis of respect for the dignity, even of a murderer (see Rachels' discussion of this issue in his 2007:133-136). The categorical imperative (of which Kant provides a number of formulations) in turn is derived from the basic assumption of our universal rational nature as human beings; given the fact that we are rational, Kant claims that we cannot but see the logical and therefore moral force of the categorical imperative.

But Kant's view is only one in the array of views concerning the source of the moral rules that deontology espouses. For others, the source of moral rules is divine revelation. For others, it is the precepts of our universal human consciousness that is driven by a universal set of moral intuitions. For yet others (such as Durkheim; cf. his 1912), the source is the dictates of society which requires moral behaviour to keep itself intact.

Can these differences ever be resolved? I am quite doubtful of that. There seems to be no definitive way to establish which source of moral rules is the most authoritative. And until this can be settled, the suspicion will remain that the defenders of radical deontology are, at most,

³ Cf. Kant 1949:311, as well as James Rachels' excellent discussion of this issue in his 2007:122-125.

trying to impose their own moral biases on society at large. With reference to our problem in this dissertation, one cannot help but to be under the impression of the inconsistency with which moral precepts about the status of prenatal life is thrown around. Many deontologists, particularly from the Christian orientation, abhor stem cell research because of its alleged disrespect for a “human being” and because it violates the prohibition to kill. Yet, killing, in the form of capital punishment or a just war is quite acceptable to these very same deontologists, as well as to Kant. We shall return to this issue.

There are also other serious problems with deontology. One of these is how absolute rules are to be taken or understood. We have already referred to Kant’s rigorous defense of the rule against lying, even if it results in the death of a person who is fleeing someone is trying to kill him and the refugee is seeking refuge in the moral subject’s house. On being challenged, in that situation, by the assailant to reveal the refugee’s whereabouts, the moral subject, according to Kant, is obliged to tell the truth.

To my mind, this is a palpably absurd position to take. It is absurd for three reasons. The first is that it absolutises a moral rule, and thereby illustrates the ludicrous consequences that such an absolutization might have. As Rachels points out, Kant simply assumes that we must take responsibility for the bad consequences of lying, but not for the bad consequences of not lying!

Secondly, it shows how preposterous an approach to moral reasoning is which insists that the consequences of an act are of no material moral import to the act. We cannot make meaningful moral decisions without paying at least a modicum of attention to the consequences of our acts. If Kant is right, morality is more concerned with logical and argumentative consistency than with the direct, moral interests of other human beings.

Thirdly, Kant’s view rests on an unreasonably pessimistic view of what we can know of the future. According to him, because we cannot know the future for certain, we cannot let our acts at all be determined what we fear might be the case in the future; we can only act in accordance with what we now know is right or wrong, such as speaking the truth. But that is not the case. In the example that Kant himself provides, there is *no doubt what the future holds for the victim* if he is revealed to the assailant: the victim will die! I cannot accept as “moral” a position that, on the assumption that “we cannot know the future”, sacrifices the life or best interest of

another human being if something that I was in a position to do, such as to tell a lie to a murderous assailant, could have prevented that death.

Maybe the way to go is to “de-absolutize” moral rules. In Kant’s example, we could, following Rachels, suggest that the rule should not be “lying is always wrong”, but rather, “lying is wrong unless to lie is necessary to prevent murder”. However, once that kind of exception is allowed, the question becomes why the exemption should only be for the case of murder. Could a case not also be made that lying could be in order to prevent suffering (e.g. when information is withheld from a terminal patient) or to save the career of a young business executive with responsibilities to a young family when he has done something illegal? The logic of deontology simply does not allow for this kind of rule qualification, the consequence of which would be a direct erosion of the moral logic of deontology.

Another well known problem with deontology is the issue of conflicting rules, and the question as to what rule ought to take precedence once such conflicts occur. As such, deontology fares quite badly in the face of the challenge of real moral dilemmas. For example, consider the situation of the medical practitioner in South Africa who diagnoses a man as suffering from HIV infection, and, after counselling, implores the man to inform his spouse and/or mistress(es) of his condition, which the man then bluntly refuses to do and also forbids the doctor to do on the basis of medical confidentiality. Here we see a real moral conflict: two values that strongly motivate moral action, present themselves, viz. beneficence to spouse (Rule 1: “Inform the spouse of an HIV patient, since her health and life depend on it”) and confidentiality in the relationship with the patient (Rule 2: “Do not ever break doctor-patient confidentiality; only make a patient’s medical information available to someone else with the explicit consent of the patient”). In this situation, it is impossible to adhere to both. Which “rule for moral action” should now take precedence? That is far from evident, since both are serious moral rules.

Applied to the problem of this dissertation: How do we *simultaneously* confer respect on the embryo *and* proceed with research that requires the destruction of embryos – research that holds the promise of truly revolutionary medical treatments for people (like para- and quadroplegics, end-stage diabetics, sufferers from Alzheimer’s and Parkinson’s diseases, etc.)? It seems pretty unlikely that, on the basis of a purely deontological approach to moral reasoning, this dilemma could ever be solved appropriately.

The trouble with utilitarianism

It is my considered opinion that a purely utilitarian-based approach to moral reasoning does not either provide an appropriate framework in terms of which to adequately reflect on the moral challenges posed by stem cell research. It is a fact that utilitarians such as Peter Singer, Michael Tooley, John Harris and Julian Savulescu have in recent years been quite prominent in writing and reflecting on these issues. In view of what I have just argued in critical response to deontology's refusal to accommodate consequences of actions in its moral evaluations, it must also be clear that I have considerable sympathy with many positions taken by utilitarians on these matters. The extent of that sympathy will become clearer when my own arguments in support of stem cell research are developed in the next chapter. But although I have sympathy with many of the substantive positions reached by utilitarians, I nevertheless am poignantly aware of the palpable shortcomings of many aspects of their approach. I shall therefore endeavour to develop an alternative broad approach or framework for my own line of reasoning in the next chapter.

I have already alluded to a number of widely acknowledged shortcomings of the utilitarian approach. Its appraisal of *mere consequences*, and the accompanying impression it creates that *consequences and the future are all that matter morally*, is flawed with shortcomings. There is the obvious critical retort about the extent of our possible knowledge of the future and of all possible consequences that might follow a particular action. Can we, in the present, ever know all possible consequences? If not, which of those can we indeed know with a relative measure of certainty? Up to which point in the future do we have to regard the consequences of actions?

But apart from the issue of insufficient knowledge of the future, there is also the question as to whether the events/commitments/responsibilities that emanate from the past do not have an effect on moral status in a way that utilitarianism can never really account for.

This can be illustrated by the now quite well known fictitious case suggested by HJ McCloskey in an article that appeared in *Inquiry* in 1965: "Suppose a utilitarian were visiting an area where

there was racial strife, and that during his visit, a Negro⁴ rapes a white woman, and that race riots occur as a result of the crime, white mobs, with the connivance of the police, bashing and killing Negroes, etc. Suppose too that our utilitarian is in the area of the crime when it is committed such that his testimony would bring about the conviction of a particular Negro. If he knows that a quick arrest will stop the riots and lynching, surely, as a Utilitarian, he must conclude that he has a duty to bear false witness in order to bring about the punishment of an innocent person” (McCloskey 1965:250).

This example could count to serve the point that *utilitarianism is often at loggerheads with the requirements of justice*; it seems as if justice can sometimes be relinquished in the name of the best consequences for the most people. (In similar vein, the case where, when an important resource is stolen from a university library, the ten students who were in the library at the time could be identified and isolated. If no one of them admits to the crime, the university could then, on purely utilitarian grounds, expel them all. Justice is not served to the nine who are innocent, but certainty is achieved that the guilty party has been punished and that the best consequence for the thousands of other students at the institution is allegedly achieved, irrespective of an apparent “injustice” to nine blameless students.)

However, the more pertinent point of McCloskey’s example is the way in which it illustrates the importance of the past when we have to deal with morally problematic situations. It seems abhorrent that, in this case, the utilitarian will lie in order to help restore order. Apart from the palpable injustice that will be done to the innocent “Negro”, the pertinent question is: what causes our moral outrage at such a possible line of behaviour from the utilitarian? The answer, I think, has been provided in a thought provoking contribution by Bernard Williams. Williams (See Smart & Williams, 1973:67-73) persuasively argues that, for the utilitarian to lie in this situation *would be to forfeit his integrity*.⁵ Integrity is the trait of character which relates to our trustworthiness as acting subjects. We act with integrity when people are able to rely on our judgement as being consistent with a set of values that we have knowingly adopted and to which we remain committed, irrespective of morally challenging situations. To acknowledge the import of integrity for the moral status of actions, is to acknowledge that we cannot simply relinquish the past and only consider possible consequences in the future when we try to act

⁴ It must be stated that, at the time when McCloskey wrote this article, the term “Negro” probably did not yet have the fully offensive racist connotations that it has today. Yet, the way McCloskey sets up the case, does reveal some racist bias in even his own thinking at the time.

⁵ Williams “adapts” the example to suggest that the utilitarian arrives at riots where an unscrupulous gang leader is on the verge of executing ten prisoners, and where he suggests to the utilitarian that, should the latter be willing to shoot one of the culprits, the rest will be saved.

morally. Utilitarianism, as is well known, tends to radically *under-value the force of promises* in the establishment of moral status. Promises are only to be kept if the good that they bring forth supersedes the bad. Integrity is, in fact, a kind of promise that is expressed by the force of one's person and personality. It is the ability and the consistency to "remain (true to) oneself"⁶. If that is moral virtue, the force of the past in the assessment of moral status cannot be as easily dismissed as is apparently imagined by utilitarianism.

A host of other problems with utilitarianism might well be raised. One of the critical questions that James Rachels (2007:101-103) for example raises, is: *Is happiness the only thing that matters morally?*, as classical utilitarianism seems to suggest? He offers the example of a concert pianist whose hands have been seriously damaged and that is prevented to perform ever again. Why is this experience bad for her? Simply because it makes her unhappy? Suppose we could cheer her up and "restore her happiness" by means that have nothing to do with restoring function in her hands? Would that be an appropriate response to the tragedy that has befallen her? Is her predicament exhausted by *the fact that she lacks happiness*, or by the *actual loss of function in her hands*? Hence Rachels' question: *is happiness all that matters?* Is the real tragedy of this woman's life *that she has lost happiness*, or that *she lost the use of her hands*? It seems absurd to suggest that her "loss of happiness" is the real tragedy, since "happiness" (in whatever form) might be restored to her in some other form – a form that could nevertheless not compensate for the irreparable loss of function in her hands. "Happiness" is most certainly not all that "counts"!

Rachels' point is that *happiness is a state of mind. It is dubious to make moral status dependent on such a state of mind.* The question is: Is something good because it makes us happy, or does it make us happy because it is good? Utilitarianism seems to assert the first, which is problematic. For example: suppose expressions of racism made most people in South Africa "happy"; does that make those expressions morally right? That can hardly be accepted.

Utilitarianism is also widely known to be *in conflict with the fundamental presupposition of the idea of individual human rights.* If the main moral precept is the maximization of happiness for all, and that is to be translated into public policy, it could well be justified that people with two

⁶ In the Afrikaans literature, the character Bart Nel (in a novel by van Melle with the same title) represents, in essence, this idea of integrity. In the book, after a series of tribulations regarding the Boer War, the rebellion and the unfaithfulness of his wife, Nel says towards the end: "Ek is nog hy! (Bart Nel)". In fact, in its earlier editions, the book's title was in fact "En ek is nog hy".

healthy kidneys be forced to donate one (thus solving the problem of the shortage of donors) or that people with big houses that they do not fully occupy be forced to take in another homeless or poorly housed family - thus alleviating the housing shortage significantly and contributing to “maximizing happiness for the most people”. The reason why such possibilities seem morally abhorrent to most of us, is the fact that such forceful policies would be in conflict with our most fundamental human rights, such as the right to bodily integrity or the right to private property. In a society run by strictly utilitarian political policies, there clearly would be little room for the idea or practice of fundamental individual human rights – rights that could be drawn upon and legally be enforced in order to “trump” the ability of lawmakers to interfere in inalienable spheres of personal, private life.

A penultimate criticism of utilitarianism is that it is a *too demanding moral position* to uphold persistently. Since each person counts, in value terms, for one, and since the moral requirements of all persons are, in terms of the strict utilitarian calculus, on par, it is unclear what the limits may be on the utilitarian claim that the best value be sought for all. This is exacerbated by the fact that, because of utilitarianism’s radical equality, it makes no provision for the claims of people in special relations to the moral agent. In terms of strict utilitarianism, my own children or my own students or my own patients do not necessarily have a stronger claim to my attention and gratuity than anybody else. If that is the case, the question also becomes: when, if ever, do the demands on my time, energy, service and resources come to a conclusion? If I have done charity or redistributed wealth to my immediate neighbours in accordance with the demand of the utilitarian calculus that the greatest good for the greatest number be sought, would it be in order to stop there? Are the claims of other people outside of that circle not equally as demanding? Do people in Zimbabwe or Britain or India not, in principle, have an equal claim to my resources? What actions are morally *obligatory* and which are *supererogatory* – i.e. such that they would be morally commendable, but not obligatory? Utilitarians do not have satisfactory answers to these concerns. However, if these concerns are legitimate, utilitarianism is indeed requiring a lifestyle from us that would in fact be unsustainable for most human beings. If that is the case, it cannot be taken too seriously as a moral approach.

The last problem with utilitarianism that I would like to raise is its *tendency to challenge seemingly fundamental, universal moral intuitions*. If strict act utilitarianism would be the

model for moral decision-making in society, it would, sometimes, be in order to lie, cheat, steal, kill, break promises and even torture.⁷ It is a serious question whether a moral approach in terms of which these kinds of acts, so palpably in conflict with very basic moral intuitions that most of us apparently share, can indeed be taken seriously. Irrespective of the undoubted beneficial outcomes that stem cell research would have for many people, the question remains whether the moral intuition that requires respect for and protection of a vulnerable life form (the embryo) from which all of us have originated, can be as easily dismissed as seems to be the case in the thinking of utilitarians such as Peter Singer and John Harris. The question is whether an approach to moral reasoning and decision-making is not possible in terms of which an appropriate consideration of the force of both deeply ingrained moral rules as well the demands of utility cannot be held in some form of a balance. It is to arguments to such effect, as well as the moral framework that informs, facilitates and justifies such a balance, that we now turn.

⁷ Cf., for example, the case where the police traps a terrorist who has indicated that he has planted a bomb in a big, packed sports stadium. The bomb is set to go off in 30 minutes, and the terrorist refuses to reveal the location of the bomb. Would it be in order to torture him in order to ascertain the relevant information and thus save more lives than would otherwise be lost in the ensuing explosion? For a consistent utilitarian, torture under those circumstances is morally fully justified; the end justifies the means, since many can be saved at the cost of the interest, dignity or life of an (evil) individual; a little pain is justified to prevent a great deal of pain if the bomb in fact does explode.

Chapter 5: The morality of stem cell research within the ambit of an ethics of responsibility

We now reach the core of this dissertation, viz. the part where I shall pay attention to the specific moral problematic implied by stem cell research. The debate about the morality of this research constitutes in large part what I refer to when I distinguish “micro” issues from “macro” issues in this regard. Macro-issues specifically refer to larger policy issues that have to do with safety concerns, commercialization, power issues, accessibility and the shortage of resources, when we are considering a public policy for the continuation (or not) of this kind of research. By “micro” issues I, purely for the sake of utility, refer to the distinct philosophic-moral aspects of the stem cell problematic. Some of the macro-issues, which will in more detail be dealt with in the next chapter, have, of course, moral dimensions, and some of those moral dimensions will be referred to and discussed in both chapters. For now, however, I shall concentrate on the specific moral issues as have been dealt with in the most prominent philosophical and ethics literature. Before specific issue of public policy is to be addressed, we first and foremost have to establish whether stem cell research represents an activity, the moral status of which is at all justifiable.

The controversy surrounding stem cell research over the past two decades since this possibility has first come to the attention of ethicists and policy makers, has been quite remarkable. It is a well known fact that the controversy is particularly pronounced in the United States, where it figures widely and prominently in the public political debate. It is so prominent in that country that, during the last presidential elections (2004), the issue of whether voters are in favour of stem cell research, and particularly whether they agree that public funding be used for it, was tested, referendum style, in a number of states. In a state such as California, which has a very large stem cell research industry, the vote in favour of this research proved to be an overwhelming majority of 59% (Willoughby 2004). The reason for this controversy is directly related to the perception that stem cell research implies acting upon, and in most cases destroying, live embryos. These embryos are, by a significant portion of people, regarded as life forms with significant personal status, and therefore also with moral status. For exactly the same reason that America’s conservatives are dead set against most forms of abortion, they also are fiercely against stem cell research. These conservatives, as has been persuasively

demonstrated by analyses of the outcome of the presidential elections in 2004, form the backbone of pres. George W. Bush's conservative Republican power base.⁸

It has been pointed out in chapter 3 that legislation explicitly forbidding stem cell research has been enacted in a number of countries of which Germany and Italy are the most prominent. In spite of the conservative mass in countries such as the USA and Britain, no such legislation exists there and stem cell research proceeds daily. (In chapter 3, I have elaborated on what the legal position in South Africa is; in terms of the newest legislation, stem cell research is possible in South Africa pending certain circumscribed conditions, the most important of which is that the Minister of Health should give permission for it, and that "reproductive cloning is forbidden, whereas "therapeutic" cloning is allowed.)⁹ In the USA, however, objections to this research have caused the Bush administration to prohibit federal funding for research on embryonic stem-cell lines derived after August 9, 2001 (Sandel, 2004:208). A number of such cell lines derived before this date, are in possession of federal agencies, and research on them may continue. (Anecdotal evidence suggests that many of these cell lines have either ceased to exist or have become so contaminated that further research on them is not possible). In 2006, as was widely reported in the press, pres. Bush used the presidential veto for the first time in his presidency when he vetoed a bill that would legislate expanded, federally supported embryonic stem cell research – a move widely interpreted as explicitly playing up to the already mentioned significant conservative base that was by and large responsible for his re-election in 2004. (Stolberg 2006; Klein 2006).

From the outset, and despite all indications of the exciting prospects that this research holds, as has been indicated earlier, stem cell research has been submerged in severe moral controversy.

⁸ According to Deb Riechmann's (2007) article in the Broward Times an analysis of people who support Bush are Republicans (67 percent); conservatives (53 percent) and white evangelicals who attend religious services at least once a week (56 percent).

⁹ Although this has been discussed, I again quote relevant parts (from article 57) of South Africa's latest Healthcare Act (Act 61 of 2003):

- (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 utilizing adult or umbilical cord stem cells...
- (4) The Minister may permit research on stem cells and zygotes which are not more than 14 days old on written application 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.

A fundamental moral objection that bioethicists, politicians, policy makers and even some scientists have raised against ES cell research is that the “harvesting” (an unfortunate term) of these cells from embryos implies the wilful “killing” of these embryos that have the potential to grow into full-fledged human beings. This amounts, for many people, to the moral equivalent of full-fledged abortion, the morality of which they generally do not accept.

If research on human embryonic (henceforth HE) stem cells is therefore immersed in controversy, the first question to arise is why the research has to be on those cells and not on stem cells derived from other sources. There are indeed three potential sources of stem cells: the inner cell mass of *in vitro* fertilized embryos (these cells are designated embryonic stem cells); the gonadal ridge of the aborted foetus; and many adult bodily tissues, such as the heart, the liver and the bone marrow which is also responsible for the production of blood cells. In fact, most differentiated human tissues contain stem cells. Whilst research on the utilization of these cells in research and therapy has not been without some promise, there are sound reasons why this does not solve the dilemma either for the ethicist or the researcher (De Roubaix and Van Niekerk 2006).

Firstly, the therapeutic potential of non-embryonic stem-cells is significantly inferior to that of ES cells. The levels of pluripotency are, for example, not the same. Secondly, non-embryonic stem cell lines are not “immortal”. Thirdly, non-embryonic (“adult”) stem cells are tissue-specific and usually reproduce only the type of tissue from which they have been harvested, although there is some evidence to the contrary (Holland et al. 2001:xvii). And finally, some adult human tissues such as myocytes (the contractile cells of the heart) contain no stem-cells; only embryonic stem cells hold therapeutic potential for the regeneration of this type of tissue. Since it is not yet clear that EG cells have the same capacities of ES cells, we restrict our discussion to the latter. (Van Niekerk 2006)

As recently as August 24, 2006, researchers of the company Advanced Cell Technology, led by dr. Robert Lanza, reported on the website of the leading scientific journal *Nature* that they have, indeed, now also “developed a technique for establishing colonies of human embryonic stem cells from an early human embryo without destroying [the embryo]... the new technique would be performed on a two-day-old embryo, after the fertilized egg has divided into eight cells, known as blastomeres”.¹⁰ One of these cells can allegedly now be removed from the

¹⁰ (<http://www.nytimes.com/2006/08/24/science/24stem.html?th&emc=th>)

embryo at this stage of development without causing damage to it. “The embryo, now with seven [blastomere] cells can be implanted in the woman if no defect is found”. “Many such embryos”, according to the researchers, “have grown into apparently healthy babies over the 10 years or so that the diagnostic tests have been used” (Ibid.). It is probably too early to tell whether this result will find wide acceptance in the scientific community. If it does, it certainly holds the promise of the removal of the principle objection to ES cell research, viz. the destruction of embryos as a result of it. At this early stage of that debate, it seems that many questions are raised about the safety of implanting embryos from which one of eight blastomeres at this very early stage of cell division has been removed. Time will have to tell in this respect.

A range of ethical problems surrounding stem cell research and its clinical applications can indeed be identified. Following a suggestion by Van Niekerk (2006) I would like to make a broad distinction between *two kinds of problems* that emerge in the debate about stem cell research. The *first* is the problem about the *moral status of the embryo*, and the extent to which this problematic has implications for the moral acceptability of stem cell research. This problem has, in the literature up till now, dominated the debate. Quite serious questions about the morality of stem cell research, even in the face of the many and exciting promises that it holds, are raised if the price for securing stem cells with significant therapeutic potential turns out to be the continuous destruction of embryos that, in themselves, have significant moral status. I shall dedicate the bulk of this chapter to this problem.

However, before doing so, a *second* set of problems can be identified that have *less to do with the inherent moral status of the research and its accompanying techniques as such, and more to do with its effects on the practice of medicine and medical research*. In this respect, following Van Niekerk (2006) I refer to issues such as the patenting of stem cell lines, the commercialisation of the therapies emanating from the research and the possible commodification of human tissue that might result from it.

In what follows, I shall *firstly* deal with the *latter* of the two identified problems. This will be followed by a *more extensive discussion of the first and seemingly central moral problem in the stem cell debate*. I shall *conclude* with developing an outline of the moral framework that I find the best suited for appropriate moral reflection on these issues, viz. the ethics of responsibility.

Possible abuses of stem cell research and applications in the practice of medicine

I shall firstly state the differently arguments that can be distinguished in this regard as succinctly as possible. In a next section, I shall develop evaluative remarks about these arguments.

i) Stem cell research as incentive for making money

The *first* issue that comes to the fore in this regard is that *stem cell research is very expensive and therefore requires significant investment from sources of public funding*.¹¹ These investors will only come on board if the financial yield of the research is significantly lucrative. This inevitably exacerbates the extent to which frontline medical research is conducted by a private sector that pursues the progress of medicine not primarily from the perspective of what is good for humankind, but mostly if not exclusively from the perspective of how much money is to be made out of it. Hence the plethora of private companies that are mushrooming all over the world (94 companies currently conducting stem cell-related research)¹² in pursuit of new techniques and patents. The moral concern in this regard is the question as to whether this is desirable in view of the more noble ends that the practice of medicine is traditionally thought to aspire to – ends such as the promotion of health, the relief of suffering and the benefit of all mankind.¹³

¹¹ On the 2nd of November 2004, for example, the Californian voters approved Proposition 71 whereby \$3 billion in public funding for stem cell research at California universities and research institutions was allocated.

¹² http://www.stemcellresearchnews.com/2006_Guide.htm

¹³ Anton van Niekerk, drawing on the insights of Albert Jonsen (1990:61-79), writes as follows about the excesses that this idea of medicine as a “noble profession” has indeed caused in recent history: “Ter illustrasie kan ons wys op die verskil tussen die etos van ‘edelheid’ (‘nobility’) wat kenmerkend was van geneeskunde aan die begin van hierdie [20ste] eeu in Brittanje, en die situasie wat ons vandag in 'n samelewing soos die VSA aantref (Jonsen 1990:61-79). Dokters het nl. in die Brittanje van die 18de eeu 'n taamlike slegte openbare reputasie gehad, maar het in die loop van die 19de eeu langsamerhand daarin geslaag om nuwe en verhoogde status te verkry - 'n ontwikkeling wat natuurlik saamloop met die sukses van die ontwikkeling van die empiriese wetenskappe in die 19de eeu, en die toepassings vandaaruit in die wêreld van medisyne. Florence Nightingale se onbaatsugtigheid gedurende die Krim-oorlog het insgelyks veel bygedra tot die ontwikkeling van 'n nuwe etos. Toenemend is oor geneesherse gedink as mense wat 'n "edele taak" verrig, en wat daarom ook as edele gesien en behandel moet word. In 'n klasse-georiënteerde samelewing soos Engeland het dit kort voor lank ook gepaard gegaan met formele inwyding in die belonings van klasse-meerderwaardigheid. Jonsen (1990:62-69) wys in dié verband veral op die hoogtepunt van hierdie kultuur, nl. die toekenning van 'n baronskap aan Sir William Osler, regius professor in geneeskunde aan die Universiteit van Oxford tydens die kroning van George V in 1910 (Van Niekerk 1997:270).

ii) Issues of the appropriateness of the research for the developing world in view of existing inequalities

This concern is strengthened when we consider a *second* question that stem cell research raises in this regard:

Stem cell research clearly requires expertise and technology that can only be obtained at very high cost, resulting in the fact that the therapies that will hopefully emerge from this research will be extremely costly and therefore only available to the richest sectors of society. The problem in this respect is exacerbated by the dire situation of health services in countries in the developing world that will, in all probability, be net importers of these therapies. It hardly requires argument to emphasise that the direst health care needs of populations in the developing world are the services provided by primary care – clean water, healthy and enough food, sanitation, inoculation against children's diseases – as well as preventative and therapeutic measures in view of the great killers of people in developing countries: Tuberculosis, Malaria, dysentery, gastro-enteritis and, above all, HIV/AIDS.

The concern in this respect is about the morality of nowadays focusing an increasing amount of resources on relatively exotic enterprises such as stem cell research, and thereby exacerbating the existing inequality between developing and developed worlds as regards health care services. It is a well-known fact that spending on health care is probably the most pronounced indicator of inequalities in this regard.

A few statistics (supplied by Benatar, Daar & Singer 2003) will illustrate my point:

- The United States spends above 50 per cent (US\$ 1.2 trillion per year) of the total health care expenditure in the world (which is approximately US\$ 2.2 trillion per year). This expenditure is in fact on only 5 per cent of the world's population.
- Compare that to the fact that government expenditure on health in Sub-Saharan Africa fell from 5.8 per cent to 1.6 per cent of GDP over the period 1980 to 1997.
- Annual per capita expenditure on health care is less than US\$10 in many African countries, as compared to between US\$ 2000 - \$4200 in industrialized nations.
- Ninety per cent of global expenditure on medical research is on diseases causing 10 per cent of the global burden of disease. Of the 1223 new drugs developed between 1975 and 1997, only 13 per cent were for the treatment of tropical diseases so prevalent in Africa.

In view of these disturbing realities, the concern is often raised whether stem cell research is not set to exacerbate the existing inequalities between not only North and South, but also between rich and poor in the societies where they eventually become prevalent.

iii) Issues related to the possible commodification and commercialisation of human tissue

Linked to the previous two concerns is, *thirdly*, the matter of the possible commodification and commercialisation of human tissue as a result of stem cell research and its emergent therapies. It seems, for example, counter-intuitive that it would be morally in order to “patent” human tissue such as stem cell lines for the simple reason that the “skill” or “commodity” that would be the contents of the patent, is not something that has been created by the patent-holder.¹⁴ The patent could at most reflect the discovery of something that the human body, as it were, “does on its own”. Secondly, is it moral to deal with bodily tissues as if they are commodities that can be bought and sold at will on the market place?

For example, in order for therapeutic cloning – essential for the current progress of this research – to proceed, there is and will be a significant need for female ova. Ideally, the expectation would be that women donate their ova for research and only be compensated for

¹⁴ For an excellent discussion of the issues related to the patenting of tissue, cf. Holtug 1998 and Ossorio 2002.

the costs and discomfort associated with such donations. But the real world will probably work quite differently. It can be expected that the demand for ova will be so great that women will be solicited to “sell” their ova at lucrative prices – a practice that will, without doubt, encourage the exploitation of particularly poor women in all societies.¹⁵ Thirdly, questions are raised about the possibly unrealistic expectations that are currently raised for stem cell research. Although results have been encouraging, it must be borne in mind that we are still very far from a situation in which tailor-made organs can be produced for transplantation or in which spectacular procedures such as restored nerve growth in paraplegics or the replacement of insulin secreting cells in the pancreas have been attained. Questions are asked about the morality of raising expectations to the level that we have recently seen in the popular press, thereby feeding on the effects of sensation in order to secure resources for research that has a very long way to go, irrespective of the question about its inherent moral status.

Evaluative comments

Let me, to conclude this first section of the chapter, make a few remarks about the problems identified till now. As I have suggested, they are problems, not about the inherent morality of the research as such, but rather about its effects on medical practice, medical research and on social and global relations.

i) Medicine driven by market economies

As far as the commercialisation of the research and its usurpation by private companies are concerned, let me be brief by saying that, although the commercialisation of medicine and research seems to be inevitable in our time, and acknowledging with appreciation and respect the fact that private companies have served us with remarkable therapies and drugs over the past century, I am convinced that medicine represents a practice and a profession that cannot be easily reconciled with the logic of markets and of unbridled monetary profiteering. Inasmuch as it is worth our while to nurture the old ideal of the nobility of medicine (cf. Jonsen), our “lords” ought to remain the sick, not the profit demands of shareholders. I believe that society, through the formulation and guidance of societal health policy, has the task of assuming responsibility

¹⁵ This has been happening on a significant scale in South Africa. The matter was given explicit attention in a series of articles in *Die Burger* in 2005. Cf. also the articles written by Anton van Niekerk (Van Niekerk 2003 & 2004) on this matter, to which I shall later return.

for health care and research on advice of a responsible scientific community in view of addressing its direst health care needs.

Many arguments can be developed in support of this position. I shall settle for two only. In the first instance, a purely market driven health care system is inevitably driven by what the market wants, and not by people's direst health needs. If medical research is only motivated by what markets require, it will be no surprise if we find that institutions doing this research are first and foremost interested in "therapies" that are intended to serve people's cosmetic, maybe even esoteric, needs rather than proper health care needs. If, while markets are basically driving health care research, a drug which can effectively prevent or "heal" obesity could be found, or one that effectively prevents hair loss (or even restores hair loss), or one that effectively prevents aging of the skin (wrinkles!), one can be assured that these drugs will be the top performers of any supplier.

In short: medical research ought to be driven by needs that are actually medically indicated. That, of course, raises the question as to what the phrase "medically indicated" means. To answer, one cannot avoid the troubling issue as to what the purpose of medicine actually entails. I am hesitant to identify that purpose as, e.g., the promotion of health, simply because that would imply that the scope of health care becomes too broad. Health, as we all know, is by far not only promoted by health care; clean water, sufficient nutrition and adequate sanitation are far more important predictors of a healthy society than mere health care facilities. If the promotion of health is the purpose of medicine, the provision of water, nutrition, sanitation, exercise facilities, etc. all fall within the ambit of health care. That, for me, is not a desirable situation.

I would also be hesitant to identify the prolongation of life as the purpose of medicine. Life can nowadays be almost indefinitely prolonged by technical scientific means, and the mere ability to do that does not necessarily coincide with what is medically indicated. I therefore opt for the position which states that the *purpose of medicine or health care is the relief of suffering*. I grant that the definition of "suffering" is no easy matter. Yet, medicine is not and need not be absorbed by the issues raised by borderline cases of suffering. Suffering is prevalent and unambiguous enough in our day-to-day life experience to ensure that the relief of suffering can, theoretically and practically, encompass the purpose of medicine. If that is agreed, my criticism of a purely market driven health care system is coherent. Medicine should provide for what

people actually need to prevent real suffering, not for what they think they need and for what they are prepared to spend fortunes on because of dispositions that often come very close to mere feelings of vanity or denialism.

The second argument that I would like to propose against the desirability of health care research being only driven by market forces is the fact that a pure market economy presupposes participants' ability to make purely rational choices. When buying a car or a bottle of wine or a computer in a market economy, one is normally able to gain sufficient information, to assess what one's actual needs are, to compare competing possibilities and to come to a rationally justifiable decision on the basis of a careful deliberation, with others, but also with oneself, on the basis of these factors. This is very seldom the case when the "product for sale" is some drug, therapy or procedure in the health care setting. In situations of emergency care, there is no time for these deliberations. Although informed consent is nowadays required for health care all over the world, we know that, particularly in the context of the developing world where a large part of the population is illiterate¹⁶ and barely able to follow and grasp even the most elementary medical information, the whole idea of "rational deliberation" is no more than a pipe dream. Even well educated and wealthy people are normally in no position to, for example, compare and evaluate different cancer protocols or anti-depressants. People are inevitably dependent on the expertise of the medical practitioner in a way that is very often quite irreconcilable with the assumptions and practices of a market economy.

Given these two arguments (and others that could be added), I am convinced that there are serious moral problems that arise in a situation where stem cell research, with all its exciting promises, only occurs and develops within a research and health care environment that is dominated by private enterprise. If the benefits of this research can be proved, they should be benefits that can be made available, not only to those who understand and are able to pay, but to all in society that can actually benefit from them.

¹⁶ Anton van Niekerk writes as follows about the literacy problem in South Africa, which is Africa's most advanced economy: "Literacy... is a huge problem in South Africa. If literacy is defined as the ability to read, write and numerate (normally conditional on 7 years of schooling), then 41% of the adult population of South Africa is illiterate (Bot, Wilson & Dove, 2000, p.73). Macfarlane, reporting on a recent conference on this topic, claims that the figure is 45% (Macfarlane 2000). A map in the *Education Atlas of South Africa* shows that in one third of the country's 354 magisterial districts – all located in the rural areas – the illiteracy rate is between 60% and 80%. In the majority of the magisterial districts, over a third of the adults are illiterate. Urban and developed residential areas have the lowest illiteracy rates of between 11% and 20%. KwaZulu-Natal, where the AIDS pandemic is at its worst (according to the latest Dept. of Health figures the infection rate in this province rose from 32.5% in 1999 to 36.2% in 2000), is also the province with the highest number of illiterate adults (1 982 845), while the Northern Province is proportionally the worst off (where 52% of all adults are illiterate)" (Van Niekerk 2005:60)

ii) *The commercialisation of body parts*

In the same vein, I have problems in accepting that human tissue or body parts can ever be regarded as items or commodities that are available for commercial transactions. Some things, of which the human body is a prime example, are of such value that it can never be bought or sold. If expendable parts of the body can be of use to do good to others, those parts can only be donated. Such a view does not under-value the body; to my mind, it exactly emphasises the real value of the body. Of interest is of course, the fact that human blood seemingly serves as an interesting exception in this regard, since it, albeit a kind of tissue, is widely bought without much apparent moral controversy surrounding the practice. However, a very strong case can be made that blood is not actually bought from the blood transfusion service in South Africa, but that what is being paid for, is only the service that makes the blood available.

I am in agreement with Van Niekerk when he writes as follows in this regard: “Ons moet buitengewone respek hê vir die menslike liggaam. Die liggaam is nie bloot ’n ding tussen dinge nie. Die mens is wat hy/sy is op die basis van die liggaam; hoewel ek kan sê dat ek ’n liggaam *het*, kan, en moet ek veral ook sê dat ek my liggaam *is*. Vir soverre die mens waarde het, het hy/sy waarde as lewende (en deurleefde) liggaam. Die respek wat menslike liggaamlikheid afdwing, bring mee dat die liggaam en/of liggaamsdele nie beskikbaar behoort te wees vir kommersiële doeleindes nie, en veral dat dit nie uitgebuit mag word vir sodanige doeleindes, waarvan winsbejag normaalweg die vernaamste is nie. Natuurlik beteken dit nie dat liggaamsdele (van lewende persone of van kadawers) nooit vir oorplantingsdoeleindes beskikbaar gemaak mag word nie. Wat is meer edel as ’n ouer of familielid wat bv. ’n nier skenk aan ’n pasiënt wat daarsonder sekerlik sal sterf, of as ’n familie wat toestem dat die hart van ’n breindood ongelukslagoffer gebruik word om ’n ander lewe te red nie? In albei hierdie gevalle gaan dit egter om orgaanskenking, en nie om winsbejag nie. Dis omdat ons die menslike liggaam soveel respekteer, dat ons weier om ’n kommersiële prys op liggaamsdele te plaas, en hulle daarom vir oorplantingsdoeleindes skenk eerder as verkoop. Daar is dinge wat so waardevol is dat geld dit nie kan koop nie. Deur hierdie dinge te vrywaar van handelstransaksies, toon ons ons respek daarvoor. Die belangrikste argument teen handeldryf in menslike weefsel en organe, is die insentief wat dit bied vir die uitbuiting van arm en weerlose mense (veral kinders en verstandelik gestremdes). Ervaring dwarsoor die wêreld, en met name in ontwikkelende lande soos Brasilië en Indië, toon dat hierdie gevaar nie uit die lug gegryp is nie, maar daadwerklik voorkom. Wanneer mense desperaat is vanweë armoede, is die idee om

‘n nier of ‘n long of selfs deel van ‘n lewer te skenk en ruim daarvoor vergoed te word, ‘n besonder aantreklike een. Sodoende word mense kwaad aangedoen, en ‘n fundamentele beginsel van die mediese etiek belet dit dat ons mense skade berokken, selfs al is dit nie altyd moontlik om aan hulle goed te doen nie. Afgesien van die kwaad wat weerlose mense aangedoen word deur hulle uit te lok om hul liggaamsdele te skenk, veroorsaak hierdie praktyk ook dat die enorme voordeel wat ryk mense bo armes in alle samelewings het, ekponensieel vergroot word. Die moraliteit van ‘n gesondheidsstelsel waarin bekombare voordele in hoofsaak bepaal word deur die vermoë om te betaal, is reeds twyfelagtig. Orgaanhandel sal die ongelykhede wat so ‘n stelsel noodwendig in die hand werk, enorm vergroot. In ‘n land soos Suid-Afrika, waar die kloof tussen ryk en arm alreeds onaanvaarbaar groot is, is orgaanhandel gewoon olie op die vuur (Van Niekerk 2003).

iii) Is stem cell research appropriate for the health needs of Africa?

Africa is not the source of the new genetic technologies, although Africa might play an important role in the future development of these technologies, particularly inasmuch the African gene pool might harbour valuable information about the ancient and recent histories of our species. However, it's safe to claim that African societies will, especially at this stage of proceedings, be more inclined to be users and appliers, rather than developers, of these technologies, including stem cell technology.

Africa, in addition, and especially as far as resources for health care are concerned, is a very poor continent. Sub-Saharan Africa generates no more than 1% of the total wealth produced in the world. The buying power of all the countries south of the Sahara, excluding South Africa, in total just about matches that of a country such as Norway.¹⁷ As has often been pointed out, Africa is the home of 10% of the world's population, lives on 1% of the global economy and carries 70% of the world's HIV/AIDS burden. As Benatar argues: "The shift in the accumulation of capital from the nation state to the multinational corporations, and the creation of unpayable third world debt, have impoverished third world countries and reduced annual per capita health expenditures to less than \$10 in most poor countries – where less than 50% of the population have access to even essential drugs. Health care services are rudimentary for many in a world in which 87% of annual global expenditure on health is directed to 16% of the world's population, who only bear 7% of the global burden of disease, and in which increasingly unethical, market driven research neglects many diseases. Of all US\$56 billion

¹⁷ Personal communication by prof. C McCarthy in the Department. of Economics at Stellenbosch University.

spent annually on medical research 90% is spent on those diseases causing only 10% of the global burden of disease” (Benatar 2001b). Furthermore, “Annual per capita expenditure on health care is less than US\$10 in many African countries, as compared with between US\$ 2000 - \$4200 in industrialized nations” (Benatar 2001a). It can therefore be accepted that Africa does not have the resources to import and implement new genetic technologies that will, initially, be quite expensive, on a large scale. This has two implications.

On the one hand, it holds the danger, as I have hinted earlier, of perpetuating the gross global inequalities in terms of health care provision between Africa and the West – a situation that, of itself, requires increasing moral assessment, as has been done in the recent work of Solly Benatar (cf. Benatar 2001a, 2001b, Benatar et al. 2003). On the other hand, Africa’s limited resources compel us on this continent to be quite selective and discriminate about those technologies that ought to be deemed appropriate for our most urgent needs. Given Africa’s resources crisis, ideas about the possibility of all kinds of genetically induced personal enhancements are far removed from the urgent and immediate health care realities that policy makers have to face on a daily basis, given the prohibitive costs that such research or technologies might imply. This particularly applies to the public health sector which, even in a country such as South Africa which is considerably wealthier than most other African states, caters for more than 70% of the population. In fact, less than 5% of South Africa’s entire population (2.2 million, out of a population of 45 million) are official members of registered medical aid schemes, and only 5.9 million people (12.4% of the population) are actual beneficiaries of these schemes (SA Health Review 2000). It is as yet unclear how these schemes will respond to genetic therapies. There is, consequently, very little scope, in the short to medium term, for exotic genetic technologies to become prevalent in African societies.

That does, however, not mean that genetic medicine in general, and stem cell technologies in particular, are irrelevant for African conditions and needs. In fact, it is quite foreseeable that certain kinds of research are very relevant for Africa. This particularly pertains to research on the genetic basis of Africa’s main health care challenges, *viz.* AIDS, tuberculosis and malaria.

As far as genetic therapies are concerned, it would, in this respect, not even be very useful or morally relevant to insist on the therapy/enhancement distinction, since a positive outcome of genetic research into the possibility of boosting people’s immune systems, as envisaged by Kitcher (1996), would be of existential importance to Africans in view of the current AIDS

pandemic. Kitcher in this respect adapts an old argument developed by Hume when he claims that “we are no more playing God by altering people genetically so that they have greater immunity than we are when we give them vaccinations” (Buchanan et al. 2001).

The therapy/enhancement distinction, in any case, can sometimes be quite misleading, particularly when it comes to AIDS treatments. Nils Holtug provides an appropriate example of this in the following case:

“Jane is infected with HIV. Her immune system is starting to give in and she is about to develop AIDS. Fortunately, there is a new kind of gene therapy available – call it therapy A – that will boost her immune system and bring it back to normal, so that she will in fact never develop AIDS. By performing the therapy, we are *correcting* her (or her immune system). Now consider Helen. She has not yet been infected with HIV, but she is a haemophiliac and, since blood reserves at the hospital have not been screened for HIV, we know it is only a matter of time before she is infected, unless she receives a new kind of gene therapy – call it therapy B – that will make her immune. (Unfortunately therapy B only works on haemophiliacs, so it cannot be used on Jane.) By performing the therapy, we are *enhancing* her (or her immune system) since we are giving her a desirable property that people do not normally (or naturally) have. The point is that, intuitively, it does not seem more problematic or less urgent to perform therapy B on Helen than to perform therapy A on Jane. But, according to the view that enhancing is more dubious, it must be so (since the cases are relevantly similar in other respects). Thus, the intuitive case for this view is not as clear-cut as it initially seems” (Holtug 1998 his italics).

The first moral challenge to public policy on genetic health in Africa is therefore to support, encourage and embrace research and technologies that hold important promise for African conditions and needs. Benatar writes in this respect: “When biotechnology is used to mass-produce drugs such as insulin and vaccines, to develop more resilient crops, to increase the efficiency of food production, or in other ways that improve the lives of individuals, this is uniformly welcomed, especially if costs are reduced and access increased for all to drugs, vaccines and food. However, it is possible, perhaps even likely, that such advances may not be available to those in poor countries because they are too costly – as for example with new drugs for treating HIV infection.” (1999:169). This is a responsibility not only for African

governments and science funders, but also for benevolent governments and sponsors of African health needs in the developed world.

iv) The abuse of stem cell research

Once these remarks have been made, it remains to note that many of the other problems that I noted in this section are not problems about the inherent moral status of stem cell research, but rather *problems related to its possible abuse*. For example, the fact that stem cell research might exacerbate the division between rich and poor in society is certainly possible, but need not necessarily be the case. The fact that stem cell research might lead to the commercialisation of female ova also can, but need not be the case. We must be careful of not morally rejecting a practice purely on the basis of its possible abuse. Most things in the world can be abused – cf. motorcars, computers, sex, alcoholic beverages, etc. That does not mean that there is anything inherently morally wrong with any of these entities. The problem lies with the way we make use of them. To prevent abuse, regulation is possible. It is to be expected that stem cell research will, where it occurs, and because of the possible ways in which it can be abused, regulated. I shall pay more attention to the nature of these regulations in the last chapter.

That brings me to the most important moral problem with stem cell research – a problem that deals, not with the possible uses/abuses or applications of the research, but with its inherent moral status. To that I finally turn.

The moral status of the embryo

i) Introductory remarks and terminology

As indicated earlier, the most contentious issue in the stem cell debate is the moral status of the embryo. Stem cell research is morally controversial because the destruction of embryos from which stem cells with the best potential of beneficial research can be extracted, seems, at this stage, inevitable, bearing in mind the new possibilities to the contrary that may come forward in the latest findings referred to earlier. I shall, however, in the rest of the dissertation, assume that ES cell research does imply that embryos need to be destroyed for this research to continue and for its possible benefits to emerge.

The issue of the moral status of the human embryo has been the subject of both public and institutional reasoning and argument. The uncertainty over the moral status of a embryonic entity has created tension between society's concern for non-maleficence and an overwhelming opportunity for beneficence. The challenge to synthesize these apparently contradictory objectives forms the main motive for investigating the moral status of embryonic entities in such a way as to provide a clear and concise assessment of the many opposing positions. The *ESHRE Task Force on Ethics and Law* (2001:1047) supports this claim by pointing out the lack of agreement at European level regarding the status of the embryo, reflected by the diverse national legal definitions given to this entity. "The complexity of deciding on this status is in turn reflected by the fact that legislation in assisted reproduction techniques is absent in several countries, or does not give a legal definition of the human embryo. For instance, Belgium, Greece, Italy and Luxembourg are currently lacking legislation, contrary to Denmark, Finland, France, Ireland, the Netherlands, Portugal, Spain, Sweden and the UK. Furthermore, in countries where there is an explicit legal definition of the human embryo, this often varies considerably. In Austrian law, cells capable of development rather than the embryo are mentioned, defined as inseminated ova and cells developed from them. German law defines the entity as the fertilized human egg cell capable of development, from the moment of fusion of the pronuclei, while in Spanish law the pre-embryo (the group of cells resulting from the fertilization of ovum until the implantation and formation of the primitive streak) is distinguished from the embryo (process of organ formation) and the foetus. Finally, the British legislation defines the embryo for the purpose of the Act as live embryo where fertilization is complete, including an egg in the process of fertilization.

This diverseness is also echoed in literature. Several prominent commentators, such as Michael Tooley, Peter Singer and Warren, have argued that no moral value should be afforded the embryo. Although many might find this exceptionally harsh, the legalisation of abortion by the 1973 *Roe vs. Wade* judgment in the United States of America, and the approval of the 1967 Abortion Act in the United Kingdom, have lead to the increasingly mainstream view that the foetus (according to Saunders 2006:17) has a lower moral status than before. According to him, the lowered status of the human embryo was given statutory force in the 1990 Human Fertilisation and Embryology Act, which allows embryo freezing, experimentation and disposal up until 14 days after fertilisation.

How do we reconcile conflicting viewpoints in a pluralistic society such as ours? As individuals, there are many intellectual, emotional or spiritual factors which may influence us to adopt one view or another. Since literature abounds with a plethora of opinions on the subject, it is important at the onset of the discussion to distinguish between the two main opposing existing definitions of an embryo and the moral worth (or lack thereof) attached to it based on the relevant definition. In essence, the embryo is either a person with the right to life, in which case embryonic stem cell research is wrong; or the embryo is not a person but essentially a type of property and therefore without rights (Lauritzen 2001), in which case there is no moral reason to object to stem cell work (NBAC 1999:49).

Having said this, all discussion with regards to the moral status of the embryo suffers from a persistent background tension and diversity. The stakes are high to many of those directly concerned, and there is much politicising involved. Polkinghorne (2004:593) summarises the whole debate about the moral status of human embryonic stem cells by arguing that, fundamentally, the entire issue about their status hinges upon whether these cells should be characterised as embryos with special rights or just as specialised bodily tissue. The starting point for contemplation on the ethics of research on human embryos is the issue taking a look at the status of early embryos, since it asks 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.

What exactly do we mean by the notion of “moral status? The concept of “moral status”, according to The President’s Council on Bioethics (2004:14), is somewhat challenging, even though its use in public and academic discourse is quite fashionable. “To have moral status is to be morally considerable, or to have moral standing. It is to be an entity towards which moral agents have, or can have, moral obligations. If an entity has moral status, then we may not treat it in just any way we please; we are morally obliged to give weight in our deliberations to its needs, interests or well being. Furthermore, we are morally obliged to do this not merely because protecting it may benefit ourselves or other persons, but because its needs have moral importance in their own right” (Warren 2000:3).

The definition given by Mary Anne Warren is a comprehensive and workable definition of the moral status of agents. According to Warren, the concept of moral status is intuitive and influenced greatly by culture, tradition and beliefs. Warren (2000:9) points out that an

important feature of the concept of moral status is its generality, and the fact that it is ascribed to a group rather than individuals. But why do we need a concept such as moral status in the first place? Warren (2005:10-13) is of the opinion that human beings need guidance and standards because we have the capacity to do harm. These standards should be understandable to the majority of people – regardless of their cultural or religious background. Such standards could be used as a minimum against which acceptable behaviour towards entities may be measured, as well as be a tool to help us determine what we ought and ought not to do.

ii) *Is the embryo a person?*

One of the very central issues in reflecting on the moral status of the embryo, is whether the embryo can be regarded as a person. This debate particularly occurred in utilitarian circles. The reason for that is that prominent utilitarians such as Michael Tooley, Peter Singer and John Harris have all argued that moral status can ultimately be related to personhood. Where one is dealing with a person, one deals with an entity that has indubitable moral status, and it is therefore an entity that may not be killed. At the same time, moral status, according to these thinkers, is not limited to members of the species *homo sapiens sapiens*. To insist that personhood is restricted to humans, would, particularly for someone like Singer, amount to a speciesist position that, for him, is the moral equivalent of racism.

For Tooley (1985:50), the distinction between *person* and *human* is of central importance. The philosopher credited most for his discussion on the concept of 'person' is John Locke. In his work Locke distinguishes persons and human beings; he also identifies characteristics of persons. A 'person' and 'human' are distinct categories - *not all humans are persons, and perhaps not all persons are human* (Holland 2003:15). This distinction merits our attention as these words are often used by pro-lifers in emotive arguments against the harvesting of embryonic stem cells.

The original Greek word, according to Wyatt (2004:10), for person - *prosopon* - literally means 'the face'; however, in ancient Greek *persona* refers to the mask actors wore to represent the character they were playing in theatre. According to the Greek and Roman view, what mattered about each individual was the face they showed to the world, the role they played in society. We have retained this meaning in reference to someone's 'persona' - the public face they show to the world.

Landman (1985:176) explains that there are two levels of in the meaning of the term *human*, namely the primary and secondary. In the primary sense, 'human' is semi-biological and semi-normative, spanning the fact-value gap because it is partial in reference to members of the specie *Homo sapiens sapiens*, while at the same time suggesting more than biological information. Tooley states: "[B]eing a member of the species *Homo Sapiens*, while necessary, is not sufficient to make one a human being. Certain other properties are also required. These are usually properties of a psychological sort..." (1985:50). Therefore human (in the primary sense) is a mixed or extended term with descriptive as well as evaluative meaning. It selects certain descriptive properties of human beings and assigns value to them.

In the secondary sense (Landman 1985:177), human is informative and a classificatory term with only a biological or physical reference. Landman points out (1985:177) that most philosophers prefer to use the terms human and human being only in the secondary sense in referring to a human organism or to a member of the species without allocating any moral worth to it.

Landman's distinction is supported by Frankfurt (1988:14) when he asserts that the difference between persons and beings which are not persons is that "persons are capable of desiring certain states of affairs which non-persons are incapable of desiring. The desires which only persons are capable of having...[are]... 'second-order' desires - desires for other desires - as contrasted with 'first-order' desires, which are desires to perform certain actions". However, Frankfurt (1988:15) argues that "distinguishing between first-order and second-order desires by describing first-order desires simply as desires to perform certain actions and second-order desires as desires to have certain desires of the first order may lead to confusion". The reason for this is that such descriptions "don't specify the relative strengths of the desires that an agent may have at a given moment. One may be able to say truthfully that one wants to perform a certain action, while, at the same time, desiring more strongly not to perform that selfsame action".

Locke's definition of *person* implies a thinking intelligent being with reason and reflection which has the ability to consider itself in different times and places (Holland 2003:15). The concept of 'person' includes rationality and self-consciousness as necessary conditions, as well as fundamental moral value. In the quest for a definition of personhood, Muelder (1983:80) describes a person as having ideals and values; as being conscious, expedient and capable; and

being able to think and choose in terms of criticized values (the conscious objects of any desire, interest, need, preference and or concern).

Landman (1985:178) demonstrates that the concept of 'person' can be used in more than one sense, namely that of an evaluative (normative, prescriptive) sense when it is used to refer to the bearer or possessor's rights and duties, and in a descriptive sense, describing a member of the species.

However, Landman (1985:179) and Tooley (1985:51) are of the opinion that the notion of a 'person' is 'a very loose concept'. According to them 'person' should be defined descriptively and the meaning tightened. It should not be used to define moral concepts. The definition of the term 'person', Tooley (1985:51) argues, should be guided by consideration of the properties that give something a right to life. For a discussion of what precisely constitutes a person (i.e. person making properties), I turn to Landman's work.

Landman (1985:181-182) summarizes the position of a number of prominent thinkers in this regard as follows: "Warren lists five such properties: (1) consciousness and in particular the capacity to feel pain; (2) reasoning; (3) self-motivated activity; (4) the capacity to communicate; and (5) the presence of self-concepts, and self-awareness. Elmer Sprague lists four properties: (1) doing, trying, intending; (2) perceiving and thinking; (3) feeling and expressing emotions; and (4) taking and assigning responsibility, and bestowing and receiving moral praise or blame. Richard Swinburne suggests that the following attributes distinguish persons from animals: (1) persons use language to communicate as well as for private thought; (2) they have second-order wants (they can, for example, want not to have certain desires or aversions); (3) they can form and state theories about things beyond observation; and (4) they can form moral judgments".

Tooley (2001:120) warns that many properties described as person making properties in philosophy would allow numerous members of other animal species (in specific mammals) the status of a person. This misallocation of properties could lead to serious problems. Landman (1985:182) agrees and illustrates the problem by pointing out that both persons and some non-persons, for example some animals, possess the property of being conscious and have the capacity to experience pleasure and pain.

In his famous work *Abortion and Infanticide* Tooley (1985:51) asserts that:“One first determines what properties suffice to endow something with a right to life. Next, one asks which of those properties are potentialities, and which are not. Those properties that are not potentialities may be referred to as 'person-making' characteristics and a person is then defined as an entity that possesses at least one of the characteristics in question.”

Landman (1985:184) agrees that a person, per definition, is a moral agent - competent not only of formulating intentions, but also of formulating intentions of a moral kind. Therefore a person has the capacity to distinguish right from wrong and of making autonomous moral choices, of carrying out moral activities and of being morally accountable. He continues that a moral agent not only possesses these capacities or abilities, but exercises them at some relevant time. He (1985:185-192) concludes that in order to call an organism a person, the organism needs to show the following attributes, namely *reflective self-consciousness* (adopting the first-person perspective), *mental rationality* (rationality that consists in the ability to manipulate concepts), *a moral sense* (the ability to evaluate desires in a strong moral sense which are autonomous and in terms of a life-plan and value system), and *language-using ability* (to communicate and also for private thought). If these abilities/capacities/properties are present, the organism can be called a person. Tooley’s (1985:56) finally defines a ‘person’ as a self-conscious being with the capacity for thought and without a rational desire to commit suicide.

Having asserted the distinction between human and person, it is also important to focus on a separate, though equally important, argument in the person-making debate. Should all members of the *Homo sapiens sapiens* species be considered persons? Tooley (2001:123-124) argues that this as an unsatisfactory assertion. He points out that it is more plausible to base an entity’s moral status on its own intrinsic properties than upon its relations to others of the same species. This is also Singer’s (1995:2) opinion when he asks the rhetorical question: “[I]f human is taken to mean no more than 'member of the species *Homo sapiens*', then it needs to be shown why mere membership of a given biological species should be a sufficient basis for a right to life.”

I wish to conclude, on the basis of these arguments, that the (pre-) embryonic organism cannot be assigned the status of ‘person’ but only that of ‘human’, since it does not have a *reflective self-consciousness* in which it can recognise itself as an individual; *mental rationality* whereby it can argue; *a moral sense* by determining what is good and what is bad; and *language-using*

ability to communicate. In essence, the (pre-) embryo lacks all qualities which are necessary to assign the concept of person to it. We may therefore recognise the (pre-) embryo as a human (secondary level) but not as a person, and its status would therefore only be as member of the species. It is thus important to refer to the ‘destruction’ of (pre-) embryos (when harvesting their stem cells) rather than to ‘killing’ them. ‘Killing’ is an emotive word which can, in light of the above discussion, only be used when a live being is involved and not when cell life has ceased to exist. We would indeed find ourselves in a problematic position if we were to consider the termination of cell life murder, given that we lose hundreds of cells throughout our bodies everyday.

It is imperative to stay clear of terminology which is inherently emotive and which does not focus on the factual. Harvesting stem cells from embryos with no future (potentiality argument) means that they are destroyed since they are human tissue and not persons. No murder has been committed and therefore no real legal position has been violated. Persons are thus able to take a legal stand in support of their actions and decisions based on the argument above.

Does the embryo have any rights? If it is not a person, it cannot have rights. Without taking up too much space, I briefly refer to Tooley’s work in this regard. He (1985:95) identifies three specific properties/notions/traits which should be associated with personhood, namely *rights, interests and capacities*.

He commences his argument with an enquiry into what gives something a *right* – more particularly, an indestructible right. He draws on Joel Feinberg’s work, namely the principle of interest which states that *the sorts of beings who can have rights are precisely those who have (or can have) interests* (1985:96). He, as well as Frankfurt (1988:12) asserts that entities devoid of desires can have neither interests nor rights. Tooley (1985:97) illustrates his argument by discussing the personhood of a zygote: “...a fertilized human egg cell. Some day it will come to have desires and interests. *Qua* zygote, however, it does not even have the capacity for having desires. What about interests? This depends upon the account one offers of the relation between desires and interests. It seems to me that a zygote cannot properly be spoken of as a subject of interests... But if it does turn out that a zygote cannot have interests, it would follow, in view of the interest principle together with the above assumption that the class of persons is contained in the class of things possessing a right to continued existence, that zygotes are not persons”.

However, Tooley is somewhat sceptical of the interest principle on the grounds that it does not answer several significant questions, for example queries related to organisms which have developed to the point where they have desires (even if only primitive) and therefore interests according to the above-mentioned theory. He proposes that one should rather look at a more particular-interest principle, which states that “an entity cannot have a particular right unless it is at least capable of having some interest which is furthered by its having a right” (1985:99). In other words, particular rights are only applicable when accompanied by particular interests.

The principle is explained by means of drawing a comparison between torturing and killing an adult and torturing and killing a kitten. While normal adult human beings have both a right to life and a right not to be tortured, a kitten has only the latter. This Tooley (1985:100) explains by using the particular-interests principle, which suggests that “though kittens have some interests, including, in particular, an interest in not being tortured, which derives from their capacity to feel pain, they do not have an interest in continued existence, and hence do not have a right not to be destroyed”.

Applying all of this to the question at hand namely, does an embryo have the right to life, the answer would be ‘no’ since an embryo does not have a want/desire for the right to life. Since it cannot exercise the ability of desiring or wanting, we are under no moral obligation to grant it personhood. Making this statement based on a principle and derived from conditions helps us reach an answer. Tooley (1985:102) introduces yet another variation on the principle, namely the modified particular-interest principle.

The modified particular-interest principle states that *an individual cannot have a right to X unless it is capable of having the corresponding desire for X*. This definition raises an important question regarding the elements involved in having the capacity, in order to establish whether the embryo has capabilities. The answer is two-fold (1985:103-104): desires can only be attributed to things that have desires and, secondly, a desire has a certain proposition attitude (that which is proposed; if a person thinks that *p*, desires that *p*, believes that *p*, *et cetera*, then she has a propositional attitude towards *p* (Blackburn 1996:307)).

Tooley (1985:104) uses these concepts to illustrate what is involved in having a particular desire: “If desires involve propositional attitudes, an individual cannot have a desire unless he understands the proposition that he desires true. Understanding a proposition, in turn, presupposes possession of the concepts involved in it. To have desires, then, one must possess the related concepts”.

Exploring the desire to exist in light of the above-mentioned definition, an entity will be the subject of experience and will have the capability to understand a certain proposition “(which involves the chronological ordering of events, together with the idea of a thing existing at one time being identical with a thing existing at another, later time)” (1985:104). Therefore, in order to have a desire one must have a sense of awareness of this desire (self-consciousness), something which (pre-) embryo lacks.

Tooley (1985:107-108) summarizes his argument and the connection between rights, desires and continued existence:

- “(1) The concept of a right is such that an individual cannot have a right that p be the case unless the individual is capable of desiring that p be the case.
- (2) An individual cannot at time t have the capacity, in the strict sense, of desiring that p be the case unless that individual possesses at time t the concepts involved in the proposition that p.
- (3) The proposition that an individual desires true when he desires to continue to exist involves the concept of a *subject of experiences*, the concept of a temporal order and the concept of identity of things over time.

Hence:

- (4) An individual cannot have a right to continued existence unless he possesses the concept of a subject of experiences, the concept of a temporal order and the concept of identity of things over time.

Moreover:

- (5) The proposition that an individual desires true when he desires to continue to exist is not merely the proposition: that some subject of experiences or other continues to exist, but the proposition that this subject of experiences continue to exist.

- (6) In order to have a desire about an individual picked out by an expression such as this subject of experiences one must in some sense be aware of the individual in question.

Hence:

- (7) An individual cannot have a right to continued existence unless he has the capacity of being aware of himself as a subject of experiences.”

Tooley (1985:121) details a final conclusion, with which I am in agreement: “An individual cannot have a right to continued existence unless there is at least one time at which it possesses the concept of a continuing self or mental substance”.

iii) Any consensus from the debate about the moral status of the embryo?

The question of the moral status of the embryo has, as all these debates show, been one of the most widely discussed issues in the history of bioethics. A huge literature exists on the topic. Yet, no definitive conclusion about the moral status of embryos has emerged from the prolonged discussion of the matter in the course of the debate about abortion since the sixties. It is safe to claim, with eminent bioethicists such as John Harris and Søren Holm, that this issue has not (yet) been adequately resolved. Harris writes in this regard: “Arguments about the moral status of the embryo are convincing and in some cases conclusive; however, they notoriously fail to persuade the groups crucial to achieving consensus on vexed policy issues. Most people are neither puzzled as to the moral status of the embryo or foetus, nor do they welcome arguments which challenge their views. What they seek from philosophical reflection on these issues is not enlightenment but confirmation of prejudice” (Harris 2004:163). This is echoed by Holm when he asserts: “If one looks at the legislation about abortion and assisted reproductive technologies it is evident that no jurisdiction has legislation that is compatible with the view that human embryos are just things with no moral status, and that no jurisdiction has legislation with the view that embryos have the same moral status as born human beings. Most legislation implicitly or explicitly adopt some kind of middle position, although it is often unclear to what extent this represents a considered view or whether it is the result of a political compromise” (Holm 2002:498). On the basis of these conclusions, it seems as if the controversy will only be resolved if it can conclusively be shown that stem cell research need not damage embryos, or that cells other than those from embryos can be utilized for the same beneficial purposes.

iv) Arguments in support of stem cell research

On the basis of the assumption that embryo loss is inevitable if stem cell research is to continue, I wish to provide the following arguments in support of stem cell research:

a) Treatment with drugs and organ transplantation: a distinction that is collapsing

In chapter 2, I indicated and discussed the possible revolution in health care promised by stem cell research – a revolution that fundamentally identifies and exploits new approach to therapy. The treatments that are foreseen on the basis of stem-cell research are expected to work fundamentally different from the way normal drugs have effects on the body. Medicinal drugs are often successful because they are able to alter aspects of a cell's metabolism. However, drugs are not able to cause the growth of new, healthy cells that will actually replace damaged cells (Okarma, 2001:4). It is in this respect that stem-cell research holds revolutionary promise.

This distinction has normally been entertained in medicine as the *distinction between treatment with drugs and organ transplantation*. It seems to me that the recent developments in genetic and reproductive technologies have a tendency to increasingly collapse this traditional distinction. It is, for example, foreseen, if not yet actual medical practice, that cells can be “injected” into a dysfunctional organ in a way that in almost every respect resembles the “injection” of any drug. In addition, as also suggested earlier, blood transfusions, which in fact, as we all know, are the most prevalent form of “organ transplants”, have over many decades paved the way to an increasing tendency to look upon “treatment with tissue” as ordinary medical treatment.

When the prospect of treatment with stem cells is thus emerging in our time, it is first and foremost important to explain to both the public and the policy makers that this procedure is simply following a path or tendency that has, for many decades, been in the making. In this sense, stem cell therapies will not be that new. Before the nineteen sixties, organ transplants, with the exception of blood transfusions, were almost not known in the medical world. The

“Scribner Shunt” and the first heart transplant in the sixties set medicine on a path where organ transplants became a standard mode of medical treatment. Stem cells, in an important sense, represent the latest outcome of that development. Now we are dealing with a treatment that holds the potential to not only replace damaged body cells with new and fully functional cells, but that even holds the potential to replace complete organs – not by removing them from the body of some “donor” whose genetic make-up differs from that of the patient, but from a process in which the patient’s own genetic material was used and that therefore renders the replaced tissue genetically fully compatible with that of the patient. The important point is that this is the way that treatment is increasingly moving in our time. Stem cells are not an aberration that come from nowhere and that are prone to upset some fundamental moral assumption about the nature of the therapies that medicine find fit to use. Stem cells and their clinical application are a consequence of growing medical insight and of increasingly established medical procedures. To rule against the use of stem cells would therefore be to try and halt a direction in current medical research and knowledge that is indicated by the logic of medical research as it has progressed over the past few decades.

b) The role of human intent in establishing the identity of “embryos”

Before I develop my next argument, let me start off by commenting on the alleged “distinction” between “therapeutic” and “reproductive” cloning in the current South African Law (cf. footnote 1). (Cloning is important in the stem cell debate since the stem cells are normally derived from “embryos” that have been cloned from the same genetic material as the patient, thus optimising or guaranteeing tissue compatibility.) This distinction is indeed significant for the moral issue about stem cell research. There are no differences between the techniques that would be applied for either reproductive or therapeutic cloning if and when they ever become prevalent. In both cases the nucleus of an ovum is replaced by that of a mature body cell *in vivo*, and the process of cell division is switched on mechanically. The resulting entity is, in principle, an “embryo” that could develop into a full-fledged human being. The legislation forbids this technique when the explicit intent of the procedure is to “create” embryos for reproductive purposes. What is then called “therapeutic” cloning in the Act is the same procedure, but with a different intent. In therapeutic cloning, an early dividing clump of cells is brought about by essentially the same technique, but with the explicit intent, not of creating an embryo for reproductive purposes, but for providing ES cells that are used for curative purposes, such as bone marrow transplants in cases of leukaemia where the patient’s original

bone marrow has been destroyed by means of chemotherapy. Also, in the case of therapeutic cloning, the mature cell nucleus comes from the affected tissue of the to be treated patient, thereby preventing the possibility of the body's rejection of the transplanted tissue extracted from or produced by the stem cells, since tissue emanating from stem cells that were harvested from the same body is, in more than 99% of cases, certain to be a perfect genetic match.¹⁸ The way that reproductive and therapeutic cloning is thus distinguished is not without conceptual problems, but the distinction does, to my mind, throw significant light on the way in which new reproductive technologies impinge on and affect our understanding of reproduction and the ethics of reproduction. To this I now turn.

The argument I want to develop under the current heading has to do with the *impact of new genetic and reproductive technologies on our understanding of reproduction, and therefore of the identity of the human embryo itself*. I have just explained that, technically, there is no difference between what happens *in vivo* when we are dealing with “reproductive” and “therapeutic” cloning. In both cases, nuclear transfer from a donor cell to an ovum whose nucleus has been removed occurs, with a cell-dividing organism as the result. Whether this procedure is to be named “reproductive” or “therapeutic” cloning, depends entirely on the *intent of the researcher or medical practitioner*. If reproduction is the aim, the cell-dividing organism *will immediately be regarded as an “embryo” and treated in such a way that its potential to become a health baby is optimised*. If, however, the intent is not the creation of an embryo that will develop to term, but a source of stem cells to be utilised for therapeutic purposes, *there is no chance whatsoever that the cell-dividing organism will grow beyond the point of extraction of the stem cells*.

To my mind, this requires attention to the following insight: in our traditional thinking about human reproduction, the existence of a clump of embryonic cells almost self-evidently implied the existence of an embryo that has only one morally legitimate purpose or destiny, namely to develop into a baby. The new reproductive and genetic technologies draw our attention to the fact that the future of embryos is much more subservient to human intention than could be imagined in earlier times and circumstances. *Whether the lump of cells is to be called and treated as an embryo, and whether it will develop to term, is to a much greater extent than conceived of earlier the outcome of human decisions*. To think of these clusters of early cells as “potential people” with an ontologically irreversible claim to full-fledged development to term,

¹⁸ For a comprehensive discussion of this matter, see Holm 2002:494-495.

is to fundamentally misunderstand the extent to which science has succeeded to manipulate life at its earliest stage of development. The embryo, to my mind, therefore not simply “is” on the basis of what happens when the development potential of the nucleus of an ovum swings into operation. Whether that clump of cells justifies to be identified as an “embryo” is increasingly the outcome of human decisions for which specific responsibility need to be taken. I shall deal with the kind of moral approach that is most appropriate in this context – the so-called “ethics of responsibility – in die course.

By making this point, I am not arguing that a scientist is at liberty to handle these primitive organisms at random or as if they have no value at all and can merely be handled as any other form of “lifeless” matter. In my opinion, they do require respect. *My point, however, is that the respect that they demand is not different from the respect that human bodily tissue always and under all circumstances demands.* It no longer makes sense to claim that, because the ovum of a woman is involved, the resulting cell dividing entity requires “special” respect. The reason is the simple fact that the fertilised ovum might, as a result of the cloning procedure, well contain the nucleus of any mature bodily cell – even, in principle, that of hair that has been cut! Put another way: the new technologies have taught us that there is, in a manner of speaking, a potential “embryo” present in every single body cell that we have. This very occurrence requires us to radically rethink some of our traditional notions of respect for human life.

c) Is embryo-loss in human reproduction always morally blameworthy?

Once these more general, philosophical points about the implications of the new genetic technologies have been made, let us now move to the question as to whether embryo loss in reproduction is always such a moral travesty. According to someone like Meilander (2001:9) research on the embryo is always an assault on its dignity. He develops an argument, the gist of which is that “... if we take respect seriously, we might find that relieving suffering is a real but not supreme imperative” (Ibid.). In other words, he challenges the argument I put forth earlier in terms of which the main purpose of medicine is the relief of suffering; he calls that argument a “modernist prejudice”. His conclusion is as follows: “It is quite true, of course, that a ban on stem cell research requiring destruction of embryos would mean that future sufferers could say to us: You might have made more rapid progress. You might have helped me. To consider how we should respond to them is to contemplate the moral point of a ban: Perhaps we could have helped you, but only by pretending that our responsibility to do well is godlike,

that it knows no limit. Only by supposing, as modernity has taught us, that suffering has no point other than to be overcome by human will and technical mastery – that compassion means not a readiness to suffer with others but a determination always to oppose suffering as an affront to our humanity. We could have helped you only by destroying in the present the sort of world in which both we and you want to live – a world in which justice is done now, not permanently mortgaged in service of future good. Only, in short, by pretending to be something other than the human beings we are (Meilander 2001:15). This is an interesting argument, not only because of his denial that the relief of suffering is the supreme purpose of medicine, but also in the sense that he apparently invokes the notion of responsibility as the fundamental moral category. However, he does this in a way that I would like to challenge diametrically. I shall come back to this point when discussing the ethics of responsibility towards the end of this chapter.

Does the fact that we respect something (in this case, the embryo) really imply that it would always be wrong to destroy it? I don't think that is self-evident. In support, I would like to draw on an article by Meyer and Nelson of the same issue of the *Hastings Center Report* where Meilander makes this the argument that has just been stated in the previous paragraph. They (to my mind) persuasively identify several examples of demonstrations of respect that are quite compatible with destruction. They write: "Sometimes people destroy something *because* they respect it, *as* when a sacred artefact is destroyed to prevent its being treated in a profane way. In contrast, embryos are destroyed in the course of research in spite of the respect they deserve" (Meyer & Nelson 2001:19, their italics).

They then go on to illustrate analogies for this phenomenon in practices such as Native American hunting cultures where animals that are held in very high respect in the clan are nevertheless killed, as well as in the Japanese practices of *mizuko kuyo*, spiritual rituals that amount to memorial services that women hold for their actively aborted foetuses. "*Mizuko kuyo* includes a variety of spiritual rituals initiated primarily by women as memorial services for their aborted foetuses. These rituals include saying prayers, making floral offerings, burning incense, lighting candles, creating wooden plaques called *ema* that carry prayers for, and messages to, the foetuses... and making reverential bows to the *mizuko jizo*, a statuary image that represents the soul of the deceased foetus and the deity that cares for departed children" (Meyer & Nelson 2001:19).

They continue to stipulate four conditions under which embryos can be the object of research in such a way that respect for them is maintained: 1) the research must be the only recourse and its goals must not be able to be attained in any other way; 2) no embryos older than 14 days should be used “since this point is regarded by some as the morally significant onset of embryonic individuation”; 3) researchers should under no circumstances regard embryos as property that can be bought and sold, and 4) researchers “should recognize that the destruction of extra-corporeal embryos provides a reason for them to have and demonstrate some sense of regret or loss” (Meyer & Nelson 2001:22).

The examples used by these authors refer to quite tangible entities such as animals and fetuses. On a more abstract level, we should also realise that we often destroy or terminate things that we respect highly. That destruction is seldom executed for frivolous reasons. It rather is executed in name of something that is valued higher. A person may, for example terminate his/her career in order to start pursuing a career of public service or philanthropy; the life of Albert Schweitzer is a case in point. Sometimes we end – with painful results – a love affair that was highly cherished, either because the uncontrollable impulse of love started to fixate on someone else, or because the demands of a chosen career (like becoming a nun or a priest) prohibit the continuation of the relationship. My point is that destruction or determination does not automatically imply loss of respect. It particularly does not do so when it is executed for the sake of such noble results as are foreseen for stem cell research.

d) The plight of surplus embryos *in vitro* and in nature

The final argument to be made in this regard is to point out the inconsistency of arguments that strongly object to the loss of fetuses in stem cell research, but that do not at the same time object to both assisted reproductive technologies (ART) and to, indeed, “normal reproduction” by means of sexual intercourse and “normal” birthing. Let us, for the sake of the argument, accept that stem cell research has an inevitable number of experimental embryonic casualties. Would this be the only area in the field of human reproduction where such casualties occur? And, if not, would it not, consequently, be inconsistent to lament or even renounce the loss of embryos in stem cell research, and yet accept it in other areas?

The fact of the matter is that all forms of assisted reproduction such as *in vitro* fertilization always result in the production of surplus embryos that cannot, for very good medical reasons,

all be implanted into the woman's uterus. There always are "spare" embryos that can either be cryo-preserved for later use by the woman or that can be donated to other women, or that have to be destroyed. Why, particularly in cases where destruction is otherwise inevitable, it would be morally preferable to destroy these embryos than to use them for research, is fundamentally unclear to me. The principle of beneficence surely in this case rather supports research than destruction.

But so-called "normal" reproduction is essentially also characterised by the production of "spare embryos". For every successful pregnancy that results in live birth, many, perhaps as many as five embryos will be lost or "miscarry" (Harris 2004:164). Anybody who consistently opposes the loss of embryos in research ought also to actively oppose embryo loss in assisted and normal reproduction. However, this just about never occurs.¹⁹

Conclusion: Stem Cell Research and an Ethics of Responsibility

We live in a time of moral ambivalence (Bauman 1993:16-36); there are very few phenomena in the social world or the world of science of which we can claim that their moral status is unambiguous. Stem cell research represents no exception. We have seen that the practice of stem cell research is steeped in moral controversy which makes a definitive judgment on its moral status a complex matter.

The question also is whether there exists a framework for moral reasoning on the basis of which definitive judgements could be constructed. The history of ethics has shown that consequentialist approaches where one bases moral approval on the best consequences for the most people concerned, and deontological approaches, where one is guided by strict moral rules or principles, such as the Kantian categorical imperative when making moral judgments, are the two most popular contenders for the provision of such a framework. Nowadays, approaches in terms of virtue ethics, the ethics of care, relativism and social contract theories are all additional and complementary approaches that are promoted in many circles.

I myself am quite sceptical of the possibility of sorting out all problems associated with a practice by relying on a single approach to moral reasoning, such as consequentialism or Kantianism. I have also, in chapter 4, argued in detail why I find these two approaches in

¹⁹ I am indebted to John Harris for the gist of this argument. See Harris 204:164-165; 172.

themselves unsuitable for moral reasoning generally, and for reflection on the moral status of stem cell research in particular. For that reason, I now, in broad outline, would like to develop an approach to moral reasoning that I find more suitable and that, as far as I can see, enables one to incorporate some of the valuable aspects of the two mentioned frameworks without succumbing to their undeniable weak points.

I therefore prefer to promote an approach that was originally introduced by the German philosopher Hans Jonas (cf. Jonas 1984) and which has become known as the *ethics of responsibility*.²⁰ To take or accept responsibility means to be able to be *held accountable for whatever decisions is taken on the basis of the assumption that reasons can be provided, that they have been thought through, even though they might be fallible*.

The concept of responsibility, according to Lucas (1993:5), is one which has developed and grown over the ages. Central to the concept is the question “Why did you do it?” - a question every person is obliged to answer as all persons are to be held responsible and accountable for their actions (or lack thereof). However, it is doubtful that it will always be possible to answer this question in a fully satisfactory manner as lack of information regarding the particular case may make it impossible to always answer persuasively. Nevertheless, whether we are informed or not, we are morally responsible for our ignorance.

An ethics of responsibility is: “an approach where, on the basis of recognition of the moral ambivalence associated with most of the phenomena in the social world, the main task of moral judgement is not deemed consistency within a single paradigm, but the acceptance of responsibility for whatever line of action is recommended. This ethics acknowledges the benefits of a variety of approaches, but also admits the failures that can be identified in most of these approaches. An ethics of responsibility is a form of ethics that makes people – all people, not only health care workers and moral philosophers – accept responsibility for the world in which we live and which we create by means of science and technology. It is an ethics that no longer allows us to accept the idea that morality is exclusively determined by rules, codes and laws behind which people can comfortably hide when justifying the morality of actions in morally complex situations. It is an ethics of responsibility because it demands that we be

²⁰ Apart from Jonas’s work, this approach has also been strongly promoted by the sociologist Zygmunt Bauman (cf. his 1993), drawing on, besides Jonas, the work of the French phenomenologist Emmanuel Levinas (cf., in particular, his 1985). This approach has also been strongly promoted by Anton van Niekerk; cf. his 2002a, 2002b, 2003 and 2006. I acknowledge my strong indebtedness to these authors, and in particular to Van Niekerk for my discussion that follows.

accountable for everything that we invent and design in our attempts to construct, apply and evaluate our life ethos – i.e., the value system according to which we live” (Van Niekerk 2002:40-41).

Since our actions affect other people, and since that which we are capable of with the increased power of technology has a more powerful effect on a greater number of people than ever before, the ethical significance of our actions has reached unprecedented heights (Baumann 1993:218). Van Niekerk writes in this regard: “This responsibility towards the other is *in space* – that is to say towards everyone who shares the planet with us – *but also in time*. With the latter I mean future generations. In this connection Hans Jonas articulates the important insight that the scale of possible consequences of human actions has significantly overtaken the moral imagination of agents in our time. Consciously and unconsciously our current actions influence environments and times that can hardly be considered by the “natural” moral impulses according to which we try to act morally. The morality that we inherited from modern times is, according to Jonas, a “morality of proximity”. As such, it is glaringly inappropriate for a society within which the actions that really matter, are not only the ones that affect the people in my immediate or close proximity, but the ones that yield effects over greater distances – in time and space. *An ethics of responsibility is therefore also an ethics of futurity*. In this respect there is an important overlap between an ethics of responsibility and utilitarianism which, unlike the more traditional rule-based approaches to moral decision-making (such as Kantianism), is concerned with the future and reveals a flexibility in view of the challenges of morally perplexing situations that Kantianism hardly ever allows” (Van Niekerk 2002a:41, his italics).

Consciously and unconsciously our actions are nowadays affecting environments and times that are hardly reckoned with by the alleged “natural moral impulse” according to which we normally act morally. The morality that we have inherited since modern time has always, according to Jonas, been “a morality of proximity”. The morality is significantly inappropriate in a society, such as ours has become, where the action that really matter no longer are those that affect people in my observable proximity, but that have significant (and possibly destructive) effects over large distances in time and space. Jonas writes in this regard: “The good and evil about which action had to care [traditionally - in pre-modern times] lay close to the act, either in the praxis itself or in its immediate reach, and was not a matter of remote planning. The proximity of ends pertained to time as well as space... The ethical universe is

composed of contemporaries and neighbours... All this has decisively changed. Modern technology has introduced actions of such novel scale, objects and consequences that the framework of former ethics can no longer contain them" (Jonas 1984:7-8).

Jonas was, in this respect, one of the original thinkers who stressed the importance of an ethics that has to deal with the interests, not only of us here and now, but of future generations.²¹ Jonas's thought, according to Arne Vetlesen, demonstrates "the utter inadequacy of any ethics which links responsibility with reciprocity". When future generations come into play, it would, if Jonas is right, be totally immoral to let ethically responsible actions be determined by reciprocally adequate responses. Future generations have an unqualified appeal to our sense of responsibility, irrespective of how they themselves act or neglect to act in their circumstances. Vetlesen, drawing on Levinas, states it as follows: "Unborn individuals cannot stand up and claim their rights; reciprocation is hopelessly beyond their reach. Yet this empirical fact... does not exclude them as addressees of our responsibility. Their basic right is the right to a life on an ecologically inhabitable planet; lest we be careful they will never see the light of day at all" (Vetlesen, as quoted by Bauman 1993:220).

This, however, raises an important issue concerning the basis of morality: to whom are we accountable for our actions? Van Niekerk (2006) (drawing on Levinas's ideas) states that an individual is: "accountable to the unconditional claim that other people make on me in space and time to be available to them and to have their interests at heart, irrespective of the question whether they, in their conduct towards me, act reciprocally, i.e. whether they always act morally and take care of my interests. ...accountability towards the other, which also implicates accountability towards the environment within which the other and I must survive, is ... the only sustainably defensible basis for morality" (Van Niekerk 2002a:41).

This idea is inspired by Levinas's insistence on the non-reducibility and ungroundability of morality. According to Levinas, moral responsibility – to be "for" the Other before you can be "with" the Other - is the first and primary reality of the self. *We are what we are only on the basis of being there for the Other.* Being-for-the-Other is the starting point rather than the product of all sociality. It precedes all other forms of relatedness to the Other, either through knowledge, evaluation, suffering or action. Moral responsibility therefore does not have any "foundation", no cause or determining factor. The question: "how is morality possible?", cannot

²¹ See Bauman's discussion of this point in his 1993:219-222.

be answered if no foundation or grounds can be identified for it. *There is no self that precedes the moral self.* Simply by being there, we are, essentially, there for the Other; by being there, we are responsible for the other. The Other, according to Levinas, makes an unconditional appeal to me – an appeal that makes him/her my responsibility irrespective of how he/she responds to my execution of that responsibility. In Levinas's own words: "Intersubjective relation is a non-symmetrical relation. In this sense, I am responsible for the other without waiting for reciprocity, were I to die for it. Reciprocity is *his* affair... I am responsible for a total responsibility, which answers for all in the others, even for their responsibility. The I always has one responsibility *more* than all the others" (Levinas 1985:98-99).

Four key elements of an ethic of responsibility are that:

- it puts upon us certain obligations, which inspires us to reach for an ethic which urges people to accept their responsibility to discover the importance of truth;
- it deals with the motives, commands, virtues, ethos and morality of different kinds of ethical approaches;
- it approaches responsibility as a multi-disciplinary action which cuts across all disciplines;
- environmental, social and cultural values should be respected in addition to technical and economic values (which are usually the only ones in our society that receive respect).

An ethics of responsibility therefore holds that one should be able to accept responsibility for whichever choices or decisions one has made and should be able to defend them accordingly. It is furthermore also a position "that recognizes the fallibility of human insight, but nevertheless takes courage from a host of examples and role models that, throughout history, acknowledged the seamless link between medicine, technology and ethics, and persevered in their efforts to develop science and technology as instruments of social progress rather than as instruments of sectional, short-sighted and eventually dehumanising power-broking. It is an approach that insists that our actions have consequences for our entire environment, that future generations have a moral claim to a habitable world, just as we have, morally speaking, such a claim on our ancestors, that a dialogue about the range and effect of those consequences is the business of every responsible citizen, that we might fail in our efforts to judge the impact of new developments exhaustively, but that our sense of moral obligation is nevertheless appropriately

administered when we are able to provide and defend the reasons for whatever course of action we participate(d) in” (Van Niekerk 2006).

To take responsibility for the moral integrity of a decision or action is not to claim infallibility, or to pretend that our moral decisions and actions are, or ought to be, correct under all circumstances. An ethics of responsibility is not a royal route to certainty, but is an implacable commitment to accountability. It accepts, in view of moral perplexity, neither the surrender of intellectual impotence (“we cannot know anything for certain; let’s trust the good scientists and let science and technology take their course”) nor the arrogance of intellectual imperialism (“we, the moral – and philosophically trained! – experts know the difference between right and wrong and will infallibly advise accordingly”).

An ethics of responsibility simply implies that I am willing and able to take responsibility for whatever decision I have made. That implies that I am equipped with the relevant intellectual tools to approach a morally complex situation. In this respect, the four classical principles of medical ethics (beneficence, non-maleficence, respect for autonomy and justice; cf. Beauchamp & Childress 2002 and Gillon 1995) serve as an excellent point of departure and reference. But a simple application of one of the principles is not always possible; more often, more than one principle is applicable, and the application of the different principles often suggest different outcomes in terms of decision. Principles therefore need to be weighed and balanced, and other considerations also sometimes come into play. However, in the end, we must come to a decision. That decision may often not be perfect; we are fallible people operating in a morally very complex world. An ethic of responsibility is an approach in which I am willing and able to, whenever confronted with a demand or challenge to motivate or legitimate what I have done/decided, supply my reasons and motivate them clearly and coherently.

As regards the ethics of stem cell research, an ethics of responsibility therefore induces us to take account of both the impact of moral principles and the question of what benefits are and will be bestowed by this research. We have noted that principles such as respect for the autonomy and deep-seated convictions about the nature of human identity and dignity place restrictions on the way we ought to deal with stem cells as a form of bodily tissue. At the same time, we have noted the imperative of moving with the times when it comes to our understanding of human tissue and the conditions underlying the transformation of cells into

full-fledged human beings. In the end, however, the question about the benefits that this research can bring to humanity must be a decisive factor in our moral deliberations about the desirability of stem cell research. The evidence of its potential benefits to a host of people who suffer terribly from chronic and debilitating diseases is currently overwhelming, and, to mind, this evidence tips the scale decisively in favour of the continued, yet responsibly regulated practice of a research that can truly revolutionise medicine for many generations to come.

In conclusion of this chapter, I would now like to apply three central ideas of the framework of the ethics of responsibility, as developed above, to the problematic of stem cell research. These three ideas are, firstly, that an appropriate framework for moral decision-making in this requires has to make room for the possibility of failure; secondly the implications of Jonas' emphasis on the need for an ethics of futurity for taking cognisance of the consequences of acts, and, thirdly, the idea that, howsoever important consequences may be, we have also to be able to bear important action guides such as rules and principles in mind when making responsible moral decisions. I shall develop this idea by drawing (unlike Jonas, Bauman or Levinas) on Aristotle's idea of *phronesis*.

An ethics of responsibility (ER) requires that we shall always be ready to bear responsibility for our actions. That means that we shall carefully reflect on our reasons for decisions and actions, and, most importantly, shall always be willing and ready to provide the reasons that we have formulated any moral decisions. At the same time, it implies an openness for rebuttal in case the reasons that we provide, turn out to be inadequate in the face of more complete information or superior reasoning. In that case, ER admits to the possibility of failure. The framework in such a situation means that the moral agent is nevertheless willing to accept responsibility for has been decided or decided, even if it implies the acceptance of blame or even penalties in situations where such penalties might be forthcoming. ER is a framework that accepts, within the context of applied ethics, that moral decisions need to be taken, at some point sooner rather than later, and that those decisions always carry the risk of incompleteness or failure. When reflecting in the moral sphere, we are not dealing with questions to which the answers are forthcoming with a comparable measure of certainty or indubitability that is often the case in the factual sciences. To apply an insight of Paul Ricoeur: in ethics one works, not with a "logic of verification", but with a "logic of validation". The conclusions reached are more a question of probability than of certainty. In the words of Ricoeur: "Validation is an argumentative discipline comparable to the judicial procedures of legal interpretation. It is a

logic of uncertainty and of qualitative probability” (Ricoeur 1981:212). The analogy with reasoning before a court, rather than verifying theoretical propositions with sense observations, is important here. Judicial reasoning has an intermediary function which shows that procedures of validation have a polemical nature, which is also typical of reasoning in bioethics. “In front of the court, the plurivocity common to texts and to actions is exhibited as a verdict to which it is possible to make appeal” (Ricoeur 1981:215). There is, therefore seldom a “last word” in the decisions about that moral status of possible actions in bioethics.

The point about fallibility in an ER has very recently been worked out in a different, though analogous way by Susanne Gibson in an article about respect for the embryo in *Bioethics* (Gibson 2007). She makes the, to my mind, excellent point that when we differ about the measure of respect that an embryo deserves, it is not similar to the situation where we enquire whether a racist deserves respect. There is sufficient consensus in society that racism is abhorrent and ought not to be tolerated. But when we differ about respect for the embryo we ought to acknowledge the limitedness of our insights. Writes Gibson: “... respect between moral agents must be understood as respect between finite moral agents. As moral agents we are able to formulate and act upon moral judgments. As finite moral agents, however, there are limits to our knowledge and understanding such that even ordinarily decent people sometimes do not know what the right thing is, and sometimes make mistakes” (Gibson 2007:377). According to Gibson, as I understand her, when arguing about issues such as the moral status of the embryo, the range of uncertainty that we are working with compels us to have respect, also for opponents of our views. Both we and they might be mistaken in our moral judgment. Our finitude typically becomes apparent when we are dealing with an issue such the moral status of the embryo.

Her position, that I would strongly support, becomes even clearer in the following passage: “Ethically acceptable uses of the embryo have to be worked out in a way that acknowledges that the human embryo is both something that may have considerable moral status and something that may well not have considerable moral status. Just because [of] this, permitting but restricting the use of the human embryo in research can be justified not so much as a compromise between competing positions nor as a balancing of competing interests, but as an acknowledgement of and respect for the seriousness of what is at stake in either allowing or preventing its use. Just as we should approach the use and destruction of the human embryo with ‘fear and trembling’ so too should we approach the prevention of its use in the same way.

By researching on the human embryo we may well be destroying something that has considerable moral status; by preventing research on the human embryo we may well be failing to alleviate the suffering of children and adults whom [sic] most certainly do have considerable moral status, for no good reason” (Gibson 2007:377).

Although Gibson does not utilize the phrase “ER”, her argument fits very neatly into the first idea that I have alluded to above: ER is an *ethics of fallibility*; at a point, we have to make a decision in order to move forward, but that decision can be wrong and can have dire consequences. Yet, *not taking the decision or preventing some action can have equally disastrous consequences*. We have to accept responsibility for whatever we decide in the end. Certainty cannot be demanded of us in these decision-making situations. What can, however, be demanded, is the full catalogue of our reasons and the arguments supporting those reasons. When thus engaging in an ER, *we have no assurance of correct moral behaviour, but we do have assurance of responsible moral behaviour*. The latter is mostly what can realistically be expected from moral agents.

The second idea, with which I want to conclude this chapter, is the implications of Jonas’s emphasis on futurity. We have outgrown an ethics that only considers circumstances and the interests of fellow human beings in the present. Because, in particular, of the unprecedented strides that technology has taken and is taking in our time, we have to consider the future - for Jonas, “future generations” indeed, on whose reciprocity we also have no possible way of relying or considering.

The simple point that would want to re-iterate in this regard, following my critical comments on deontology in chapter 4, is that an ethics of responsibility, because it has to consider the future, *has to consider the consequences of actions*. It is, given both the constructive and destructive potential of technology – including the very technology that facilitates stem cell research – at best irresponsible and at worst ludicrous to disregard consequences in moral decision-making. The invocation of the term “responsibility” as the most pivotal moral category in the framework for moral argumentation that has just been developed, inevitably points us as moral agents towards the future. Kant and others retort that the future is too uncertain to base any moral decisions on surmises about future events. But on that score, Kant and his followers are simply wrong. What the future will be, is no fundamentally uncertain entity, but a time and circumstances that are, to a considerable extent, influenced by what

happens today. And what happens today could make that future liveable and better, particularly for those who now suffer terribly, or it could make the future insufferable as such. If one reflects on the morality of stem cells, its consequences for the future are inevitably and necessarily to be taken into account. When an author like Meilander therefore fantasizes that when some future person might blame us for not allowing stem cell research in the present, our answer to such a reproach could (and should!) be: “We could have helped you by destroying in the present the sort of world in which both you and we want to live – a world in which justice is done now, not permanently mortgaged in service of future good” (Meilander 2001:15, also quoted earlier), he is simply wrong and is dismissive of a factor – the future good for mankind – that can never simply be ignored when deciding on the moral status of actions.

We are, in the words of Ernst Bloch, *hoping animals*. Or, to use an expression of Eric Hobsbawm, “we dream forward”. And not only do we concern ourselves with the future and live important parts of our lives in the mode of the dream; we can make significant predictions of the future. Predictions, of course, should be distinguished from mere desires. When one engages in predictions, one must be able to ground it in relevant and accurate analyses of past and current trends, without falling in the trap of historicism.

Hobsbawm also reminds us that to say that we can *predict* the future, is not the same as claiming that we can *know* the future. We can work with the justified assumption that, as Hobsbawm writes, “by and large, the future is systematically connected with the past, which in turn is not an arbitrary concatenation of circumstances and events. The structures of human societies, their processes and mechanisms of reproduction, change and transformation, are such to restrict the number of things that can happen, determine some of the things that will happen, and make it possible to assign greater and lesser probabilities to much of the rest. This implies a certain (admittedly limited) range of predictability – but, as we all know, this is by no means the same as successful forecasting.” Hobsbawm continues, in a statement with which I largely agree: “...[I]t is desirable, possible and even necessary to forecast the future to some extent. This implies neither that the future is determined nor, even if it were, that it is knowable. It does not imply that there are no alternative choices or outcomes, and even less that forecasters are right. The questions...are rather: How much prediction? Of what kind? How can it be improved?” (Hobsbawm 1998:51).

This brings me to the last aspect of the framework developed above that is of significant importance to the reflection on the morality of stem cell research, *viz.* the dialectic between

appeals to moral norms, on the one hand, and consideration of consequences, on the other hand, in the functioning of the ER. I have just argued that a consideration of future consequences is inevitable and necessary in an appropriate moral approach as regards stem cell research. A possible critic of my position could then well ask: why are you not a full-fledged consequentialist? My answer results from the critique of consequentialism/utilitarianism that I developed at the end of the previous chapter and that I shall not now repeat. Suffice it to say that, as unacceptable as it is to disregard consequences when arguing about the morality of stem cell research, it is, to my mind, equally unacceptable to flatly ignore or disregard moral action guides such as norms, values and principles.²² To do that, would be to simply ignore almost all of our most basic moral intuitions, as well as the collective wisdom of our moral education at the hand of moral principles.

Is there, then, a model of moral reasoning that has the potential to adequately accommodate *both* the force of moral rules *and* the responsible consideration of consequences? Or is such a possibility merely a figment of my own imagination that I then want to project onto the framework that I call the ER?

My answer is that the reconciliation of the force of moral rules and the need to consider consequences is no imaginary possibility, but is indeed foreseen and developed in the oldest tradition of moral philosophy in the West, viz Aristotelianism, and particularly the ethics of Aristotle as developed in his *Nicomachean Ethics* (Aristotle 1953). I am particularly referring to Book 6 of this work where Aristotle deals with the “intellectual virtues” (1953:203-225; resp. 1138b1b-1145111). What I would like to devote some attention to, is his notion of “prudence” or “practical wisdom” – these notions are the best English translations of the forceful Greek word *phronesis* that Aristotle explicates in this part of his *Ethics*.

Phronesis, for Aristotle, is the kind of knowledge that ethics aspires to. It is to be distinguished from two other kinds of knowledge: *theoria*, which is the theoretical knowledge, and *techné* which, as is the case with *phronesis*, is also a kind of practical knowledge, but of a different kind. Aristotle’s ethics differs quite fundamentally from that of his great teacher Plato in the sense that ethical knowledge, for Plato, was, as is the case of all true knowledge, an instance of *theoria*. The way in which moral knowledge was acquired, according to Plato, was through

²² It is, for my purposes in this dissertation, not necessary to engage in an intricate analysis of the possible different meaning of these concepts. For a lucid discussion in this regard, cf. Beauchamp & Childress 1994 (Fourth Edition):14-20.

recollecting (*anamnesis*) the knowledge gained of the Idea of the Good – the highest of the Forms in Plato’s famous Realm of Forms. In our pre-existence we contemplated the Idea of the Good; in this life, we are “reminded” (*anamnesis*) of what we saw there. That means that *ethical knowledge, for Plato, is essentially theoretical knowledge*; we aspire to know what the Good is.

For Aristotle, however, this is an impoverished idea of moral knowledge. Moral knowledge, for him, is not theoretical, but *practical*. It is *phronesis* – prudence or practical wisdom. In the sense of *phronesis* it is a knowledge that enables us to act in a host of practical situations that we encounter in everyday life. *Phronesis* is not simply to know what good is, what virtue is and what the rules that govern our behaviour is. It is, more importantly, to know how to act in the practical situations of everyday life where the norms and rules need to be applied. Practical situations researchers, governments, policymakers, physicians and any other influential groups or people, should pay attention to. Such situations should influence policy forming rather than rules cast in stone. Yet, at the same time *it is not mere techne*, i.e. the knowledge that we gain in order to apply technical skills. *Techne* would, for example, be the skill to fill a tooth or to fix a computer. It is a skill that is acquired, but that skill (i.e. the ability to do it) remains the same in every application. It is a skill that we can do better and better – “with eyes closed”, as the proverb goes! However, what is learned and applied in *techne* remains the same.

Phronesis, in this respect, is quite different. *Phronesis* is *practical knowledge of how to live the good life*. But the end of *phronesis*, the “good life”, is not a fixed, circumscribed entity about which we are all in agreement, such as a painless tooth or a working computer. The good life is even not necessarily the same for everyone. What the good life is, as has been indicated by Alasdair MacIntyre, is what we acquire when we strive for the Good Life! MacIntyre, in explicating Aristotle’s claim, writes: “the good life for man is the life spent in seeking for the good life for man, and the virtues necessary for the seeking are those which will enable us to understand what more and what else the good life for man is” (MacIntyre 1981:204). Put differently: *phronesis* is a kind of knowledge of both means and ends. The end that we choose will influence the means we adopt to acquire it, and *vice versa*.

In addition, the *content* of *phronesis* is not necessarily the same in every practical situation in which I find myself. What, for example, does it mean to be courageous? – a typical issue of *phronesis*. That very much depends on the circumstances. In some circumstances, it might

mean the willingness *to die for the sake of others*. In other circumstances, as was the experience of Victor Frankl in Auschwitz, it is the *determination not to surrender and die*, but to try and find meaning in the simplest things in order to maintain the strength to carry on.

Most importantly, also for the topic that concerns us at the moment, *phronesis* (or prudence) is a kind of knowledge where I try to act in accordance with precepts or action guides that I acknowledge, but in such a way that they are prudently applied to the situation in which I find myself and where I must act in a way that I can live with the consequences. That application requires *deliberation* – a deliberation that moves to and fro between the requirement of the norm and the requirements of the situation. The following passage from Aristotle makes this clear: “But prudence is concerned with human goods, i.e. things about which deliberation is possible; for we hold that it is the function of the prudent man to deliberate well; and nobody deliberates about things that cannot be otherwise, or that are not means to an end, and that end a practical good. And the man who is good at deliberation generally is the one who can aim, by the help of his calculation, at the best of the goods attainable by man. *Again, prudence is not concerned with universals only; it must also take cognizance of particulars, because it is concerned with conduct, and conduct has its sphere in particular circumstances*” (Aristotle 1953:213, my emphasis).

This last sentence is the crux of my current argument. Here we see Aristotle penetrating to the essence of what we call moral knowledge. That knowledge is a knowledge that takes its departure in the norms and action guides that pervade societal life and that I inherit from my education, my religion, my conscience and the conventions of society. But simply to know the rules is far from enough. They need to be responsibly applied in a host of practical situations. How they are to be applied, is far from self-evident. That is something that I learn in the practice of daily life. It does not occur overnight; it takes time. I learn it in many ways. The way that Aristotle particularly emphasises, is *deliberation*. Deliberation is an argumentative strategy that requires dialogue with myself and with others. It implies the careful weighing up of the claim of the norm against the requirement of the situation – bearing in mind, especially, the consequences of what my deed will have. In this sense, deliberation – the essence of *phronesis* – is a dialectic movement between action guide and the requirements of the practical situation, as well as the possible consequences of the action.

Although Aristotle did not use the phrase “ethics of responsibility”, this is, to my mind, is the essence of the ethics of responsibility that I developed as the overarching framework for moral argumentation in this chapter.

It is against this background that I will discuss macro-issues such as safety concerns, commercialization, power issues, accessibility to resources, the allocation of such resources and the setting of priorities. These issues prevalent in society and at the forefront of many contemporary debates contribute significantly to the unique challenges nationally as well as internationally stem cell research levies against society.

Chapter 6: Macro-issues

The promises stem cells research holds (as illustrated in chapter two) affect more levels of society than merely the patient receiving the new technologically advanced regenerative medicine to help him cure his gene deficiency or other ailment. The influence of this new form of technology cuts across all levels of our existence and has the potential to transform medicine as we know it today. However, as was the case with Nobel's discovery of dynamite, discoveries in the field of stem cell research can also be used adversely to the disadvantage of human kind.

In this chapter I will investigate the most popular concerns in the present debate about the macro-issues surrounding stem cell research. My investigation will look firstly at the safety aspects surrounding stem cells, as this is, apart from the moral status arguments, often the most used by opponents against the benefits of stem cells research. Second, I will turn my attention to the problem surrounding the commercialization of the products of stem cell research. As the search for a cure for a specific ailment or defect is a time-consuming process, researchers ought to be reimbursed for their endless efforts to find it. With every new discovery in the medical field the pioneers or, as is quite often the case, the multi-national pharmaceutical companies who sponsor most of this research, gain power. Once again, this leads to a discrepancy between those who can afford new treatments and those who cannot. I will take a more in-depth look at the issue of power surrounding new technology.

We live in a country where the majority of citizens do not have ready access to health care. This raises the concern that stem cell research cures could cause greater injustice than good in our society by exacerbating the inequalities between rich and poor. This point will be discussed in terms of the unique problems we face here in South Africa and the final chapter will address the matter by proposing a policy for stem cell research to the benefit of all South Africans.

Once the issue of accessibility has been addressed, I will examine the allocation of limited resources or, rather, the allocation of severely limited public money to further research which could benefit all of society. The question which will be dealt with in the last section of this chapter relates to whether stem cell research can truly justify a demand for further public investment when reality shows a large percentage of our fellow countrymen and women

struggling against AIDS, Tuberculosis, Malaria, and hundreds are orphaned by AIDS every day. Shouldn't stem cell research be left to those countries which do not struggle to provide even basic health care?

The rationale for the inclusion of this chapter into my study is an attempt to include both sides of the argument. The promises stem cell research holds in the laboratory and the debate (on micro issues, as discussed earlier) surrounding it differs vastly from the reality many face outside of the lab. Everyday people are dying due to malnutrition, dirty water and lack of basic medical care. At the same time, however, we cannot deny the existence of stem cell research and the fact that the absence of a policy regulating such research might leave the back door wide open for companies to abuse our human resources and society. It is therefore essential to consider the matter in its entirety and to look at micro and macro-issues before proposing a morally (micro) justified policy (macro) for the regulation of stem cell research for South Africa. The line of my argument throughout will be that in South Africa the macro-issues definitely overshadow stem cell research and the money spent on it. However, as mentioned before, we cannot remain ignorant of the fact that stem cell research holds great promises and should be taken into consideration. Against this background I would like to address a few commonly stated macro-issues. The first point of public concern regarding stem cell research, namely the safety aspects surrounding stem cell research, will be discussed next.

Safety concerns

Beyond the dictum of “doing no harm”, safety concerns also have an impact on biomedical research. Embryonic human stem cell isolation holds the promise of numerous new and exciting therapies and tissue regeneration and repair are expected to be successful in the management of an array of medical conditions (as demonstrated in chapter two). However, in our health and safety conscious culture of today, many people are concerned about the possible outcomes of new therapies and the safety of pursuing them.

Ventures to evaluate and consider the safety of applying human stem cells in tests, or even implanting them into humans, are of fundamental importance. This section will illustrate that human stem cells - including transplanted human stem cells - are vibrant entities that are influenced by and interrelate closely with the functioning of other cells and entities in their immediate environment. Before pursuing any therapeutic application it is therefore important to

address and resolve the safety concerns raised by interventional action. Those arguing against the harvesting of stem cells for therapeutic reasons argue that the safety of the cultured cells could introduce other illnesses into the recipients and are therefore not safe. Against this background I would like to address three aspects in particular. The evidence from this will show that stem cells research should only be done if control under strict measures is applied.

i) Human stem cells in tissue cultures

After stem cells have been extracted and before they are transplanted, cultured human stem cells are preserved under conditions that advance either the self-renewing expansion of undifferentiated cells, or the acquisition of the differentiated properties similar to that of the phenotype cells or tissue (Evans and Kaufman 1981:154; Martin 1981:7634; NIH 2001:93; PCB 2004:118).

Human stem cells from almost every source other than blood-derived haematopoietic stem cells can be stored in tissue culture for a defined period of time (Evans and Kaufman 1981:154; Martin 1981:7634; NIH 2001:93). Culturing human stem cells requires the use of a formulated liquid media supplemented with growth factors and other chemical substances that encourage cellular reproduction and direct the differentiation of the cultured human stem cells (NIH 2001:95).

The National Institutes of Health (NIH) (2001:95) explains that neglect to regulate the procedures for keeping stem cells in culture could result in unintended changes in the basic properties of the cells. Changes such as the frequency with which the culture medium is refilled and the concentration cells are allowed to achieve before subdividing them, may influence the characteristics human stem cells maintain in culture. The liquid concentrate will also determine the cells' growth rate, expression of defining cell markers, and differentiation potential. These changes in the stem cells' properties will most likely affect their success once transplanted.

There also exists the chance of variation being introduced during the processes of growth and cell division. As Sadler (1990:3) describes, a normal cell (which includes human stem cells) consists of 23 pairs (46) of diploid chromosomes. During the mitotic division of a cell to form two daughter cells (identical to the mother cell), rare mistakes can occasionally occur that lead to the formation of abnormal chromosomes. Cells with abnormal chromosomes or chromosome

numbers can progress to malignancy, so retention of the normal human chromosome number and structure is an essential characteristic of useful human stem cell preparations (PCB 2004:119).

According to Verfaillie (2004:305), as well as Carpenter and his colleagues (2003:79), stem cells which are maintained *in vitro* for over 1 year remain stable. However, Draper and his colleagues (2004:54) presented contradictory evidence from two different laboratories, reporting abnormalities in chromosome number and structure in some samples of cultured stem cells. This was raised as a point of concern as early as 1999, when the NBAC (1999:71) stated that stem cells are not indefinitely stable in culture and that as these cells are grown, irreversible changes may occur in their genetic makeup.

The use of “feeder layers” (cells used to maintain pluripotent stem cells) can also influence the safety of the cultured stem cells adversely. In the past, human embryonic stem cells were maintained on top of mouse cell “feeder layers”. Although the mouse cells were treated to prevent their cell division, human embryonic stem cells stored in this way might have contained some viable mouse cells and/or have been contaminated by mouse viruses (PCB 2004:117; 120). The risk of cross-transfer of micro-organisms that can cause diseases from xenogenic (obtained from an organism of a different species, i.e. mice or pigs) or allergenic (human) feeders limits their medical applications. In addition, not all human feeders support the growth of human stem cells equally well (Stojkovic 2005:306).

The President’s Council on Bioethics (2004:120) extends their reasoning regarding contamination and argue that mouse viruses might even jump the human line, causing stem cell preparations originally isolated from humans also to be variably contaminated by human viruses, bacteria, fungi and mycoplasma (micro-organisms).

ii) Toxicology

From the perspective of toxicology, the potential of undifferentiated human embryonic stem cells evokes the greatest level of concern (NIH 2001:97). A characteristic of human embryonic stem cells is their capacity to generate teratomas (a tumour consisting of tissue foreign to the site of growth, caused by the development of independent cells (Collins 1993:1547)) when transplanted into immunologically inept strains of mice (Solter and Gearhart 1999:1468). This

reaction, according to the Committee on the Biological and Biomedical Applications of Stem Cell Research (2004:36), is believed to be associated with the multi-potency of the undifferentiated cells in an *in vivo* environment.

A group of researchers (Rubio 2005:3035) from Spain in 2005 showed that although stem cell transformation can be managed safely during the standard *ex vivo* expansion period (6-8 weeks), human mesenchymal stem cells can undergo spontaneous transformation following long-term *in vitro* culture (4-5 months). This is one of the first reports of spontaneous transformation of human adult stem cells, supporting the hypothesis of cancer stem cell origin.

On the other hand, in studies on rodents, human embryonic stem cells that have been allowed to begin to differentiate before transplantation have not resulted in noteworthy tumour formation (Brustle *et al.* 1997:14809; Klug *et al.* 1996:216).

The National Institutes of Health (2001:97) continues to emphasize that undifferentiated embryonic stem cells are not considered suitable for transplantation due to the risk of unregulated growth. The President's Council on Bioethics agrees (2004:287) that "longer-term testing is still needed to address the teratoma formation issue more carefully". It is therefore vital that careful toxicology screenings are carried out during the transplantation of undifferentiated or partially differentiated embryonic stem cells and adult stem cells.

iii) Immunological rejection of stem cell-based therapies

Immunological rejection and the risk of infection are important concerns for stem cell-based therapies, since the body discards human cells or tissues that do not belong to it (Biological and Biomedical Applications of Stem Cell Research 2004:36; Goessler *et al.* 2005:899). Immune rejection is one of the major causes of organ transplant failure and is one of the problems which needs to be overcome in order for any stem cell-based therapy to be effective (House of Lords 2002:24).

It has been suggested that embryonic stem cells carry a lower risk of an immune reaction than a whole-organ transplant. However, some types of cells, such as dendritic cells, immune system cells and vascular endothelial cells, carry more of the histo-compatibility antigens that provoke

immune reactions than other cells (Biological and Biomedical Applications of Stem Cell Research 2004:38).

However, tissue extracted from embryonic stem cells, such as liver tissue, does not contain these cells and therefore would in theory prompt a lower immune response. This tends to illustrate that the use of an individual's own cells or tissues and/or the use of "matching" tissues, in conjunction with the use of immuno-suppressant drugs, could reduce the immunological rejection of stem cell-based therapies.

The ability to differentiate and proliferate that is innate to human stem cells holds both the potential for therapeutic worth and the challenge of their safe application. Addressing human stem cell safety requires that every stage of the human stem cell development process be scrutinized - the extraction, storage, manipulation and transplantation. Only once this has been successfully recorded with no exception of possible negative outcomes, can the transplantation of stem cells into human subjects be considered.

Moving away from cell structure concerns and more towards the sociological problems surrounding stem cell research, I would like to focus first of all on the issues concerning the commercialization of research.

Commercialization

When a worker was killed, no one wept, but when a brick fell, all wept.

(Midrash Rabbah)

The commercialization of stem cell knowledge and technology is an important matter since it embodies two very important aspects of our everyday life, namely potential and danger. This section will investigate the economic drive behind biotechnological development. It will be followed by an investigation into the (ab)use of power and the implementation of intellectual law and patents. Specifically, I will take a look at the negative effect of patents on the price and accessibility of products.

South African law is reflected in American federal law as summarized by the NBAC (1999:36):“state statutes on organ transplantation now typically prohibit the sale of human

organs or parts, but none include language likely to impede research involving human embryos”. The South African National Health Bill indeed does not make any provision for the sale of human embryos, but only refers to “payment in connection with the importation, acquisition or supply of tissue, blood, blood products or gametes”.

This loophole could become problematic within a capitalistic society where influential and money-driven companies could exploit such a shortcoming. This is illustrated clearly by the case of women at Ivy League universities in the United States who are being paid high sums of money for the donation of their ova. As Holland (2001:80) indicates:

[A]dvertisement taken out in several Ivy League student newspapers a couple of years ago seeking white women of high intelligence to whom parents-to-be would pay \$50,000 for their donated eggs in a private fertility clinic. I am told by a colleague at an Ivy League university that a year later ads appeared in the student paper seeking specific kinds of egg donors with a \$40,000 payment attached. Presumably, the market has driven down the demand for Ivy League women donors from the prior year's level! Neither must we overlook Internet auction attempts, however specious, to auction off a kidney—and now the eggs of models...

Suzanne Holland (2001:82) correctly points out that the key is to find ways to keep women from potential exploitation. She points out that the potential profitability of cell lines derived from donated embryos is huge given the promise of regenerative medicine.

The NBAC (1999:74) suggests a solution, namely that “[e]mbryos and cadaveric foetal tissue should not be bought or sold”. They point out that the intention of such a ban would be to stop the exploitation of economically disadvantaged women - especially those in developing countries - who might be persuaded by companies, research institutions or other groups to begin and end pregnancies for reasonable compensation. The argument against giving compensation revolves around the notion of commodification, which holds that there are limits to what we can buy and sell as commodities (de Castro 2003:142). The fears about exploiting women – especially in developing countries – are that the compensation usually does not outweigh the risks, and the market is not regulated (since it is usually done on the black-market). My biggest concern is that women might be coerced into selling their ova and that the

economically and socially deprived might be prejudiced. Furthermore, women might not be willing to donate their ova if they know they can be financially remunerated. Genetic research in general represents a window of opportunity for large Western corporations to exploit those less fortunate.

According to Holland (2001:82), however, the chief moral value of American (or developed) culture under late advanced capitalism is “thou shalt not regulate the free market”.

Whether one likes it or not, progress in biology and biotechnology is now intimately bound up with industry and commerce. More and more scientists work in partnership with industry. And the emergence of a vigorous biotech industry, growing rapidly ... even before it has delivered very much of its great promise, is a sign of things to come. Whatever one finally thinks about the relative virtues and vices of contemporary capitalism, it is a fact that progress in science and technology owes much to free enterprise ... The competition to succeed provides enormous incentives to innovation, growth and progress. We have every reason to expect exponential increases in biotechnologies and, therefore, in their potential uses in all aspects of human life.

The President’s Council on Bioethics (2003:303)

Shannon (2001:181) cautions interested parties that commitment to stem cell research is a commitment to business as usual in the medical community. According to him this is the dominant mode of medicine practiced across much of the United States, particularly in wealthier areas. It is where the money is to be made. Pursuing stem cell research continues this practice and continues to draw large sums of money from other possible uses, which those who oppose stem cell research keep on reminding us of. This reminder is true not only for the American context, but also in the South African milieu.

i) Biotechnology

Biotechnology is an expanding economic venture and gaining momentum if one considers the growth of shares on the stock exchanges throughout the world of such companies. This is evident from the report issued by the House of Lords (2002:53) which details that by the end of 2000 the total value of Europe's publicly quoted biotechnology companies stood at 75 billion

Euros, compared with 36 billion Euros a year earlier. It also states that in the United States, the leader in this field, market capitalisation of publicly quoted biotechnology companies was estimated to stand at \$330.8 billion, and biotechnology stocks significantly outperformed internet stocks and the NASDAQ index. The leading names in the field are those of Geron Corporation in the United States, which is generally regarded as a world leader. The best known company in the United Kingdom in this field would probably PPL Therapeutics, the commercial arm of the Roslin Institute, which created Dolly the sheep (House of Lords 2002:53). PPL was acquired by Geron in 1999.

It is important to note that Europe and the USA are not alone in the race. In China (House of Lords 2002:53) the government has encouraged a number of universities to invest heavily in stem cell research, with the help of big companies such as the Beijing Stem Cell Med-engineering Company. Similarly in Singapore, the Economic Development Board has provided initial finance for the Singapore Genomics Programme. By 2005 some \$7 billion dollars have been invested in relevant research (House of Lords 2002:53). According to Campbell (2007:16) South African State research institutions and private-sector companies are forecast to spend R2,5 billion on bio-technology and genetic engineering research and development over the next three years until 2010.

However, regardless of all these investments, researchers such as Papadimos and Papadimos (2004:5) recognize that there is a worldwide scarcity of human ova for *in vitro* fertilization and stem cell technologies. They maintain that health care providers and bureaucrats who are connected with assisted reproduction projects are aggressively recruiting egg donors through the electronic and print media (as mentioned earlier).

Brokerages compile databases of individual profiles (including photographs, biographical data, information on physical characteristics, medical histories, and so on). According to The President's Council on Bioethics (2004:148), one such brokerage, *Egg Donation, Inc.*, seeks in a donor someone who is "bright and attractive, between the ages of 21 years to 30 years, of any ethnic background, who has preferably completed a college degree or is presently pursuing a college degree and is in excellent health." Another brokerage, *Tiny Treasures*, specializes in Ivy League ovum donors (PCB 2004:148). The President's Council (2004:148) points out that compensation for ovum donors from pooled brokerages varies. For example, *Egg Donation, Inc.* advises potential donors that the donor fee "will range from \$3,500 to \$12,000." "...A tall,

attractive donor with a masters or doctorate degree will always receive higher compensation than most other donors." Ivy League donors from *Tiny Treasures* may receive anywhere from \$8,000 to \$20,000 compensation for a cycle of ova retrieval (PCB 2004:149).

Several people advertise openly for ovum donors. One such advertisement at Vassar College (PCB, 2004:149) offered \$25,000 in exchange for the ova of a "healthy, intelligent college student or college graduate, age 21-33 with blue eyes and blonde or light brown hair." To quote Holland (2001(b):266):"The 'gift of life' is big business in America."

Fear about the morality of trading gametes and embryos have been examined at length in the bioethics literature, both with regards to reproductive and embryonic stem cell research (Andrews and Nelkin 2001:58; Resnik 2002:130). Monetary enticement increases supply and might just be the answer to the scarcity of ova Papadimos and Papadimos refer to. However, if some body parts are worth more than others, and in this case, some eggs are worth more than others (as seen in the different prices paid for different graduates), Alpers and Lo (1995:39) suggest it might create an inequitable and unethical situation of supply and demand. It pits two groups of women against each other in terms of market desirability. This in effect creates inequality and is the cause of some women been discriminated against.

Papadimos and Papadimos (2004:5) argue that young female university students without the financial resources to fund their education lack the autonomy to give informed consent for donation of their ova as a means of paying their tuition due to the constraining influence of their situation. They warn that society should be vigilant in monitoring the ethical and moral approaches of the "industrial" aspect of assisted reproduction, not only toward young university females, but also toward women of the third world and Eastern Europe.

Lori Knowles takes another point of view and draws attention in her article (1999:38) to the fact that there is an apprehension between the legal and ethical traditions. On the one hand there exists a desire for progress brought about by stem cell research, especially with regard to patenting embryonic stem cell lines and, in so doing, ensuring gigantic returns for patent holders, while on the other hand the commodification of embryonic life is condemned. As The President's Council on Bioethics (2004:253) points out, patents have been sought and granted for human adult stem cell work as well as for embryonic stem cell technologies. According to the European Group on Ethics in Science and New Technologies, as of October 2001 two

thousand twenty-nine patents were applied for or granted to stem cells, and 512 patents were applied for or granted to embryonic stem cell work. Resnik (2002:130-131) suggests that the next stage of the stem cell debate will need to involve a battle over property rights relating to stem cells.

ii) Patents

Ethical, commercial and scientific concerns emerge from the patenting of research findings and stem cell lines. Such patenting developments have considerable implications for society's approach to reproductive biotechnologies, and for the creation of public and private outlooks regarding the ethical and social importance of these technologies and practices. It also has noteworthy implications for the way society values property in the human body (PCB 2004(b):147). In the South African context it cannot simply be taken for granted that the granting of monopolies is the best method of not ensuring the greatest benefit to all, since the majority of our community is economically disadvantaged. The price of granting patents would inevitably mean the reduced access of potentially essential medical products (MRC 2002:43) to marginalised groups.

Nevertheless it is not surprising, as the House of Lords (2002:54) reports, that American companies have been particularly effective in securing patents which make it costly for others to pursue certain lines of research. The U.S. Patent and Trademark Office (PTO) has already stated that purified and isolated stem cells are patentable subject matter and according to the PTO, stem cell products and research tools meet the three criteria for patentability: novelty, utility and non-obviousness (Chapman *et al.* 1999:38). Companies are in the position to make products derived from stem cell research - which they hold the patents to - available only under very qualified agreements, and also to set terms and limitations which reduce access to these cells. Given the universal promise of stem cell research, it is imperative to encourage the development of generally beneficial therapeutic products with extensive access.

It is important to mention that, should the public sector be unable to fund stem cell research, the private sector might take up the challenge. Given that the first basic business principle is to safeguard one's investment, it can be assumed that private investors will do everything in their power to protect their assets should any breakthrough be made in the field. Mostly likely the guarantee such investors would be looking at would be in the form of intellectual property

rights or patent rights. It is important to recognise that by patenting something, ownership over the rights (method) of how to create the product is transferred. No ownership can be bestowed upon the product – only the process. Therefore, the patent holder must give his/her consent should anyone else wish to make/create the same product. No ownership is bestowed on the end product – only on the method. This basic misnomer is often used by pro-lifers to argue that big corporates will own “life” in the form of stem cells. However, the stem cells *per se* cannot be owned, only the process can.

The patent holder is granted a monopoly over the method for a few years, after which it is returned to the public realm – and could benefit the broader public.

Patents encourage research and valuable advancements in biomedical knowledge and technology. By permitting researchers to safeguard “the fruits of their labours” for a period of time, patents provide investors with the incentive to entrust resources to research, while researchers are given the incentive to make discoveries which eventually benefit the public through improved medicine and increased scientific understanding. Lincoln aptly summarizes the relationship between investors and researchers by commenting that patents “add the fuel of interest to the fire of genius” (PCB 2004(b):159).

The American Patent Act, which has been altered modestly since it was authored by Thomas Jefferson and enacted in 1793, provides patent rights for three types of patents: plant patents, design patents and utility patents (inventions or discoveries of any new and useful process, machine, manufacture or composition of matter, or any new and useful improvement thereof) (PCB 2004(b):158). For an invention to be patentable, it must be new, of use and fall within one of the “statutory classes of subject matter” (PCB 2003(b):25).

It is interesting to note that although traditionally the examination into a proposed invention's “usefulness” might have considered the moral value of the innovation, existing US patent practices do not take “morals” into account. Patent systems are therefore not ethically impartial since their fundamental purpose is to reward inventors for their imaginative endeavour. The Ethics Committee of the MRC of South Africa (2002:42) points out that “profit becomes the incentive for research and development”. Thus, a patent is a prize for entrepreneurship (PCB 2003(b):4), for transforming an idea into a piece of property.

There are sufficient examples in US and European patent law of instances where patentability was restricted in circumstances where the proposed patent carried serious risks to the public, such as biomedical development that would permanently change humankind through inheritable genetic transformation (PCB 2003(b):27). There exists, according to Holtug (2001:213), exceptional apprehension relating to patents on humans. He argues that patents that would impede human autonomy or freedom would be quite doubtful according to almost any moral view. According to Murphy (2001:203), however, it appears that some processes and products of genetic investigation will be patentable to the degree that they meet the conditions of novelty, non-obviousness and utility. International policies in this area are still emerging and will involve some mix of public opinion, statute and judicial interpretation.

For about the first two centuries of its existence, the Patent and Trademark Office (PTO) of the United States declined to grant patents for inventions that were "products of nature," including living organisms, as these were not seen to fulfil the requirements of originality and improvement (with some exceptions, such as Pasteur's 1873 patent for a form of yeast). However, according to The President's Council on Bioethics' report (2003(b):30) the Supreme Court in 1980 departed from the "rule of nature" principle in the statute-changing case of *Diamond vs. Chakrabarty* (447 U.S. 303, 1980). The applicant sought a safeguard for a variety of bacteria that had been genetically engineered to break down numerous components of crude oil, useful, for example, to clean up oil spills.

After being initially rejected by the PTO, the Supreme Court had to consider whether living organisms could constitute a "new and useful process, machine, manufacture or composition of matter" within the meaning of the Patent Act (PCB 2004(b):160). Consequently the Court embraced the belief that "anything under the sun that is made by man" - whether a chemical compound, a machine, a process or a living organism - is an appropriate subject matter for a patent. In 1988, the Court of Appeals for the Federal Circuit extended the Chakrabarty's finding beyond microbial organisms to multi-cellular organisms (oysters), confirming that higher life forms may constitute "anything under the sun that is made by man" for purposes of patentability. In that same year, the PTO issued the first patent approved on a higher animal, a transgenic mouse modified to be prone to cancer (the "Harvard Mouse") (PCB 2004(b):161).

In April 1988 the US Congress eventually decided that human beings could not for the moment be patented. This prohibition also extended to the current protection afforded to the products of

patented processes under 35 U.S.C. § 271(g). Thus, human beings would not be subject to the exclusionary rights accompanying a patented invention. The proposal would, however, permit patents on processes, even if the processes resulted in human beings (PCB 2003(b):33).

However, there is no clear definition of what precisely constitutes a human being. How much genetic code would need to be changed? It is very well to prohibit the patenting of an entire human being, but as has been shown, all that is required is the contents of a single human nucleus containing altered DNA (PCB 2004(b):161). The problem of definition is bound to make successful laws progressively more complicated and a worldwide legal structure is therefore of the essence. Without a legal safeguard corporations would be reluctant to invest heavily in research, without which the therapeutic and economic benefits of stem cell research might be lost (Dixon 1995:38), and hence making the accessibility thereof limited to a broader spectrum of people who could benefit from these. This theme I'll pick up again later in this chapter when we have a look at the accessibility argument in more detail.

There is much that can be said in support of the progress and advantages of technologically advanced medicine. Amongst the noticeable merits and benefits are the vast sources of intellectual and human enhancement, prestige and satisfaction in research advances; quicker and more trustworthy diagnoses; and more successful healing. High-tech medicine has frequently demonstrated its contribution to the continuance of life, the combating of disease and infirmity, the securing of health and reason, the improvement of pain and suffering, and the improvement of the quality of life (Van Rensburg 2004:26).

Nonetheless, the list of demerits is just as long. With sophisticated medicine came the reinforcement of the 'medical model' (doctor-patient dichotomy). Van Rensburg (2004:26) believes that the average patient is counselled to see a doctor on a regular basis for a 'check-up' and for a repeated 'screening', with wellbeing being portrayed as a state of continued negative reports for hidden disease. Other disadvantages include the overemphasis on invasive diagnostic and therapeutic technologies, the significant commercialisation of health care or supplier-induced demand, and rising costs driven by profits (Van Rensburg 2004:26).

Notwithstanding biotechnological progress, the global health system is faced with the burden of universal health problems (such as the AIDS epidemic), unsuccessful delivery on equity and access. Van Rensburg argues (2004:25) that while scientific progress advances the

improvement of health care and technology, it also spawns opportunities for abuse and power. The independence of individuals is being lessened by the concentration of control in economic organisations or big multi-national organisations. In this regard, let's turn our attention to the issue of power in the biotechnology arena. This is also an important factor in the discussion on the macro-issues related to stem cell research since the use of such knowledge could provide a few people with the power to exert unprecedented control over others.

Power issues

...no practical philosophy can be adequate for our time unless it confronts the analysis of power and how it operates in our everyday lives.

(Bernstein, as cited by Flyvbjerg 1993:11)

[W]hat we call Man's power over Nature turns out to be a power exercised by some men over other men with Nature as its instrument.

(Lewis 1978:35)

The power of an individual or institution is the ability to achieve something, whether by right or by control or influence. Power is the ability to mobilize economic, social or political forces in order to achieve a result.

(Blackburn 1996:295-296)

... research should be evaluated not only in terms of its effects on the subjects of the experiment but also in terms of its connection with existing patterns of oppression and domination in society.

(Susan Sherwin, as cited by Holland 2001:73)

It often happens that increased knowledge leads to increased power, and with increased power comes the potential for misuse or abuse of that power. The classical pluralist and also Marxist view is that power should be diffused throughout society, so that no one group holds total power over others. However, the reality is often quite different. Gill Walt (1994:36) rightly

asks whether power is not in fact in the hands of a few, a small group of elites within or even outside government.

According to Holsti (1988:141), influencing others is a means of exerting power in order to obtain a particular end. He asserts that influence for its own sake is usually instrumental for achieving or defending other goals (which might include prestige, security or alliances). This influence or aspect of power is usually successful because there exists an anticipated-reaction-relationship between those who hold the power and those on whom it is exercised (Holsti 1988:143). This relationship refers to anticipated rewards or punishments from the exerting agent and is solely based on the perceptions of influence.

An important factor in retaining power is the utilization of resources. In the case of stem cell research the resource is the application of knowledge. The social scientists, Sears, Peplau and Taylor (1991:251) identified the usage of knowledge, training and skill as sources of power.

Attained knowledge mobilizes the exerting agent to control the actions of those without the knowledge, unless they acquire it themselves. According to Holsti (1988:147), the response to the exertion of power is therefore of paramount importance. He identifies five possible reactions, namely to accommodate, to ignore, to procrastinate, to bargain and to resist.

Power can be exerted through a number of means. Blackburn's definition of power illustrates that it can be exercised economically, socially, technologically or even politically. Both group and individual power are dependent on a single principle, namely: when a reward becomes scarce it becomes more valuable to the person who gets it, and its loss becomes more costly to the person who foregoes it (Smelser 1967:50). Smelser (1967:54) also argues that differences in power depend as much on differences in the capacity to punish as differences in the capacity to reward.

I would next like to briefly turn the discussion about power to the debate surrounding the application of technology or discoveries as an instrument of power.

i) Technology

According to the definition cited by Barbour (1993:3), technology is the application of organized knowledge (including inventions, medical discoveries as well as those based on scientific theories) to practical tasks (production of goods, rendering of services or just addressing a need) by ordered systems of people and machines (social institutions). Rephrased the definition can also read: the application by companies of knowledge derived from research to address needs (medical and non-medical).

[T]echnology is neither inherently good nor inherently evil but is an ambiguous instrument of power whose consequences depend on its social context. Some technologies seem to be neutral if they can be used for good or evil according to the goals of the users. A knife can be used for surgery or for murder... [M]ost technologies are already molded by particular interests and institutional goals. Technologies are social constructions, and they are seldom neutral because particular purposes are already built into their design.

(Barbour 1993:15)

Those who are in control of technology today are not a technical elite or technocrats trying to control society, but rather executives of corporations and government bureaucracies who are dedicated to *the interests of institutions*. Barbour (1993:16) is of the opinion that the goals of research are determined largely by the goals of institutions: corporate profits, institutional growth, bureaucratic power and so forth. Expertise serves the interests of organizations and only secondarily the welfare of people or the environment.

This is quite a harsh allegation from Barbour. Many contemporary Marxists share his conviction that although technology is essential for solving social problems, under capitalism it has been an instrument of exploitation, repression and dehumanization, with large corporations dominating government and political processes serving the interests of the ruling class by ensuring inequalities, so that class distinctions and poverty amidst luxury remain (Barbour 1993:17). Although the attack in true Marxist terms is against capitalism, technology is still used to reach the end.

However, all is not bleak for technology.

[T]echnology directed to genuine human needs is a legitimate expression of humankind's creative capacities and an essential contribution to its welfare. In a world of disease and hunger, technology rightly used can be a far-reaching expression of concern for persons.

(Barbour 1993:18)

However, how does one reach this point in a world of injustice and discrepancies between private and public rights and needs?

ii) Private vs. public

The emergence of new expertise, skills and knowledge may evoke anxiety and cause doubt among many in the community who do not have expert knowledge. People may feel threatened or even in danger of new developments when they lack basic knowledge of these new technologies. As human stem cell research develops, opportunities should be presented for public review and continued public discourse should be stimulated and encouraged. Any concerns that arise from new discoveries should be addressed. Transparency should be the object of the companies involved in research and public opinion should be valued.

However, Chapman and his colleagues (1999:25) point out that many private companies establish their own *in camera* Ethics Advisory Boards. If, however, an objection is raised to a Board's findings, there is no assurance that the company concerned would abide by the Board's conclusions and advice, which could damage public confidence and increase concern about the manner in which stem cell research is developing.

The authors maintain that there are also some other concerns relating to the exclusive dependence on private sector stem cell research, such as the abuse of the market forces and the perceived investment opportunities by companies who could exert a disproportionately powerful influence on the progress of stem cell research without sufficient consideration to public concerns. Concerns such as economic exploitation, where the focus of stem cell research could be on diseases which are more likely to lead to profit. This could be at the expense of more common and severe diseases, but which is less likely to create profit. Another concern is

the possibility that stem cells might become part of an expanded marketing of human body parts (Chapman *et al.* 199:37).

iii) Abuse of power

Closely related to the power issue is the principle of punishment. This punishment is usually governed by the abuse of power, where authority figures decline to take responsibility for the wellbeing of others in order to enhance their own cause. Ownership of the knowledge of stem cell research and its benefits could be a power which might be used illegitimately by further marginalising those who are already marginalised.

It is believed that this assertion of power over others may unjustifiably be used to exploit or harm innocent people, for example by withholding cures from those who need them but cannot pay for them. It therefore seems reasonable that the main principle of ethics and morality - in line with the Kantian maxim (guide for living) - ought to be to avoid harm and the abuse of power. The French philosopher Michel Foucault (1994:28) stated in his infamous lecture of 7th January 1976 that power is neither given, nor exchanged, nor recovered, but rather exercised, and that it only exists in action.

We should admit rather that power produces knowledge; that power and knowledge directly imply one another; that there is no power relation without the correlative constitution of a field of knowledge, nor any knowledge that does not presuppose and constitute at the same time power relations. These power-knowledge relations are to be analysed, therefore, not on the basis of a subject of knowledge who is or is not free in relation to the power system, but, on the contrary, the subject who knows, the object to be known and the modalities of knowledge may be regarded as so many effects of these fundamental implications of power-knowledge and their historical transformations.

(Foucault 1975:27-28)

A significant element of Foucault's power-knowledge dualism is the principle that those who are in power have expert knowledge. In areas of specialized knowledge one's actions are governed by the element of the power structures themselves; consequently power is not

possible without knowledge. In order therefore to escape the influence of power, one is encouraged to attain the knowledge which creates power.

Since medicine is not a pure science, but part of an economic and power system (Foucault 2004:19), it is necessary to determine the links between medicine, economics, power and society. The reason for inclusion of this theme in my discussion concerns the well-known debate concerning the haves vs. the have-nots. One has to wonder whether the advances made with stem cell research will give a selected few power over the majority – hence a minority rule again. The next two matters I would like to address are age-old bio-ethical issues, namely that of accessibility and allocation.

Accessibility

The latter half of the 20th century witnessed the continued phenomenal progress of immensely capital-intensive and specialized scientific medicine. Transplant surgery and biotechnology have captured the public imagination. Alongside, major chronic and psychosocial disorders persist in the advanced world, and there is little sign that the basic health problems of the developing world are diminishing. The situation exemplifies and perpetuates a key facet and paradox of the history of medicine: the unresolved disequilibrium between the remarkable capacities of an increasingly powerful science based biomedical tradition and, on the other hand, the wider and unfulfilled health requirements of economically impoverished and politically mismanaged societies.

Porter (2001:385), as quoted in van Rensburg (Ed) (2004:28)

Extraordinary efforts should be made to encourage equitable access to the benefits of stem cell research (Chapman *et al.*, 1999:x).

According to Chapman and his colleagues, the therapeutic potential for addressing and possibly curing many severe diseases constitutes a major justification for significant investments of public and private resources in human stem cell research. The justification for this funding of stem cell research is based on the underpinning of its potential benefits. However, the use of

public resources necessitates some guarantee that those in need will have access to the remedies as they become available.

Many critics (PCB 2003:281; van Rensburg 2004:28) point out that numerous aspects make it doubtful that equitable access to the benefits of this research will realise. Suzanne Holland states that “embryonic stem cell research conducted in the private sector has particular implications for particular kinds of persons and can be seen to be connected to existing patterns of domination and oppression in society about which we ought to be suspect.” (2001:74)

Consequently, if stem cell research were to result in unduly costly therapies, health insurers might be unwilling to fund such treatments. This inaccessibility will serve to further stigmatize the disabled and endorse the concept that some lives are not meaningful. There exists a real possibility that the gap between the "haves" and the "have-nots" in society will be widened and worsened, merely through the restriction or notion of those who can afford it. However, the World Health Organization (1998) has reminded member states that “justice demands equitable access to genetic services”. The WHO (1998) has also stated that “[G]enetic services for the prevention, diagnosis and treatment of disease should be available to all, without regard to ability to pay, and should be provided first to those whose needs are greatest”.

As Holland suggests (2001:84), serious debate is needed, the result of which should be a commitment to the have-nots. This would require sincere and honest *courage on the part of policy makers*. She continues to argue for a sound public course of action that will not submit to the ethical split results from a dichotomous worldview in which the lives of those on the margin are subject, on the one hand, to the moral whims of legislators and, on the other hand, to the amoral whims of the private sector economy.

i) The global picture

Shannon (2001:182) asks the rhetorical question: who will be the beneficiaries of stem cell research? Given the WHO (1998) point of view, all would hopefully benefit. However, as Shannon points out, the benefit will be garnered by two groups: those who are insured and whose insurance will cover any resulting treatments *and* those who can afford to buy it. Individuals whose earnings are not in the upper five percent would not be able to pay for such therapy, hence the number of possible beneficiaries narrows.

According to the 1996 Human Development Report (UNDP 1996:2), the world's 358 richest individuals controlled assets equivalent to the combined annual incomes of countries where 45 percent of the world's people live. Of the \$23 trillion global gross domestic product (GDP) in 1993, \$18 trillion accrued to the industrialized countries and only \$5 trillion to the developing countries, home to 80% of the world's people. The poorest 20% of the world's population saw their share of global income decline from 2.3% to 1.4% in the past 30 years. Meanwhile the share of the richest 20% increased from 70% to 85% (UNDP 1996:2).

With the change in economic distribution across the world comes globalization. The adverse effects of globalisation (Van Rensburg (Ed) 2004:23) are seen in human and environmental exploitation, widening economic disparities between rich and poor, increases in both absolute and relative poverty, growing inequalities in health and health care, and new global health threats and risks. To address some of these disparities the World Health Organisation adopted in 1978 the Declaration of Alma-Ata. Health was seen as a “fundamental human right”; the aim was “the attainment by all peoples of the world by the year 2000 of a level of health that will permit them to lead a socially and economically productive life” (WHO 1978:3).

ii) The South African picture

To rectify the inherited discrepancies of apartheid, the former Minister of Health, Dr Dlamini-Zuma, tabled the White Paper on the Transformation of the Health System in South Africa on the 16th of April 1997. The White Paper sets out a plan for the reformation of the health system to guarantee accessible and equitable health care for all. Its goals and objectives were:

To promote equity, accessibility and utilisation of health services:

- i. increase access to integrated health care services for all South Africans, focusing on the rural, peri-urban and urban poor and the aged, with an emphasis on vulnerable groups;
- ii. establish health care financing policies to promote greater equity between people living in rural and urban areas, and between people served by the public and private health sectors; and
- iii. distribute health personnel throughout the country in an equitable manner.

Although this might be the ideal, the reality in South Africa presents many stumbling blocks that prevent those in need from receiving treatment. In addition to the lack of adequate numbers of health workers, problems include distance to the facility, transport, opening times and cost of care.

Rising above these obstacles and guaranteeing unbiased access to the benefits of health care - not even touching on and addressing the advantages of stem cell research - in South Africa will be a politically and financially demanding undertaking.

To people on the boundary that are overwhelmed by life-and-death concerns, embryonic stem cell research and other genetic expertise may appear to be luxury issues. The danger exists that public funding, already scarce for the real health concerns and reality many South Africans face, will be diverted away from those life-and-death needs. Conversely, even if public funding focused awareness on the health needs of persons on the margin, as Holland (2001:84) points out, the private sector has neither obligation nor incentive to do so. No possibility exists for return on venture which can be collected through genetic technologies and pharmaceuticals targeted to those with the ability to pay. She argues that this is the legacy of the "free market".

This legacy, together with the inequitable access to health (and eventually to the therapies stem cell research will deliver), cannot be viewed objectively without an overview of resource allocation and, in specific, the justice principle, as formulated by Beauchamp and Childress (2001:225-282), which focuses on the moral obligation of fairness and is essentially about treating people equally in relation to criteria acknowledged to be morally relevant, will guide the next part of my discussion.

iii) Justice

Discrimination in access to health care and in health insurance, combined with dramatic increases in the costs of health care and the allocation of scarce resources, have fuelled debates about what social justice requires (Beauchamp and Childress, 2001:225).

Justice, as defined by these two authors (2001:226), is

...fair, equitable, and appropriate treatment in light of what is due or owed to persons. Standards of justice are needed whenever persons are due benefits or burdens because of their particular properties or circumstances, such as being productive or having been harmed by another person's acts. A holder of a valid claim based in justice has a right, and therefore is due something. An injustice thus involves a wrongful act or omission that denies people benefits to which they have a right or distributes burdens unfairly.

Munson (2000:37) reasons that:

[J]ustice has two major aspects. Seeing to it that people receive that to which they are entitled, that their rights are recognised and protected ... and with the distribution of burdens and benefits.

Beauchamp and Childress (2001:26) explain that the phrase “distributive justice” refers to just, impartial and proper distribution guided by acceptable norms that structure the terms of social cooperation, such as policies. However, it is common knowledge that problems of distributive justice arise under circumstances of insufficiency and the struggle to acquire goods, or even to avoid burdens. This highlights the concern about an unfair distribution of burdens, which includes inequitable access to therapies (due to geographical, financial or even political reasons) and the prioritizing of allocation scares resources.

All public and institutional policies on distributive justice are in the end derived from the acceptance or rejection of some material values and procedures for denoting, refining or debating them. Principles which specify the relevant characteristics for equal treatment are called material since they identify the substantive properties for distribution (Beauchamp and Childress 2000:228). The principle of need is one such a principle - an extension of the egalitarian principles of equal distribution, which asserts that distribution of social resources based on need is acceptable. This principle holds that when a person needs something, without it the person will be harmed or at least detrimentally affected (Beauchamp and Childress 2001:228). However, in a free-market-distribution-culture one would oppose a principle of need as a basis for public policy, and rather focus on material needs.

Material principles, in essence, identify significant characteristics or “needs” that persons must hold to qualify for justice to be “allocated” to them. It can be argued that the standard of justice depends on the principle of utility (we should act in such a way as to bring about the greatest benefit and the least harm) (Beauchamp and Childress 2001:231; Munson 2000:36). The principle of utility can be seen as a moral principle that presents us with a *prima facie* duty that maximizes net social benefit.

Munson (2000:36) reasons that the aim of social policy is to balance the competing needs of the society. With limitless resources no trade-offs would have to be made; however, with finite resources ranks must be established as to determine what outcome would benefit the most of those concerned.

Looking at needs from a more libertarian point of view, as Blackburn (1996:218) defines:

Libertarians advocate the maximization of individual rights, especially those connected with the operation of a free market, and the minimization of the role of the state. In the libertarian vision, exercises of state power for positive ends, such as amelioration of social disadvantages through social welfare programmes, constitute infringements of the rights of others.

The dichotomous South African picture of health care is based upon this theory, which functions on the material principle of ability to pay, either directly or indirectly through insurance. In general, under this notion, a just society protects the rights of property and liberty, allowing persons to improve their circumstances and protect their health on their own initiative (Beauchamp and Childress 2001:231). The “father” of the libertarian theory, Robert Nozick, appeals to the Kantian initiative that people should not merely be treated as a means to an end, but rather as rational beings. According to this theory health care is not a right, and the best health care system is privatized.

Beauchamp and Childress (2001:232) note that according to the libertarian interpretation of justice, the focus falls not on increasing public utility or meeting the health needs of society, but on the creative process of fair procedures. Therefore a theory of justice should affirm individual rights rather than generate patterns of financial allocation in which governments redistribute the assets obtained by individuals under the free market.

Nozick, as illustrated in Beauchamp and Childress (2001:232), acknowledges an outline of procedural justice with only three principles: justice in acquisition, justice in transfer and justice in rectification. Consequently, justice consists in the process of just actions (such as fair play), not in the creation of just end results (such as an equal distribution of resources). There are no welfare rights and therefore, according to this theory, no rights or claims to health care can be based on justice. To summarise their point of view: any distribution of goods, including that of health care, is just and justified if individuals in the relevant group freely choose it.

Communitarians respond pessimistically to forms of the social order that support individual interaction on privileges and agreements. Tönnies' theory "stresses ties of affection, kinship, and a sense of common purpose and tradition, as opposed to the meagre morality of contractual ties entered into between a loose conglomeration of individuals" (Blackburn 1996:70).

For communitarians principles of justice are pluralistic, originating from as many diverse origins of the good as there are diverse moral communities (Beauchamp and Childress 2001:232). Thus communitarians stress either the accountability of society to the individual or, more recently, the accountability of the individual to society. Justice is positioned in the guarantee that services will be presented to fulfil a particular community-endorsed conception of social objectives (Beauchamp and Childress 2001:233).

A society where justice prevails according to the doctrine of egalitarianism, is one which holds that life should be intended at respecting and advancing the equality of persons, thereby advocating that all individuals should receive an equivalent distribution of some goods, and unrestricted access to basic health care.

Arguably the most noted qualified egalitarian is John Rawls who holds that:

[C]onsiders the basic institutions of a society that could be chosen by rational people under conditions that ensures impartiality. These conditions are characterised as an original position so that it is as if the participants are contracting into a basic social structure from behind a veil of ignorance, leaving

them unable to deploy selfish considerations, or ones favouring particular kinds of persons.

(Blackburn 1996:319)

A just health care system based largely on a Rawlsian principle of "fair equality of opportunity", according to Beauchamp and Childress (2001:234), relies unconditionally on the significance of health care requirements and on a considered conclusion that fair prospect is fundamental to any acceptable theory of justice. Rawls's theory identifies a society's responsibility to attempt to diminish or eradicate obstructions to fair equality of opportunity and access. Therefore, a health care system intended to meet these needs should endeavour to avoid ailment, infection or injury by ensuring justice through fair equality of opportunity (Beauchamp and Childress 2001:234).

In a society where justice prevails the aim is therefore for all citizens to have access to health care. In such a society the benefits of stem cell research would be for all and not a selected few. However, as mentioned numerous times before, modern life dictates that the free market system prevails and one is entitled to anything one has the means to pay for. However, should one not have the means to pay one is forced to go without and might even become part of a "vulnerable" community. This merits the inclusion of the debate surrounding the existence or absence of a moral responsibility to protect the vulnerable of society - and to give them access to the benefits of stem cell therapies even though they cannot afford to pay for it. Since large parts of the South African community cannot (and I would even venture to say might never be able to) pay for the benefits of stem cell therapies our moral responsibility towards them comes into play.

iv) Protecting the vulnerable of society

The question is raised whether the vulnerable (the have-nots) can claim a corresponding "right to accessibility" from the state based on their inability to gain access to the benefits of stem cell therapies and the state's special moral duty towards them. The question is relevant because the have-nots have no supportable case based on which they have the right to demand the benefits connected with stem cell research. Therefore, if the state does not have an obligation to provide these therapies - even though it is creating an unjust society by not enabling access for all - how should it allocate its limited resources? Should stem cell research receive any funding at all if it

could be the cause of injustice? The next section will focus on this problem by addressing the allocation of limited resources and by setting priorities.

While it is relatively easy to argue that stem cell research is not unethical on a micro level, it could be harder to defend on a macro level. Having established that it is not immoral to make use of the stem cells of cryopreserved embryos, it is necessary to take into account the context of our present health system. There are enormous demands on already limited resources and the question remains whether it would be ethical to demand a part of the cake? I would argue that while it would not be unethical to request some public funds, it is necessary to realise that we cannot allocate the same amount (proportionally) as developed countries. In the next section, I will first discuss the concept of macro-allocation and the principles which guide it. Thereafter, I will take a look at the ethical considerations (namely quantity and quality of life; individual responsibility), followed by priority setting. Once I have explored the theoretical base of the argument I will turn my focus to more practical examples relevant to the South African context. The section will close, and therefore add value to the relevance of this point, by offering a possible solution.

Allocation of limited resources and setting possible priorities

The complex changes which have occurred in health systems globally over the past few years raise ethical dilemmas regarding the allocation of scarce health care resources, and consequently also setting priorities. The new demands for medical research and progress set against uncontrollable costs have put great burdens on both public and private sectors of health care systems (Fortes and Zoboli 2002:266). This background forms an important part of this study. From a utilitarian moral point of view, scarce resources should be distributed to those persons / that research which will lead to the beneficence of the majority. It can be said with some certainty that within the South African context stem cell research would certainly not bestow the most beneficence to the most number of people compared to other health priorities.

Having said this it is, however, important that we do not neglect the possibilities stem cell research holds and allocate all our health benefits to the combat against STD and illnesses such as TB and malaria. Until now, this study has focused on micro and a few macro-issues, and it has been shown that embryonic research would be beneficial. Having established this, a

discussion on stem cell research cannot be complete without considering whether such research should / could be funded with public money.

To appreciate the prospective health benefits of stem cell research will necessitate a large and continuous investment in research. Chapman and his colleagues (1999:vi) argue that in American society the federal government would be the only realistic source for such an infusion of funds. They reason that “[f]or those who are challenged daily by serious diseases that could in the future be relieved by therapies gained through stem cell research, public funding holds the greatest promise for sooner rather than later research results that can be transferred from the bench to the bedside”.

However, Van Niekerk (1991:14) correctly asserts that the matter of cost cannot be ignored either in South Africa or the rest of the Third World. He points out that this concern raises a whole array of questions relating to priorities of allocating scarce resources in the practice and possibilities of medicine.

The inconsistency between barring embryo research and refraining from financially supporting it has frequently been distorted by both those for and those against such research. The difficulty lies not in what ought and ought not to be done with regard to stem cell research; it extends rather to the issue of the moral right in spending vast amounts on research while millions are dying each day of illnesses which can be cured because they lack the financial backing to pay for such treatment. To illustrate this Rebecca Dresser (2002:252) adamantly states that “[m]illions of patients in the United States lack access to establish health care that could improve and extend their lives. People in developing countries lack access to the most basic medical assistance. Because helping patients is the ethical justification for conducting stem cell and other forms of biomedical research, improved access to existing and future therapies must be part of the national discussion”.

In the light of such disagreements, it is essential to bear in mind that public policy in a pluralistic democracy, such as South Africa and most of the Western world, cannot expect to include all the opinions and ethical priorities of all those who make up the democracy. Chapman *et al.* (1999:22) identify the aim of public policy as “to protect and promote the basic values essential to civic order and the pursuit of widely different individual conceptions of the good”.

Since resources for research are inadequate, choices must be made about which needs should be the first (and the last) priority. This does not mean that stem cell research should not be funded, but only that one must take into account that resources are also essential for many other therapies. Those in favour of pursuing stem cell research could argue that a constant focus on the present needs could blur the future needs of a developing nation. These critics also respond that an excessive preoccupation with existing health care needs can impede new medical research and progress. They argue that present medical knowledge which assists with basic needs was also once considered experimental.

In order to address the problem of allocating the already limited resources, I propose that we take four approaches into account, namely macro-allocation, ethical considerations, principle setting and legal position.

i) Macro-allocation

“Macro-allocation of health care resources involves decisions over the share of a society's total resources which are to be devoted to health, and also the division of the health care budget between different possible uses. Macro-allocation involves issues of distributive justice because health care resources are nearly always scarce relative to need.” (Wikler and Marchand 2004:306)

Resource distribution in health care expenditure is predetermined in all societies. Conversely, according to Van Rensburg (2004:582), resource allocation needs to be considered at several levels: *firstly*, at the national level, where the budget for public health services is determined; *secondly*, within regional geographical areas, which are influenced both by the national and provincial governments; *thirdly*, for particular diseases or forms of treatment; *fourthly*, at the level of eligible patients, where decisions are usually made at the institutional level by committees; and *finally*, at the level of the individual patient, where such decisions are characteristically made by practitioners at the bedside.

To help with the process of macro-allocation, Wikler and Marchand (2004:307) and Beauchamp and Childress (2001:251-252) have identified a few principles of macro-allocation.

First of all one should determine the overall health care budget. Developing countries often allocate less than 3 % of their gross domestic product (GDP) to health, while most developed countries allocate between 6% to 14% of their GDP to health (Wikler and Marchand 2004:307) – South Africa’s health GDP according to the World Health Organization was 8.6% for 2003. Such allocation usually reflects a country’s affluence.

Secondly, one should take a look at the allocation within the health care budget. Wikler and Marchand (2004:308) concur that no agreement exists on which principle or principles should direct the distribution of resources within the health care budget. They explain that the most widely advocated principle is that of maximization of benefit, or 'value for money'. Beauchamp and Childress (2001:251) stress that “[h]ow society might appropriately mix preventative and treatment strategies will depend, in part, on knowledge of casual links, such as those between disease and environmental and behavioural factors”.

It is interesting to note that many societies permit some health services to be allocated according to ability and willingness to pay (Wikler and Marchand 2004:308). However, this principle is repeatedly in conflict with other principles which also seem appropriate, such as giving precedence to those in the direst need, or even to those individuals who are most needed by society.

Thirdly, take the health needs and benefits into consideration. Wikler and Marchand (2004:308-309) explain that an approach which maximizes health benefits is pursued through an analysis of cost-effectiveness which requires that diverse goods be quantified in comparable units.

Treatments for different conditions, if they are to be graded in precedence, must employ a more universal appraisal, such as net loss or gain in years of life. Therefore, the highest priority would be allocated to health care interventions which entail the least cost per unit of health related quality of life. The most extensively used universal unit of assessing medical benefit discounts life years compromised by symptoms and functional limitations. An alternative measure relies on experts' approximations of the impact of the symptoms and functional limitations on the quality of a person's life. These and other health metrics can be used to calculate the benefits of health care interventions, and consecutively, their return of health benefits for money spent (Wikler and Marchand 2004:309).

ii) Ethical considerations

The use of quantity of life as a measurement for resource allocation is problematic. Wikler and Marchand (2004:309) correctly assert that at a most abstract level it may refer to longevity, in which case it would be giving more weight to those at the start of their lives than those on the other side of the spectrum.

The extent of quality of life as a norm also involves challenges. One such a challenge involves the difficulty of assigning the value of quality of life by asking people who are / have never been in a similar position. Wikler and Marchand (2004:310) dispute that healthy people without fail rate conditions such as rheumatoid arthritis as imposing greater burdens than do rheumatoid sufferers themselves. It is not easy for the well to genuinely understand what living with a chronic condition is like, and as such it is difficult to use their value judgments as the basis for health measurements. For Wikler and Marchand (2004:310) the answer to this enigma possibly lies in combining objective and subjective evaluations.

Another ethical consideration is the maximization of the total sum of units of health related quality of life or paraphrased as being the highest total amount of health benefit is more important than its distribution among individuals. This inevitably means that patients in terminal states of illness lose out with respect to health funds to a number of patients in better condition (Wikler and Marchand 2004:310). The authors continue to sketch the bleak picture where a person with a life-threatening, treatable condition would be endorsed to die so that others could have assistance for mild discomfort. Thereby the total maximizing strategy presupposes that adequate quantities of the latter can outweigh the former.

A very emotive argument cites that one is to a degree responsible for one's own state of health. According to proponents of this presumption, individuals should be penalised or even receive no benefit if a specific illness is directly caused by behaviour they have committed. An example is the alcoholic who is in line for transplant of a new liver.

Although this viewpoint seems to be sound, it is also riddled with problems. One such a problem relates to the uncertainty regarding which habits are within the power of an individual (Wikler and Marchand 2004:313).

iii) Priority setting

The fundamental hypothesis of such an approach to limited health care resources is (a) to guarantee that all citizens with low income receive a respectable minimum of health care treatment, and (b) to find as many top priority-ranked services as feasible for all entitled citizens under the standard that there is a basic social responsibility to offer universal access to a respectable minimum of health care.

Law makers and citizens in the State of Oregon in the United States of America pioneered a world-first and closely scrutinized plan to ration health care funds. It included, as identified by Beauchamp and Childress (2001:256), access to care, cost-effectiveness and a decent minimum. In July 1989 the Oregon Health Services Commission (OHSC) was formed by virtue of the Basic Health Services Act. OHSC employed a public prioritization method to rank a wide-ranging set of primary and acute medical and mental illness conditions and services. The commission incorporated health care suppliers and patrons who determined which category of health services were most essential and most probable to result in a healthier society. The final list incorporated 745 conditions and treatments. The legislature then approved financial support for items 1 through 606 on the list. This list is continuously being updated for both the clinical effectiveness and cost-effectiveness of health services by determining their relative importance using peer-reviewed medical literature. Hence, limited resources are used to assure the maximum health care gain for the most people at the lowest price.

Another approach, namely the age-based rationing approach focuses on rationing by giving individuals lower priority, or even excluding them, by virtue of their age. This approach could be beneficial – such as Medicare in the USA – or detrimental. Beauchamp and Childress (2001:260) explain that justification for this approach lies in the probability of successful treatment and shorter recovery periods. The authors (2001:261) furthermore argue that “the old have had an opportunity to live more years and, on grounds of fairness, the young deserve chance to live those additional years”.

The communitarian justification to this approach lies in the belief that medicine ought to undertake to provide civilized and basic care to all, but should not make indefinite efforts to triumph over all illnesses and death. Death should become the acceptable outcome of a full life, rather than be seen as a failure of it.

Criticism of this approach is also bountiful. Norman Daniels argues from the Rawlsian theory of fair equality of opportunity (Beauchamp and Childress 2001:234). He reasons for a situation where age is not a variable in the allocation of health resources, since every individual has equal rights to receive a fair share of the normal range of opportunities present in that culture.

A third approach I would like to address is the approach in determining the allocation of scarce resources is the application of a cost-effectiveness analysis. Beauchamp and Childress (2001:257) point out that the cost-utility analysis is a very influential theory used in the determination of cost effectiveness. Health benefits - using this strategy - are therefore calculated in terms of predictable health gains, whereas expenses are calculated in terms of expenditures of resources. Health benefits are measured, and an effort is made to include the outcome by determining the impact of interventions on both the length and quality of life. Using this strategy one is again applying the maxim where the most people benefit for the least expenditure.

Once again criticism against this approach includes discrimination against those who cannot advocate for themselves, such as infants and the disabled, and the uncertainty of who is to decide on the quality of life.

iv) Legal positions

Another possible way in addressing the question of allocating scarce resources is by adopting the position of legal positivism which concludes that there are no rights other than what have been codified and which justifies demands. Failure to comply could lead to suffering (Blackburn 1996:213). This category would constitute policies and acts.

The legal right to resource allocation, as Norman Daniels (2004:316) explains, should reflect what society is morally obliged to provide by way of medical services.

The right to health care is a positive as opposed to a negative right (Daniels 2004:317). Positive rights oblige others to do something valuable or enabling for right-bearers, whereas negative rights require others to refrain from doing something which is usually harmful. However, a right to health care enforces a responsibility on others to support the right-bearers in obtaining needed and appropriate services.

Daniels (2004:318) focuses on a few rights, namely that society has a duty to its members to allocate an adequate share of its total resources to health-related needs; that society has the duty to provide a just allocation of different types of health care services; and that each person is entitled to a fair share of such services. According to Daniels (2004:318), health care rights form part of a broader family of positive welfare rights, which a society is obliged to honour.

a) South African context

South Africa's fiscal assets are very restricted and high and sustainable economic growth will be critical to make available the necessary funds to reduce inequality within the country. Therefore, it is imperative to encourage cost effectiveness and to consider the country as a whole.

Given South Africa's history and the backlogs that exist in basic services, one must accept that some form of redistribution will be necessary (Croeser 1993:56). The transformation and restructuring of health care services rank among the most important transitions currently taking place in South Africa. According to Croeser, problems facing health care in South Africa are not only political; they range from demographic and economic to ethical.

One of the world's most progressive constitutions, the South African Constitution declares that all the country's citizens are eligible for the allocation of resources to enable them to have a civilized life. One of the best known illustrations of this is the case of *Soobramoney versus the KwaZulu Natal Minister of Health*. The plaintiff was terminally ill with chronic renal failure. Although Mr Soobramoney's life could have been extended by standard renal dialysis, he was declined admission for such treatment at the state hospital because he did not meet the criteria for admission under guiding principles which the hospital had put into action because of a scarcity of resources.

The appellant applied to the High Court for an order instructing the hospital to make ongoing dialysis treatment available to him. The plaintiff argued that he had a right to receive renal dialysis treatment based on section 27(3) of the 1996 Constitution which states that "no one may be refused emergency medical treatment" and section 11 which stipulates that "everyone has the right to life". Upon denial of his claim, he turned himself to the grace of the highest court in South Africa, the Constitutional Court. Mr Soobramoney contended that his constitutional right to emergency medical treatment (s 27(3)), interpreted with the right to life (s 11), obligated the hospital to offer ongoing treatment for his illness without charge and the state to make supplementary means available to the hospital to enable it to do so.

However, the Constitutional Court in its judgement said that Mr Soobramoney's explicit right could not imply that the treatment of a terminal illness had to be prioritised over other kinds of medical care, such as preventative health care. Furthermore, the right not to be refused emergency medical treatment was autonomous from the right to life and had to be understood in the framework of the availability of health services in general. It was also held that the state has a constitutional responsibility within its existing assets to offer health care, as well as sufficient food, water and social security. Therefore the hospital was unable to provide the plaintiff with the treatment he had demanded.

b) A challenge for South African health care

With a past where a minority of the population enjoyed most of the resources, and the majority was left mostly to their own devices, the South African health care system is faced with the immense problem of having to adjust the inequality of the past and redistribute all resources equally in order to provide all citizens with equal access to basic health care. However, priorities must be set for the allocation of technologically sophisticated and expensive health care resources.

Government faces the challenge to devise policies which offer equal access to health care to all citizens. The most widely used approach is that of allocation based on "basic health care services". This approach sees primary health care as important, since it not only addresses an individual's health needs but also extends his or her social, cultural and political self.

This viewpoint is summarized in the WHO's (1978) Declaration of Alma-Ata's point V:

Primary health care is essential health care based on practical, scientifically sound and socially acceptable methods and technology made universally accessible to individuals and families in the community through their full participation and at a cost that the community and country can afford to maintain at every stage of their development in the spirit of self-reliance and self-determination. It forms an integral part both of the country's health system, of which it is the central function and main focus, and of the overall social and economic development of the community. It is the first level of contact of individuals, the family and community with the national health system bringing health care as close as possible to where people live and work, and constitutes the first element of a continuing health care process.

Measured from a perspective of social effectiveness, the benefit of the primary health care approach is that the basic health care needs of more patients can be satisfied.

However, in a polarised country such as South Africa where there exist two separate health care providers (the public and the private sector), this kind of allocation of resources could be seen to oppose equity and equality. For a group plagued by illnesses such as tuberculosis or even AIDS, basic health care could mean trying to stay alive, while for those to whom tuberculosis, AIDS and pneumonia are not a direct threat to their survival the absence of access to stem cell therapies could be defined as a violation of the right to basic health care.

Some individuals argue that since the haves contribute most of the economic resources in form of their tax contributions, health care resources should be allocated to the treatment of those disease conditions which usually affect this group and which require expensive and specialised medical care. However, money is of course generated by all the classes of society, often at the expense of the health of the so-called lower socio-economic. The severe limits on the availability of taxpayers' money to correct the imbalances in the allocation of resources are understandable. But we are still left with a problem. Who should the restricted funds be allocated to?

c) A possible solution

One of the only real viable solutions to the crisis of the allocation of resources in the South African context is the prioritization principle. In the pursuit of equity and equality, priority setting in the macro-allocation for high-cost interventions should be low. Priorities have to be selected which not all may be satisfied with. However, health care should be seen as a social need – the end result of which is that the national health system brings health care as close as possible to where individuals, the family and the community live and work.

The discussion concerning access and the allocation of scarce resources shows that there is no straightforward or practical solution to priority setting in health care. The best argument presented would be for maintaining the time-honoured method of rationing - as is currently the policy in the United Kingdom and South Africa. Advantages of this method are (1) that it is based on trust, (2) that it is more sensitive to the complexity of medical decisions and personal and cultural preferences of patients, and (3) that it is best applied at the micro-level of individual patient care (Van Rensburg 2004:582).

There will always be opposing views as to whose rights should prevail and who should receive the allocated resources. However, what cannot be postponed or debated any longer is the urgency which so many citizens face with regards to poor health care and dire living conditions. Open, sincere and continuous public debate on how to make the hard choices about who should benefit from limited resources should be encouraged.

All that has been said in the previous chapter has particular relevance with respect to understanding the health care needs in South Africa and the country's position in terms of the sustainability of bio-technology and the impact and cost of patents on the South African health system. Although South Africa is faced with bleak prospects as far as the AIDS pandemic is concerned, it cannot sit back and pretend that stem cell discoveries have not been made or that is irrelevant. Even if such discoveries address only 10% of all deaths, the power of these breakthroughs must be recognized and policy on them prepared. South Africa must ensure that it is not caught off guard and ill-equipped.

Conclusion

The aim of this chapter was to highlight the macro-issues pertaining to the debate surrounding stem cell research. Outlining my discussion I concluded that from a safety point of view, although stem cell research holds the potential for therapeutic worth, the challenge still exists to prove its safe application beyond reasonable doubt. This is of paramount importance as science cannot afford any mistakes which will cause the cure to become the poison.

Addressing human stem cell safety requires that the human stem cell development process be scrutinized at every stage - extraction, storage, manipulation and transplantation. Only once this has been successfully recorded with no exception of possible negative outcomes, can the transplantation of stem cells into human subjects be considered. Research should be careful not to base all its evidence and arguments on animal models and conclude from this that stem cells would be safe to use. Although this comment addresses a whole new discussion about animal *vs.* human research subjects, it is not the scope of this study to address it. My opinion is merely that one should not hold that stem cell research is the cure for all humanity's health problems based only on animal models. As identified in the discussion, some stem cell research in Spain found that stem cells become cancerous, and we should therefore be careful in administering such therapies in human models until it is certain that it is purely to the beneficence of man.

From a commercialization point of view, I drew the conclusion that the independence of individuals is being lessened by the concentration of control in economic organisations or big multi-national organisations. These organisations are attaining the patents on new stem cell therapies, which means they gain control of the market. A policy is therefore of great importance to guide government to implement tougher action to prevent companies (or even individuals) from gaining control over the human genome and all the parts thereof. Although the incentive of reward should exist for those labouring in the labs trying to find cures, I strongly feel that the human body should never become a commodity where the *ova* with the most beautiful, most intelligent, tallest, thinnest genes fetch the highest price. Researchers should be able to patent their work; however, the question would need to remain whether the genome and or even stem cells are really new innovations which could become patentable.

The next point of my discussion focused on the acquisition of control and the exertion of power over the individual consumer. Knowledge is seen as one of the most powerful tools in the

power struggle which could be “won” by multi-national companies who would have infinitely more knowledge about the subject. With this knowledge these companies can manipulate the markets (and even society’s perceptions) and thereby control society.

The section dealing with accessibility argued that the gains from stem cell research should be open to the benefit of all. However, the truth about South African society is that many of our fellow citizens do not even have access to the basic things in life (running water, security, clothes, food, etc.).

The final section of this chapter considered the allocation of scarce resources and discussed the reality of a country in the grips of an AIDS pandemic. Once again, in the South African context it is clear that the resources available for medical research cannot be spent entirely on stem cell research and such therapies are luxury therapies which do not help the majority of the South African society. Priority setting needs to be done and according to this allocation from the health budget should be made towards a stem cell research fund – only then can such an allocation be satisfactory.

As mentioned several times, the funding required in order to obtain results from stem cell research is vastly more than any private company could contribute – funding would thus essentially rest on the state. Pro-lifers often use this argument to mobilize the public against research by arguing that tax money will be used to sustain possibly “futile” research. The issue must be addressed, however, whether the South African government should fund stem cell research in order for our medical community to acquire access to and benefit from the new medical knowledge and technologies which will be developed.

Taking my discussion on the macro-issues into consideration, I cannot but conclude that from a macro point of view stem cell research does not seem to be a viable and important exercise within the South African context. Although our country will benefit from the knowledge and possible cures stem cell research holds (especially when one considers the great number of people who suffer from illnesses stem cell therapy could address), we are also faced with circumstances and a health care crisis far greater than the beneficial contributions of stem cell research. Our immediate need is to address the HIV/AIDS crisis and to come to grips with the medical, social and economic challenges it brings. My recommendation, however, would be that our government engages with other “richer” governments in order to facilitate a transfer of

knowledge and technology in order to benefit all medical practitioners in South Africa, and even on the whole continent.

However, the need still exists for a policy to guide future lawmakers who might need to address stem cell research, and to guide decisions and actions. Such a policy would need to identify different alternatives and priorities, and choose from among the alternatives and priorities the best option based on the impact it will have. Since a policy is an active contribution to society, it is important that it stays dynamic and guide decision-making. It is imperative that no back door is left open for abuse by the multi-national companies from other developed countries. The next chapter will therefore explore the different policies in place in other countries; it will investigate the formulation of a well deliberated policy while taking into account the South African position, before proposing a morally justified policy which could serve as a guide in decision-making for when we have overcome our present problems.

Chapter 7: A morally justified policy

Wisdom entereth not into a malicious mind, and science
without conscience is but the ruin of the soul.

François Rabelais (c. 1494–1553)

In a dynamic democratic system citizens will always face disparities about which actions should be allowed and which should be prohibited. Both camps focus on different motivations and deterrents in supporting those values in their unconditional form.

This is illustrated, sometimes to an unusual degree, in the stem cell debate. Both sides - those who hope to protect the rights of embryonic human life, and those who wish to advance scientific research concentrating on the relief of pain through the cure of fatal diseases – focus and argue from moral tenets.

Gbadegesin (2001:24) quotes Chiavacci: “Each people and each culture finds its own dignity within its own cultural identity. Moreover, cultural identities, if properly respected and understood, can offer new richness of thought to the whole human family. Therefore each culture and religion, with its own ethical perspectives, must be respected and appreciated.”

Therefore, every culture ought to develop a response to new technologies in its health care system, which might amount to either rejecting or accepting these expertises and their consequences (Gbadegesin 2001:25). Gbadegesin explains that this would create a truly universal bioethics. However, as is the case in South Africa, society is characterised by pluralism where more than one culture exists. This multi-culturalism inevitably will lead to a great variety of perspectives and opinions, based on inherent value and belief systems. Out of this melting pot of ideas, opinions and tenets the need arises for the development of public policies which can accommodate and respect these differences. The challenge for a good public policy in a tolerant democracy is to endorse a society where citizens can make educated and conscientious choices.

According to Walt (1994:40-41), [p]olicy is the selection of non-contradictory means to achieve non-contradictory ends over the medium to long term... [It is] an expression of a general purpose or a desired state of affairs or a specific proposal.

This chapter will attempt to propose a morally justified policy for stem cell research in South Africa. Since no policy is created out of nothing, this chapter will draw from a few general policies, such as the Nuremburg Code and the Declaration of Helsinki, as well as a few specific policies, such as public policy on stem cell research in northern America, Australia and the EU.

Development of policies

Ironically, as McNeill (2001:371) and Manasse (2005:1080) mention, it was Germany who, as early as 1900, first developed codes of ethics for experimenting on human subjects. These policies were in effect during the period of the Third Reich but were obviously ignored. As a result of the inhumane wartime medical experimentation on humans, a Code was developed at Nuremberg in 1946 to prevent the future occurrence of such atrocities.

i) The Nuremberg Code

The protagonists of the inhumane human experimentation during the war defended their actions on the foundation that such research contributed towards the good of society by encouraging a better understanding of human disease and human nature. Although many who oppose stem cell research play on the sentiment that the embryonic unit is being subjected to Nazi-like treatments, they tend to lose sight of the aim the Nuremberg Code championed, namely responsible and conscientious research.

The Nuremberg Military Tribunal laid down ten principles, comprising the first internationally recognised policy which laid down a set of guidelines to direct experiments on human beings. Amongst other requirements, the Nuremberg Code (see Addendum A) expresses the condition of voluntary informed consent of the human subject, enabling the subject to be in control of his or her own body.

The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so

situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment. The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs, or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

Furthermore, attention is paid to the principle where risks must be evaluated against the likely advantage, and that unnecessary pain and suffering must be avoided. The principles established by this code for medical practice have now been extended into general codes of medical ethics (The Nuremberg Code 1996:1448).

According to McNeill (2001:371-372), the Nuremberg Code contained in the court's judgement was not itself very influential. In 1964 the World Medical Association issued another code for research and experimentation, known as the Helsinki Declaration, which gained more publicity than the Nuremberg Code and was more influential within the medical profession. The Declaration of Helsinki dealt with the complex questions surrounding subjects who are incompetent to make informed judgements.

ii) The Declaration of Helsinki

The Declaration of Helsinki (see Addendum B) does not hold an absolute obligation that informed consent be obtained in the setting of therapeutic research, but introduces the notion of guardianship as a means of obtaining consent from incompetent subjects (British Medical Journal 1996:1413).

2. 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. Medical research involving human subjects includes research on identifiable human material or identifiable data.
3. It is the duty of the physician to promote and safeguard the health of the people. The physician's knowledge and conscience are dedicated to the fulfilment of this duty.

According to the editorial in the prestigious British Medical Journal (1996:1413), incorporated into both the Code and the Declaration are objective conflicts of interest and conflicts of role: “the physician seeks the best for his or her patient and yet seeks to pursue medical science for the good of society”. Both documents ascertain an unconditional obligation for informed consent in performing experimental research, but the Declaration allows the physician, under certain circumstances which he or she must defend, to waive the requirement for informed consent.

Since its writing, the Declaration of Helsinki has had a vast influence on researchers' overall sense of duty to individual patients. These advances have reflected the development of public concern over the possible conflict of interest between different value systems and unfettered scientific progress.

Having discussed the two most influential policies in modern health care, the next section will turn to the already established international policies regulating stem cell research.

Types of policies

Given the great potential, support of and objection to stem cell research, there exists a need for a policy that makes a plain and considered assessment regarding whether to proceed with such research or not. If the majority of society is of the opinion that no rules or guidelines should regulate stem cell research, it should do so intentionally, not by default.

According to Walt (1994:43) policies vary, and the type of policy may affect political behaviour. She continues to explain that maintaining the core values and the long-term

objectives of the state would result in a “high” policy, whereas a lack of fundamental or key concerns relating to the state’s national interests leads to a “low” policy. Health reforms will fall into the latter category, which means that the policy process is much more open. Groups with particular interests may have significant access to government, and may be given opportunities to influence policy. This was, for example, the case in the USA where many religious and scientific groups made extensive contributions to the writing of the stem cell policy. Public participation would be the ultimate goal in policy writing.

South Africa is a pluralistic society with many diverse groups holding different views. The next section will therefore outline three possible options for a stem cell public policy. These outlines should be evaluated against the background of more formal international and local policies (as discussed earlier).

The advantages and disadvantages of each policy will be briefly explained in the following sections.

i) Option One: Governmental guidelines (possibly by a body), with no legal ban

This approach supports the notion of flexibility. The regulatory body would offer guidelines to help those involved in the field of study, and would also decide if certain stem cell research techniques are adequately safe to merit attempts. The agency would furthermore act as a licensing authority, establishing clear-cut guidelines outlining acceptable and unacceptable applications of any techniques.

Many researchers who champion stem cell research warn that society might be so blinded by the proverbial tree that it prohibits them from seeing the forest. As science and technology develops in the field of animal stem cell research and the developments prove to be positive, this option would prevent society from being locked in the grips of misguided legal positions. This option propagates caution, but not restrictiveness.

Objections against this option include that stem cell research - as earlier discussions have shown - is not a neutral, unambiguous topic. It is important to raise the question – as has been by many in the debate – that it should not be a case of who should regulate the research, but rather should there be any research at all to be regulated. The importance of this question is

caught up in the whole debate again of whether society really need the advances stem cell research possibly could hold?

Furthermore, it is argued that the largely unregulated field of *in vitro* therapy has proven that the establishment of such a regulatory body would take a long time, if it happens at all.

ii) Option Two: Self-regulation by professionals, with no legislative action

This option would allow researchers to choose individually whether to engage in stem cell research and would carry no legislative restraint. The researcher's discretion on self-regulation, as an expert in the field, would guide his or her actions. These experts would establish within their own community their own system for self-regulation to prevent abuse of the technology. This approach would discourage the great brain-drain which many countries are facing. It holds that stem cell research does not hold the dangers so frequently referred to.

Government's regulation of this field of study would be minimal and its only role would be to keep the checks put in place by the experts. Hindering and regulating scientific research and reproductive medicine by those who are not experts in the field would therefore be discouraged by this approach.

This freewheeling approach would seem to disregard the extensive public mistrust of scientists' intentions, as well as different views of the good stem cell research holds.

iii) Option Three: A temporary ban on stem cell research

This approach would prohibit stem cell research for any reason, enacted in a ban. However, it would also facilitate public debate and impose an obligatory re-examination of the ban after a specific period of time. It is important to note that a temporary ban isn't an effort to stall progress. It is rather a mechanism aimed at providing those involved with an opportunity to try and find the best way forward. Its goal is to create a healthy environment where both opponents and proponents can discuss the dangers and advances of stem cell research and create an incentive for more diverse research to support their notions.

The key benefits of a temporary ban would be that researchers are given the scope to try and find alternatives to the proposed way, as well as permitting time within which a regulatory body could be established to help institute certain guidelines.

The last option discussed is held by the United States federal government (not including all the states, i.e. California and New Jersey) to be the most satisfactory. While the public debate regarding the advantages and disadvantages are discussed, the implementation of a public policy commences.

A general policy

Public outlook on specific subjects should influence those specific public policies in a democratic political system. Since it is argued that a democracy is based on the idea of a government for the people, by the people, government should take into account popular claims when making public policy. However, paramount to this notion is the requirement that these policies should not be prepared in isolation. All citizens are the custodians of such policy making and the onus of creating public opinion should be placed on the private as well as the public sector. Thus, this proposal will attempt to stimulate public commentary and influence public debate.

Since this study is trying to formulate a public policy for a country which is culturally diverse, one shouldn't assume that a system of health care is a clearly delimited entity without any external influences (Herselman 2004:137). In trying to develop a public policy one should not lose sight of the fact that traditional health care systems focus on the promotion of interpersonal relationships and group harmony, which in effect reduce people's vulnerability to both physical and emotional conditions. In biomedicine, on the other hand, health care focuses on restoration of the health of an individual (Herselman 2004:144).

As have been discussed, the study of bioethics is occupied with assessing the moral validity of different procedures. This is even truer of a progressive technique such as stem cell research, especially in a society as diverse as South Africa's. This diversity consequently has an influence on what is perceived as right and wrong, useful and useless, good and bad. In an ideal world one would hope that all ethical reference points would value the same issues as essentially important. However, the real aim is not to create a new trans-cultural ethical

framework, but rather to create sensitivity amongst different members of different cultures and backgrounds in order to establish a universally accepted code of behaviour. The goal is therefore to establish the best alternative solution which – preferably - all involved can agree with.

i) General ethical principles

As has been pointed out by this study, the ethical opinion on the use of embryos in research, and especially stem cell research, is divided. Chapter two dealt with some of the possible advantages which stem cell development could hold. However, as illustrated by chapter three, the current legislation in terms of the new National Health Bill recognises the unique status of an embryo as a potential human being, but accepts that it is justified to use early embryonic cells for serious research purposes that may benefit others, upon approval of the Minister of Health. In light of this Bill a morally justifiable policy that would be beneficial to all should be put in place and should address the following issues:

a) Respect for autonomy

Personal autonomy, according to Beauchamp and Childress (2001:58), is a minimum self-rule that is free from both controlling interference by others and from limitations, such as inadequate understanding that prevent meaningful choices. The autonomous person is well informed about the dangers and consequences of each technique or treatment and can make an unbiased, informed decision, without being pressured into any specific camp or school of thought. It is the duty of the researcher to disclose all available information to the individual – whether adverse or not.

Only when an individual is properly informed by having received all information available on the subject matter, can he or she give informed consent to participate in a study or research on a voluntary basis. This consent, as pointed out in the abovementioned definition of autonomy, also stresses that no person should be coerced into making a decision. The person should participate voluntarily and be given adequate time to reach a decision. Once such a decision has been reached, positively or negatively, the decision should be respected by the researcher, and there should be no consequences for the decisionmaker.

Consent may not be induced, as pointed out by the MRC (2002b:13), by fear, force, threats, duress, coercion, compulsion, deceit, fraud, undue influence, perverse incentives or financial gain. Hence there should be no personal gain or loss if the individual decides to participate or not to participate in the research. Another important aspect of consent, as once again pointed out by Beauchamp and Childress (2001:68), is that the decisionmaker should be able to retract their consent at anytime during the procedure.

The principle of informed consent, which in essence advocates patient autonomy, constitutes a triumph over the previous system of medical paternalism as the ultimate decision whether to undergo any type of medical decision or not now rests with the patient and not with the doctor. This kind of decision can only be made by a well informed patient; a patient to whom the right amount of knowledge that the particular patient would deem necessary to make a calculated decision, have been disclosed. The patient may even make decisions contrary to the advice of a medical practitioner, with possible detrimental effects, as long as that patient has been informed properly beforehand. It is clear that the information given to the patient should be accurate and understandable to that patient. Consent must be freely given. It must not be induced by force, fear or fraud. In relation to the current study, the moment during which a person is informed as regards stem cells is crucial in the giving or refusal of consent.

Another factor which may affect the granting of consent is the provision of financial rewards in return for a person's genetic material. Financial gain could be a monetary benefit which befalls both the patient and the doctor obtaining informed consent to the procedure. A doctor who does not disclose his interests in the matter may find that his attempts to obtain informed consent from a patient are considered coercion. One possible way to avoid this scenario is for government to take a more active role in embryo-based stem cell technologies, to regulate this field of research and invest in developing cell therapy methods, from the basic science to the establishment of "cell factories" for the production of tissues for transplantation. Although it would initially be expensive, governments would be able to utilize these technologies within non-profit systems, thus overcoming commercial complications connected with selling human tissues (De Vries 2005:88).

With regards to the issue about autonomy where embryonic entities are involved, the progenitors of the entity (male and female gamete contributors) should be well informed as to

the status of the entity and their rights and obligations when they do decide to donate the entities for stem cell research.

b) Nonmaleficence

Research utilizing surplus IVF embryos can be directed by the principle of double effect. This approach (Beauchamp and Childress 2001:128) incorporates a fundamental distinction between intended effects and merely foreseen effects - effects being consequences of actions. Many authors on morality include this principle in their discussions to illustrate why (or why not) some acts are permissible. In order to aid my discussion and to underline my argument, I will first reflect on the traditional (religious) view of the principle before moving my focus to a more secular perspective.

The principle is often used to explain the acceptability of an act which has to cause harm – as a side-effect – in order to promote a good end (Darley *et al.*, 1996; Hessing *et al.*, 1996; Russel, 1977; Twycross, 1996). In other words, the end justifies the means. The principle of double effect originated in the philosophy of one of the great doctors of the Catholic faith, St. Thomas Aquinas (and was morally approved in 1957 by Pope Pius XII). St. Aquinas introduced the principle in the *Summa Theologica*, which deals with the acceptability of self-defence. As noted by Baumbarth and Regan (1988:226), Aquinas observes that “[n]othing hinders one act from having two effects, only one of which is intended, while the other is beside the intention.” Aquinas also states that the acceptability of an action is not absolute: “And yet, though proceeding from a good intention, an act may be rendered unlawful if it be out of proportion to the end.”

Connell (1967:1021) provides four conditions from the New Catholic Encyclopedia for the application of the principle of double effect, namely:

- The act itself must be morally acceptable or at least indifferent.
- The agent may not positively desire the bad effect, but may allow it. If he could attain the good effect without the bad effect he should do so. The bad effect is viewed to be indirectly voluntary.
- The good effect must be produced directly by the action, not by the bad effect. Otherwise the agent would be using a bad means to a good end, which is never allowed.

- The good effect must be sufficiently desirable to balance the allowance of the bad effect.

The principle may also be seen from a more secular perspective (Quinn 1989:343): there is a justification for causing some bad effects - as a side effect – which might not be sufficient for causing that effect as a means to the same good end under the same circumstances. Quinn (1989:343-344) argues that the principle:

... distinguishes between agency in which harm comes to some victims, at least in part, from the agent deliberately involving them in something in order to further his purpose precisely by way of their being so involved, and harmful agency in which either nothing is in that way intended for the victims or what is so intended does not contribute to their harm. ...direct agency requires neither that harm itself be useful nor that what is useful be causally connected in some especially close way with the harm it helps bring about.

In another article Quinn (1991:511) explains that:

some cases of harming that the doctrine intuitively speaks against are arguably not cases of intentional harming, precisely because neither the harm itself nor anything itself causally very close to it is intended.

In the utilisation of surplus IVF embryos, the intent is not to destroy them but merely to extract their stem cells. The embryo consequently dies, but the agent's intent was correct, i.e. not to destroy, but to extract the stem cells.

The unintended (and undesired) consequence is the death of the embryos. Beauchamp and Childress (2001:129) identify four conditions which usually apply to the principle of double effect:

1. the act itself must not be fundamentally immoral, but must be a good or neutral act;
2. only the good effect must be anticipated by the researcher, not the bad effect, even though it is foreseen;
3. the negative effect must not be the means of the good effect; and
4. the good effect must prevail over the bad that is permitted.

Many proponents apply these four criteria to stem cell research and find that the potential cures by far outweigh the consequences, and hence recommend that the doctrine of double effect is morally viable.

It is, however, imperative to stress that the doctrine of nonmaleficence would only really be applicable to surplus embryos. The use of embryos that were cultivated with the express intent to be used as research subjects should be discouraged as the intent would not be nonmaleficent. Referring back to my discussion on the status of the embryonic entity, I would like to stress my belief that these entities do not have moral worth in as far as they lack person-making properties and have no sentience (i.e. cannot feel either pain or pleasure). Therefore this principle will not be violated.

In theory the principle of double effect assumes that all agents are well-intentioned and concerned whether harm may be caused. However, according to the theory, attempting to achieve a good end by overruling moral value when it is – regrettably – not feasible to attain the good end without the harm, may be seen as a violation of the principle.

c) Beneficence

According to the guidelines presented by the MRC (2002b:83), beneficence refers to the practise where individuals are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their wellbeing.

The moral obligation of beneficence is paramount to ethics where actions are weighed for their possible good against the costs and possible harms. This principle holds that failure to enhance the good of others when one is in a position to do so is morally wrong. It could be argued that stem cell research is encouraged and justified by the principle of beneficence. The beneficence principle is often seen as referring to charitable acts; however, beneficence should in this context rather be seen as an obligation to maximize benefits and minimize risks that might arise.

The MRC (2002b:84) points out that a difficult ethical problem remains when applying the principle of beneficence. Some research presents more than minimal risk without immediate

prospect of direct benefit to the community. Therefore all risks and benefits should be carefully assessed by analysing all relevant data.

Once again the embryonic entity doesn't qualify under this principle as it lacks status of personhood and consequently cannot be treated unethically by putting them at risk.

d) Justice

In short, the principle of justice asks two simple questions, namely: "Who ought to receive the benefits of research and bear its burdens?" (MRC 2002b:84). Beauchamp and Childress (2001:226) present justice as fair, equitable and appropriate treatment in light of what is due or owed to a person.

Therefore, the reverse of justice would involve the undue burdening of a person who is entitled to a benefit. To summarize briefly, justice plays an important role when the allocation of resources takes place. Marginalised groups should not be unduly burdened to profit the dominant group. Furthermore, the results of the research should not benefit only a selected few, but rather the community as a whole.

A proposed morally justified policy

Taking into account the content of this study and the discussion surrounding the status of the embryo, it would suffice to conclude that the pre-embryonic entity does not have any moral standing and that the extraction of its stem cells will not be a moral violation of any kind. In light of the macro-issues discussed, it is necessary to mention that in view of the basic ethical principles stem cell research proposals should be scrutinised by a regulatory body so as to prohibit any violations, i.e. the allocation of already scarce resources in a context where the AIDS pandemic and accompanying illnesses (pneumonia, etc.) present a more pressing need to the majority of the citizens. This said, it would be unwise to adopt an ostrich-like attitude and pretend that the reality of stem cell research and the promises it holds do not exist. Based on this, I would like to propose a morally justified policy for stem cell research which could be implemented by a regulatory body should private funding (or even public funding at a later stage) be used for such research.

I would like to propose a policy which respects and values the autonomy of the progenitors' choices (provided they have not been coerced) and which focuses on the beneficence of the greater society. Furthermore, it is paramount that the goal of any stem cell research should be for therapeutic use ONLY. Before commencing with the extraction of the stem cells, scientists should be obligated first to present convincing evidence that they have tried alternative ways to reach the same result. Once this has been proven, a regulatory body could issue the scientist/team with a license to undertake the specific research with a specific therapy as goal in order to prevent abuse. If they are found to be guilty of any unethical conduct their licenses should be revoked and an investigation launched.

As with any policy, detailed guidelines outlining acceptable and unacceptable applications of what is allowed must be available. Since this is not a microcellular study, I will not venture to propose scientific methods which should be used to extract the stem cells and maintain stem cell lines. Other fields of public activity, where different views of moral values on the one hand and proposed health benefits on the other hand require such cautious balancing, focus on more than reproductive genetics. Finding this synthesis can be very challenging, as is illustrated by the magnitude of writings on both sides of the debate. Indeed, (as pointed out earlier) different countries have varied approaches to these issues. However, given the lack of agreement regarding embryonic stem cell research in general – thanks, in part, to increasing moral doubt and concerns – the use of a legislative ban would most certainly be a mistake. The reality is that – whether one would opt for a more conservative framework or one which is a bit more liberal and less regulatory – a more receptive attitude seems only logical. Scientific advances are made at an increasingly rapid pace, and the framework should be able to address new social concerns and advances in a relatively short time span. One may be sure that moral consensus on scientific development will never be achieved; with new advances new moral concerns will be raised. Insofar as it is relevant to our discussion concerning the morality of embryonic stem cell research, I would like to propose the following:

i) Surplus embryos

The only source of embryonic stem cells should be surplus embryos remaining from infertility procedures, or those which would not be viable once implanted and which have been identified as inappropriate for transfer because of their poor quality. Embryos should under no circumstances be created specifically for research purposes.

My reasons for opposing the creation of embryos purely for research purposes (and not as the by-product of *in vitro* fertilization) are based on the recent, well-publicised case of Dr Hwang Woo-suk (from South Korea), who exploited his own junior researchers by coercing them into donating their ova. I believe that a real danger exists that the donor might not voluntarily consent to the sale of his or her tissue, and that the economically and socially deprived might be prejudiced. Furthermore, people might not be willing to donate their tissue if they know they can be financially remunerated. Genetic research in general represents a window of opportunity for large Western corporations to exploit those less fortunate (as said earlier). Dr Eddie Mhlanga, Chief of Maternal, Child and Women's Health in the National Department of Health, commented that ... 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 (Schuklenk & Lott 2002:782).

Furthermore, the only aim of the medical practitioner who stimulates the *ova* cycle should be the creation of embryos for IVF treatment, and for nothing else. This raises the question why a person is allowed to donate blood or even an organ, while a woman (or even a couple) is not allowed to donate ova if she so wishes. In my opinion it is important to ask this question as this situation increases the possibility of a black-market in ova, especially considering the discussion of Papadimos and Papadimos' (2004:5) assertion that there exists a world-wide scarcity of human ova. A prime example of this is the 2005 case in which 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".

Before the option of donating the surplus embryos for research purposes is discussed, the embryos should have been cryopreserved for some time. Furthermore, the couple who is the

embryo's progenitors should be given the opportunity to donate these "snowflakes", as they are commonly known in the USA (Davidson 2001:229) or to have them disposed of. However, after all these options have been discussed with the progenitors and they decide to go ahead with the donation of the embryos for research purposes, proper consent should be obtained from them.

ii) Consent

Once the embryo's progenitors have made the decision that they do not wish to cryopreserved the embryos any longer, but wish to put them up for adoption or discard of them, their consent should be sought. This decision should be unequivocally renewed prior to getting the progenitors' consent to use the embryos in embryonic stem cell research.

Informed consent necessitates that the couple should have considerable understanding of the whole process and should give their consent without being subjected to any controlling pressure. The recommendation of this study is therefore that the couple should give their consent in two stages. The two-stage method would protect the couple from any coercion, as different people would be assisting the couple in their attempt to become pregnant, and requesting embryos for stem cell research. In essence the first stage will involve those who help the couple to get pregnant. They will inform the couple of the choices they face after conception has taken place and the couple is certain that they do not want to have another child. Only once the couple has definitely decided that they do not want to extend their family and they have chosen the "donation for research" option, should they be approached by the second team to get consent to use the embryos in embryonic stem cell research. It is important that consent from both gamete donors should be obtained, and there should be no incentives at any time during the procedure.

The written consent form must contain detail such as the reason for, nature and extent of, and justification for the research. The researchers must ensure that all those responsible for the embryos are given all available and appropriate information regarding the planned research, supported by written information in simple language and in ample time for it to be taken away, read and thought about before consent is given. It is important to include that if, for whatever reasons, a disagreement arises or a responsible person dies without stating clearly what his or her desires or wishes were, the embryos may not be used in research.

Since the destruction of embryos cannot be reversed, a fixed period of time should be allowed in which the person or couple could retract their consent, without any consequences or penalties.

iii) Development of the embryo

It is imperative that the surplus embryos which are donated for research with consent should not have developed beyond the 14-day point after fertilisation of the ovum (ignoring the time which they have been cryopreserved).

iv) Research team

Research should be tightly controlled or monitored by a governing body. This body should enact legislation that the research team should keep accurate records of research, including information about the source, use and outcome of each embryo used in the research. These records should also be made available. Only valid and approved research protocols should be allowed. A licensing system is also necessary in order to make sure that researchers are adequately qualified, that proper protocol was followed in the research on the embryo, that the legislative requirements were fulfilled and that proper record keeping is done in order to re-qualify for a licence.

The regulatory body should furthermore be responsible for an overview of human stem cell research, and should enact sufficient guidelines relating to privacy, confidentiality, adequate guidance and the securing of informed consent in order to prevent abuse (and any legal recourse). The body should also ensure that the donors of the surplus embryos (for research purposes) are given appropriate guidance as to whether they wish to donate their surplus embryos or not – free of any coercion. The governing body's influence should include procedures relating to pre-*in vitro* fertilization, where the progenitors of the embryos have to complete a form where they give (or do not give) their directives as to how they want their surplus embryos to be managed (the scenario of one of the donors dying whilst the cryopreserved embryos are still in storage should be included).

The members of the governing body must be knowledgeable and should be informed regarding scientific, technological and ethical issues relating to embryonic stem cell research. If they are not experts in these areas, they should be allowed to become such as this will encourage insight into the relative problems and challenges faced by those in the field. Proposals for authority should be generally defined to allow the body to adapt to changes in science and social morals. The main task of this body should be to facilitate an ongoing debate between the broader public, stakeholders and scientists. The facilitation should be based on articulated relevant values and guiding principles, and the setting of standards for analysis of research teams.

The powers of the governing body should include oversight of both the private and the public domains. The members of the governing body should at all times be able to evaluate protocols and be very well schooled in the principles of the Bill of Rights. It is important to stress that the governing body should not be tied up in administrative duties only. The body should at all times try to encourage public dialogue and monitor the advances in the field.

v) *Chimeras*

It is important to note that no chimeras, where human cells and cells from other animal species are mixed, should be allowed since this will be creating offspring of unknown moral standing as well as the offspring would be hard to define in terms of humanness. This function is also one which will need to be regulated by the governing body as many animal viruses can jump the species-line and we could be faced by yet another pandemic in the light of having created a new species – half animal half man.

Conclusion

Bans and proscriptions mostly answer only to immediate concerns and do not provide a solution for the long-term. Science, and especially reproductive medicine and genetics, are two of the most dynamic fields in medicine. It will be a matter of months before they have developed beyond the policy of a ban. A good policy will attempt to find a balance between all the different viewpoints. Such a policy will need to be fluid in as much as it needs to adapt to the new scientific and social environment it is continuously faced with.

It has been repeatedly said that the health crisis in South Africa necessitates that government spend time and money on the primary needs of the society, and that limited resources should rather be allocated to address primary problems. However, government also owes a duty of care to its citizens to protect them from exploitation by outside groups. This proposal hopes to inspire more debate about the subject of stem cell research and what can be done to protect those most vulnerable against exploitation, without ignoring the immense potential of the science.

Chapter two dealt in detail with the clinical applications of stem cell research, as well as with the sources of stem cells. In essence, stem cells present a new chapter in regenerative medicine as we know it, and they could hold unprecedented advances for the treatment of previously incurable diseases. It was also found that while adult stem cells have not proved able to differentiate into any kind of cell and may be limited to becoming cell types within their tissue of origin, stem cells from a newborn's cord blood produced only blood cells. Recently though, cord tissue has been found to contain mesenchymal cells capable of generating bone and cartilage. Therefore, embryonic stem cells extracted from surplus embryo, which are the products of *in vitro* fertilization, have the best ability to develop into any type of cell. In summary then, the prospects of the answers stem cells might hold are unrivalled by any discovery of medicine as yet.

The encouragement of the values of human life and dignity, as endorsed by our progressive constitution, obligating the state to control abortion and embryonic stem cell research in order to take care of developing human life, was addressed in chapter three. It was also pointed out that the state has a concern in maternal health, which cannot be separated from the abortion

debate. Section 14 of the Constitution, which addresses the right to privacy as paramount for the protection of an individual's dignity, including his or her physical, psychological and spiritual wellbeing, was analysed in specific. Section 14 also allows citizens to make personal decisions about their lives, free from interference by the state. Therefore, together with section 7(5) of the Choice on Termination of Pregnancy Act, a woman has the freedom to choose whether or not she wants to donate surplus embryo for research purposes – which will coincide with the scope of personal and intimate decisions that must be exercised without interference from the state.

This study acknowledges the fact that there is huge excitement, as well as expectations, regarding the potential cures stem cell research might hold. However, as with all new technology, advancement in the field is watched not without scepticism and moral concern by many groups. Life is seen as sacred by many and therefore the mere notion of having to destroy such life is seen as a violation of one of the most basic human rights. This study thus attempted to answer the question whether it would be morally justifiable to use embryonic stem cells in research seen against the background of a morally justified policy. The study investigated the ethical, religious, legal and macro-position of the human embryo and foetus in South Africa, and found that from a micro-issue perspective it would not be morally wrong to perform such research, as no legal or ethical prohibition could be found.

Attention has to be brought to the fact that most Western religions oppose stem cell research, which is at best a controversial issue. One of the first aims of this study was to ascertain the nature and starting point of human life, followed by a discussion on whether the embryo deserves the same legal rights and obligations as born human beings. A further purpose of this study was to ascertain the legal and ethical issues which influence the legal protection of the human embryo, and whether or not embryonic stem cell research is constitutional and should be allowed to continue. The Constitution, Acts and international regulatory frameworks were studied, analysed and discussed in depth. However, seen from a macro-perspective (chapter six), South Africa is challenged with other concerns and I have concluded that funding for support of research in the field can be better allocated to address more contemporary health issues and risks. Having said this, I would recommend that the government look towards the brokerage of allegiances with those countries that can afford to allocate funds towards stem cell research and share the knowledge they have acquired with medical researchers in our own country in order for all of humanity to profit from the cures embryonic stem cells might hold.

To summarise the last chapter, and the aim of this study, it is essential that any proposed regulation or policy needs to be adequately flexible to provide sufficient answers to the rapidly developing field of bio-technology. It is important that such a policy will facilitate – rather than prohibit – stem cell research, as these new techniques could hold unsurpassed potential treatments.

As with any study and policy, there are shortcomings. However, it is easier to improve an existing policy framework than to create a new one. Future research should take a serious look at how the present situation in South Africa - characterized as it is by apathy towards human life in general - influences the view of society towards the rights and moral status of the embryos / embryo.

Stem cell research is the new alchemy, but instead of turning lead into gold it is turning researchers into miracle workers, and redefining the boundaries of medical intervention. The excitement that is surrounding stem cell research is sometimes overwhelming, but becomes justified when compared to its incredible potential.

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Addendum A
The Nuremberg Code (1947)

The judgment by the war crimes tribunal at Nuremberg laid down 10 standards to which physicians must conform when carrying out experiments on human subjects.

PERMISSIBLE MEDICAL EXPERIMENTS

The great weight of the evidence before us to effect that certain types of medical experiments on human beings, when kept within reasonably well-defined bounds, conform to the ethics of the medical profession generally. The protagonists of the practice of human experimentation justify their views on the basis that such experiments yield results for the good of society that are unprocurable by other methods or means of study. All agree, however, that certain basic principles must be observed in order to satisfy moral, ethical and legal concepts:

1. The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment. The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs, or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.

3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results justify the performance of the experiment.
4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
5. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.
6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.
7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability or death.
8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.
9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.
10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him, that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

Addendum B

Declaration of Helsinki (1964)

WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI *Ethical Principles for Medical Research Involving Human Subjects*

Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964, and amended by the

29th WMA General Assembly, Tokyo, Japan, October 1975

35th WMA General Assembly, Venice, Italy, October 1983

41st WMA General Assembly, Hong Kong, September 1989

48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996

and the 52nd WMA General Assembly, Edinburgh, Scotland, October 2000

Note of Clarification on Paragraph 29 added by the WMA General Assembly, Washington 2002

Note of Clarification on Paragraph 30 added by the WMA General Assembly, Tokyo 2004

INTRODUCTION

1. 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. Medical research involving human subjects includes research on identifiable human material or identifiable data.
2. It is the duty of the physician to promote and safeguard the health of the people. The physician's knowledge and conscience are dedicated to the fulfilment of this duty.
3. The Declaration of Geneva of the World Medical Association binds the physician with the words, "The health of my patient will be my first consideration," and the International Code of Medical Ethics declares that, "A physician shall act only in the patient's interest when providing medical care which might have the effect of weakening the physical and mental condition of the patient."
4. Medical progress is based on research which ultimately must rest in part on experimentation involving human subjects.

5. In medical research on human subjects, considerations related to the well-being of the human subject should take precedence over the interests of science and society.
6. 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.
7. In current medical practice and in medical research, most prophylactic, diagnostic and therapeutic procedures involve risks and burdens.
8. Medical research is subject to ethical standards that promote respect for all human beings and protect their health and rights. Some research populations are vulnerable and need special protection. The particular needs of the economically and medically disadvantaged must be recognized. Special attention is also required for those who cannot give or refuse 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.
9. 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. No national ethical, legal or regulatory requirement should be allowed to reduce or eliminate any of the protections for human subjects set forth in this Declaration.

BASIC PRINCIPLES FOR ALL MEDICAL RESEARCH

10. It is the duty of the physician in medical research to protect the life, health, privacy, and dignity of the human subject.
11. Medical research involving human subjects must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and on adequate laboratory and, where appropriate, animal experimentation.
12. Appropriate caution must be exercised in the conduct of research which may affect the environment, and the welfare of animals used for research must be respected.
13. 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. This independent committee should be in conformity with the laws and regulations of the country in which the research experiment is performed. The committee has the right to monitor ongoing trials. The researcher has the obligation to provide monitoring information to the committee, especially any serious adverse events. The researcher should also submit to the committee, for review, information regarding funding, sponsors, institutional affiliations, other potential conflicts of interest and incentives for subjects.

14. The research protocol should always contain a statement of the ethical considerations involved and should indicate that there is compliance with the principles enunciated in this Declaration.
15. Medical research involving human subjects should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person. The responsibility for the human subject must always rest with a medically qualified person and never rest on the subject of the research, even though the subject has given consent.
16. Every medical research project involving human subjects should be preceded by careful assessment of predictable risks and burdens in comparison with foreseeable benefits to the subject or to others. This does not preclude the participation of healthy volunteers in medical research. The design of all studies should be publicly available.
17. Physicians should abstain from engaging in research projects involving human subjects unless they are confident that the risks involved have been adequately assessed and can be satisfactorily managed. Physicians should cease any investigation if the risks are found to outweigh the potential benefits or if there is conclusive proof of positive and beneficial results.
18. Medical research involving human subjects should only be conducted if the importance of the objective outweighs the inherent risks and burdens to the subject. This is especially important when the human subjects are healthy volunteers.
19. Medical research is only justified if there is a reasonable likelihood that the populations in which the research is carried out stand to benefit from the results of the research.
20. The subjects must be volunteers and informed participants in the research project.
21. The right of research subjects to safeguard their integrity must always be respected. Every precaution should be taken to respect the privacy of the subject, the

confidentiality of the patient's information and to minimize the impact of the study on the subject's physical and mental integrity and on the personality of the subject.

22. In any research on human beings, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail. The subject should be informed of the right to abstain from participation in the study or to withdraw consent to participate at any time without reprisal. After ensuring that the subject has understood the information, the physician should then obtain the subject's freely-given informed consent, preferably in writing. If the consent cannot be obtained in writing, the non-written consent must be formally documented and witnessed.
23. When obtaining informed consent for the research project the physician should be particularly cautious if the subject is in a dependent relationship with the physician or may consent under duress. In that case the informed consent should be obtained by a well-informed physician who is not engaged in the investigation and who is completely independent of this relationship.
24. 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 authorized representative in accordance with applicable law. These groups should not be included in research unless the research is necessary to promote the health of the population represented and this research cannot instead be performed on legally competent persons.
25. When a subject deemed legally incompetent, such as a minor child, is able to give assent to decisions about participation in research, the investigator must obtain that assent in addition to the consent of the legally authorized representative.
26. Research on individuals from whom it is not possible to obtain consent, including proxy or advance consent, should be done only if the physical/mental condition that prevents obtaining informed consent is a necessary characteristic of the research population. The specific reasons for involving research subjects with a condition that renders them unable to give informed consent should be stated in the experimental protocol for consideration and approval of the review committee. The protocol should state that consent to remain in the research should be obtained as soon as possible from the individual or a legally authorized surrogate.

27. Both authors and publishers have ethical obligations. In publication of the results of research, the investigators are obliged to preserve the accuracy of the results. Negative as well as positive results should be published or otherwise publicly available. Sources of funding, institutional affiliations and any possible conflicts of interest should be declared in the publication. Reports of experimentation not in accordance with the principles laid down in this Declaration should not be accepted for publication.

ADDITIONAL PRINCIPLES FOR MEDICAL RESEARCH COMBINED WITH MEDICAL CARE

28. The physician may combine medical research with medical care, only to the extent that the research is justified by its potential prophylactic, diagnostic or therapeutic value. When medical research is combined with medical care, additional standards apply to protect the patients who are research subjects.

29. The benefits, risks, burdens and effectiveness of a new method should be tested against those of the best current prophylactic, diagnostic, and therapeutic methods. This does not exclude the use of placebo, or no treatment, in studies where no proven prophylactic, diagnostic or therapeutic method exists.

30. At the conclusion of the study, every patient entered into the study should be assured of access to the best proven prophylactic, diagnostic and therapeutic methods identified by the study.

31. The physician should fully inform the patient which aspects of the care are related to the research. The refusal of a patient to participate in a study must never interfere with the patient-physician relationship.

32. In the treatment of a patient, where proven prophylactic, diagnostic and therapeutic methods do not exist or have been ineffective, the physician, with informed consent from the patient, must be free to use unproven or new prophylactic, diagnostic and therapeutic measures, if in the physician's judgement it offers hope of saving life, re-establishing health or alleviating suffering. Where possible, these measures should be made the object of research, designed to evaluate their safety and efficacy. In all cases, new information should be recorded and, where appropriate, published. The other relevant guidelines of this Declaration should be followed.

Note:Note of clarification on paragraph 29 of the WMA Declaration of Helsinki

The WMA hereby reaffirms its position that extreme care must be taken in making use of a placebo-controlled trial and that in general this methodology should only be used in the absence of existing proven therapy. However, a placebo-controlled trial may be ethically acceptable, even if proven therapy is available, under the following circumstances:

- Where for compelling and scientifically sound methodological reasons its use is necessary to determine the efficacy or safety of a prophylactic, diagnostic or therapeutic method; or
- Where a prophylactic, diagnostic or therapeutic method is being investigated for a minor condition and the patients who receive placebo will not be subject to any additional risk of serious or irreversible harm.

All other provisions of the Declaration of Helsinki must be adhered to, especially the need for appropriate ethical and scientific review.

Note: Note of clarification on paragraph 30 of the WMA Declaration of Helsinki

The WMA hereby reaffirms its position that it is necessary during the study planning process to identify post-trial access by study participants to prophylactic, diagnostic and therapeutic procedures identified as beneficial in the study or access to other appropriate care. Post-trial access arrangements or other care must be described in the study protocol so the ethical review committee may consider such arrangements during its review.

The Declaration of Helsinki (Document 17.C) is an official policy document of the World Medical Association, the global representative body for physicians. It was first adopted in 1964 (Helsinki, Finland) and revised in 1975 (Tokyo, Japan), 1983 (Venice, Italy), 1989 (Hong Kong), 1996 (Somerset-West, South Africa) and 2000 (Edinburgh, Scotland). Note of clarification on Paragraph 29 added by the WMA General Assembly, Washington 2002.

Addendum C

Universal Declaration of Human Rights

PREAMBLE

Whereas recognition of the inherent dignity and of the equal and inalienable rights of all members of the human family is the foundation of freedom, justice and peace in the world,

Whereas disregard and contempt for human rights have resulted in barbarous acts which have outraged the conscience of mankind, and the advent of a world in which human beings shall enjoy freedom of speech and belief and freedom from fear and want has been proclaimed as the highest aspiration of the common people,

Whereas it is essential, if man is not to be compelled to have recourse, as a last resort, to rebellion against tyranny and oppression, that human rights should be protected by the rule of law,

Whereas it is essential to promote the development of friendly relations between nations,

Whereas the peoples of the United Nations have in the Charter reaffirmed their faith in fundamental human rights, in the dignity and worth of the human person and in the equal rights of men and women and have determined to promote social progress and better standards of life in larger freedom,

Whereas Member States have pledged themselves to achieve, in co-operation with the United Nations, the promotion of universal respect for and observance of human rights and fundamental freedoms,

Whereas a common understanding of these rights and freedoms is of the greatest importance for the full realization of this pledge,

Now, Therefore,

THE GENERAL ASSEMBLY

proclaims

THIS UNIVERSAL DECLARATION OF HUMAN RIGHTS as a common standard of achievement for all peoples and all nations, to the end that every individual and every organ of society, keeping this Declaration constantly in mind, shall strive by teaching and education to promote respect for these rights and freedoms and by progressive measures, national and international, to secure their universal and effective recognition and observance, both among

the peoples of Member States themselves and among the peoples of territories under their jurisdiction.

Article 1.

All human beings are born free and equal in dignity and rights. They are endowed with reason and conscience and should act towards one another in a spirit of brotherhood.

Article 2.

Everyone is entitled to all the rights and freedoms set forth in this Declaration, without distinction of any kind, such as race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status. Furthermore, no distinction shall be made on the basis of the political, jurisdictional or international status of the country or territory to which a person belongs, whether it be independent, trust, non-self-governing or under any other limitation of sovereignty.

Article 3.

Everyone has the right to life, liberty and security of person.

Article 4.

No one shall be held in slavery or servitude; slavery and the slave trade shall be prohibited in all their forms.

Article 5.

No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment.

Article 6.

Everyone has the right to recognition everywhere as a person before the law.

Article 7.

All are equal before the law and are entitled without any discrimination to equal protection of the law. All are entitled to equal protection against any discrimination in violation of this Declaration and against any incitement to such discrimination.

Article 8.

Everyone has the right to an effective remedy by the competent national tribunals for acts violating the fundamental rights granted him by the constitution or by law.

Article 9.

No one shall be subjected to arbitrary arrest, detention or exile.

Article 10.

Everyone is entitled in full equality to a fair and public hearing by an independent and impartial tribunal, in the determination of his rights and obligations and of any criminal charge against him.

Article 11.

(1) Everyone charged with a penal offence has the right to be presumed innocent until proved guilty according to law in a public trial at which he has had all the guarantees necessary for his defence.

(2) No one shall be held guilty of any penal offence on account of any act or omission which did not constitute a penal offence, under national or international law, at the time when it was committed Nor shall a heavier penalty be imposed than the one that was applicable at the time the penal offence was committed.

Article 12.

No one shall be subjected to arbitrary interference with his privacy, family, home or correspondence, nor to attacks upon his honour and reputation Everyone has the right to the protection of the law against such interference or attacks.

Article 13.

(1) Everyone has the right to freedom of movement and residence within the borders of each state.

(2) Everyone has the right to leave any country, including his own, and to return to his country.

Article 14.

(1) Everyone has the right to seek and to enjoy in other countries asylum from persecution.

(2) This right may not be invoked in the case of prosecutions genuinely arising from non-political crimes or from acts contrary to the purposes and principles of the United Nations.

Article 15.

(1) Everyone has the right to a nationality.

(2) No one shall be arbitrarily deprived of his nationality nor denied the right to change his nationality.

Article 16.

(1) Men and women of full age, without any limitation due to race, nationality or religion, have the right to marry and to found a family. They are entitled to equal rights as to marriage, during marriage and at its dissolution.

(2) Marriage shall be entered into only with the free and full consent of the intending spouses.

(3) The family is the natural and fundamental group unit of society and is entitled to protection by society and the State.

Article 17.

(1) Everyone has the right to own property alone as well as in association with others.

(2) No one shall be arbitrarily deprived of his property.

Article 18.

Everyone has the right to freedom of thought, conscience and religion; this right includes freedom to change his religion or belief, and freedom, either alone or in community with others and in public or private, to manifest his religion or belief in teaching, practice, worship and observance.

Article 19.

Everyone has the right to freedom of opinion and expression; this right includes freedom to hold opinions without interference and to seek, receive and impart information and ideas through any media and regardless of frontiers.

Article 20.

- (1) Everyone has the right to freedom of peaceful assembly and association.
- (2) No one may be compelled to belong to an association.

Article 21.

- (1) Everyone has the right to take part in the government of his country, directly or through freely chosen representatives.
- (2) Everyone has the right to equal access to public service in his country.
- (3) The will of the people shall be the basis of the authority of government; this shall be expressed in periodic and genuine elections which shall be by universal and equal suffrage and shall be held by secret vote or by equivalent free voting procedures.

Article 22.

Everyone, as a member of society, has the right to social security and is entitled to realization, through national effort and international co-operation and in accordance with the organization and resources of each State, of the economic, social and cultural rights indispensable for his dignity and the free development of his personality.

Article 23.

- (1) Everyone has the right to work, to free choice of employment, to just and favourable conditions of work and to protection against unemployment.
- (2) Everyone, without any discrimination, has the right to equal pay for equal work.
- (3) Everyone who works has the right to just and favourable remuneration ensuring for himself and his family an existence worthy of human dignity, and supplemented, if necessary, by other means of social protection.
- (4) Everyone has the right to form and to join trade unions for the protection of his interests.

Article 24.

Everyone has the right to rest and leisure, including reasonable limitation of working hours and periodic holidays with pay.

Article 25.

- (1) Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.
- (2) Motherhood and childhood are entitled to special care and assistance. All children, whether born in or out of wedlock, shall enjoy the same social protection.

Article 26.

- (1) Everyone has the right to education. Education shall be free, at least in the elementary and fundamental stages. Elementary education shall be compulsory. Technical and professional education shall be made generally available and higher education shall be equally accessible to all on the basis of merit.
- (2) Education shall be directed to the full development of the human personality and to the strengthening of respect for human rights and fundamental freedoms. It shall promote understanding, tolerance and friendship among all nations, racial or religious groups, and shall further the activities of the United Nations for the maintenance of peace.

(3) Parents have a prior right to choose the kind of education that shall be given to their children.

Article 27.

(1) Everyone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits.

(2) Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.

Article 28.

Everyone is entitled to a social and international order in which the rights and freedoms set forth in this Declaration can be fully realized.

Article 29.

(1) Everyone has duties to the community in which alone the free and full development of his personality is possible.

(2) In the exercise of his rights and freedoms, everyone shall be subject only to such limitations as are determined by law solely for the purpose of securing due recognition and respect for the rights and freedoms of others and of meeting the just requirements of morality, public order and the general welfare in a democratic society.

(3) These rights and freedoms may in no case be exercised contrary to the purposes and principles of the United Nations.

Article 30.

Nothing in this Declaration may be interpreted as implying for any State, group or person any right to engage in any activity or to perform any act aimed at the destruction of any of the rights and freedoms set forth herein.

Addendum D

Chapter 2 - Bill of Rights

7. Rights

1. 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.
2. The state must respect, protect, promote and fulfil the rights in the Bill of Rights.
3. The rights in the Bill of Rights are subject to the limitations contained or referred to in section 36, or elsewhere in the Bill.

8. Application

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 the rights and the nature of that juristic person.

9. Equality

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. ^{*1}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.

10. Human dignity

Everyone has inherent dignity and the right to have their dignity respected and protected.

11. Life

Everyone has the right to life.

12. Freedom and security of the person

1. 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, inhumane or degrading way.
2. 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; and
 - c. not to be subjected to medical or scientific experiments without their informed consent.

13. Slavery, servitude and forced labour

No one may be subjected to slavery, servitude or forced labour.

14. Privacy

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.

15. Freedom of religion, belief and opinion

1. Everyone has the right to freedom of conscience, religion, thought, belief and opinion.
2. Religious observances 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; and
 - 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.

16. Freedom of expression

1. Everyone has the right to freedom of expression, which includes
 - a. freedom of the press and other media;
 - b. freedom to receive or impart information or ideas;
 - c. freedom of artistic creativity; and
 - 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; or
 - c. advocacy of hatred that is based on race, ethnicity, gender or religion, and that constitutes incitement to cause harm.

17. Assembly, demonstration, picket and petition

Everyone has the right, peacefully and unarmed, to assemble, to demonstrate, to picket and to present petitions.

18. Freedom of association

Everyone has the right to freedom of association.

19. Political rights

1. Every citizen is free to make political choices, which includes the right
 - a. to form a political party;
 - b. to participate in the activities of, or recruit members for, a political party; and
 - c. to campaign for a political party or cause.
2. Every citizen has the right to free, fair and regular elections for any legislative body established in terms of the Constitution.
3. Every adult citizen has the right
 - a. to vote in elections for any legislative body established in terms of the Constitution, and to do so in secret; and
 - b. to stand for public office and, if elected, to hold office.

20. Citizenship

No citizen may be deprived of citizenship.

21. Freedom of movement and residence

1. Everyone has the right to freedom of movement.
2. Everyone has the right to leave the Republic.
3. Every citizen has the right to enter, to remain in and to reside anywhere in, the Republic.
4. Every citizen has the right to a passport.

22. Freedom of trade, occupation and profession

Every citizen has the right to choose their trade, occupation or profession freely. The practice of a trade, occupation or profession may be regulated by law.

23. Labour relations

1. Everyone has the right to fair labour practices.
2. Every worker has the right
 - a. to form and join a trade union;
 - b. to participate in the activities and programmes of a trade union; and
 - c. to strike.
3. Every employer has the right
 - a. to form and join an employers' organisation; and
 - b. to participate in the activities and programmes of an employers' organisation.
4. Every trade union and every employers' organisation has the right
 - a. to determine its own administration, programmes and activities;
 - b. to organise; and
 - c. to form and join a federation.
5. Every trade union, employers' organisation and employer has the right to engage in collective bargaining. National legislation may be enacted to regulate collective bargaining. To the extent that the legislation may limit a right in this Chapter, the limitation must comply with section 36(1).
6. National legislation may recognise union security arrangements contained in collective agreements. To the extent that the legislation may limit a right in this Chapter, the limitation must comply with section 36(1).

24. Environment

Everyone has the right

- a. to an environment that is not harmful to their health or well-being; and
- b. to have the environment protected, for the benefit of present and future generations, through reasonable legislative and other measures that
 - i. prevent pollution and ecological degradation;
 - ii. promote conservation; and
 - iii. secure ecologically sustainable development and use of natural resources while promoting justifiable economic and social development.

25. Property

1. No one may be deprived of property except in terms of law of general application, and no law may permit arbitrary deprivation of property.
2. Property may be expropriated only in terms of law of general application
 - a. for a public purpose or in the public interest; and
 - b. subject to compensation, the amount of which and the time and manner of payment of which have either been agreed to by those affected or decided or approved by a court.
3. The amount of the compensation and the time and manner of payment must be just and equitable, reflecting an equitable balance between the public interest and the interests of those affected, having regard to all relevant circumstances, including
 - a. the current use of the property;
 - b. the history of the acquisition and use of the property;

- c. the market value of the property;
 - d. the extent of direct state investment and subsidy in the acquisition and beneficial capital improvement of the property; and
 - e. the purpose of the expropriation.
4. For the purposes of this section
 - a. the public interest includes the nation's commitment to land reform, and to reforms to bring about equitable access to all South Africa's natural resources; and
 - b. property is not limited to land.
 5. The state must take reasonable legislative and other measures, within its available resources, to foster conditions which enable citizens to gain access to land on an equitable basis.
 6. A person or community whose tenure of land is legally insecure as a result of past racially discriminatory laws or practices is entitled, to the extent provided by an Act of Parliament, either to tenure which is legally secure or to comparable redress.
 7. A person or community dispossessed of property after 19 June 1913 as a result of past racially discriminatory laws or practices is entitled, to the extent provided by an Act of Parliament, either to restitution of that property or to equitable redress.
 8. No provision of this section may impede the state from taking legislative and other measures to achieve land, water and related reform, in order to redress the results of past racial discrimination, provided that any departure from the provisions of this section is in accordance with the provisions of section 36(1).
 9. Parliament must enact the legislation referred to in subsection (6).

26. Housing

1. Everyone has the right to have access to adequate housing.
2. The state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of this right.
3. No one may be evicted from their home, or have their home demolished, without an order of court made after considering all the relevant circumstances. No legislation may permit arbitrary evictions.

27. 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.

28. Children

1. 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, and at 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 best 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.

29. Education

1. Everyone has the right
 - a. to a basic education, including adult basic education; and
 - b. to further education, which the state, through reasonable measures, must make progressively available and accessible.
2. Everyone has the right to receive education in the official language or languages of their choice in public educational institutions where that education is reasonably practicable. In order to ensure the effective access to, and implementation of, this right, the state must consider all reasonable educational alternatives, including single medium institutions, taking into account
 - a. equity;
 - b. practicability; and
 - c. the need to redress the results of past racially discriminatory laws and practices.
3. Everyone has the right to establish and maintain, at their own expense, independent educational institutions that
 - a. do not discriminate on the basis of race;
 - b. are registered with the state; and
 - c. maintain standards that are not inferior to standards at comparable public educational institutions.
4. Subsection (3) does not preclude state subsidies for independent educational institutions.

30. Language and culture

Everyone has the right to use the language and to participate in the cultural life of their choice, but no one exercising these rights may do so in a manner inconsistent with any provision of the Bill of Rights.

31. Cultural, religious and linguistic communities

1. Persons belonging to a cultural, religious or linguistic community may not be denied the right, with other members of that community
 - a. to enjoy their culture, practise their religion and use their language; and
 - b. to form, join and maintain cultural, religious and linguistic associations and other organs of civil society.
2. The rights in subsection (1) may not be exercised in a manner inconsistent with any provision of the Bill of Rights.

^{*2} **32. Access to information**

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.

^{*3} **33. Just administrative action**

1. Everyone has the right to administrative action that is lawful, reasonable and procedurally fair.
2. Everyone whose rights have been adversely affected by administrative action has the right to be given written reasons.
3. National legislation must be enacted to give effect to these rights, and must
 - a. provide for the review of administrative action by a court or, where appropriate, an independent and impartial tribunal;
 - b. impose a duty on the state to give effect to the rights in subsections (1) and (2); and
 - c. promote an efficient administration.

34. Access to courts

Everyone has the right to have any dispute that can be resolved by the application of law decided in a fair public hearing before a court or, where appropriate, another independent and impartial tribunal or forum.

35. Arrested, detained and accused persons

1. Everyone who is arrested for allegedly committing an offence has the right
 - a. to remain silent;
 - b. to be informed promptly
 - i. of the right to remain silent; and
 - ii. of the consequences of not remaining silent;
 - c. not to be compelled to make any confession or admission that could be used in evidence against that person;
 - d. to be brought before a court as soon as reasonably possible, but not later than
 - i. 48 hours after the arrest; or
 - ii. the end of the first court day after the expiry of the 48 hours, if the 48 hours expire outside ordinary court hours or on a day which is not an ordinary court day;

- e. at the first court appearance after being arrested, to be charged or to be informed of the reason for the detention to continue, or to be released; and
 - f. to be released from detention if the interests of justice permit, subject to reasonable conditions.
2. Everyone who is detained, including every sentenced prisoner, has the right
 - a. to be informed promptly of the reason for being detained;
 - b. to choose, and to consult with, a legal practitioner, and to be informed of this right promptly;
 - c. to have a legal practitioner assigned to the detained person by the state and at state expense, if substantial injustice would otherwise result, and to be informed of this right promptly;
 - d. to challenge the lawfulness of the detention in person before a court and, if the detention is unlawful, to be released;
 - e. to conditions of detention that are consistent with human dignity, including at least exercise and the provision, at state expense, of adequate accommodation, nutrition, reading material and medical treatment; and
 - f. to communicate with, and be visited by, that person's
 - i. spouse or partner;
 - ii. next of kin;
 - iii. chosen religious counsellor; and
 - iv. chosen medical practitioner.
 3. Every accused person has a right to a fair trial, which includes the right
 - a. to be informed of the charge with sufficient detail to answer it;
 - b. to have adequate time and facilities to prepare a defence;
 - c. to a public trial before an ordinary court;
 - d. to have their trial begin and conclude without unreasonable delay;
 - e. to be present when being tried;
 - f. to choose, and be represented by, a legal practitioner, and to be informed of this right promptly;
 - g. to have a legal practitioner assigned to the accused person by the state and at state expense, if substantial injustice would otherwise result, and to be informed of this right promptly;
 - h. to be presumed innocent, to remain silent, and not to testify during the proceedings;
 - i. to adduce and challenge evidence;
 - j. not to be compelled to give self-incriminating evidence;
 - k. to be tried in a language that the accused person understands or, if that is not practicable, to have the proceedings interpreted in that language;
 - l. not to be convicted for an act or omission that was not an offence under either national or international law at the time it was committed or omitted;
 - m. not to be tried for an offence in respect of an act or omission for which that person has previously been either acquitted or convicted;
 - n. to the benefit of the least severe of the prescribed punishments if the prescribed punishment for the offence has been changed between the time that the offence was committed and the time of sentencing; and
 - o. of appeal to, or review by, a higher court.
 4. Whenever this section requires information to be given to a person, that information must be given in a language that the person understands.
 5. Evidence obtained in a manner that violates any right in the Bill of Rights must be excluded if the admission of that evidence would render the trial unfair or otherwise be detrimental to the administration of justice.

36. 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.

37. States of emergency

1. A state of emergency may be declared only in terms of an Act of Parliament, and only when
 - a. the life of the nation is threatened by war, invasion, general insurrection, disorder, natural disaster or other public emergency; and
 - b. the declaration is necessary to restore peace and order.
2. A declaration of a state of emergency, and any legislation enacted or other action taken in consequence of that declaration, may be effective only
 - a. prospectively; and
 - b. for no more than 21 days from the date of the declaration, unless the National Assembly resolves to extend the declaration. The Assembly may extend a declaration of a state of emergency for no more than three months at a time. The first extension of the state of emergency must be by a resolution adopted with a supporting vote of a majority of the members of the Assembly. Any subsequent extension must be by a resolution adopted with a supporting vote of at least 60 per cent of the members of the Assembly. A resolution in terms of this paragraph may be adopted only following a public debate in the Assembly.
3. Any competent court may decide on the validity of
 - a. a declaration of a state of emergency;
 - b. any extension of a declaration of a state of emergency; or
 - c. any legislation enacted, or other action taken, in consequence of a declaration of a state of emergency.
4. Any legislation enacted in consequence of a declaration of a state of emergency may derogate from the Bill of Rights only to the extent that
 - a. the derogation is strictly required by the emergency; and
 - b. the legislation
 - i. is consistent with the Republic's obligations under international law applicable to states of emergency;
 - ii. conforms to subsection (5); and
 - iii. is published in the national Government Gazette as soon as reasonably possible after being enacted.
5. No Act of Parliament that authorises a declaration of a state of emergency, and no legislation enacted or other action taken in consequence of a declaration, may permit or authorise
 - a. indemnifying the state, or any person, in respect of any unlawful act;
 - b. any derogation from this section; or

- c. any derogation from a section mentioned in column 1 of the Table of Non-Derogable Rights, to the extent indicated opposite that section in column 3 of the Table.

Table of Non-Derogable Rights

1 Section Number	2 Section Title	3 Extent to which the right is protected
9	Equality	With respect to unfair discrimination solely on the grounds of race, colour, ethnic or social origin, sex religion or language
10	Human Dignity	Entirely
11	Life	Entirely
12	Freedom and Security of the person	With respect to subsections (1)(d) and (e) and (2)(c).
13	Slavery, servitude and forced labour	With respect to slavery and servitude
28	Children	With respect to: - subsection (1)(d) and (e); - the rights in subparagraphs (i) and (ii) of subsection (1)(g); and - subsection 1(i) in respect of children of 15 years and younger
35	Arrested, detained and accused persons	With respect to: - subsections (1)(a), (b) and (c) and (2)(d); - the rights in paragraphs (a) to (o) of subsection (3), excluding paragraph (d) - subsection (4); and - subsection (5) with respect to the exclusion of evidence if the admission of that evidence would render the trial unfair.

6. Whenever anyone is detained without trial in consequence of a derogation of rights resulting from a declaration of a state of emergency, the following conditions must be observed:
- a. An adult family member or friend of the detainee must be contacted as soon as reasonably possible, and informed that the person has been detained.
 - b. A notice must be published in the national Government Gazette within five days of the person being detained, stating the detainee's name and place of detention and referring to the emergency measure in terms of which that person has been detained.
 - c. The detainee must be allowed to choose, and be visited at any reasonable time by, a medical practitioner.
 - d. The detainee must be allowed to choose, and be visited at any reasonable time by, a legal representative.
 - e. A court must review the detention as soon as reasonably possible, but no later than 10 days after the date the person was detained, and the court must release

the detainee unless it is necessary to continue the detention to restore peace and order.

- f. A detainee who is not released in terms of a review under paragraph (e), or who is not released in terms of a review under this paragraph, may apply to a court for a further review of the detention at any time after 10 days have passed since the previous review, and the court must release the detainee unless it is still necessary to continue the detention to restore peace and order.
 - g. The detainee must be allowed to appear in person before any court considering the detention, to be represented by a legal practitioner at those hearings, and to make representations against continued detention.
 - h. The state must present written reasons to the court to justify the continued detention of the detainee, and must give a copy of those reasons to the detainee at least two days before the court reviews the detention.
7. If a court releases a detainee, that person may not be detained again on the same grounds unless the state first shows a court good cause for re-detaining that person.
 8. Subsections (6) and (7) do not apply to persons who are not South African citizens and who are detained in consequence of an international armed conflict. Instead, the state must comply with the standards binding on the Republic under international humanitarian law in respect of the detention of such persons.

38. Enforcement of rights

Anyone listed in this section has the 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. The persons who may approach a court are -

- a. anyone acting in their own interest;
- 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; and
- e. an association acting in the interest of its members.

39. Interpretation of Bill of Rights

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
 - c. 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.

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1. See Sch 6 item 23 (1).

2. Sub-s. (1) deemed to read as set out in item 23 (2) (a) of Sch 6 until the legislation envisaged in sub-s. (2) is enacted. See Sch 6 item 23 (1) for enactment provisions and item 23 (3) for lapsing provisions.
3. Sub-ss. (1) and (2) deemed to read as set out in item 23 (2) (b) of Sch 6 until the legislation envisaged in sub-s. (3) is enacted. See Sch 6 item 23 (1) for enactment provisions and item 23 (3) for lapsing provisions.