UK and European Policy in Stem Cell Research:

Proposals for the Ethical Grounding of Future Regulation

Benjamin J Capps

A dissertation submitted to the University of Bristol in accordance with the requirements of the degree of PhD in the Faculty of Medicine, Centre for Ethics in Medicine, in November 2003.

Word Count: 84,700

Abstract

This thesis evaluates the European Union (EU) Member States' deliberations regarding the destructive use of human embryos in stem cell (therapeutic) research. It explores the position of the Member States' advisory groups so as to establish the present, and likely future, national policies in stem cell research, and the justification(s) for the permissibility or prohibition of embryo research for such purposes. Additionally, I also look at the policy moves of the European institutions and their likely effect on national regulation in this area. This analysis aims to assess the necessity for, and prospect of, establishing an EU wide harmonised policy.

It is evident that there are two predominant opinions. On the one hand, it is argued that embryos can be used and destroyed in this research, because either their status does not prohibit such actions, or because the benefits of research outweigh any limited status. On the other hand, it is contended that research is unjustified because the moral status of the embryo prohibits harmful actions, and/or regardless of its moral status, there are less controversial alternatives available.

I resolve these issues by contending that, firstly, there is sufficient scientific scepticism regarding the latter claim, that for the timely and successful development of therapeutic applications, embryo research is necessary.

Secondly, I argue that the EU's commitment to human rights is grounded in claim rights, and because of this, the human embryo cannot be the object of human rights protections. I contend that attempts to confer a moral status through species membership or *potential* rights normally fail. However, by revising the latter argument, it becomes evident that uncertainty as to the ontological status of the embryo means that its possible status as an agent cannot be entirely discounted – and for this reason it should have a marginal status.

In conclusion, I argue that a harmonised EU policy should in certain circumstances endorse embryo research, and at the least should refrain from unjustifiably restricting research. Instead, it should actively encourage national regulations which reflect the precautional status of the embryo, by insisting upon justification of research for agent-centred benefits.

Dedication and Acknowledgements

First, I should like to thank Alastair V. Campbell for his encouragement, incisive comments (and time taken to read earlier drafts), and passing on at least some of his academic expertise. Secondly, I owe a huge debt of gratitude to Richard Ashcroft and Roger Brownsword for agreeing to examine this thesis, and in providing invaluable comments on the work. I am also in debt to Richard for encouraging me to embark upon this thesis in the first place. My thanks to the staff and associates of the Centre for Ethics in Medicine, past and present, who made this thesis possible; and the support of my collegiate colleagues at the University of Bristol.

I am indebted to the Wellcome Trust, who supported my studies in Bristol. I also must express thanks to the groups that took the time to respond to the questionnaire.

I received support and assistance from innumerable people when writing this thesis. Special mention must go to those two individuals, who in addition to their friendship, also helped me considerably with discussions regarding this thesis and the time spent reading earlier drafts – my brother Patrick Capps, without whose support and spurring on, I could never have achieved much of what I set out to do; and Richard Huxtable, for his encouragement in all things academic. Both had to put up with a lot, and they were often the first people to be subjected to my theoretical rants. Thanks also to Julie Woodley for proof-reading an earlier draft. Melanie McCarry – thanks for your support and friendship which was invaluable, and in the last few months, instrumental in completing this thesis.

I would like to thanks all those friends and colleagues that have supported me during the writing of this thesis. I would especially like to mention those who have provided friendship and amusement throughout; namely, and in no particular order, Alex Jarman, Callum O'Callahan, Emma Williamson, James Dale, Kurt Perry, Lisa Branny, Mark Wetherell, Matt Rollenson, Phil Syrpis, Stephen Robinson, Tonia Novitz, Nathan King, Stephen Brown, John Critchley and Simin Hussain.

Finally I would like to thank my family, and particularly my parents, Alan and Naomi, for their encouragement and support (not just monitory!) throughout my time at University in Cardiff, Sheffield, and Bristol; and also Richard Beaudet, Margaret, Bill and Neil Elliott, and Tom Dollar.

Benjamin Capps 27th October 2003

This thesis is dedicated to

Dorothy and 'Bert' Sheppard

(1903 - 1997) (1905 - 2003)

Author's Declaration

I declare that the work in this dissertation was carried out in accordance with the Regulations of the University of Bristol. The work is original except where indicated by special reference in the text and no part of the dissertation has been submitted for any other degree.

Any views expressed in the dissertation are those of the author and in no way represent those of the University of Bristol.

The dissertation has not been presented to any other University for examination either in the United Kingdom or overseas.

SIGNED: .....

DATE: 6/4/04.....

Table of Contents

Chapter Two

A Moral Framework for European Union Stem Cell Policy

Introduction:

Methods and Overview

This thesis describes and evaluates the science of stem cell research, and the policies and approaches to regulating embryonic stem cell (SC) research adopted by the Member states of the European Union (EU or the 'Community'). This analysis will form the basis for assessing the necessity and practicalities of implementing a Community-wide research policy. Stem cell research concerns the derivation of cells that are capable of self-replication and differentiation into at least one other cell type. They are found in embryos, foetuses, cord blood, and somatic tissue (so called 'adult' stem (AS) cells). They are considered as having important and profound implications for the therapeutic treatment of diseases and injury of cells, organs and tissues. This thesis answers three main questions: first, what is the state of present scientific progress and its implications for moral discourse; secondly, what is the significance of this for the basis of EU policy in human rights regarding human embryo research; and thirdly, is there a need for a European policy, and if so, how should it be established?

In the first chapter I will address the issues of *science*. I define the concept of the 'stem cell' and introduce the present necessity for, and prospects, limitations and goals of, state of the art research[1]. This chapter will address the *scientific* arguments as to the best policy for progress in SC research, and will highlight the basis for disagreement, as prevalently expressed from the two positions of pro- and anti- embryo research.

There are two central arguments. First, embryo research should not be permitted because it is either not *necessary* for medical progress, because less contentious alternative and equally (if not superior) sources are available, or not *possible*, because the significant moral status of the embryo rules out research altogether. This argument tends to focus upon the derivation of AS and cord blood stem cells as alternatives, because although the use of abortuses is less controversial than destroying embryos, there are still contentious issues regarding the separation of the act of abortion from the subsequent derivation of cells (and for this reason, SC from foetal sources are not discussed in this thesis).

[1] This is correct up to October 2003.

The second argument claims that without embryo research, SC research may not progress as far or as satisfactorily. The first chapter therefore concentrates on the scientific basis of the adult versus embryonic derivation of stem cells. The subsequent chapters address *ethical* questions and primarily the status of the human embryo, since if, as I argue, embryo stem (ES) cell research is necessary on a scientific basis, then policies must justify disregarding any moral status that the embryo allegedly has, if destructive embryo research can be sanctioned. Primarily, this thesis attempts to resolve, not whether human embryos can be used as a successful tool in stem cell research, but whether such endeavours can even be contemplated[2].

In Chapters Two and Three, I lay the grounding of EU policies and the theoretical framework that follows from this. In Chapter Two, I argue that *human rights* are an overarching paradigm for international and national research policies. I discuss the weaknesses and strengths of this common approach to show that the familiar understanding is often plagued by inconstancies and vagueness. Additionally, because of such misinterpretation, the attempts to confer human rights on human embryos through 'dignity' fail. I conclude that human rights must be understood as *claim rights* if their importance and effectiveness is to be realised.

Accordingly, this Chapter leads on to a theoretical basis of the claim rights as an agent-centred claim to requirements that are necessary for freedom and wellbeing. This is based on Beyleveld's (most recently with Brownsword 2001) modified argument of the *Principle of Generic Consistency* (PGC), which claims that anyone who accepts there are human rights must also hold that they contradict their own status as a (human) agent if they do not accept the PGC as the supreme principle governing the permissibility of actions (Gewirth 1978). The implications for accepting this argument is that human embryos, as they lack the necessary and sufficient capacities of agency, cannot have human rights.

In Chapter Three I dismiss the two main arguments that attempt to assert that the embryo has the same status as an agent by association; although the human embryo is not an agent, it is argued that it has at least a degree of moral status because of its *marginal agency*. The first argument states that the human embryo, as a genetically human individual, by implication has the same rights as any human agent. The 'genetic

---

[2] The narrow remit of this thesis concentrates on the debate concerning the necessity and applicability of an ethical framework for stem cell science in the EU. This debate is at present confined to the primary issue of the status of the embryo, its use in research, and the pluralistic nature of regulation in this field.

school' reasons that the primacy of the moral status of human beings is due to a common genetic heritage, and therefore one can avoid actions that may disregard the moral status of human beings that do not attain, or lose, the status of agent. The second argument relies on the metaphysical observation that the human embryo is a *potential* agent, and this must at least confer some intrinsic moral status with regards to an interest in becoming an agent. It is claimed that both arguments unjustifiably inflate the protections required by the intrinsic status of the embryo (or else deflate the rights of 'full' agents), and therefore the embryo, it is concluded, cannot have a status comparable to that of an agent.

With this framework in place, I then turn to the present discussions occurring within the EU with regards to stem cell and embryo research that suggest a common moral ideology. The status of the embryo has been discussed in limited circumstances, and it is evident that an absolute status has not been conferred through a 'right to life'. However, the institutions of the Community have not attempted to derive a common status of the embryo, instead leaving the matter to the Member States. Moreover, the Member States are individually and in the majority pressing towards a more permissive position with regards to embryo research in light of stem cell progress (with regards to both legislation, and ideology, through the positions of national advisory bodies[3]). It therefore seems inappropriate for the Community as a whole to stipulate strict protective measures towards the embryo in research, as favoured by a minority of states with restrictive policies (which in some cases are already in place).

In Chapter Five, I discuss the need for a harmonised policy based on the requirement of the Community to foster and promote human rights, and argue that while there are significant difficulties in applying one common morality to the Member States, there are benefits to harmonising policy in at least some areas of research. The implications for an EU common policy are therefore based on two arguments: (1) leave the individual states to legislate as they see fit according to the democratic consensus or; (2) encourage or ensure minimal regulative standards on agreed limits. While the first argument may be the least damaging to Community solidarity, it fails to accomplish Community goals that further the freedom and wellbeing of European citizens. Furthermore, it leaves the way open for *laissez-faire* attitudes and controversial state measures. I conclude that the Community should at least insist on minimal standards

---

[3] The methodology used to identify national policies will be discussed in detail in the text.

based on achieving common European goals in SC research, that Member States may exceed, should they so wish.

Chapter One

Setting the Scene: State of the Art Stem Cell Research and the Human Embryo

Introduction

This chapter will consider the present progress in stem cell research, with particular emphasis on the most controversial source of these cells, the human embryo. Those opposed to embryo research focus upon the least controversial alternatives for therapeutic applications, so called 'adult' or somatic stem cells and cord blood. The developments in embryo stem cell research will therefore be juxtaposed with the concurrent developments in these fields, to reveal rival claims about scientific uncertainty and the likely benefits of using different sources.

The stem cell (SC) has the capacity for prolonged self-renewal and can produce at least one type of highly differentiated or specialised descendant. There is no universally acceptable definition, and this is because of the characteristics of the SC can be influenced and altered by the biological environment in which it can be found or placed; however, in all cases the SC is involved in one (or both) of cell multiplication and differentiation. This makes it distinct from the remaining cells *in situ* (Marshak et al. 2001). It can be defined *in vivo*[1] in the context of normal human development. The process of embryogenesis is the development of a mature being from an ancestral cell, capable of biologically autonomous existence. The stem cell in this context is the unit of spatial-temporal development, growth and cellular specialisation of one (or more) individual beings. For this reason the stem cell is initially understood, and therefore at the outset discussed here, in the *in vivo* context.

However, the SC has profound implications for basic and therapeutic research, and this requires a separate definition in the *in vitro* context. It will become clear that the stem cell as an *in vitro concept* requires considerable unpacking and clarification distinct from it normal developmental surroundings.

---

[1] Occur or are observed occurring within the bodies of living organisms. *In vitro* describes biological phenomena that occur outside the living body.

This thesis concerns the derivation of stem cells for research from human embryos. These cells are termed embryonic stem (ES) cells. ES cells are isolated from the *in vivo* context for research *in vitro*, and this partially moves the research away from issues of embryonic gestation *in vivo*, or specifically *in utero*. In the context of research, ES cells can be derived from embryos: (1) created using *in vitro* fertilisation (IVF) techniques (embryos that are created either for a fertility project, but are no longer required or discarded as unsuitable; or specifically for research); and (2) created in the absence of 'fertilisation' (either through 'cloning'[2] or parthenogenesis[3]). In all cases, the derivation of the stem cells results in the non-viability of the embryo for continued development (the human parthenogen is already non-viable). For this reason, and also because the intention is the specific derivation of stem cells, 'cloning' in this perspective is sometimes referred to as 'therapeutic' cloning to distinguish it from 'reproductive' cloning, where the object is to produce viable offspring.

Stem cells are also obtained from amninoic fluid, from foetal tissue as embryonic germ (EG) cells, cord blood (CBS cells) (see Appendix One), and somatic tissue and organs ('adult' stem (AS) cells).

The controversy of ES cell research is therefore, on the one hand, that there is a strong case that research activities should not be permitted because the destruction of the embryo is the killing of a being with moral status. On the other hand, there are less controversial alternatives available. Proponents of ES research argue that embryo research can be justified, either because killing the embryo is not morally problematic, or because the promise of ES cell research outweighs any protection that the embryo deserves.

This opening chapter will critically evaluate the scientific progress in these fields of research to juxtapose it against the prospects of ES cell research. I will conclude that progress in stem cell research, and its timely and scientifically validated application to therapeutic treatments, requires equal commitment to the use and derivation from all cell sources.

---

[2] *Infra* s. 6.1.3. Generally, where the nucleus of a somatic cell is transferred to an enucleated oocyte.
[3] *Infra* s. 4. Developmental activation of an oocyte in the absence of male gametes.

1. Why the Interest in Stem Cells?

The excitement about stem cell research derives principally in their regenerative potential in therapeutic applications. This is not least because of their *proven* and successful use for some blood disorders (e.g. whole blood transplants) (Domínguez-Bendala et al. 2002; Hows 2001). SC can self re-new and differentiate into specialised progeny, and as such they are a potentially unlimited supply of specific cell types that may be acquiescent to transplant therapy. The three main prospective benefits are: (1) for the therapy of conditions that are presently untreatable because of unattainable or difficult access to certain internal organs, or their cellular complexity; (2) to produce readily available cells and organs, that may be presently in short supply or of a type that is non-transferable and; (3) to avoid or minimise immunological problems.

It is more likely that cell therapies will be more readily forthcoming, since engineering multi-cell 3-D organs will be difficult (Bianco & Robey 2001; Mooney & Mikos 1999). Therefore, immediate targets are cell based, and where cell replacement may be able to integrate into complex organs and offer long-term treatment is cases of damage or dysfunction caused by insult or disease (Thomson 2001; Paul et al. 2002; Okarma 2001). The main therapeutic barriers are the *in vitro* and *in vivo* differentiation of stable and functional SC, avoiding cancer formation *in vivo*, integration in target tissues, and avoiding immunological rejection. Apart from regenerative medicine, the application of SC themselves in the identification of chemical teratogens (induces 'cancers') and drug toxicity testing (Thomson 2001); and in transgenesis and gene targeting technologies (for gene therapy technologies) (Domínguez-Bendala et al. 2002). However, initial research will be devoted to understanding the basic science of stem cells and of human developmental biology (Okarma 2001)[4].

[4] There is also a link between the SC and the repeated generation of cell types in systems of cellular turnover, that leaves them susceptible to malignancy and cancer (Presnell et al. 2002). Many cancer-like conditions are a result in a switch in cellular fate of the differentiation *in vivo* of cell populations. Instead of producing the correct specialised cells, it is suspected that the SC produce and proliferate defective cell populations (Alison et al. 2002; Buckingham 2000). Understanding this may lead to progress in the identification of 'cancer stem cells' (Reya et al. 2001).

2. Stem Cells *InVivo*

SC are a unit of biological development (differentiation and cellular specialisation) and growth (cellular division), and therefore I will begin by defining these cells in their natural environment and role in embryo development. The beginning of embryogenesis is marked by the appearance of a single ancestral cell from which the entire organism derives – the zygote – that is the result of the fusion of the female and male gametes. From the zygote arise all the cells of the adult and all the cells necessary to support the embryo in its development. These cells are limited to one of the three germ layers formed in the early embryo: endoderm[5], mesoderm[6], and ectoderm[7]. Ensuing cells from each layer continue asymmetrically to proliferate on the one hand, and differentiate on the other, until the multi-cellular adult being is biologically autonomous. SC therefore facilitate the specialisation of multi-cellular organisms to gain a higher degree of biological complexity (Grosschedl & Watt 2001). Once maturity is reached, 'stem-like' cells remain in systems to facilitate the process of cellular turnover and regeneration that maintain the homeostatic integrity of that being (Weissman 2000a; Odorico et al. 2001; Fuchs & Segre 2000).

Within the mature being, there are prospectively three types of cell: (1) germ cells that retain a full capacity in the appropriate conditions to become a new multi-cellular being; (2) stem cells that retain a limited proliferative and differentiative capacity and; (3) a majority of somatic cells which reside in a terminally differentiated and functional status within a defined niche[8], where they remain until their cellular death. This thesis will discuss two sources of these cells – adult somatic tissue and cord blood.

Recent discoveries *in vitro* have reported that it is not just the common ancestry cells or the normal sites of homeostasis that retain this ability. It has been suggested that cells capable of multi-lineage differentiation may be present in a wide selection of tissues, including those not typically associated with cellular regeneration and turnover.

---

[5]Gives rise to the cells of the alimentary canal and associated glands, liver, gall bladder and pancreas. It also forms the lining of the bronchi and alveoli of the lung and most of the urinary tract.
[6] Forms the cartilage, muscle, bone, blood, kidneys, gonads and their ducts, and connective tissue.
[7] Gives rise to nervous system and sense organs, the teeth, and lining of the mouth, and to the epidermis and associated structures (hair, nails etc.).
[8] The physical microenvironment and molecular milieu in which a SC resides (Jones 2001; Watt & Hogan 2000). The niche can control and maintain a cell's characteristics; altering the niche can consequently change the status of a cell.

2.1. Definition of the Stem Cell

The following SC hierarchy refers to the present deriving source of the relevant cells. These discrete categories may be a fiction, potency being a function of the SC, and not dependent on its cellular niche. However, certain attributes (that may not be restricted to any one type of cell) may be assigned to cells from different sources to distinguish them from the remaining cells in the tissue where they are traditionally found (Marshak et al. 2001).

A generalised scheme of the stem cell places it at the beginning of a biological system (for example in embryogenisis, the zygote, or a particular system such as the haematopoietic [blood] system), with cell loss or death at the other end.

SC are: (1) clonogenic (i.e. capable of unlimited and symmetric and asymmetric self-renewal, so that maintenance of the cell population can occur while progeny cells differentiate into restricted and specialised cell types); (2) considered as rare populations within a niche of predominantly specialised cells and; (3) capable of multi-lineage differentiation[9]. *In vivo*, SC self-renewal and differentiation is regulated by intrinsic signals and the immediate environment (Watt & Hogan 2000). Furthermore, an unlimited capacity for self-renewal is not normally demanded of cells *in vivo* because they often become committed to a cellular fate, unless liberated from this context. *In vitro*, the SC and their derivatives must retain a normal chromosome complement, be karyotypically stable, and retain their functional properties; furthermore, they should maintain their potency state and be susceptible to inducement to produce specific differentiated cells (Rosenthal 2003).

2.1.1. Totipotency

Totipotent stem cells (TSC) are present at the top of the hierarchy of potency, and are only present at the earliest cleavage stages of the embryo (2 and 4 cell stages of the mouse embryo). After this point the blastocyst forms, consisting of the inner and outer cell masses, which are the first steps in lineage commitment. TSCs are able to form the

[9] Often producing committed progenitors (transit-amplifying cells) with a limited proliferative capacity and which themselves commit cells to differentiate progeny, thus they protect and maintain the initial small stem cell population.

embryo independently and *de novo*, and therefore differentiate into all the cells of the organism.

2.1.2. Pluripotency

In vivo, the pluripotent stem cells (PSC) of the inner cell mass (ICM) are able to differentiate into the three germ layers of the embryo proper. When removed from their normal embryonic environment and cultured under appropriate conditions, these cells proliferate and replace themselves indefinitely. *In vitro*, these cells are referred to as ES cells because instead of undergoing rapid differentiation as they would *in vivo*, they are abnormally locked in a continuing cycles of division in the undifferentiated state (Mann 2001). While in this state they are able to maintain their development potential. When different factors are added to the culture they are able to differentiate into most cells of the germ layers, but they cannot form an embryo *de novo*.

There are three means of demonstrating pluripotency: (1) transferral to the ICM of an embryo where differentiation into all three germ layers can be traced in the chimeric animal; (2) injecting a stem cell into an *in vivo* animal model and detecting descendants of the three germ layers in the resulting teratoma and; (3) *in vitro* differentiation into descendants of all three germ layers in the formation of embryoid bodies (3D cell aggregates that resemble a disorganised representation of the early stages of embryonic development).

2.1.3. Multipotency, Unipotency and Progenitor Cells

Recent progress in somatic stem cell research, as well as characterising cells typically able to differentiate into limited progeny, points to the presence of multipotent stem cells (MSC) in some unexpected tissues and organs. Typically, AS cells are limited to a few discrete and related differentiated cell types. They are capable of producing a limited range of cell lineage appropriate to their location (normally restricted to a single germ layer lineage).

This term may become redundant if research continues to produce evidence of cross-lineage differentiation into distinct cell lines from different germ layers, with the

distinction between pluripotent and multipotent becoming increasingly blurred (Alison et al. 2002; Vats et al. 2002).

Unipotent stem cells are restricted to generating one other specific cell type while concurrently regenerating the stem cell population. Some have argued that there is no such thing as a unipotent stem cell and really these should be called *committed progenitors* (*supra* fn. 9; Alison et al. 2002).

2.2. The Ontology of the Human Embryo[10]

When it comes to firmly categorising or referring to the human embryo, a great deal of emotive language is often resorted to; on the one hand, 'little people' or the 'tiniest of human beings'[11], and on the other hand, it is described as merely a clump of phenotypically indistinct cells[12]. At this early stage, the embryo is a small cluster of cells that will, all things being equal[13] – and given the right environment and treatment – change and develop into a larger, more complex mature being (therefore having the *potential to become* the mature being)[14]. While the early embryo (up to around 14-23 days from fertilisation[15]) is undoubtedly 'complex' on the cellular level, on the macroscopic level, it *resembles* a 'clump' of cells. Only after this point does the embryo begin to show signs of an overall organisation.

There are four basic concepts concerned with embryogenesis: (1) in the early embryo, SC self-renew and begin to establish specific cell lineage; this occurs to increase the number of cells available for growth and specialisation; (2) a progression of increasingly differentiated cells that facilitate multi-cellular existence, and which soon outnumber the early SC; (3) stereotyped lineages that are not necessarily a single root for a terminal differentiated cell (lineage crossover may be possible) and; (4) terminal cells that are maintained in that state by continuous and specific gene expression

---

[10] This account of embryo development is summarised from Larson (2001).
[11] CARE 1999.
[12] See Thomson 1971 p. 48.
[13] This term will be used throughout this thesis to refer to the successful and uninterrupted development of the embryo to maturity.
[14] The 'normal' adult human being is capable of agency, so the embryo is at this earliest stage a *potential agent.*
[15] Reference material on human embryology normally gives a day-by-day account of the major events in the development of the embryo. However, embryos of the same fertilisation age do not necessarily develop at the same rate.

(importantly, if this state is altered, cells may be reprogrammed to a more primitive state).

Much of the debate as to the moral status of the human embryo centres on the ontogenetic patterns of the embryo's development. There are various 'landmark' events that occur, some of which are thought to be sufficient to delineate the emergence of an entity with an intrinsic moral status. The following account will highlight these events and will be used later to consider the validity of certain paths of argument.

The period that covers the first 12-14 days of development from fertilisation is variously termed the 'pre-embryo', 'pro-embryo' or *conceptus* stage, to refer to it as a single entity which will become the *embryo proper* and the extra-embryonic tissue (e.g. placenta). The distinction is made because, among other reasons, at this point it is impossible to predict which cells will commit to each lineage (Jones & Veeck 2002; Gardner 2002; Tacheva & Vladimirov 2002; also see the dissenting view of Thorne & Kischer 2002). It is normally distinguished from the later phase by implantation in the uterus wall (*in vivo*) or the observance of cellular commitment to the *primitive streak* (*in vitro,* the first evidence of cellular commitment in the embryo). It is this stage that is the focus of this thesis, as ES cells are derived from the 6-7 day old human embryo.

Obstetricians refer to the subsequent stage as the *embryonic period*, which concerns the time between the third through the eighth week (sometimes twelfth week). This is a period of *organogenesis*, during which the organs and systems of the body are formed. During this phase, the *embryo proper* can be distinguished from the extra-embryonic tissue in the beginnings of complex cellular development and organisation[16].

The foetal stage is normally clinically stated to last from the 12th week to birth. It is during this time that maturation of the organs and systems occur (but this also continues after birth).

2.3. In Vivo Fertilisation

The process of embryogenesis begins with the fertilisation of the oocyte (female gamete) by the sperm (male gamete). *In vivo* fertilisation refers to the fertilisation of the oocyte *in utero* (within the uterus). *In vitro* fertilisation, on the other hand, is the

[16] See Appendix One.

artificial means of creating an embryo that can then be either implanted or remain *ex utero*.

2.3.1. The First Week

The embryo *normally* begins its existence after fertilisation with the fusion of the male and female gametes in a process called *syngamy*. It is the first of a series of process that occurs in the *natural* creation and development of a (or more than one) human individual. 'Normally' is emphasised because there are artificial phenomena such as IVF and artificial 'cloning' (where there is no 'fertilisation'), and natural (but uncommon) phenomena of parthenogenesis (development of an oocyte without fertilisation by male gametes[17]), and twinning (where the embryo naturally divides into two (or more) identical embryos); both can also be caused artificially.

Syngamy is initiated by chemo-attraction of the sperm to the oocyte when they are first in the uterus. The sperm travel up the fallopian tube and make contact with the oocyte where normally one penetrates the egg's outer membrane (zona pellucida). Once this occurs, a host of chemical changes cause the sperm to undergo acrosome reaction where the sperm's head containing the male DNA separates from the rest of the cell body and passes through the zona into the egg's cytoplasm. Within seconds of this occurring, an electrochemical message is sent to the zona that makes it impenetrable by other sperm. Thus only one package of male DNA will *normally* meet with one female package of DNA[18].

Once inside the egg, the presence of the paternal gamete causes the female chromosomes to separate into two sets of 23 chromosomes (the oocyte becomes an ovum). One set becomes the polar body and is not involved in the development of the *conceptus*. The remaining set migrates to the egg's centre, where, 18-20 hours later they line up with the 23 chromosomes of the male's sperm. This results in the cell having the full diploid (46 chromosomes – half from each parent, as opposed to, for

---

[17] *Infra* Section 6.1.3.

[18] A hydatiform mole is formed where the sperm (normally more than one) and egg cells have joined but there is no developing embryo in the uterus. Instead the tissue formed resembles grape like cysts with no foetal structures, which can spread from the uterus to other parts of the body and require cancer therapy, hysterectomy or induced abortion. A complete mole can develop alongside a coexistent foetus from the degeneration of an identical twin. Partial moles can develop in which some foetal structures (i.e. placenta) are present.

example, triploid where there is three sets of parental DNA present) DNA complement in human beings. At the moment of syngamy the *zygote* is said to come into being, and the development of the embryo begins through successive cell divisions.

The single celled zygote (after 20 hours) undergoes a series of *mitotic* divisions, increasing the number of cells by double each time. This is called cleavage, and the cells are *blastomeres*. The fundamental difference between the zygote and the daughter cells is that, whereas the former derives from the fusion of the male and female gametes, the blastomeres derive only from division of the zygote. The subsequent cell-mass and early embryonic stages is referred to as the *conceptus*. At this point there is no way of determining which cells will subsequently form the embryo proper and which will create the supporting membranes and placenta. The cells are phenotypically indistinguishable and by implication are all totipotent, although to date no human TSC have been isolated *in vitro* that mirror this state (Hadjantonakis & Papaioannou 2001). The genes in each cell of the embryo do not begin to actively determine developmental fate until the 4-6 cell stage (indeed, the male chromosomes are not at all functional until the four- or eight-cell stage).

From the blastomeres derive, through proliferation and differentiation, *all* the cells of the adult being and support tissue (each blastomere is a theoretical embryo itself if removed from the conceptus). The blastomeres in the cleavage cycle do not engage in net growth between divisions; they are in the process of assembling enough stem cells to begin the hierarchical commitment to cellular differentiation.

At the 8-cell stage a process called *compaction* occurs. At this point 1 or 2 cells are pushed to the centre of the cluster while the remaining cells are left on the outermost side. The former cells will eventually become the inner cell mass (ICM) which will mostly derive the *embryo proper*, while the remaining outer cells will form the *trophoblast*, which will ultimately form the placenta and supporting membranes. At the 16-32-cell stage (3^{rd} or 4^{th} day) the embryo is termed the *morula*.

Once the embryo reaches 64-128 cells, on around the 5^{th} day, the beginnings of a discernible organised structure can be seen – called the *blastocyst*. The blastocyst moves freely in the uterus resembling a hollow ball of cells containing at one pole the ICM that resides in the fluid-filled cavity (blastocoele). The site of the ICM signals the location where the embryo proper will develop (or *embryoblast*), which is surrounded

by the flattened epithelial wall, called the outer cell mass (OCM) or trophoblast[19]. Extra-embryonic structures of the trophoblast are essential for the structural development of the embryo. Up to this point the embryo has been termed the 'pre-embryonic' stage, with the term embryo being reserved when the embryo proper begins to develop as a separate entity from the support tissue. These two groups of cells are no longer totipotent, since the trophoblast cells will make the extraembryonic tissue, and the embryoblast will go on to form the embryo proper. The cells appear not to be able to form the other, and have made their first genomic commitment to cellular fate.

The cells of the embryoblast are now pluripotent; they will form the entire adult organism but will not contribute to the extra-embryonic tissue. They cannot generate a blastocyst *de novo*, and hence are not sufficient to produce an embryo *de novo* (see Smith 2001 p. 439 for review)[20].

2.3.2. The Second Week[21]

The blastocyst begins to attach and implant in the uterus wall (6-7th day; complete around the 9th-12th day). At this point the cells are still pluripotent. The embryoblast differentiates into two layers: the *hypoblast* layer and the *epiblast* layer. The two layers of cells resemble a flat disc and together are known as the *bilaminar germ disc*. A small

---

[19] Cells of the OCM are routinely removed to determine sex of the embryo. There are concerns as to whether this damages the embryo which may show up after birth (McKie 2002); and may be a reason as to why research embryos should not be implanted subsequent to manipulation. Trophoblast stem (TS) cells are distinct from the ES cells derived from the ICM, and are restricted in their potential (i.e. they can only derive the extra-embryonic tissue found in the placenta and cannot derive any embryonic-origin somatic cells (Rossant 2001)). It seems that TS and ES cells are restricted from crossing into each others lineage; thus both are theoretically necessary for embryo (or totipotent) development. It has not been possible up till now to isolate human trophoblast stem cells (Smith 2001); although there is an unsubstantiated report of deriving pluripotent stem cells from the human placenta (Vogel 2001a).

[20] It seems likely that ES cells alone can generate the entire foetus because when injected into the blastocyst cavity of embryos with defective ICM, the develops normally. However, microsurgical replacement of the ICM *de novo* has not been reported and would be conclusive of this property (see Smith 2001 p. 439 for review).

[21] Cells can be derived from the embryo subsequent to cellular commitment. Embryonic carcinoma (EC) cells are isolated from either primordial germ cells (cells that arise in the postimplantation embryo and later derive the gametes) that have spontaneously formed tumours, and from the implantation of normal blastocysts or germ cells into extra-uterine sites where they form tumours. They are not derived from embryonic tissue, and are called EC cells because they resemble, as distinct entities, ES cells (Prelle et al. 2002). The developmental potential of EC cells varies but in general is rather limited; they can form one or two differentiated derivatives; they consistently, and without control, form teratomas (Thomson & Odorico 2000), and appear to have genetic anomalies (such as an aneuploid karyotype) (Edwards et al. 2000; Thomson & Odorico 2000). This makes them unsuitable for *therapeutic* applications, but useful in studying development and cancer (Lovell-Badge 2001a; Paul et al. 2002; Prelle et al. 2002).

cavity begins to develop in the epiblast called the *amniotic cavity*. On the 9th day the trophoblast begins to develop its connections with the uterus wall (the *endometrial stroma*). The embryo still resembles a hollow ball. The embryo proper is a small cell mass within this, situated at one pole.

Around the 12th day the trophoblast is tenuously connected to the maternal blood supply establishing the *utero-placental circulation*. Growth of the bilaminar germ disc is relatively slow; consequently it remains vary small (0.1-0.2mm). Around the 13th day the *chorionic cavity* is formed. The early remnants of the connecting stalk are seen (this will develop to become the umbilical cord that connects the embryo proper to the maternal blood circulation).

By the fourteenth day the implantation is complete and the embryo proper (consisting of two cell layers: the epiblast and hypoblast; and suspended in the chorionic cavity [or chorion; previously the outer wall of the blastocyst]) is attached to the wall of the uterus and begins noticeable development of the *primitive streak*. Twinning, or the division of the embryo into two separate entities, can no longer occur. The fourteenth day of development represents an important stage of development – and has sometimes been referred to as the delineation between the 'pre-embryo' and the later stages of embryo development. The cells of the embryo are now thought to be multipotent except for the germ cells (gamete forming cells), which do not undergo commitment until sexual maturity.

3. Embryo Stem Cells *In Vitro*

This section attempts to give a scientifically objective account of stem cell science. It is important to appreciate that we are confronted by major challenges to current knowledge and understanding. Much of the research is restricted to animal studies which may apply to human stem cells; indeed, it should be guarded against assuming that stem cell science is readily transferable between species (see Smith 2001; *infra* section 3.4). This account is also likely to be contemporary for a relatively short period of time because of the intense research and interest in this field. (All research presented in this thesis is correct and up to date as of 21st October 2003).

There are distinct differences between all SC types, but whether this is a biological or culture derived is presently unknown (Odorico et al. 2001). Without

knowing the characteristics of cells derived from different sources, they are presently given names to distinguish their origin of derivation (although they may be the same types of cell).

3.1. The Derivation of ES Cells

Human embryonic stem cells were first isolated in 1998 by Thomson et al. (1998). The researchers derived the pluripotent cells from culturing the ICM cells of human embryos. In Thomson's report, the embryos were created by IVF and donated for research because they were surplus to the fertility treatment. The embryos were around 5-6 days from their creation *in vitro*.

Thomson's cell lines became standards for the definition of embryonic pluripotent stem cells: they had the potential to contribute to any cell in the body; they were immortal, in that they showed the capacity for continuous undifferentiated proliferation; and they retained the ability to form derivatives of all three embryonic germ layers. ES cells additionally express specific cell surface markers and high levels of telomerase activity (an enzyme associated with immortality in human cell lines; see Verfaillie et al. 2002 pp. 369-374) and are karyotypically [i.e. genetically] normal over a period of time in culture (see Odorico et al. 2001).

Since then they have been repeatedly isolated from human embryos created by IVF, either donated from a fertility project (Reubinoff et al. 2000) or created specifically for research (Josefson 2001; Lanzendorf et al. 2001); and from human 'parthenotes' (Lin et al. 2003). In animals they have also been derived from embryos created by cloning (Munsie et al. 2000; Wakayama et al. 2001)[22]. We thus have to consider three possible embryonic sources of human ES cells: IVF embryos, cloned embryos, and parthenotes. All three require the isolation of the cells from the inner cell mass (so in *in utero* terms, pre-implantation or around the 6^{th}-7^{th} day from creation); either the technique of creation differs (IVF and CNR) or the *intention* differs (specifically for research or as a consequence of some other non-research intended act).

The removal of the cells necessarily results in the destruction of the embryo and therefore any future development that it may have. Without intentional destruction of

---

[22] *Infra* section 4.

the embryo, its development cannot proceed beyond 14 days *in vitro* unless it is implanted *in utero*.

3.2. ES Cells and Toti- and Pluri- Potency[23]

Mouse ES cells have been shown to be pluipotent by introducing them into ICM where they contribute to the chimeric *embryo proper* (Odorico et al. 2001). (The human equivalent of this has not been attempted). Theoretically they may form an entire embryo by itself because they have the sufficient capacity to generate the foetal component of the conceptus. However, this claim has not been demonstrated, and it is likely that some of the trophoblast cell lines that originate in the OCM, may be absent (Smith 2001). Therefore ES cells cannot generate a blastocyst *de novo* and hence are not sufficient to produce an embryo by themselves (*infra* section 3.3)[24]. So, unlike totipotent cells, ES cells cannot form the entire conceptus. They retain pluripotency even after extended propagation and manipulation *in vitro* (Smith 2001).

Human ES cells have been shown to differentiate into derivatives of all three primary germ layers when introduced to immunosupressed mice (Amit et al. 2000). When ES cells are removed from culture (that maintains them as undifferentiated) they begin to derive both differentiated cells (from all three germ layers) and also concurrently self-renew, maintaining the stem cell population of the colony (Odorico et al. 2001). Reubinoff et al. (2000) has since demonstrated that ES cells could differentiate *in vitro* under 'natural selection' using culture conditions that favour one cell type over another. Furthermore, it is possible to cause the *in vitro* differentiation of human ES cells into embryoid bodies containing representatives of all three germ layers with the addition of different growth factors (Schuldiner et al. 2000; but none of the growth factors direct differentiation exclusively to one cell type). Taken together, this demonstrates the possibility of directing human ES cells into specific cells and tissues. Furthermore, *in vitro*, the ES cell differentiation has demonstrated the normal features

---

[23] See O'Shea (2001) and Odorico (2001) for review.

[24] There is also evidence that ES cells can develop into the trophoblast, suggesting that they may be totipotent and able to derive the entire embryo (Hübner et al. 2003; Weissman 2000a). However, this seems not to have been directly confirmed, and therefore, embryonic stem cells are presently considered to be pluripotent *in vivo* and *in vitro* (Drukker et al. 2002; Rossant 2001; Solter & Gearhart 1999). Nagy et al. (1993) argues that ES cells are totipotent because in the correct environment they may derive every cell of the conceptus.

of complex tissue architecture and structures are reproduced such as hair follicles, teeth and gut. When injected into genetically engineered mice, teratomas (cancers) develop including muscle, bone, cartilage, gut, respiratory epithelium, amongst others.

3.3. The ES Cell as an Embryo

As individual cells, human ES cells are not biologically equivalent to the embryo (from which they are derived). ES cells can form all the tissues of the body but do not appear to be able to carry out structural organisation (form the body in an ordered fashion and basic axis formation), which may be why they form disorganised embryoid bodies, and not structurally organised embryos. This information may be restricted to the oocyte and not persist in ES cell cultures, and requires the organisational influence of the zygote to direct orderly development (Pera 2001). Although the embryoid body does resemble the early embryo, there is no consistent structural relationship between cells (perhaps due to the absence of trophoblast cells), as found in the embryo (see Odorico et al. 2001; O'Shea 2001; Pera 2001). It is therefore suggested that it is not an embryo, nor does it have the potential to become one (Edwards et al. 2000). Implanting an ES cell into a uterine environment will not result in the development of an adult organism (Solter & Gearhart 1999; Verfaillie et al. 2002); but they will form an entire embryo proper when transplanted into blastocyst environment (Nagy et al. 1993; Solter & Gearhart 1999).

3.4. ES Cells and Species Differences

ES cells isolated from other species have some markedly similar characteristics, but there are important differences (Amit et al. 2000; Bishop et al. 2002; Edwards et al. 2000; Evans & Hunter 2002; Odorico et al. 2001; O'Shea 2001; Pera 2002; Prelle et al. 2002; Reubinoff et al. 2000; Rossant 2001; Watt & Hogan 2000; Wilmut 2001)[25]. Indeed, until Thomson's derivation of human ES cells, it was not a forgone conclusion

[25] Rubinoff et al. (2000) speculate that the difference is because of discrepancies between embryonic development between species or a reflection in the embryonic stage of origin of ES cells.

that ES cells could be derived from human embryos (as was the case at that time in other species).

While mouse ES cells are fully characterised, many of the attributes of human ES cells remain theoretical (most notably their pluripotential)[26]. ES cells derived from human origin have been reported to grow more slowly and require more fastidious handling (so there is a greater chance that the human cells may be untowardly altered or damaged); there are also evidential differences in propagation and expansion (Smith 2001). Rapid advancement in human ES cell science may only be possible if human ES cells are similar to their extensively characterised mouse counterparts (Solter & Gearhart 1999). Otherwise, potential applications may be further off than presently imagined. This also rules out relying extensively on animal models of ES cells.

3.5. Therapeutic and Clinical Use of ES Cells

Animal studies show the great *potential* of these cells to treat disease and damage, but can only be illustrative of human therapeutic applications. The encouraging result from animal studies may not equate to immediate transformation to human ES cell research (Thomson 2001). The benefits and failures of human ES cells will result from research with *human* ES cells (using insights gained from animal ES cells), and this presumably (and probably inevitably) will be subsequent to primate models (which itself is not without its ethical concerns) (Odorico et al. 2001). It is anticipated that *therapeutic* applications will only be possible using human ES cells (because of species differences; see Chen et al. 2003).

3.5.1. Basic Research

Therapeutic benefits will presumably lag somewhat behind basic and developmental research. *In vitro* study of ES cells will be an important tool for understanding and gaining new insight into early human embryonic development, and will help researchers make observations of events that are essential to the proper and

---

[26] Producing a human chimera, as has been achieved using mouse ES cells, would conclusively demonstrate that the cells could contribute to the cells of the entire organism.

healthy development of the embryo (Thomson 2001). The understanding of such effects will have important ramifications for such fields as IVF treatment, fertility, contraception and spontaneous abortions. The ES cell therefore offers an opportunity to study an otherwise largely inaccessible period of development (O'Shea 2001).

There are potential pharmacological uses of ES cells such as in the *in vitro* study of molecular and environmental factors on growth and differentiation of human somatic cells (Wobus 2001). This may offer scientific study of embryo-toxic effects of chemical and biological compounds and environmental influence and stress.

3.5.2. Generation of Cells de Novo and the Prospect of Human Therapeutic Progress

Prospective ES research is directed towards the development of techniques to generate specific cells, organs and tissues *in vitro,* or the *in vivo* introduction of cells to the whole body or specific areas, to repair cells or tissues and replace whole organs, damaged by disease or injury. While organ formation *in vitro* is a far off possibility (Thomson 2001 p. 22), the directed differentiation of cell populations, both *in vivo* and *in vitro* are distinct prospects.

Research on the controlled differentiation of ES cells has been a fruitful enterprise; and indeed, a number of tissue types have been produced (for a review see O'Shea 2001). The exciting potential of ES cell research points to treating multi-cell deficiencies that at present are not treatable, or treatments remain unsatisfactory. Particular interest is given to the treatment of those diseases that are the result of the destruction or dysfunction of cells within an organ, or tissue that cannot be easily replaced by traditional transplants (such as the central nervous system), or are caused by the change to, or failure of a specific cell type.

The potential treatments arising from ES cell research would also circumvent some of the present restrictions affecting present treatments. We are familiar with the restrictions on organ transplantation, such as the unavailability of immunological matches and the requirement for lifelong immuno-suppressive drugs, and these difficulties may be overcome by ES research. Furthermore, therapies may only be required to be administered once (i.e. we implant the new cells and they reconstitute or repair the damage).

Generation of tissues and organs would offer a potential solution to the present chronic shortage of availability and donors of such tissues and organs. Creating an organ *de novo* is a tall order, however, and it is far more likely that the remnants of existing *in vivo* organs (or ex vivo) will be used as scaffolding for the transplantation of differentiated cells (Solter & Gearhart 1999).

Ultimately, the study of ES cells may enable the clinical use of other, less contentious sources of stem cells (Reubinoff et al. 2000). If researchers can find out what makes a stem cell like it is, then this will inevitably aid the isolation and characterisation of 'adult' stem cells (Vogel 2001c).

3.5.3. Results so Far...

The interest in ES cells is their ability to differentiate into cell derivatives of all three germ layers even after prolonged culture, that presently distinguishes them from AS cells (Amit et al. 2000; Reubinoff et al. 2000; Schuldiner et al. 2000). Although the pluripotency of ES cells is undoubted, there are questions of the specific isolation and functional integration of cells. Work on this has begun in animal models (for a review see Gepstein 2002).

3.5.3.1. Research Related to Neurones

ES cell derived neurones have been demonstrated to survive and exhibit at least some aspects of appropriate region-specific neuronal differentiation when introduced into the developing mouse brain (Brustle et al. 1997). Experiments have shown that glial cells (insulating cells) derived from ES cells have resulted in a degree of re-myelination in a rat model of multiple sclerosis (Brustle et al. 1999). There are promising results showing the experimental treatment and alleviation of the symptoms of Parkinson's disease in animal models by deriving functional dopaminergic neurones from ES cells (Björklund et al. 2002 implanted undifferentiated mouse ES cells into rat brains; also see Kim et al. 2002; & Vogel 2002a). Freed (2002) in a review of ES cells in the treatment of Parkinson's disease, speculated that early results with mouse models

(particularly Björklund et al. 2002; & Lee et al. 2000), are more promising than the problems associated with foetal neurone transplants into affected individuals[27].

Transplanted ES cell lines survive, differentiate and promote recovery in injured rat spinal cord (Liu et al. 2000; McDonald et al. 1999). Further to this work, ES cells have been isolated and coaxed to produce specific spinal cord classes of neurones *in vitro* (Cassidy & Frisén 2002). If these differentiated cells can be shown to be stable and functional, then treatment of spinal cord injuries may be a realistic possibility. It has also been possible to differentiate primate parthenogenetic stem cells into neurones and heart-like (cardiomyocyte) cells (see below; Vrana et al. 2003)

3.5.3.2. Research Related to the Heamatopoietic System and Heart

The reconstruction of the entire haematopoietic (blood) system has been possible using ES cells (Rideout et al. 2002; Kyba et al. 2002). Kaufman et al. (2001) have shown that ES cell cultures can be induced to form haematopoietic precursor cells, which in turn would produce some of the blood cell lineages (Young 2001a; see Appendix One s. 2). This research may offer a means of generating supplies of donor blood, which can be controlled to be free of contaminants and possibly, engineered to be an exact patient match.

Human ES cells have been directed to form spontaneously contracting cells that have structural and functional properties of cardiomyocytes (Frankish 2001; Gorman 2000; Hescheler et al. 1997; Kehat et al. 2001). Moreover, genetically purified ES cell-derived cardiomyocytes have been shown to graft into mice models without the development of tumours (Klug et al. 1996). Human ES cells can differentiate into multiple types of cardiomyocytes displaying functional properties characteristic of embryonic human cardiac muscle. Thus, ES cells provide a renewable source of distinct types of human cardiac-like cells for basic research, pharmacological testing, and therapeutic applications (He et al. 2003: Vanderlaan et al. 2003).

---

[27] Although foetal dopamine cell transplants are a promising treatment for Parkinson's disease (Björklund & Lindvall 2000), the difficulty in recovering the specific cells is difficult, time consuming and requires large numbers of donated foetal abortions. The cells also appear to have poor survival chances in the recipient. Clinical use of foetal tissue transplantation is not without its own risks, with reports of tissue overgrowth and tumourgenic formation (Edwards et al. 2000).

4. Cloning Technology and Stem Cell Research

Cloning technology is intimately associated with SC research because of the potential use of the technique to create cells and organs genetically matched to the donor. This technique also has implications for reproductive technologies – not least in the creation of cloned embryos (but here notably for the creation of embryo for the derivation of embryonic stem cells).

4.1. The Concept of Cloning

Cloning techniques have been proposed to be a means around the prospect of immunogenicity of transplanted cells. Embryos could be created through cloning the cell nucleus of the patient, SC isolated from the ICM (achieved in animal studies; First & Thomson 1998), differentiated *in vitro*, and then used to treat the cellular damage or disease (perhaps to even grow genetically matched organs *de novo*). The idea is not to develop human foetus or later stage human beings, but to harvest the ES cells from embryonic stage human beings.

'Cloning', can be considered in two ways: (1) making a genetically identical copy (usually by asexual reproduction) of a cell or organism; or (2) making an exact copy of a gene, either by the cell itself (DNA transcription) or genetic engineering. In the context of SC research, when a clone is created, it is an unaltered copy of the complete genome of the parent cell that can be encouraged to develop into a human individual (through embryogenesis). It therefore should be distinguished from (2), which is the copying of fragments of DNA. Cloning an individual is not a new or indeed necessarily unnatural process (certainly within the microbial world). Furthermore, a type of cloning, called 'embryo splitting' or twinning, is the process whereby human monozygotic twins are formed naturally *in utero*.

The recent interest in cloning has come from two lines of research. The first was in the use of *cell nuclear replacement* (CNR) to produce viable animal offspring. The first successful, and widely publicised success in this field, was in the artificial cloning of 'Dolly', a sheep, by Wilmut et al. in 1997[28]. The procedure uses the transfer or

[28] Since then, many animals have been cloned with different degrees of success (see Gurdon & Byrne 2003 for a recent review of cloning technology).

replacement of a somatic cell nucleus (in Dolly's case, from the mammary cell of one sheep) into an enucleated oocyte. The cloned oocyte is than implanted so that it develops to a desired stage or birth. There are other forms of cloning, all of which are essentially the same process of *transferring,* by different means, the nucleus of a somatic cell into the vacant nuclear content of an enucleated oocyte (so that it now has a full genetic content), and then inducing that oocyte to develop as if it had been fertilised[29].

Clones are not identical due to mitochodrial DNA[30] (Evans et al. 1999; Millard 2001). There are inherited diseases associated with this small but significant cellular content, which emphasises its genetic importance (Roberts 1999). There are also notable phenotypic differences between clones[31].

The main contention that resides in cloning is the intention of the research. *Reproductive* cloning is the use of the technique to create an individual that is gestated *in utero* to birth. The main medical purpose of this research would be to create children for biologically infertile couples or couples unable to have children themselves (Burley 1999; Schüklenk & Ashcroft 2000)[32]. Reproductive cloning can have therapeutic applications such as the objective of correcting heritable abnormalities transmitted thorough the mitochondria of the oocyte (see DoH 2000)[33].

Therapeutic, or *Non-reproductive* cloning[34], creates an early stage embryo but does not have the intention of implanting it in a uterus. Instead, the embryo will be studied or used in the derivation of stem cells (which in therapy could be immunologically matched to the donor) (Kind & Coleman 1999). It is envisaged that

---

[29] *Somatic Cell Nuclear Transfer* (SCNT) (also *Nuclear Transfer* (NT) and CNR) can be achieved by direct transfer (sometimes called *substitution*) of an isolated somatic cell nucleus into an oocyte; or fusion of a somatic cell containing its nucleus, or an isolated nucleus with, an enucleated oocyte (Gurdon & Byrne 2003; Humphreys et al. 2001; Tada et al 1997; Wakayama & Yanagimachi 2001; Wilmut et al. 1997; Wilmut 2002); *Embryonic Cell Nuclear Transfer* (ECNT) is where the nucleus of an *embryo* is injected into an enucleated oocyte (Meng et al. 1997). Twinning is a natural event where the embryo splits to form two identical monzygotic twins; this has also been achieved by artificial means in animals (Mitalipov et al. 2002).

[30] CNR embryos are authentic nuclear clones, but in fact genetic chimeras, containing somatic cell-derived nuclear DNA (from the donor cell) but oocyte-derived mitochondrial DNA.

[31] See Bhattacharya (2003b); Cohen (2002).

[32] There is also the prospect of creating foetus 'organ banks' for organ donation, which would call into question the moral status of such beings (Schüklenk & Ashcroft 2000 p. 36).

[33] Mitchodrial disease has been targeted for treatment using *oocyte nuclear transfer*, where the nucleus from an effected egg is removed and inserted into a unaffected enucleated egg. This point was drawn out in the Donaldson Report where recommendations were made to permit research into he treatment of such diseases (Burley 1999; DoH 2000).

[34] There are calls from scientific corners to remove 'cloning' from the terminology altogether, instead calling it 'nuclear transplantation' (O'Mathúna 2002; Stenson 2002).

cells and tissue created through the cloning of embryos and derivation of stem cells could avoid the pitfalls of allotransplantation donation (requiring immuno-suppressive drugs and shortage of appropriate donor organs) or xenotransplantation (i.e. potential cross-species transferral of disease). The embryos will perish at most at the 14th day, but normally prior to this, as a consequence of the derivation of SC. However, both techniques involve exactly the same starting material and procedures. For this reason, some have argued that cloning is properly associated with the ultimate outcome or object of the research, not the mechanism or techniques used to achieve that objective (Vogelstein et al. 2002).

ES cell research has been closely implicated with this latter form of cloning. Although there is an undeniable link in the two types of cloning 'research', I will not discuss those issues central to reproductive cloning[35]. Therapeutic cloning will be discussed in the context of *creating and destroying* human embryos solely for the purpose of research. I will contend that the human embryo, regardless of its mode of creation, is the same ontological entity, and therefore, if it is legitimate to use embryos in research at all, then cloned embryos should have no different status, and therefore should not be treated any differently.

4.2. Animal Cloning

Cloning research at present is primarily concerned with animal studies. Producing cloned animals in combination with transgenics may have medical purposes (e.g. breeding animals with transplantable organs; Highfield 2003) or agricultural purposes (Tsunoda & Kato 2002). It may also be applied to the preservation of endangered species or reintroduction of extinct species (ibid.), or extrapolation to human biological development.

---

[35] Arguments to prohibit both types of research are common, although Schüklenk & Ashcroft state that there are no good reasons to prohibit *research* in either (2000). The main contention is that because therapeutic cloning involves exactly the same techniques, allowing such research will perfect reproductive cloning, and thus be an incentive to proceed with it in practice (Holm 2001 pp. 40-42). Bernard Williams argues: '...it seems to me that the slippery slope style of argument can carry weight, and is to be taken seriously; but that, equally, it need not necessarily carry the day, in the sense of proving that the first step should never be taken ...drawing a line ...is a perfectly reasonable reaction, in the right circumstances, to the challenge that is indeed imposed by the slippery slope considerations' (1986 p. 191; also see Beyleveld & Brownsword 2001 pp. 166-168).

The link with human cloning is twofold. Firstly, animal cloning allows scientists to research basic science in biology, development and experimental procedures. This then can be applied to human developmental biology, cloning and SC research[36]. The second involves the study of the clones themselves. It has become increasingly clear that cloned animals are subject to unforeseen genetic abnormalities. Most cloned mammals either spontaneously abort before birth or suffer from developmental abnormalities during life and the process is also exceptionally inefficient (Dean et al. 2001; Hill 2002; Humphreys et al 2001; Lanza et al. 2003; Wilmut 2002)[37]. However, it has been shown that seriously defective cloned frog embryos that cannot survive can nevertheless provide functional SC (Byrne et al. 2002).

An important recent report has claimed that using a mouse model of Parkinson's disease, ES cells had been derived from a cloned embryo and coaxed in culture to differentiate into functioning (and immunologically matched) neurones, and implanted into the brains of the affected adult mice (Barberi et al. 2003).

4.3. The First Human Clone?[38]

Cloning a human has been reportedly successfully attempted using human somatic cells and oocytes (Cibelli et al. 2001). The most developed clones grew to the six-cell stage after a week. Since the clones were created for therapeutic use, the embryos would have to develop to at least 64 cells before they would be useful in stem cell research (Vass 2001). The experimental procedure was very inefficient (Marshall & Vogel 2001). The report is also plagued by controversy, and the results have been widely criticised because of experimental flaws (Marshall & Vogel 2001; Stix 2001; Talan 2001)[39].

---

[36] Stem cell lines have been isolated from cloned monkey embryos (Gottlieb 2001).
[37] The problem may reside in epigenetic changes in the chromosomes which cause gene inaction or dysfunction (heritable changes in gene function that cannot be explained by changes in the DNA such as DNA methylation and imprinting) (Surani 2001).
[38] Human therapeutic cloning has been over shadowed by the *claims* of Severino Antinori and Panayiotis Zavos and their quest to create the first human cloned baby (Cohen & Carrington 2003; O'Mathúna 2002). Their research is not aimed at SC therapy and furthermore, these claims have not been published or substantiated, and therefore will not be discussed here (McDowell 2003a, 2003b).
[39] It is claimed that primate cloning is difficult because of key changes in molecular biology brought on by the cloning techniques (Cohen 2003). Only one live birth of a primate using ECNT has been reported, and this has not been replicated (Simerly et al. 2003). These reports are sceptical that human cloning has even occurred (Alison et al. 2002).

Stem cells have reportedly been derived from a cloned human/animal hybrid embryo (Chen et al 2003). The embryo was created by fusing a human somatic cell with an enucleated rabbit oocyte. The oocyte was then induced to develop, before cells were removed from the ICM. These cells appear to be 'stem cell-like', but apparently have limited developmental potential and life in culture, perhaps because of an incompatibility between the human nuclear DNA and the rabbit mitochondrial DNA (Dennis 2002, 2003). The embryos were not created with the intention of reproductive cloning, and were destroyed in the derivation of the stem cell-like cells.

5. Limitations on Embryonic Stem Cell Research and Theoretical Solutions

Most researchers are quick to point out that ES cell research is in its infancy, and this may be a reason to establish a regulatory framework now. There are many things that we do not understand; there are anomalies and unforeseen occurrences, and often research lacks valid or authenticated confirmation (Frankish 2001; Pera 2002). Nevertheless, these reports of ES cell progress show promising glimpses of applying ES cell research to clinical treatments. There are a number of limitations at present, but controlling of cell differentiation, cell selection methods, and the clinically effective implantation of these cells in animal models, is a great step forward (Schuldiner et al. 2000).

Questions that at present remain unanswered are, firstly, whether animal models are an accurate representation of human ES cell models. This will only become evident when human models are tested. Secondly, it has not been unequivocally established whether the ES cell derivatives are fully functional after transplantation (Smith 2001). Finally, the long-term stability of grafted cells has not been demonstrated. In the following, I will address specific questions regarding ES stem cells research.

5.1. The Claims of ES Cell Research are Misleading

There are reports that some of the most promising results with ES cells may require a second critical look. In one case, claims that researchers had created cells resembling the islet cells of the pancreas (which produce insulin) were cast into doubt

by reports that the cells did not produce insulin in a manner expected of such cells (Vogel 2001b).

Experiments have shown that ES cells have a tendency or bias to form neural cell types, but are reluctant to give rise to endodermal lineages (Cassidy & Frisén 2002). Furthermore, treatments have not been overly successful in animal models, for example, recovery from Parkinson's disease in rats was notable but limited (Vogel 2001a).

5.2. Genomic Imprinting

In mammals, genomic imprinting is a process whereby certain genes are differentially expressed depending on whether they are inherited from the maternal or paternal germ line. This specific control whereby genes are activated or suppressed is essential for normal and complete development. The imprints are altered during germ cell formation and then reprogrammed in the early embryo.

Recently, it has become evident that the status of imprinted genes is altered in some mouse ES lines, possibly due to the effects of long-term culture (Cervantes et al. 2002; Dean et al. 1998). The effects seen in these cells were an increased risk of tumour formation and abnormal development in chimeras; Nagy et al. (1993) has suggested that the premature death of entirely ES cell derived embryos is due to DNA alteration caused by prolonged culture.

5.3. Tumour Formation

There is concern that pluripotent stem cells will form tumours. ES cells do form a particular tumour (teratoma) when introduced in animal models, because they continue to proliferate unless caused to differentiate (Edwards et al. 2000; O'Shea 2001; Paul et al. 2002). However, once an ES cell has been differentiated *in vitro*, it does not seem to form tumours or teratomas following transplantation (Morris 2002).

In the treatment of a rat model of Parkinson's disease, injected ES cells on occasion developed into fatal brain tumours (Gardner 2002; Solter & Gearhart 1999). Therefore, experimental models so far have shown that the development of teratomas from undifferentiated ES cells present in the grafted population is a distinct possibility

(Smith 2001). However, by differentiating cells *in vitro* before transplantation the graft can contain tissue specific and pure precursor cells. This does seem to result in combating the problem by having no further tumour forming potential (Klug et al. 1996; Wobus 2001). Furthermore, the problem may be avoided by engineering a genetic failsafe mechanism into implanted ES cells, such as a suicide gene that can be activated in the cell should anything go wrong (Solter & Gearhart 1999; Schuldiner et al. 2003).

5.4. Immune Rejection of ES Cells

In the case of mouse ES cells and their differentiated progeny, the expression of major histocompatibility complex (MHC) proteins, which initiate immune rejection, is either absent or greatly decreased compared with adult cells. However, it is still possible that ES cell lines derived from unrelated embryos may have a lower, but still recognisable, immunogenetic effect, causing the cells to be rejected by the recipient's immune system (Drukker et al. 2002). This could be handled in the same way that present transplants are, by the administration of immuno-suppressive drugs. These, however, have harmful side effects and would have to be taken for the duration of the transplant. While the concurrent administration of immuno-suppressive drugs would be undesirable, the potential lower rate of graft-versus-host disease may require lower doses, thus also reducing the risk of opportunistic infections, drug-related toxicity and related malignancies.

Alternatively, ES cells could be screened for transplantation from a collection of cell lines held within a bank. The ES cell-line bank would represent coverage of the MHC antigens. One would be able to select cell matches from the bank as and when needed. However, Kaufman et al. (2000) point out that, depending on the degree of need and match, thousands or perhaps millions of cell lines would be necessary. The same authors also point out that minority racial groups may have a lower proportion of suitable matches due to genetic polymorphisms. Both of these problems are not restricted to ES cell research, and are indeed a major problem of all donor programmes.

Genetic modification of ES cells may be possible to reduce the effect of the MHC proteins (Amit et al. 2000; Edwards et al. 2000; Kaufman et al. 2000; Odorico et al. 2001). The genes that produce the MHCs may be altered or even deleted entirely. However, there is evidence that a 'indirect' rejection is possible for cells deficient in

MHC antigens, and thus manipulation of the MHC genes may not altogether remove the rejection response (Kaufman et al. 2000). It may therefore be necessary to tailor the modified MHC cells for each recipient. However, the creation of the 'universal donor cell' may also leave the resulting tissue (because of the very purpose of MHC molecules) more susceptible to infections and tumours, because of the reduced MHC protein production (Vogel 2002b).

Therapeutic cloning to create embryos to procure ES cells is a fourth possibility (Edwards et al. 2000; Kaufman et al. 2000). Munsie et al. (2000) derived pluripotent ES cells from CNR mice embryos, and this was followed by Wakayama et al. (2001) deriving specialised cells from cloned ES cells, and then using them to create chimaeric, apparently healthy, offspring. Parkinson's disease has also been treated using this method (Barberi et al. 2003). Therefore, cells could be cloned from the recipient, but such an approach is dogged by the apparent genetic (and biological) instability of cloned animals, therefore causing concern for the appropriateness of cloned cells. While the illness and defects seen in some cloned animals is obvious, there may be less detectable errors in clonally derived ES cells (Humphreys et al. 2001). Bearing in mind the high levels of foetal abnormalities and perinatal mortality involved in cloning, it will be important to demonstrate that any ES cells derived in this way are not compromised (Smith 2001).

6. The Use of Embryos in Research

The act of removing the cells from the ICM necessarily results in the destruction of the embryo and halts any further development. Even if the embryo could be preserved in taking the cells (such as in the present technique of removing cells for preimplantation diagnosis), there would be concerns over the health of that embryo as a consequence of the research manipulations, and therefore suitability for implantation for development (McKie 2002). In the event, most research policies recognise the concern for this latter possibility and prohibit the implantation of research embryos (see Chapter Four section 3). So we must assume that the research will result in the destruction of that embryo. It must be borne in mind that stem cell research and the application of therapeutic cloning applies only to the embryo of around 5-7 days old. Research

involves utilising human embryos *in vitro*, with no intention to implant within a uterine environment.

6.1. Types of Embryo

The embryo may be simply seen as the first stage in the development of the mature being. However, how this entity first comes into being, and the *developmental* potential that it possess (biologically and situational), is often used to separate *types* of embryo.

6.1.1. IVF Embryos

Embryos created by *in vitro* fertilisation (IVF) are created either specifically for research or for a fertility project; the latter can be donated to research. It is important to recognise that fertility treatment itself was the result of research on donated gametes and embryos (Edwards 2001). These embryos only differ in the specific intention of their creation. In the case of fertility projects, the *in vitro* embryos are selectively implanted and those remaining are frozen for future use, donated to another couple, or destroyed. Embryos used in research, on the other hand, are either destroyed in the process of, or subsequent to, research. ES cells have been isolated from human IVF embryos (Thomson et al. 1998).

6.1.2. Cloned Embryos

Cloned embryos are essentially the same *type* of thing as an IVF embryo. The difference being that the former has not gone through a process of fertilisation. The main problem with cloned embryos is that the technique uses developed somatic cells which are reprogrammed in the cloning procedure. They may therefore contain chromosomal modifications (genomic imprinting) that are incorrectly switched on or off causing the cells to be compromised.

Cloning can be achieved through a number of means, the similarity between all of them is that an enucleated oocyte is modified to contain the nucleus from a somatic cell, then induced to develop as a fertilised egg would. If kept *in vitro* for research purposes, development, in the same way as an IVF embryo, will cease in around 14 days. These embryos can be implanted and developed to term. This has been reportedly achieved in a number of animals (and claimed in humans). ES cells have reportedly been isolated from a human clone (Chen et al. 2003).

Human cloning is controversial for other reasons apart from the destruction of the cloned embryo in therapeutic research. These issues concerning the intention of *reproductive* cloning will not be addressed in this thesis; but I will argue that the cloned embryo for the intention of *therapeutic* research is essentially the same *type of embryo* as the IVF embryo (Hansen 2002)[40]. However, I will also have to show that no embryo deserves full moral status, otherwise all embryo research would be prohibited[41]. Therefore, in medical research, if it is justifiable to use the latter because of its intrinsic status, then it will also be justifiable in the case of the former (not withstanding the genetic stability of the cloned embryo and the potential limited medical applications).

6.1.3. Parthenotes

One further source of ES cells is from artificially created parthenotes. Parthenogenesis ('virgin birth') is the process by which an oocyte can develop into an 'embryo' in the absence of the male gametes. (There is evidence of totipotency in some animal species, where parthenotes have developed to maturity in vertebrates, and to advanced stages in mammals, see Mann 2001). The eggs divide on their own as though they had been fertilised by a sperm. Parethenotes are limited to the female genome because the oocyte is stimulated to develop before it ejects half of its DNA (as happens normally, so as to accommodate the male DNA content). It may be possible to create male derived parthenotes by inserting two male gametes into an egg whose own DNA has been removed (Vrana et al. 2003).

---

[40] For discussions of these wider issues, see Coors 2002; Hansen 2002; Kind & Colman 1999; Lanza et al. 2000; Rehmann-Sutter 2002; Savulescu 1999.
[41] For an account of this latter interpretation, see Coors 2002.

Human parthogenesis can be caused artificially by electrical or chemical stimulation of the oocyte. The parthenote often cleaves for several divisions. During early divisions, it behaves exactly like a normal embryo. This is because the early embryo only relies on the activity of the maternal DNA. As soon as the paternal DNA is required, the parthenote, lacking this nuclear content, ceases development (see Cibelli et al. 2002). The parthenote can have a normal karyotype and is capable of deriving chimeric and apparently normal offspring in animals, however, up to now no mammalian parthenote has been taken to full-term. In humans, the parthenote fails to develop to full-term, but closely resembles normal early embryonic development.

Cibelli et al. (2002) and Vreana et al. (2003) have succeeded in isolating apparently normal primate ES cells from artificially created primate parthenotes. These ES cells have been shown to derive all three germ layers and generate specialised somatic cell types. Human parthenotes have been created and stem cell-like cells derived from them (Lin et al. 2003). However, these cells had a limited proliferative life and therefore, may not have the same potential as other human SC (Dyer 2003; Westphal 2003).

6.1.4. Chimeras

Chimeras could be used to circumvent the problem of human donors of oocytes and the problems that may go with this (particularly the potential exploitation of women, see Cohen 2001 pp. 212-217; Cloman & Kind 2000; McKinnell 2002). Instead of using human oocytes, animal oocytes could be used to create human ES cells (by creating human-animal embryos but not implanting them), by replacing its nucleus (through CNR) with a human somatic nucleus (Chen et al. 2003). Perhaps more immediate would be the experimental injection of human ES cells into animal embryos to investigate differentiation (Karpowicz 2003). At present however, it is not envisaged that there will be an immediate medical/research application (DeWitt 2003).

6.2. The Potential of Embryonic Stem Cells

Animal models of the potential therapeutic potential of ES cells should be viewed with continued caution, despite the evident promise. There are presently theoretical limits to the prospective uses of ES cells also, but there are proposed ways around these. The important results from animal studies is that ES cells can display a terminally differentiated, physiologically mature phenotype and exhibit normal physiological functioning *in vitro* and *in vivo* (Bain et al. 1995; Soria et al. 2000; Wobus et al. 1991).

We therefore have to decide whether there are: (a) alternatives to embryonic research and; (b) whether there is sufficient research evidence to warrant the continued use of human embryos. We also have to look at the potential consequences that may befall stem cell research if we decide on a moral basis that embryo research should not proceed.

If we take the first question as to the alternatives, then we have to now turn a critical eye to the success and failure in other avenues of stem cell research. Whether parthenogenetic stem cells (if considered as an ethically acceptable alternative[42]), will suffice remains to be conclusively shown, although studies suggest that such cells may be clinically significant in research (Cibelli et al. 2002).

Success in the application of alternatives to embryo research would give a boost to the prohibitive stance from the pro-life position. The application of cord blood derived SC has been widespread and therapeutically valuable for some time. Foetal neural transplantation from aborted foetuses has been shown to work in animal models, and there has been limited success in human trials (Björklund & Lindvall 2000; Freed et al. 2001). Claims, however, that primate research could replace human ES research are not valid because of species differences (and the morality of using primates in such research). Therefore, policy makers must look equally carefully at the alternatives to ES cells.

Equal attention should be paid to the reports that reject the potential of ES cells, and those that support their success. If nothing else, on these grounds we should be careful to monitor that what is being reported on both sides stands up to scientifically rigorous vindication; and neither side's potentially beneficial development is dismissed out of hand.

---

[42] See Dyer 2003; Holden 2002; Weiss 2003; & Westphal 2003.

For these reasons, there is widespread support for the continued use of human embryos in stem cell research, and indeed that it might be essential to pursue this direction of study for realising the therapeutic potential of stem cell research (Amit et al. 2000; Lanza et al. 2001). Anderson et al. (2001) and Pera (2001; 2002) argue that the experimental proof of pluripotentiality has not been met in foetal or AS cells. This further suggests that there is still no alternative cell type with equivalent properties; and indeed, at present, there is no alternative equivalent to ES cells.

At the very least, policy makers should be prepared to concede that ES cell research *may* be necessary because '...we do not know enough about adult stem cells or ESC [ES cells] to make dogmatic statements about the limitation of either' (Prockop 2001 p. 11). Therefore, to maximise research progress, we should be prepared to pursue concurrent research in all fields of stem cell science and not play up to unrealistic levels any particular avenue of research (Edwards et al. 2000).

If ES cell research is necessary for the advancement of stem cell research per se, then the prohibition of such research will slow up possibly promising treatments or even mean that stem cell research benefits are never realised. This will have a detrimental effect on those people requiring urgent treatment. But then, the potential benefits of science should not dictate what we are prepared to justify in the absence of moral justification. Scientists cannot alone decide what is justifiable, and it is up to scientists in partnership with others, to define the ethical limits that should be permitted.

There is, of course, strong resistance to the use of ES cells because of the source of those cells. At one end are objectors who maintain that regardless of the potential benefits of ES research (and they are prone to point out that the benefits are only a possibility) there can be no justification for destroying human life. At the other end are objections from those who hold that ES cells are fundamentally flawed as a therapeutic tool, and regardless, SC from other sources are sufficient, if not better than, ES cells. In the next section I will evaluate the claims for the superiority (or lack) of potential from less contentious sources of SC, and will concentrate on AS and CBS cells. I will not consider SC from foetuses, because although embryonic germ cells may show therapeutic promise, they are not without controversy in their derivation, and for this reason they may not be an acceptable alternative.

7. Non-Embryonic Stem Cells

Stem cells can be isolated from other sources other than embryos. In the following I concentrate on those from cord blood (also see Appendix One s. 2) and somatic tissue (AS cells) (see Appendix One s. 2 for an account of foetal stem cells).

7.1. Stem Cells From Cord Blood: Therapeutic Applications

Cord blood (CB) can be collected at birth from the umbilical cord that is routinely discarded (Annas 1999; Senior 2001; see Appendix One s. 2). These cells have been commonplace in the treatment of blood disorders in young children (Ebrahim 2002; Glukman 2000; Wynter & Testa 2001). Furthermore, these cells have a reduced risk of graft-versus-host disease (Kirn 2001; Rygaard & Lindenburg 2002); although even a limited reaction may require a degree of matching.

The possibility of the presence of pluripotent haematopoietic and mesenchymal stem cells (see below) in CB has an important therapeutic potential (Erices et al. 2000); due to its ease and relatively low degree of contention in collection (Donaldson et al. 1999; Proctor et al. 2001; Sugarman et al. 1997). The cells in the CB have been reportedly used to treat brain damage induced in animal models by directing them to differentiate into neurones *in vitro* or introducing undifferentiated cells *in vivo* (BBC News Online 2001; Labat 2001; Young 2001b).

The main problem with CB research is that the SC may have a limited potency, that they cannot be collected retrospectively (which can be overcome by banking the cells), and the limited yield of cell in any one collection, which can be countered by improved collection protocols and *in vitro* expansion of cells (Rogers & Casper 2003).

7.2. Stem Cells from Somatic Tissue: 'Adult[43]' Stem Cells and Therapeutic Applications[44]

SC from somatic tissue may not be as restricted in proliferative and regenerative potential as was once thought. In the past, paradigms of the differentiation of these cells have been of two types: (1) mature cells derived from embryonic development and now 'fixed' in a particular organ or tissue; and (2) linear and irreversible pathways linked to homeostasis.

However, recent progress in somatic stem cell research has shown that cells removed from their specific tissues are capable of adapting to the new cellular niche. These AS cells may be highly plastic in differentiation and can seek out damaged tissues and repair them (Prockop 2003)[45]. A clear benefit of AS cells would be their use in autologous donation/transplantation and their lack of contentious use.

The potential of somatic cells may be explained either by: (1) cells that are capable of reversing their differentiated state to becoming primitive multi- and pluri-potential stem cells (i.e. de- then re-differentiation) (Blau et al. 2001; Fuchs & Segre 2000; Morrison 2001; Orkin 2000; Robey 2000)[46]; (2) tissue specific stem cells (multi- and uni- potent) existing in different and distinct organs and normally confined to that niche, but able to *trans-differentiate* according to the new context in which they are placed (i.e. tissue specific multipotent stem cells that share similar, but distinct properties throughout the organism) (Rosenthal 2003; Weisman 2000a) or; (3) true pluripotent stem cells existing in postnatal organisms which can cross lineage boundaries to become differentiated cell types[47] (Verfaillie et al. 2002 pp. 383-385). The jury is still out as to the precise mechanism (Clarke & Frisén 2001; Poulsom et al. 2002; Verfaillie et al. 2002). If there are pluripotent cells present in the adult, then these

---

[43] Stem cells from somatic tissue is often termed as 'adult' stem cells. This is incorrect as stem cells from somatic tissue can be theoretically derived from any somatic tissues, and not just those in adults.
[44] For reviews see Almeida-Porada et al. 2001; Eridani 2002; Kuehnle & Goodell 2002; Presnell et al. 2002; Wulf et al. 2001; Clarke & Frisén 2001; Poulsom et al. 2002; Preston et al. 2003; & Weissman et al. 2001.
[45] This was most dramatically established by the successful cloning of a mammal from the nucleus of an adult tissue cell (Wilmut et al. 1997) and demonstrated that the somatic cell nuclei could be reprogrammed to a truly totipotent state, suggesting that no somatic cell loses its stem cell capacity.
[46] This is clearly demonstrated through CNR whereby somatic cell nuclei can be transplanted into enucleated oocytes to give rise to entire organisms (Blau et al. 2001).
[47] See reviews of recent progress: Blau et al. 2001; Clarke and Frisén 2001; Fuchs & Segre 2001; Lemischka 1999, 2001; Morrison 2001;Rosenthal 2003; Stocum 2001; Weissman 2000b; & Poulsom et al. 2002;

would be truer stem cells than the cells of the ICM, since the latter do not persevere indefinitely (Eridani 2002).

Regardless of the mechanisms, in the *in vitro* and *in vivo* state, evidence suggests that at least some somatic (stem) cells are susceptible to differentiation when removed from their normal niches and transferred to a new site; somatic stem cells can adjust their properties according to their surroundings (Fuchs & Segre 2001). These rare cells (as opposed to those in obvious sites of high turnover) may be activated *in vivo* after tissue injury or other pathological conditions (Presnell et al. 2002).

For these reasons, it is argued that stem cells must be described by their *function*, and not by the tissue they reside in (Kooy & Weiss 2000); and therefore, most, if not all stem cells share an intrinsic genetic programme that is not present in non-stem cells (Chu & Gage 2001). Because these cells can 'adapt' to new cellular niches by reprogramming (cloning), cellular commitment and subsequent re-commitment may therefore be a function of epigenetic (genetic) restraints. The reason why ES cells are pluripotent may then be because they express most genes at once (or no gene expression indicative of cell commitment), and subsequent non-DNA modification of the genes causes commitment to cell lineage (Clarke & Frisén 2001).

Somatic stem cells have been known to migrate towards and take up residence in a tissue that has been damaged in some way and contribute to its repair and regeneration (Rosenthal 2003; Vats et al. 2002). AS cells would also be of particular interest in autologous cell therapy (using the patient's own cells) because of the avoidance of immunological matching (Clarke & Frisén 2001). There is also evidence that they can be genetically manipulated (Farley 2003). There are numerous reports of progress in somatic stem cell research. The following are perhaps the most significant.

Bone marrow (BM) contains at least two distinct populations of stem cells: *mesechymal* and *haematopoietic stem cells* (HSC) (Abkowitz 2002; Clarke & Frisén 2001). HSC[48] (also from the spleen, peripheral blood system, and liver; see Körbling et al. 2003) have been used successfully for some time in treatment of blood disorders (for review see Blau et al. 2001; Lemischka 1999). HSC can be genetically modified, which may circumvent problems of allogenic donation (BBC News 2002). They have been used to some success in autologous treatment of patients with differentiated muscle cells for heart damage (ibid.). Partial recovery in mouse models of Duchenne's

[48] For review see Bonnet 2002; Gunsilius et al. 2001; Little & Storb 2002; Orkin 2001.

muscular dystrophy have been reported by injection of HSC (Gussoni et al. 1999). Furthermore, human trials have demonstrated partial recovery from liver damage (Lagasse et al. 2000); and chronic ischaemic heart failure (Perin et al. 2003b). HSC have also been differentiated into endothelia precursors (that can be used to treat ocular degenerative disease in murine models) (Otani et al. 2002; Powell 2002; Senior 2002); and epithelial cells of the liver, gastro-intestinal tract, lung, and skin (Alison et al. 2000; Körbling et al. 2003; Krause et al. 2001; Schwartz et al. 2002). HSC can also be genetically manipulated and expanded in culture (Farley 2003).

Mesenchymal stem cells[49] (MS Cells) (marrow stromal cells; found in the bone marrow) normally give rise to the various connective tissues, notably the bone and adipose (fatty connective and insulating) tissue (Vats et al. 2002). MS Cells have been isolated from humans, and can generate differentiated non-mesenchymal related cells (Pittenger et al. 1999; Sanchez-Ramos et al. 2000; Woodbury et al. 2000). There is evidence that they may be pluripotent (Clarke and Frisén 2001; Jiang et al. 2002; Verfaille et al. 2002[50]), although, it is thought that this may only be a rare population of cells in the BM (Rosenthal 2003). It is also evidence that MS Cells cause little or no immune reaction (Lodie et al. 2002; Westphal 2003).

Neural stem cells[51] (NSC) have been isolated from the human brains of living and dead individuals, and have wide implications for treating certain neurological diseases (see Clarke & Frisén 2001; Stendler & Pincus 2002). They have been shown to migrate and home to specific sites of damage or regeneration in the brain (for review see Blau et al. 2001). NSC can give rise to all three major cell types of the central nervous system thus categorising them as at least multipotent to that lineage and have been used in autologous treatment of Parkinson's disease with some promising results (Wesphal 2002a). In mice, adult NSC have been injected into models of multiple sclerosis and shown tentative results of recovery (Pilcher 2003a; Pluchino et al. 2003). NSC have been differentiated to become muscle cells, skeletal myotubes (Galli et al. 2000), and blood cells (Bjornson et al. 1999), providing evidence that NSC may be pluripotent (Clarke et al. 2000; Clarke & Frisén 2001). Neural stem cells have also been isolated

---

[49] For review see Miguell et al. 2001; Pittenger & Marshak 2001.
[50] Verfaillie and co-workers called these cells Multipotent Adult Progenitor Cells (MAPCs). The cells could become most of the cell types of the developing being when injected into mouse embryos.
[51] For review see Clarke et al. 2000; Gage 2000; Kennea & Mehmet 2002; Stendler & Pincus 2002; Vescovi et al. 2001.

from a human cadaver brain (Paler et al. 2001) – which may provide an additional source of AS cells for therapy.

Other significant progress has been made with *Skeletal muscle stem cells*[52] which normally operate to regenerate muscle damage. They have also been shown to differentiate into heamatopoietic cells (Jackson et al. 1999); and to repair damaged myocardium (heart cells) in human trials (Pagani et al. 2003). Stem cells from *skin*[53] are responsible for the high turnover of the epidermis. Human skin cells have been differentiated into new blood vessels (BBC 2002); and cow skin cells into beating heart cells (Coghlan & Young 2001). These cells may be at least multipotent (Toma 2001). Skin cells, being an easily accessible source of stem cells, would have clear advantages to less convenient and contentious sources.

Stem cells have been isolated from *teeth* that have differentiated into neural cells, adipocytes, and odontoblasts *in vitro*; and bone formation *in vivo* (Miura et al. 2003; Zandonella 2003). These cells have the advantage of being accessible and providing a plentiful source of stem cells for therapy (Josefson 2003). There has also been significant progress in the treatment of heart diseases using AS cells (Kereiakes 2003; Perin et al. 2003a; Strauer & Kornowski 2003[54]).

7.3. The Problem with AS Cells

Until it was allegedly demonstrated that AS cells could differentiate into unrelated phenotypes, it was assumed that only ES cells had the potential to become different cell types. The evidence present above is claimed to show that this is not the case. However, despite this evidence for the existence of at least multipotent AS cells, there are several questions to be addressed before the development of clinical applications (Kuehnle & Goodell 2002). The difficulty with somatically derived stem cells is their paucity in parent tissues (Eridani 2002; Jones 2001), heterogeneity, and technical difficulties in their identification and isolation (Blau et al. 2001; Rosenthal 2003).

---

[52] For review see: Deasy et al. 2001; Goldring et al. 2002.
[53] For review see: Janes et al. 2002
[54] SC may also be present in the pancreas (for review see Bonner-Weir & Sharma 2002); liver (Forbes et al 2002; Fuchs & Segre 2000), lung (Otto 2002), gastrointestinal tract (Brittan & Wright 2002), and heart (Hughes 2002).

Furthermore, there are concerns as to the accessibility of some somatic stem cells in adult tissues and organs (Vats et al. 2002).

However, the main concern with AS cells is that some of the results are open to different interpretations, erroneous results and lack repeatability (Rosenthal 2003). These considerations seem to be underplayed (or hyped) by those who oppose ES cell research. While these cells may be exceptionally important for therapeutic application, the plethora of reports in recent years has lacked authentication or functional analysis (Anderson et al. 2001). Castro et al. (2002) have shown that contrary to earlier reports (Brazelton et al. 2000; Mezey et al. 2000), pluripotency may not be a general phenomenon[55]. Likewise, Wagers et al. (2002) reported that there was little evidence for the developmental plasticity of HSCs (also see D'Amour & Gage 2002; Morshead et al. 2002 for discussion). In 1999, it was reported by a group that they could not repeat earlier reports that cells from brain could become blood cells (D'Amour & Gage 2002; Vogel 2002c); and McKinney-Freeman et al. (2002) reported that their earlier claims that adult muscle stem cells could become blood cells (Jackson et al. 1999), was in fact due to rare blood cells in the culture (see Vastag 2001). The claim that fat-like cells (adipose tissue) could become cartilage (Zuk et al. 2001), bone and muscle has been cast in doubt (Vogel 2001a). Reports that NSC form brain cells were not authenticated, and the cells had a limited lifetime in culture (Vogel 2001a). Furthermore, claims that embryonic-like SC can be derived from bone marrow (Kruse et al. 2001) had not been independently validated (Vastag 2001); and it is evident that bone marrow SC could not, contrary to previous reports, become functional heart cells (Burgermeister 2003).

In 2002, two separate research groups concurrently (Terada et al. 2002; & Ying et al. 2002) reported that the reason for some HSCs and NSCs adopting the phenotype of other cells was due to *cell fusion* with embryonic stem cells that are present in culture to support the AS cells (Gillis 2002; Lichtarowicz 2002; Mayor 2002; Wurmser & Gage 2002; Vassilopoulos et al. 2003; Wang et al. 2003[56]). Furthermore, these cells contain an irregular karyotype, probably making them unsuitable for therapeutic and clinical application (Highfield 2002). However, Tran et al. (2003), Jiang et al. (2002) and

---

[55] This it has been subject to counter-claims (Mezey et al. 2003; Theise et al. 2003; and replies by Castro et al. 2003 & Wagers et al. 2003). These comments generally are of the opinion that no assumptions of AS cell plasticity should occur, and that far more research is required to conclusively argue that AS cells will be clinically useful.

[56] '...it seems questionable whether HSCs really have any differentiation potential other than the blood lineages ascribed to them traditionally' (Wang et al. 2003; also see Pilcher 2003b).

Alison et al. (2003) have shown that human bone marrow derived stem cells do seem to differentiate (albeit rarely), and this is not always the result of fusion (also see Pilcher 2003b; Preston et al. 2003). Most recently, Alvarez-Dolado et al. (2003) has show that *in vivo* circulating BM stem cells fuse with various organs, but retain their BM molecular markers, leading researchers to assume that they have transdifferentiated. They found *no evidence* that this was the case. (This finding is implicitly corroborated by Weimann et al. 2003).

The important questions to ask are therefore whether AS cells do in fact differentiate, the mechanism of this[57], and their functional usefulness *in vivo* and *in vitro* (Anderson et al. 2001; Preston et al. 2003; Prockop 2003). The main question is whether the differentiation of AS cells in culture is actually due to a single multi- or pluri- potent stem cell, and whether this is a normal event of the cells behaviour. (Indeed, neurones suitable for treating Parkinson's disease have yet to be identified, which is unlike ES cells; BBC News Online 2003b). It is important to determine whether there are tissue specific stem cells or actually one or two discrete stem cells that provide the regeneration and turnover of all somatic tissues.

8. The Emerging Concept of the Stem Cell: Entity or Function?

Since the isolation of human SC from embryos and foetuses there has been a rush of reports claiming the discovery of stem cells in tissues and organs typically regarded as non-self-renewing, slow self-renewing, or with a limited capacity for repair from somatic tissue. From this it has been proposed that 'stem-ness' should be made broader and applicable to a *function* that can be induced in cell types, rather than a single and discrete entity (so contradicting definitional delineation of ES cells from other types of cell). The proponents of this view argue that because all cells from a single being have the same genome, different phenotypes (although the genotype remains the same) are expressed by evidently temporary or reversible structural and chemical modifications to the DNA – therefore there is a functional/developmental relationship between all SC. This is borne out by the observation that any differentiated somatic cell can be

[57] For review see Tosh & Slack 2002.

reprogrammed to become totipotent through CNR, thus have a 'blank canvas' with regards to the expression of its genome.

This had led to a description of the 'stem cell' as a discrete *in vitro* artefact (Kooy & Weiss 2000). It is emerging that the functional characteristics of the stem cell, whether derived from the embryo or adult, are recognised '...not necessarily by what they do in their dependent tissues within an organism, but rather by what they can do in the laboratory' (Robey 2000 p. 1489). For example, the ES stem cell only exists as truly pluripotent *in vitro* (*in vivo* their pluripotency is transient). Why then should AS cells be considered any different *in vitro*? Only AS cells are present throughout the life of the being and therefore may be the only true stem cells that exist *in vivo* (Watt & Hogan 2000).

There are emerging structural attributes that are associated with all stem cells, such as cell surface markers and telomerase activity, but to differing degrees. Identification and characterisation of these will be important to isolate somatic SC and to validate their (functional) characteristics (Donovan 2001). This would point to the stem cell being a definitive entity at the molecular and morphological level. Stem cells should be defined by their end state; as opposed to where they came from, because it is their ability to differentiate wherever they are put that determines the potential (Moore 2001).

9. Comparison of Different Sources of Stem Cell

The resolution of the discrepancies between different types of stem cell is fundamental to this thesis. If the research with, for example, AS cells can progress and promise as much research and therapeutic potential as is claimed by protagonists against embryo research, then the debate is effectively killed off.

However, true pluripotency of only ES cells has been shown in mouse models (by inserting pluripotent stem cells into mouse embryos), and their *in vitro* differentiation potential is at present superior to those of other sources (for review see Grosschedl & Watt 2001). ES cells are also the easiest to grow and expand in culture and show a high degree of stability (Lovell-Badge 2001a).

AS cells, on the other hand, are not yet comparable with the potential of ES cells. Despite claims to the contrary they have not been shown to be pluripotent (Antoniou

2001). In many studies, the origin of the putative pluripotent cell is not clear, there is little or no evidence that the cells are immortal, the differentiation occurs in a limited set of conditions at low frequency, and there is no evidence to support the clonal origin of differentiated cells (see Verfaillie et al. 2002). On the other hand, there are clear benefits of using AS cells, such as the accessibility of certain sources (e.g. skin) and the immunological compatibility of autologous treatment (Rosenthal 2003).

However, a cautious approach should be taken to evidence of the plasticity of AS cells due to questions about erroneous reports (Daley 2002); and lack of repeatability or authenticity of results (Alison et al. 2002; Holden & Vogel 2002a; Wells 2002). There is relatively little evidence to authenticate AS cell claims, with few published results meeting the rigorous criteria for the identification of such cells (D'Amour & Gage 2002; Weissman 2002); the significance of AS cell research progress is therefore difficult to assess (Andrews et al. 2001). Despite notable progress, AS cells are still hard to isolate and difficult to grow in culture (Holden & Vogel 2002a). Furthermore, research on AS cells will require in some cases the donation of organs and tissues (which arguably may be put to better use in transplantation). Other human organs and tissues, such as that from the brain, may be difficult obtain for research purposes and therapy (Gardner 2002).

While supporters of AS cell research promote their superior progress of over that of ES cell research (especially in therapeutic treatments) (Daley 2002), they fail to realise that *human* ES cell research lags behind other forms of stem cell research (CARE 2001), because of the controversial derivation of cells, and not because of the science. They also fail to recognise that the great deal of progress made in SC research originated in ES cell research, and continues concurrently through ES and AS cell research. (It has been argued that on the basis of promising pre-clinical evidence, therapeutic trials of ES cells in neuro-degenerative disease may be imminent (Rosenthal 2003)). Furthermore, opponents of ES cell research have seized on any suggestion of plasticity in AS cells, sometimes hyping or disregarding validation in AS cells to make the case that ES cells are unnecessary (Holden & Vogel 2002a).

It is also contended that some pro-ES cell scientists, patient advocacy groups, and politicians have exaggerated the prospects for immediate clinical impact if ES cell research is pursued with vigour (Daley 2002). Furthermore, reports have stated that AS research has been misleadingly 'discredited' or is being 'hushed up' in the scientific

press[58]. The rejection of ES research clearly is supported by 'pro-life' groups (and some reputable scientists may also be of this position) (Preston et al. 2003).

In fact, relatively few researchers have either dismissed the potential of ES research in light of somatic cell progress, or more importantly, publicly stated that the former should be sacrificed for the sake of somatic cell research[59]. The main problem, which both sides are guilty of, is that in policy debates (because so much is at stake), non-peer-reviewed claims are being made with increasing frequency (Check 2002). All SC claims should be assessed on an equal, timely and peer-reviewed manner (Brivanlou et al. 2003).

Most researchers and policy documents are quick to acknowledge the controversy in embryo research, but are equally adamant that progress in therapeutic SC research would either be severely hampered, or at least held back without ES cell research (Nature Neurosciences Editorial 1999; Hescheler & Fleischmann 2001). Moreover, AS research should not be considered a scientifically (and therefore, ethically) acceptable alternative, because the therapeutic benefits of all SC research are dependent on continued and concurrent progress. Furthermore, the dramatic reports of the versatility of AS cells must be tempered with a note of caution (Check 2002; Rosenthal 2003). The prospective benefits of each should therefore be conveyed as a realistic, but potentially distant goal; and not overly played to win the political debate[60] (Byrne & Howells 2003; Paul et al. 2002; Verma 2001a, b). A number of reputable researchers agree that ES cell progress offers at present the greatest prospect and most flexible approach for rapid therapeutic application (Alison et al. 2002; Lanza et al. 1999; Moore 2001; Orkin & Morrison 2002). Furthermore, the results from ES research may enhance the use of somatic stem cells (Perersen & Terada 2001; Rosenthal 2003; Verma 2001a; Weissman 2002)[61]. Some have gone as far as to argue that some benefits of stem cell research cannot progress without the support of ES research (Solter & Gearhart 1999), while a more moderate view sees at least all research progressing concurrently and progress being complementary (Gavaghan 2001; Lovel-Badge 2001b;

---

[58] See http://www.i-sis.org.uk (accessed June 2003). Although this claim can be countered with the equal publication of reports from both sides (see Alison et al. 2003).

[59] Some have concluded that there are no differences between ES cell research and IVF research and fertility treatment (Edwards 2001; & Lovell-Badge 2001a)

[60] In which stake holders (who may underplay or overplay recent developments) and potential benefactors (e.g. patient advocacy groups) should be made aware (Daley 2002)

[61] For example, an 'immortality' gene has been reportedly isolated from mouse ES cells (Chambers et al. 2003). It is hoped that this research could contribute to turning somatic stem cells immortal (Bhattacharya 2003b).

Morris 2002; Papaioannou 2001; Petersen & Terada 2001)[62]. Advocates of this latter view argue that without a full picture of stem cell science, it would be unwise to hastily implement ES cell limiting policies (Mayor 2002; Wurmser & Gage 2002).

Conclusion

Stem cells are recognised by their *in vitro* capacities for clonogenicity, and dedifferentiation. This, it would seem, is dependent upon their properties *in vitro*, and on this basis that ES cells would seem to be at present the best hope for rapid progress in SC therapies. Coincidentally, these stem cells also cause the most controversy.

The argument for embryo research can be set out consistently with the evidence accordingly: (1) stem cells are discrete entities depending on where they are derived or; (2) all stem cells are essentially the same. The properties of SC are, however, unclear. If (1) is correct, then it is clear that concurrent research is necessary in all types of research if progress is to be made rapidly towards therapeutic goals (because it has not been determined which source is scientifically best). If (2) is correct, then ES cell research is necessary for rapid progress in isolating and utilising AS cells from less controversial sources (because ES cells are the best characterised).

There are benefits and disadvantages in all stem cell types, involving issues of *in vitro* culture, potency, tumour formation, functional and stable progeny, and immunogenetics. Likewise there are issues of validation and repeatability in all types of SC. I conclude that all of these issues need to be addressed before any one type of cell can be promoted above another, and for this reason, research should progress on a complementary basis, and policy should not rule out any one avenue based solely on *scientific* evidence.

---

[62] Scientists are not often forthcoming as to where the ES cells should come from with regards to spare or embryos created specifically for research. There is a marginal, but significant group with the opinion that new cell lines will be necessary however, and limiting research to existing cell lines may not be sufficient for therapeutic progress (Weissman 2002).

Chapter Two

A Moral Framework for European Union Stem Cell Policy

Introduction

Here, I argue that the basis of policy within the European Union (EU) is a framework of *human rights* and, therefore, any harmonised policy on embryo research should reflect this consensus. However, there are considerable misunderstandings implicit in this framework which leads to critical comprehension. I will attempt to address these misunderstandings by defining clearly the basis of the 'human' right as a *moral claim* right. This account will then be used as a basis for a moral grounding of Community stem cell research policy. The details of the Community's and Member States' policies will be discussed in Chapter Four, while the implications of the prudent acceptance of human rights as a policy determinant will be tackled in Chapter Five.

Human rights are viewed alternatively as a philosophical idea, a legal concept, or a political project. These views are used to different degrees in a concerted effort to build a public[1], political and legal consensus around the idea of international human rights, and they are ever-present as a paradigm in the Member States political, social and legislative policies[2]. Underlying this is the implicit bedrock concept of the grounding of human rights as *moral* justifications in public discussions and case

---

[1] 'Amnesty International's mission is to undertake research and action focussed on preventing and ending grave abuses of the rights to physical and mental integrity, freedom of conscience and expression, and freedom from discrimination, within the context of its work to promote all human rights [and to] ...mobilize [sic.] the public to put pressure on governments and others with influence to stop the abuses...' (http://www.amnesty.org/).

[2] This thesis concerns the 15 member states (as of 2003) of the EU: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Italy, Ireland, Luxembourg, The Netherlands, Portugal, Spain, Sweden, and the United Kingdom. In this Chapter I will be concentrating on the influence of the United Nation's *Declaration on Human Rights and Fundamental Freedoms* (UDHR) (1948); the *European Convention on Human Rights and Fundamental Freedoms* (ECHR) (1950) which at present has been ratified by 44 (of 45) European states; and the *Consolidated Text of the Treaty of the EU and of the Treaty Establishing the European Community* (consolidated text 2002 OJ C325; see Articles 6, 7, & 181); also including the proposed *Charter of Fundamental Rights of the EU* (CFREU) at: http://europa.eu.int/comm/justice_home/unit/charte/index_en.html (accessed September 2003). The Charter will make the rights within the EU a '..."more evident" framework of protection before public authorities within the European context' (Garcia 2002 p. 492). Denmark, Greece, Portugal and Spain have ratified the *European Convention on Human Rights and Biomedicine* (ECHRB) 1997.

decisions[3]. For this reason, this thesis will unpack the morality that underlies the 'rights' doctrine used in the EU. This will show that they are used as a necessarily abstract concept of legal international relations, but that at the same time, are an inconsistent apparatus for moral grounding in policy decisions. This is because the moral basis of governmental policies fails to recognise explicitly that, correctly deployed, human rights are only the property of all (human) beings that have a propensity to act for rationally chosen purposes (*infra* fn. 6); and that they are *especially valuable* from a moral point of view. Because of this, claiming that certain persons have or do not have rights has particularly serious moral repercussions. Regardless of our beliefs about a being's moral status and the moral relations in which we stand to it, we deny it proper respect if we fail to recognise, and then violates its status, as a possessor of rights; or conversely, we are guilty of moral inconsistency if we falsely inflate the protection that is rationally required of those without rights (Feinberg 1964 p. 642; Gordijn 1999; Sapontzis 1981).

As a consequence of this, policies can (indeed should) decide whether an act is permissible by finding out exactly what the implications are to those persons of equal moral standing, within a framework of human rights. The policy is therefore committed to an egalitarian ethos. By asserting the primacy of moral rights, policy makers are committed to identifying the human rights at stake, and which individuals are threatened or harmed in this light. (But although one should be assessing the rights and wrongs of moral *acts*, our understanding of the moral content of the act expresses itself in the prediction of the expected consequences of that action for the possessors of rights; one cannot define a moral system that appeals solely to general utility, as such a system would fail to recognise the egalitarian status of all morally important individuals).

The difficulty is, however, that often it is not at all clear what are the 'rights' are and to whom they apply. The concept of the right has a long and often muddied past. And while most will allege the importance of human rights as set out in international law and their basis for egalitarian social systems, there are few indications that the leading documents are based on firm moral grounding.

---

[3] 'For us, present-day 'Eurocentric intellectuals', the human rights culture we have inherited is a more settled part of our intellectual landscape than any philosophical argument devised in its defence could ever hope to be' (Tasioulas 2002 p. 80).

1. Stem Cell Policy

1.1. The Relationship Between Research and Therapeutic Application

Developments in medicine are intended to create better standards of living and life-saving treatments, but also bring with them new legal and moral challenges (the viability of research in moral terms is not dissociated from social applications). This thesis, due to space, will not comment on the social aspects of stem cell research (SC), such as justice (economic implications) and equal access (to research benefits). That said, clearly once the developments are 'out there' (regardless of the *morality* of that development), there are issues as to the morally responsible *application* of that research. Instead, it will concentrate solely on the status of the embryo in research, and in this case, the derivation of human embryonic stem (ES) cells. This issue has been particularly demanding to those engaged in policy decisions throughout Europe. The permissibility of SC research fundamentally lies in the acceptance or prohibition, in the first place, of the derivation of the cells from the various sources. Secondary, but no less important, issues arise from the use of these cells. These latter issues, such as access to health benefits and patents, will not feature predominantly in this discussion; not because they do not warrant significant unpacking, but because the consequences of the cells' derivation is prior and demands immediate discussion (and which has dominated Community debates). The focus of this thesis will, therefore, be twofold; firstly, to assess the difficulties and merits of an EU policy from the scientific evidence of the envisaged promises and dangers of the cells' derivation (in the preceding chapter I argued for a 'dual track' approach to adult and ES cell research). Secondly, and for the remainder of this thesis, I will concentrate on the moral treatment of the human beings (biologically defined) involved in the derivation of ES cells.

In the first instance, there are arguments that permit the derivation of ES cells on the grounds that the therapeutic promise of the research allows one (temporarily) to bypass the moral conjecture of the intrinsic moral status of *all* human life, or that, in some cases human life does not deserve *full* moral protection. At the other end of the spectrum, there are arguments that state that the perceived benefit to society cannot allow the use of human embryos because human life, in any form, deserves full moral protection. There are many variations between these extreme positions.

Arguments that allow the circumvention of moral norms can be accused of permitting, or implicitly allowing, the atrocities that have harmed certain spheres of humanity through the inhuman exploitation of (often vulnerable) individuals, in the name of 'science' or 'progress'. Arguments that can deny individual interests, such as utilitarianism (and other *purely* consequentialist theories) do so by appealing to the interests of the community or society. Maximising aggregate 'human welfare'[4] or contending that a '...society is better off if its members are on average happier or have more of their preferences fulfilled'[5] are justifications for permitting *research* policies in which the few may suffer because the individual's worthwhile and important interests only count (equally) between all others. In the practical deployment of these arguments, it is entirely possible that an individual may be harmed for the greater 'good'. Rights, on the other hand, do not allow individuals, as right-holders, to be arbitrarily denied their status on account of community welfare. Instead each individual is treated with equal standing regardless of societal interests (see Rawls 1973 pp. 180-181).

1.2. Structure of Chapters Two and Three: The Grounding of a Moral Framework

This chapter will first address the existence of human rights, which will then be followed by the argument that human rights are actually the property of rational agents[6], and this category clearly does not include the human embryo. In Chapter Three, I will look in detail at two arguments that are committed to providing the embryo with rights and are expressed in the national policies: the 'speciesistic'[7] claim of the primary moral status of the human being, and the *potentiality* argument, that grounds rights for the embryo as a potential agent. However, both arguments either over emphasise the

---

[4] See Lyons 1984 pp. 110-11.
[5] See Dworkin 1984 p. 153.
[6] Alan Gewirth argues that an agent and a prospective purposive agent (PPA) are beings that do things voluntarily for purposes that they have chosen. A PPA is a being with the capacities required for agency with at least some disposition to exercise them (see Gewirth 1978). Unless otherwise stated, agent will refer to both 'agents' and 'PPAs' as defined by Gewirth. Kant's 'rational being with a will' is equivalent to Gewirth's 'agent' - a rational being with a will is a being that follows maxims that are its reasons for acting. Often, then, an agent is referred to as 'it', simply to make the point that there is nothing that necessarily makes it human or gendered. This does not mean that it is used as a term of mere preference (see Singer 2000 p. 190; & Beyleveld 2002 p. 458).
[7] 'Speciesism, in short, is not simply the view that two entities belonging to different species may, *as a matter of fact*, differ in moral status. It is rather the view that there are basic moral principles that involve species concepts, thereby making it the case that species membership can be morally significant in itself' (Tooley 1998 p. 7).

protection that certain forms of human life (as a species) are morally permitted, or they deny the protection to other life that may be equally, or more, deserving of protection. The consequence of this latter claim is that human individuals of a more justifiable moral status are contradictorily demoted as moral beings.

I contend that these arguments, as well as an often-misrepresented rights doctrine, fail to recognise the basis of human rights as the necessary bedrock of the individual's moral existence *within*, and not separate from, the community in which she finds herself. Rights here provide for the fulfilment of the individual's needs as an equal member of the community. Each person has the necessary and sufficient capacity to claim rights against arbitrary harms, and to impose appropriate duties on others to not interfere with her important interests. Where appropriate, she can make claims on others to assist having these rights as the means that are necessarily required for the accessibility, achievement and security of the necessary goods of agent freedom and wellbeing. The content of 'human rights' requires social rules and institutions that provide the means to implement policies to recognise the strong claims of an individual to the protection of her basic needs. These protections should be attributed equally for each individual agent within any human society, and not sacrificed on purely maximising the general happiness or aggregate welfare (see Gewirth 1978). The basis of morally sound policy is therefore to avoid harming, violating or infringing an agent's (specific) rights and to promote all agents' freedom and wellbeing equally, that will achieve the basis of security and benefits in any given society.

2. Human Rights and Morality

2.1. Why a Supreme Principle of Morality?

A supreme principle of morality derives and justifies, as a final end, general rules regarding right and wrong actions (Gewirth 1978 pp. 7-9). These rules are supported by intermediate principles which establish particular moral judgements from the grounding premise, or supreme principle. Human rights, it would seem, are an ever present and contemporary instrument for achieving right and wrong answers to conflicting moral actions within legal and policy circles (and so provide general rules). Although it is difficult to pinpoint their exact nature (grounding premise), there is apparently enough

known about them that allows one to enter into political dialogue and practical resolutions (intermediate principles). These abstract concepts, based on 'dignity' and 'human being', allegedly convey the message that rights are the means to securing *effective* protections of persons' important interests.

Unfortunately, such a simplistic (even optimistic) position on the importance of human rights is plagued by inconsistencies, and fails to help in difficult cases. In the practical application of international human rights there have been some notable failures, and this has been (for some) proof that they are an inadequate framework on which to base moral action. For example, alleged rights can be used as a cover-up for (unilateral) illegitimate action or have failed to solve a humanitarian crisis (Smith 1998; Zhen 2002).

Possible reasons for this are that a mode of action is a result of conflict within the case where there is no obvious solution based on the limited (or mis-) understanding of human rights, or they are influenced by cultural and historical subjectivism[8] (Gewirth 1978 p. 22). If the immoral act is not the result of a hidden agenda, then it may be the case that the alleged use of rights doctrine is based on flawed or biased logic. In such cases, a rationally and objectively[9] defensible position has to be found that can justify one of, or supersede, the conflicting opinions. We must therefore pin down the rational derivation of human rights and then follow the precepts to a logical conclusion.

This may result in answers that are wholly different from intuitive, accepted or established practice. The reason for this is that a subjective grounding may reside in empathy or sympathy (as well as reason), but also feelings of antagonism, aggression and elitist superiority (as well as irrationality). How do we get past the natural subjectivism of human nature? After all, we are all variable in our understanding, feelings, knowledge, culture, history, and so on (and this itself is a valuable thing). The answer must surely lie in firm guidelines that supersede the variability and detract from subjectivism, and count us all, as persons, as equal, regardless of our belief or backgrounds.

---

[8] 'Subjective' refers to discrete-feeling responses of individuals to situations real or imagined. Subjective arguments evaluate moral judgements as simply individual avowals of feeling or the expression and evocation of emotions and attitudes (see Nagel 1986).

[9] 'Objective' applies to moral judgements that can be rationally defensible, true or false, that there are rational procedural tests for identifying morally impermissible actions, or that moral values exist independently of the feeling states of individuals at particular times (see Nagel 1986). This thesis argues that the rules that follow from a moral theory require the agent to accept and conform to its prescriptions, regardless of her subjective beliefs or aims.

But what if someone's worldview is at odds with the prescriptions of the guidelines? I would summarise five possible choices which one may make[10]: (1) reject the framework (which if rationally watertight, would be irrational or contradictory to my status and capacities as an agent); (2) 'tweak' the framework so that it contains elements of the worldview (but this may force inconsistencies into the framework); (3) reject one's own beliefs (or at least the ones that conflict with the framework). If the principles that you are testing are rationally valid, then the last option may be your only choice; after all, it was a generally accepted (and literal) worldview that the Earth was flat. (4) Integrate the framework into one's own worldview; although one may have strong religious or cultural beliefs, these may be compatible with the supreme principle (for example, both religion and philosophy can argue for the supremacy of a similar formulation of the *Golden Rule*; see Singer 1988). Finally, (5) 'retest' the framework against the case, as the limits of human understanding and the gathering of all necessarily empirical knowledge is rarely sufficient – human nature is inherently prone to mistakes. In the latter case, one can never be certain of all the consequences of a given action, and therefore a decision made on the best available data may be reasonable. What is more, the 'right' answer may be restricted by constraints that are wholly out of the tester's hands. For example, everyone should have access to health care, but this is out of the question for many because of rationing. In such cases, the best outcome under the circumstances may be forced upon the tester.

This does not mean that on a day-to-day basis one cannot have subjective views. It is only where there are important decisions to be made, in this case regarding establishing a SC research framework, that one must attempt to be objective, not least to remove (unjustified) bias or blind prejudice; but also to add structure to one's worldview.

2.2. The Status of Rights in International Law

There are two leading interpretations of human rights. In legal and political arenas, they are a universally accepted method to bring the fractured world to a greater degree of unity and to combat discriminatory establishments - a Twentieth Century (and

[10] A similar point is made by Michael Boylan (1999b).

Western[11]) political aspiration rather that a statement of moral force (Waltz 2001). Some philosophers, on the other hand, have argued that human rights are a fundamental and supreme theory of social relations on which international law should be based (Gewirth 1978; & Beyleveld 1995, 1996).

Although human rights were predominately derived from, and would act towards, legal concepts, it is hard to see how they could fail to be paralleled by moral rights – after all, the legal backbone of the original complaints was perpetuated through *immoral* treatment and injustices. In turn, the authority of, for example the UN recognised documents, like the European Convention on Human Rights, is supported by monitoring bodies which attempt to maintain a states' obligations with regards to their international legal commitments. There is an underlying conviction that the mistreatment or suffering of human beings violates common morality, and that all human beings are morally obliged to do something about such treatment, individually or through political and institutional means (Henkin 1981 p. 257). The move from individual state sovereignty and responsibility for its own citizens to the interest and protection of citizens in the international arena was remarkable, not least because it would lead to outside interference in matters that affected the citizen as a category of individual that ought to be protected for their own sake[12] (Kamenka 1978 p. 9).

The initial 'lists' of rights were deeply influenced by the horrors of World War Two and the Holocaust. However, these occurrences may have been more of a catalyst to the international developments. Widespread disenfranchisement of citizens within the Empires and other countries, racial inequality and segregational policies, and the treatment of refugees were, and continue to be, called into question and declared contrary to human rights through the use of the multilateral treaty process.

International human rights conventions are intended, at least by way of avowal, to promote the message that the international community is obliged to take measures to confront human rights violations. One would be right to view such developments sceptically (i.e. the political intention behind, and use of, human rights conventions), but in terms of intention it was recognised that there is a case for implementing measures

---

[11] A further reason for the establishment of human rights as an international framework was because it was a view propounded with the greatest force by the Western Powers in punishing the atrocities of the First and Second World Wars (See Cassese 2001 p. 351). However, Waltz argues that the multi-authorship of the UDHR, for example, reflected a multicultural project of numerous actors, thus not solely a document grounded in Western philosophy (indeed, many Western countries greeted the international human rights movement with lukewarm enthusiasm) (Waltz 2001 p. 67).

that would stop states from unjustifiably putting matters of state interests over those of individual citizens (see Campbell et al. 2001). Ultimately, the aim was to declare that there was a basic standard of living that should be maintained for everyone, and that all people are born free and equal, regardless of the political status of that country. Furthermore, there had to be dedicated effort to construct a framework of specific international norms. To this end, human rights have been used as a tool against systematic and brutal regimes that are a threat to world peace and stability, or guilty of domestic violations; through them, state conduct and internal affairs can be monitored, condemned and influenced.

2.3. Medicine, Research and Human Rights

The emphasis of international human rights has been for the most part, directed by large-scale abuses of human rights. These political violations often affect medicine and the provision of health care[13], and some aspirations of ruling powers use the medical profession as a tool for systematic genocide or torture (Beyrer & Kass 2002; and this includes democratic states sanctioning *torture* in their dealings with terrorism; see Rubenstein 2003; Silove 2003; Summerfield 2003).

Within the EU, such gross atrocities are a thing of the past, and attention is directed to those continuing violations elsewhere (mainly through the auspices of the Council of Europe and the UN), and consolidating the existing Community. In the case of the latter, there has been a gradual acceptance that certain norms must exist within the context of bioethics (and again one is historically drawn back to the War atrocities[14]). There have been regulatory and legislative developments within states in

---

[12] Previously, State sovereignty insulated national events from international scrutiny on account of them being matters solely within the domestic jurisdiction (Cassese 2001 Chpt. 16; & Reisman 1990).

[13] 'The health status of populations facing political and human rights violations generally is poor and worsens as violations or inequalities (with respect to race, sex ethnic origin, or religion) increases' (Beyrer & Kass 2002 p. 247). Cassese (2001) contends that in some cases, for example in the Developing countries, there is a indifferent agenda with regards to human rights, and more concern may be towards establishing a central authority and to establish an economic basis for development (pp. 356-357).

[14] Of major importance was the development of international research ethics from the war crime trials. *The Nuremberg Code* (1947) was drawn up in the wake of the experiments carried out by the Nazi doctors. The principles of the Code were subsequently incorporated into the World Medical Association's (WMA) *Declaration of Helsinki* (1964; amended 1975; 1983; 1989; 1996 & 2000) and explicitly refers to the conduct of physicians in medical research trials. They do not generally refer to the treatment of human beings at the fringes of what is normally referred to as a *legal* 'person', and mainly

some notable areas of research, with region-wide measures not generally recognised as an imperative. Those states that have acted have separately delineated what can and cannot occur within their boundaries with regards to biotechnology. For some, however, these levels are not explicitly defined, and there is therefore a move to set out important regional human rights within bioethics in concrete conventions and Community law[15]. This has created a conflict between the interests of the state and the influence and power of the Community in the progress of medical research.

There are deep-set questions as to the necessity, interpretation and enforcement of international standards within biotechnology. International law requires states to co-operate or international agreements become ineffective. Therefore many see international law variously as unnecessary or unacceptable to attain its desired aims. States that see international law as unnecessary argue that commitments to moral standards are for the most part better dealt with by that state. Those that see universal measures as unacceptable resent the influence or intrusion of other nations. This is a paradoxical affair, as states that commit human rights violations are often unwilling to co-operate with international law, particularly since there may be unwelcome consequences for the controlling powers. States are also unwilling to recognise international law in biotechnological affairs, either because of a profound distrust in the circumstances of meddling in internal policies, or because it would limit their political actions. Such states may maintain that it is illegal for '[i]ndividual state sovereignty... [to] be overridden whenever the behaviour of the state even within its own territory threatens the existence of elementary human rights abroad and whenever the protection of the basic human rights of its citizens can be assured only from the outside' (Smith 1998 p. 77). However, Falk argues that certain acts cannot be shielded by claims of sovereignty, but neither can these claims be overridden by unauthorised uses of force delivered in an excessive and inappropriate manner (Falk 1999). Thus any intervention (forceful or otherwise) must have a just cause – that human rights are being violated by

---

deal with medical research on consenting and non-consenting persons. 'Rights' are mentioned explicitly in paragraphs 8, 21 & 22 of the Helsinki Declaration.

[15] See EU Directives: 83/570/EEC (1983) on the approximation laid down by law, regulation or administrative action relating to proprietary medicinal products; 98/44/EC (1998) on the legal protection of biotechnological inventions; 90/219/EEC (1990) on the contained use of genetically modified micro-organisms; and 2001/18/EC (2001) on the deliberate release into the environment of genetically modified organisms. These Directives are binding to the community's states. Also see the proposed Directive COD/2002/0128 on *Setting Standards of Quality and Safety for the Donation, Procurement, Testing, Processing, Storage and Distribution of Human Tissues and Cells* (this Directive will be discussed fully in Chapter Four).

an identifiable authority. Those in the latter camp look to the continuing failure of the international community to strengthen the ability of international law to deal effectively with human rights violations.

3. The Criticisms of the Doctrine of Human Rights

3.1. The Alleged Basis of Human Rights

The expression 'right' is a concept that '...in its degree of ambiguity and vagueness is hard to beat... [which has led to a] fruitless dispute about what is correctly called a "right"' (Alexy 2002 p. 120). The debate is far from new; Jeremy Bentham found himself dismayed by the fundamental grounding of the French Declaration of Rights:

> That which has no existence cannot be destroy'd: that which cannot be destroy'd can not require any thing to preserve it from being destroy'd. Natural rights is simple nonsense: natural and imprescriptible rights, rhetorical nonsense, nonsense upon stilts (Bentham 2002 p. 330).

In continuing this line of reasoning, Bentham argued that 'rights' doctrine did not, and indeed could not, cite the grounding or means of deriving the very rights they espouse.

Declarations of rights did not demonstrate what rights were, only what rights there ought to be. Bentham '...was determined to *show*, not merely to assert, that right-talk could be made intelligible if and only if it was reduced systematically to the language of positive law and its utilitarian underpinnings' (Waldron 1984 p. 2; also see Postema 1985 Chapter Five and *passim*); and '...that the only rights anyone has or could have are rights conferred by means of positive law, enacted, decreed, and enforced by some legitimate government' (Bedau 2000 p. 270)[16]. Such rights, therefore, had to have a means of expression (positive law) for them to exist.

Thus, according to Bentham, rights are a naturalistic fallacy that purports to derive certain norms or evaluations from descriptive premises about human nature[17] – but how could *human* rights be valid in the face of oppressive and inhumane practices taken for granted around the world; what could there possibly be in human nature that could

---

[16] Cf. Nelson 1976 p. 153.

derive these 'impresciptible' rights? Therefore, the ratification of the Conventions is largely a formal, and in some cases, empty, gesture.

Because 'rights' cannot, normally at least, be subordinated by the general interests, others have criticised them as antisocial – rights form claims to privacy and 'to do your own thing' that is polar to the competing ideal of community (Pennock 1981): A '...celebration of the claims that the individual might make on his own behalf, asserting his own exclusive interests' (Waldron 1984 pp. 1-2). Therefore, '[i]t is alleged that a preoccupation with rights encourages a selfish and litigious mentality – a sprit of strident and querulous concern for one's own interests and a devaluation of those wider moral considerations that are essential for the sustenance of human society' (Waldron 1988 p. 726).

Stem cell research has once again, and importantly, focused attention on the right to life of human beings. However, the self-limitation of rights to *human beings* or *rational beings* concerns those who see not all human beings, as biological entities, as equal; or that narrowing the definition of agent leaves some human beings out of the 'moral club'. If all biologically defined human beings have rights, then the embryo must also have this right. If, on the other hand, it is a value found in some capacity, then not only will the embryo fail the mark, but also will human beings at other stages of existence. And this leads to disagreement as to whether 'humanness' or agency is the base of human rights. Furthermore, such general categorisations fail to appreciate that not all human beings or human agents are equal (Nielsen 1968). People have different needs and capacities which *ought* to be morally recognised[18]. Perhaps more fundamentally is that if 'persons' do have equal rights, how does one resolve the inevitable conflicts?

Some writers are entirely unconvinced that a right necessarily entails correlative duty[19] – purveyors of this point may argue how can a dead body, which may deserve 'respect', also have rights or duties? Or, conversely, how can our duties to dead bodies derive from its natural right? (And indeed, while the international documents are implicit in the nature of the right, they are for the most part silent about any corresponding duties).

---

[17] Bentham 2002 pp. 323-326; Schofield et al. 2002 pp. 1I-1iii.
[18] But see the *social or status* differences that Bentham states should be recognised – the apprentice and his master, wife and husband, or physician and nurse (Bentham 2002 p. 325-326). Later I will argue that these are *not* differences that any moral significance can be placed upon.
[19] Or 'correspondent obligation' (Bentham 2002 p. 334)

It seems that in a number of thorny cases, the EU has so far found it impossible to reach any agreement on the definition of human rights. For this reason, the legislative bodies have now directed attention to the application of rights doctrine, according to which '[t]he conceptual battle is over, and the focus has shifted to the implementation of human rights' (Heyns & Viljoen 2002 p. 484). But this has only added to an '...unease [found] at the philosophical level... [where] there seems so little that is clear and convincing about the criteria by which we recognize [sic.] something as a right, or how we decide what to do in cases where apparent rights are in conflict' (Glover 1999 pp. 105). The answers to many of these questions, it would seem, are not to be found in the reasoning in international documents, which purport to be the grounding of the very rights they derive; such unstable grounding is question begging and according to Bentham, a fallacy (Bentham 2002 p. 320).

3.2. The Alleged Subjectivism of Human Rights

One problem is particularly levelled at international human rights – that of the subjectivity of human rights doctrine. Because the human rights doctrine became a popular force after the Second World War, the pre-modern existence of rights has been disputed, despite the accounts of the striving for human rights standards as a desirable and attainable project well before the worst Nazi atrocities were known (Waltz 2001 p 48). The detractors claim that human rights are an 'idea of our time' (Heyns & Viljoen 2002 p. 484); and have little to do with the pre-modern value that traditionally attributed superior value to the group, clan, or tribe or to a social or divine order in which the individual as such has a subordinate role (see Gewirth 1978 p. 98)[20]. One author uses the example of ancient China as a society that had a notion of 'duty' but no knowledge of 'right' (Singer 1999 p. 152) – showing the 'right – duty' correlation is a modern construction and therefore restricted to modern societies. This highlights further concerns regarding the relationship of rights *vis-à-vis* other conceptions of justice, and in relation to the capacity to implement rights objectively.

---

[20] Also see MacIntyre's criticism that claims about the possession of rights presuppose the existence of a socially established set of rules that is historically contingent, and Beyleveld's reply: in Beyleveld 1991 pp. 153-156.

It is argued that the common feature of human rights is that they are contextualised and interpreted in an ad hoc manner when considered in legal and policy discussions. Despite this, rights are still set out in legal documents and purveyed in a seeming air of overarching completeness – rights are portrayed as a 'fact of the post-Holocaust world' (Tasioulas 2002 p. 82) – even though they are ostensibly lacking in firm philosophical grounding.

This may result in idle indeterminateness in the advocacy employed by a political and social 'bandwagon' that has for some time been in vogue (Young 1978). As a consequence, Jonathan Glover points out in retrospect to Bentham: 'In parts of the world with frequent floods, houses on stilts save people's lives' (Glover 1999 p. 106).

However, while it is indeed important that individuals are protected, it should not be the given case that rights are 'part of the furniture', so that they *seem* to be the best way to go about organising a legal and political system. This proves to be unhelpful; when we are confronted with a list of rights, how does one organise them? Are some more important than others? Are there any absolute rights or are they all *prima facie*, each one subjectively deployed depending on the situation[21]?

But, the existence of rights can be traced back to pre-modern societies in one form or another - such as entitlements due to individuals through property and contracts and abstention and punishment for crimes (see Gewirth 1978 pp. 98-102). Arguably, the predominant reason for rights being held in high esteem in modern societies is due to historical events and from them, a popular demand for constitutional protections and judicial review. Their prominence in modern international relations derived from a claim made by individuals (or on behalf of those individuals) against serious wrongs perpetuated by ruling regimes.

Although many cultures[22], may have indeed only written about 'duties', it is not certain that one cannot maintain that although they believed that someone else has a duty to refrain from certain actions, that they also should have recognised, at least implicitly, that there was a correlation that the target of the duty also had a right (to be free from certain actions). 'Right' may well be used as a 'modern' term, but equally, it may have been called an 'elephant' in pre-modern cultures, and this would make no

---

[21] 'A prima-facie right is one whose claim has *prima-facie* justification, i.e. is justified, unless there are stronger counter claims in the particular situation in which it is made, the burden of proof resting always on the counter-claims' (Vlastos 1984 p. 47). Thus it is a right that an agent can always exercise, if one chooses, if no stronger moral consideration supervenes (Nielsen 1968).

difference to its content if it had the same conditional connotations -- the concept of the 'right' is historically universal, while the term may not be.

It is not difficult for any modern-day person to reason that because of her important interests, such as to be free from the threat of death or torture, that it is also in *her interests* not to be subjected to such treatment, or the threat of such treatment in the first place (and not merely a duty or agreement for someone else to refrain from such action). She could reason that because such interests are important, that she has a claim against others not to subject her to such oppression for her own sake, and for this reason any *society* should impose a duty on each individual to refrain from such action (not just that a society decides that this would be good for all). That there was a rudimentary basic right (that is claimed by that individual) not to be exposed to means of oppression would surely be recognised (perhaps not by the word 'right') by those who were the objects of such oppression; while the political structure of society would impose, for the same reasons, a duty upon its subjects to also refrain from such action. The *idea* of a 'right' was at least implicit: 'While the objects of these rights are... very general, they do not depart in principle from the contents that have been upheld for rights in many other times and places' (Gewirth 1978 p. 101).

4. How Do States Recognise their Moral Commitments?

Perhaps because of a lack of a philosophical grounding of human rights, policy decisions in international law are based on a baffling range of ideological claims regarding the primary status of human beings. The Conventions themselves are living entities, requiring interpretation and evolving through adoption, incorporation or transformation, judicial decisions in case law, policy changes and reporting, individual and state complaints and inquiries (see Heyns & Viljoen 2002). They are generally an expression of attitude (political aspiration or goal), and are appropriately seen as not fallacious entities, but something to be esteemed or to value above all else. On these grounds, it is hoped that agreement becomes possible between those states that share certain fundamental values or principles in common. This is not a watertight proposition, however, and states often do hold different values or interpretations. In

---

[22] The concept of the right may have been the same in many pre-modern cultures, but the rights they acknowledged were had by, or were distributed among, only a limited group (Gewirth 1982a p. 3).

these circumstances, one needs to reason which rights, or a form of rights, should prevail in a conflict when the protagonists come from different worldviews.

A practical means around this, but philosophically unsatisfactory, would be to carve the right in stone in an explicit law; in such cases, no one can be in any doubt as to the existence of the right. But then without further explicit meaning, states may differ in the foundational basis or interpretation. This also becomes problematic when that right calls for similarly implicit 'duties', since it is often unclear how one should exercise one's responsibilities.

So, human rights remain, in the content of the aforementioned documents, contingent upon an unsatisfactorily defined principle(s). The key international human rights documents, which are intended to be accepted widely by those with divergent interest and ideological commitments, are deliberately not forthcoming about their justificatory underpinnings (Tasioulas 2002). For example, the preamble in many conventions does not mention any philosophical basis purposely (however, some do, and this will be discussed specifically in the context of 'dignity'; *infra* s. 5.5). This fails to help in a wide range of hard cases. One only has to look at the disagreement that exists about the 'dignity' of the human being and the status of the human embryo to see that such vague concepts leave one with little concrete to go on. What remains to be shown is whether all human beings (biologically defined) have dignity and therefore rights (and therefore the embryo would have equal rights to every other human being) or whether something else exists that can explain the relationship between dignity and rights and the human condition. The indiscriminate and indeterminate application of so called human rights discredits and erodes the meaningful intentions of the rights doctrine. Furthermore, the weight that is accredited to human rights threatens to annul matters of justice and fairness that are important in our lives but are not solely matters of human rights. The term 'right' becomes indeterminate and defective (especially in borderline cases) if its justification remains vague, uncertain or contested.

The non-perceivable grounding of rights leaves their interpretation problematic as individual States attempt to express them according to their own cultural, historical and legal values (D'Oronzio 2001). The critics argue '...whether such rights are so indispensable for the achievement of an adequate conceptual framework for morality that such flaws must be overlooked' (ibid. p. 63).

We therefore see the practical deployment of rights, which controversially derives from an alleged moral justification. This justification is used in the upholding of

peoples' rights – the use of unilateral action to remove a cruel dictator from power through the use of force and terror is a radical measure, often itself necessarily leading to brutal and destructive measures to life and property. In the more 'grey' areas between the unequivocal promotion of the peoples' popular will through internationally supervised, observed and validated elections and those of atrocities that warrant humanitarian action, are situations where international action to promote human rights are either unnecessary, unwarranted or aimed at enforcing itself as an external will. In such actions, the concept of the human right is used as a façade for some other (perhaps) illegitimate action (Capps 2001).

The evolution of human rights into wide international political acceptance may be criticised as nothing short of cultural imperialism, especially if it has a detrimental effect on their capacity to sustain their valued ways of life – a force pressuring other societies to the point of disintegration (Tasioulas 2002); and sweeping cultural values under the carpet (Cassese 2001 p. 39).

Some cultures do not accord the same significance to human rights, perhaps attaching greater importance to living harmoniously with others (including other species); creating balance and harmony that transcends the individual, creating duties and obligations to society and other off-world forces; or cultivating refined aesthetic and religious sensibilities (Tasioulas 2002; & Kamenka 1978). Social systems, some writers contend, would work as well as or better than so called 'international human rights', if they were based on consequential, relativist or principled approaches; but then these are rejected in their own ways for being in various ways over-ambitious, simplistic, or subjective. While one may be able to resist criticisms of alternative theories (on there own merit), a grounding of human rights requires why it is rational to assert, and to supply the tools to work out, that *x*, rather *y* is the right thing to do in the context of an individual's rights within the society in which she resides.

So it is by no means convincing that the instruments of international law which are not works of philosophical arguments, nor commitments to particular theories of human rights should gain '...widespread acceptance throughout the globe – at least by way of avowal – to be explained as the upshot of people becoming convinced of its congruence with any such theory' (Tasioulas 2002 p. 80). There are no clear foundations of any philosophical assumptions, either for the human rights that are being recognised or the human rights system which has been established, but then, through this, we have the basis for at least meeting at the political table.

Regardless, '...[t]hose of us who support Amnesty International's work can hardly avoid the shorthand phrase: of course we support human rights. But some of us do so with the uneasy hope that the ground on which the stilts rest may be firmer than it looks' (Glover 1999 pp. 105-106). Moreover, '[i]t is frequently argued that defining, developing, and applying intentional human rights standards are ultimately "political ends", and that the question of which values are to be excluded from or included in the so-called "emerging global moral culture" of the post-Cold War era is a purely *political* one' (Monshipouri & Welch 2001 p. 370).

It is clear from the episodes of the past that the human being had a 'right' not to be subjected to certain wrongs regardless of any other goals. Most notably, acts of torture, genocide, and gross degrading and inhumane treatment were occurrences that could not be sufficiently banished and condoned by purely utilitarian or other consequentialist lines of reasoning. The positive attitude to human rights, at the very least, promotes the ideal that all human beings, regardless of the supposed 'interest' of the community, have *rights* to life, respect, and to decent treatment. The struggle to maintain the importance of rights is in part to convince those who are sceptical, or more seriously, guilty of violations, that a sound basis can be found for the primary justification of human rights. But it is also hampered by the continuing acts of cruelty and aggression that some direct towards members of the human race. It would seem that for some the lessons from the past have been disregarded, ignored or simply, and regrettably, forgotten – it is the continuing acts of barbarity and cruelty that make the active promotion of human rights as important today as they ever were before:

> During political crisis, human rights are usually the first victim. Under the pretext of national interests, defending the country from its own enemies or the "fifth column", waging war against the enemies of the state, or preserving the national unity, governments usually claim that their human rights violations are legitimate and justifiable ...allegations of human rights violations [are rejected] as mere interferences in internal affairs or their "specific" values (Alnajjar 2001 p. 188).

5. Moral Rights and Duties

5.1. The Definition of a Moral Right

Clearly, the definition of the right, and the framework that follows from this will have important implications for the rights of the embryo and the moral grounding for stem cell research. The applicability of any framework *in this context* will depend entirely on the status of the human embryo as a particular entity that is *used* in this research. It will then be a case of drawing out the commitments of the agent in relation to these entities within moral society, and the corresponding moral rules that institutions must operate under this relationship. Thus institutional policies will be limited to what emerges from this approach (with regards to the two type of *things* that the agent and embryo are).

A moral right is commonly explained as being some sort of claim which ought to be recognised. All rights assert a 'claim'[23], but different types of right make different claims which are established by the nature of that right and the circumstances of its deployment[24]. Wesley N. Hohfeld distinguished four different meanings of a 'right' - claims[25], liberties[26], powers[27] and immunities[28] (Hohfeld 1966).

I will be dealing exclusively with claim rights – rights that entail correlative necessary duties to forbear from interfering with persons' having the objects of their rights or, in some situations, to help persons to have these objects. Claim-rights are the most important kind of right because they protect a person's possessing, retaining and

---

[23] See Flathman (1976) p. 35-38, who argues that the term 'right' not only has many meanings and connotations in the legal and moral conception, but also in entirely unrelated fields.

[24] For example, a legal right may exist as a consequence of a contract that empowers someone to make a claim against signatories. A right to position enables an individual to make a claim on other to recognise that position and any corresponding powers and immunities.

[25] Sometimes called 'strong' rights (Beyleveld & Brownsword 2001 p. 71). Liberties, powers and immunities conversely are referred to as 'weak' rights, because they require a 'special' relationship to be *created* by law or contract, and actively *preserved* by promises, contracts etc. (McClosky 1965).

[26] A liberty is to be able to '...engage in a certain action [that] is ...free from any duty to eschew the action; likewise, to have a liberty [is to] abstain from a certain action [that] is ...free from any duty to undertake the action' (Kramer 1998 p. 10). Liberties entail no obligations, positive or negative, on the part of other persons (Gewirth 1978 p. 67).

[27] 'Someone who holds a power can expand or reduce or otherwise modify, in particular ways, his own entitlements or the entitlements held by other person(s)' (Kramer 1998 p. 20). For example: '...only the President can sign bills into law. This does not mean that I couldn't move my hand to write my name, but only that my signature would not have the legal effect which Mr. Nixon's signature had' (Nelson 1976 p. 153).

[28] 'The holder of an immunity is not exposed to the exercise of a power by someone, with respect to any entitlements covered by the immunity' (Kramer 1998 p. 21).

being helped to having access to the basic[29], nonsubtractive[30] and additive[31] goods. Furthermore, these rights are owed to that individual for their own sakes, and not on any cultural, historical or societal whim (or legal, or otherwise, contract). This right does not require to be established by any legal framework[32] or cultural or historical recognition, rank or status; or held against any one in particular (although in fact there will be someone or institution that has harmed the person's interests). The defining property of claim rights that they are held by *all* members of the moral community to the *fullest* and most *equal* extent, and regardless of any non-moral value or desire. They are not held to any *degree*. So that if one has the capacities for the having of rights, then she has those rights as fully as the next person (should two people have the same need for that right). The having of a right depends upon the agent's (non-generic) *needs* which can differ between different people (although the generic content of agency remains the same between all agents).

Claim rights are distinguished by their legal and moral deployment from other 'rights'. I will be dealing primarily with their moral importance (as opposed to the jurisprudential relationship of morality and law). The moral right is one which is a question of why persons have rights in isolation and independent from any given social, political or legal system (what Alexy called the 'ethical question') (Alexy 2002).

Gewirth states that moral requirements are categorically binding in the sense that:

> ...compliance with them is mandatory for the conduct of every person to whom they are addressed regardless of whether he wants to accept them or their results, and regardless also of the requirements of any other institutions such as law or etiquette, whose obligatoriness may itself be doubtful or variable... although one moral requirement may be overridden by another, it may not be overridden by any nonmoral requirement, nor can its normative bindingness be escaped by shifting one's indications, opinions, or ideals (Gewirth 1978 p. 1).

Therefore:

---

[29] Basic goods are the things that are the most important for the general and proximate success of any of her actions. If she is denied these goods then she cannot act at all (or has a low chance of success) (see Gewirth 1978 pp. 53-55).

[30] Required for an (already achieved) level of purpose-fulfilment, that if lowered will deny her present interests (ibid.).

[31] Those goods that will raise her level of purpose-fulfilment or ability to achieve her interests (ibid.).

[32] Moral rights may require a system of recognition because all to often the correlative duties require enforcement or implementation, although they exist prior to any legal, or any other, foil. Furthermore, they are not mere 'aspirations' to be recognised by law. Therefore, if international human rights documents assert that they are documents of *moral* rights, then they are binding on agent actions regardless of legal implementation (see Beyleveld 1995; cf. Gewirth 1999; McClosky 1965; *infra* fn. 80).

> In their strongest sense, rights are justified claims to the protection of persons' important interests. When the rights are effective, this protection is provided as something that is owed to a person for their own sakes (Gewirth 1995 p. 776).

Thus, a '...right is a claim that it would be wrong... to deny to individuals even though it would be in the general interest to do so' (Dworkin 1978 p. 269). To this one can add that to '...claim that one has rights is to make an assertion that one has them, and to make it in such a manner as to demand or insist that they be recognised' (Feinberg 1980 p. 150). Importantly, this 'claim' may be implicit, in that to have a right, one does not necessarily *have to actively claim one has it*; for if one has the necessary and sufficient capacities to have a right, then one has that right regardless of their willingness or any other capacities that they have or lack. Only the necessary and sufficient conditions for having a right bestow a right, and any other conditions are irrelevant.

Thus, claim rights are already (and always, unless waived) held by all those who have them (all agents), and they can be claimed when one wishes to express them to protect her interests or to avoid violations that may undermine them. They may never be claimed by an individual, but this does not mean that she does not have them. Likewise, she may not have the *physical* ability to express them; all that is required is the mental ability to appreciate their value to herself and envisage that there may be situations when it is necessary to make such a claim. Therefore:

> To claim that one has rights is to make an assertion that one has them, and to make it in such a manner as to demand or insist that they be recognized [sic.] ...Having rights, of course, makes claiming possible; but it is claiming that gives rights their special moral significance (Feinberg 1980 p. 150-151).

Importantly, this claim to what one is due for the sole reason of having interests in the goods that require such protection, can be relinquished or waived (since the right-holder necessarily autonomous), on the understanding that the agent knows that she has the right and has decided to use it otherwise. In this way, the agent can make sacrifices for the sake of others, voluntarily give up what is rightfully her own, or freely make a gift that one is not obliged to make. However, this autonomous use of the right does not affect the possession of it. Should I choose to waive my rights, then I no longer have them until I decide, or am in a position to decide, that I no longer want to waiver them. (Of course, I may no longer be in a position to express that right if the initial waiver damaged my ability to have later rights; this is why rights can only be autonomously waived).

Finally, there are two main theories behind the claiming of a right. This is either based on the subject of the right being in a position to *benefit*[33] directly from the intended action of someone else, who is in a position to perform a good-providing duty; or that the subject is in a justified position to determine by one's *choice*[34] how another person shall act. The 'benefit' and 'choice' theories are often pitted against one another, although there is probably a case to be put forward of a middle way between the two; that a person in a vulnerable position will *benefit* from the good action of another (to either secure or remove the threat to that right) and that the person under threat can *choose* whether to, or how to, secure that benefit.

5.2. Features of Claim Rights

I will be utilising the *direct*[35] application of claim rights. That is, 'actions' that directly relate to agent-agent interactions. In this case judgements are imposed on the individual actions of individual agents (so the effects on agents that have a right to be *morally* protected from someone else's actions, or to secure their help or assistance when they withhold access to such rights)[36]. Claim rights are held individually by all agents within social groups, and therefore will be influenced by the actions of the group (Hohfeld argued that such rights were '*in rem*' in that there exists an indefinite number of [legal as equivalent to moral] relations; 1966 p. 67) and of other agents (in the words of Hohfeld - '*in personam*' – or in limited and known relations; ibid.).

The general structure of a right claim is given by the following:

A has a right to *X* against *B* by virtue of *Y*.

---

[33] 'Benefit' or 'Interest' theory states that an individual has a right when some one else has a duty to perform or omit an act that is in the right holder's interests (or will benefit). This is not a general benefit, so that a great number of right holder will benefit from an act, but must be proximate and intimately related to the rights of the bearer; making the right a benefit to the most important interests of the right holder (Waldron 1984 p. 9-12).

[34] 'Choice Theory' singles out the right-bearer in virtue of the power that she has over the duty in question. So in this case the duty-respondent can be required or discharged from her duty (Waldron 1984 p. 9-12).

[35] This is as opposed to *indirect* applications of claim rights, which are the moral guides placed on social rules and institutions.

[36] Thus reasons to *fulfil* and not *infringe* (or violate when this is unjustified) certain rights by carrying out the correlative duty (i.e. the required action is performed [positive] or refrained from [negative]). Furthermore, it will give one conditions when it is possible to justifiably *override* certain *prima facie* rights.

The five main elements are firstly, *A*, the subject of the right or the right holder; secondly, the object of that right, *X*; thirdly, the respondent of the right, or duty bearer, *B*; and fourthly, the justifying ground of the right, *Y*. The fifth element is the *nature* of the right, which encompasses the needfulness of that right and therefore its *prima facie* importance in the 'hierarchy' of rights within the moral framework, and the means that *A* must employ using if she is to have or protect *X*. However, there are clearly literal and subjective questions of the nature of that *right*.

For example, does this hold in all circumstances? Or is it a *prima facie* right, and therefore '...the claims of any one of them may be overruled is special circumstances... [it is] considerations of justice which allow us to make exceptions to a natural right... but the same considerations require us to uphold it in general' (Vlastos 1962 pp. 38-39).

5.3. Duties

Hohfeld argued that any right would also have a correlative (Hohfeld 1966 pp. 5; 35-37; Kramer 1998), in the case of the claim right, this was a corresponding *duty* placed upon those influencing the holding and expression of an individual's right (from the viewpoint of *X*'s rights with regards to *B* duties [this relationship can of course be reversed with regards to *B*'s rights). But here we have two major difficulties, which can be seen with regards to the *human rights conventions*: firstly, are duties as specific as 'Commandments', or are they a reasonable expectation that a *dutiful* action should or should not be done within the international community (therefore, what is the force of a duty)? Secondly, there seems to be no systematic attempt to draw out the details of the complex relationships between rights and duties (therefore, what international commitments, as duties, are expressed by any correlatively?) (Waldron 1984 p. 2).

I will start with the assumption that: '[m]any have held that one person's right is correlative with, is the necessary or sufficient ground of, or is the other side of the same coin as, another person's duty' (White 1984 pp. 59-60). This is sometimes called the 'Doctrine of the Logical Correlativity of Rights and Duties' (Feinberg 1980) or 'Correlativity Axiom' (Kramer 1998 p. 24). So that all duties entail other person's rights and that all rights entail other person's duties; or, as Kramer describes the axiom, '...each is the other from a different perspective, in much the same way that an upward slope viewed from below is a downward slope viewed from above' (ibid. 1998 p. 24).

It seems undeniable that one does entail the other. However, although the rights–duties correlative is indeed a 'bedrock axiom', it must be understood in two important ways. Firstly, one can talk of 'rights' and 'duties' without referring to what Hohfeld called a 'right' or 'duty' (Hohfeld 1966; see below). Secondly, one can put different importance on one's perspective of Kramer's 'slope'.

White maintains that:

> A doctor has certain duties to his patients …which do not give them any rights, however "extra-regarding" these duties may be, as when a doctor dutifully does not indulge the patient's desire for drugs …If we have duties to the dead, for example to tend their graves or not to slander their memory, it does not follow that they have the corresponding right (White 1984 p. 62).

Thus, it is alleged that the existence of a right as a necessary and sufficient condition for the existence of a duty, and vice versa, may lead to problems. Clearly, any claim of a 'right' entails a correlative duty against someone, and likewise, any duty also derives a corresponding right. But we are faced with the problem whereby 'duties' may entail ridiculous or non-moral (but undeniable) 'rights'.

This, however, misses the point of the derivation of specific moral rights. Kramer argues that while there indeed is not a 'right' for the patient to be indulged whenever she makes a request, a patient does have a right to be treated as skilfully and correctly as the doctor can manage (Kramer 1998 p. 30). This second *right* demands that the doctor has a duty to care for his patients and in accordance with professional standards. In White's example, the 'no-right' is a non-substantiated demand on the part of the patient. There is no right, and therefore there is no alleged duty. Likewise, one can locate numerous classes of 'duty' that are not logically correlated with the *moral* rights of persons[37].

White's argument rests on the assumption that we have duties to the dead (and additionally animals and to infants; White 1984 p. 31). But this clearly depends on the content and nature of 'duty'. Furthermore, they can only have 'rights' if the derivation of them is not restricted to any property that dead people, animals and infants lack. If they are held by human beings, then infants may have rights, but animals on such grounding cannot. However, if rights are dependent upon rational agency, then possibly both children and certain animals may have them, and the dead would not.

---

[37] There may be a legal duty for you to do or not do something that is imposed by a legal authority, which

Instead, it may be that the duties to dead persons may actually be duties to the dead person's relatives (and they may have rights) or a duty that is created by a desire to live in a world where dead people are treated out of respect for previous wishes; or avoidance of harm to *living* persons. Thus, the 'duty' and 'right' that White refers to are not the same rights and duties that one normally talks of in moral interactions (Kramer 1998 p. 31). We may have duties to dead people (for whatever reason), but on this understanding, we are not forced to accept that the dead *have moral (claim) rights*[38].

In summary, the claim rights-duties framework justifies protection for the vital interests of individual right holders. In this case, duties are not especially significant or commendable in themselves; the duties imposed by the framework are significant and desirable only because they are necessary for the protection of the vital interests that are of real concern. They are value only instrumentally, and not intrinsically. An agent isolated on an island may prudentially derive rights for herself because she can envisage a situation where her rights may be infringed; where there are *actual* duties directed at *actual* persons. It is only when she returns to society that the same rights she had on the island may demand duties from non-interference.

5.4. Reason and Rights

Rights are social and originate from a claim by an individual or a group against another individual, group or institution, and they indicate:

> ...categorically obligatory... requirements for action that are addressed at least in part to all actual or prospective agents and that are concerned with furthering the interests, especially the most important interest, of persons or recipients other than or in addition to the agent or speaker (Gewirth 1982a p. 1).

When a right is violated (or interests are not protected) the claimant (ideally) can make a complaint in response to someone else or institution failing in their duty - *rights are therefore only those which can be claimed by agents*. This puts an immediate

---

requires certain actions or omissions thereof, under pain of penalty (Feinberg 1980 p. 144).

[38] If moral rights are a claim by an individual to have the necessary goods that support the attainment and maintenance of interests, then dead bodies can have no right - dead persons have no interests in this manner. Kramer argues further that '[t]o say that dead people have rights, then, is simply to say that they are entitled to the states of affairs which our duties to them require... in ordinary discourse, we do not hesitate to speak of the "claims" which the dead have on the living' (Kramer 1998 p. 32). In the cases of

restriction on who can have moral rights[39] to those who have a degree of rationality. Agency is therefore not a capacity inherent in all human beings, and that there can be no '...*morally* relevant attribute that is so equally distributed among all human beings that it can serve as the basis of an egalitarian moral principle'[40] (my emphasis; Gewirth 1982b p. 667). The relevant, morally neutral, capacity that grounds rights for agents is an ability to act purposively, which necessarily correlates to the ability to make claims[41]. The claim therefore requires an ability to reason on the basis of 'performing' some kind of activity (necessarily and sufficiently mental, but not physical)[42].

Therefore, the *rational nature of agency* is central to the actual claiming rights (and the realisation of the importance of such rights to that agent), and that through *purposeful actions*[43] (rational behaviour), at least acknowledge the duties placed upon it. Importantly, there are certain biological and metaphysical differences between agents and non-/marginal agents (entities, as we shall see, that lack any/full features of agency; the particular case of the potential agent to be discussed in Chapter Three). This can be summarised by acknowledging the explicit difference between: (1) rational behaviour (based on consciousness and reasoned action in acting for purposes one has chosen[44]; Beyleveld 1991 p. 66; Harris 1985 pp. 197-198; Hollis 1977 pp. 124-125; Gewirth 1978

---

infants and animals, there is great debate as to their ability to 'claim' a right to something. This is a subject of Chapter Three.

[39] This restriction is what Ben-Zeev called a 'status-attribute' – moral status is '...gained by the fulfilment (usually passive) of certain necessary and sufficient conditions. The fulfilment of these conditions is not a matter of degree; one either fulfils them or does not. Hence there are no degrees of membership having such status' (1982 p. 648).

[40] At least one that is not biologically, historically or culturally biased.

[41] However, rights may be held even when they are not claimed, and claims are also not in general sufficient to establish or justify that there objects are rights (see Gewirth 1982a pp. 46-47).

[42]Hobbes maintains that the *rational* act is correlative with the capacities of agency, and agency is a mental capacity: 'There be in Animals. Two sorts of *Motions* particular to them: One called *Vital*; begun in generation, and continued without interruption through their whole life ...to which Motions there needs no help of Imagination: The other is *Animall motion*, otherwise called *Voluntary motion*; as to *go*, to *speak*, to *move* any of our limbes, in such a manner as is first fancied in our minds. ...it is evident, that the Imagination is the first internal beginning of all Voluntary motion' (Hobbes 1985 Part I, chapter 6 [paragraph 1, p. 118]; cf. Locke 1975 & 1988; Aristotle 1998 III.I 111a13 pp. 51-52; Velleman 1992 p. 461).

[43] Having a right does not necessarily correlate with *acting rightly* (Wasserstrom 1964 p. 630).

[44] The significant difference between agent rational purposive behaviour and that which is purposive *simplicter* may be made by the distinction between purposive action that is (a) *information based but unreflective* and that that which is (b) *done for reasons* (Butterfill 2001). Type (b) behaviour can be distinguished from (a) based actions, because to act for purposes in the sense of (a) requires relatively little cognitive ability ('To act purposively is just to fit your actions to a purpose in whatever way you can... [there are no signs] of being able to reflect on reasons' (Butterfill 2001 p 143)). However, type (b) actions rests on the observation that '...the agent is in a position to care about the rationality of his actions, and not just about whether they fulfil his purposes' (Butterfill 2001 p. 141). Agents will often act without reflection, and such behaviour is often habitual (information-based but unreflective) or not act at all, but this does not mean that the agent is capable of purposeful action (Hollis 1977 pp. 124-125; see Held 1999).

p. xi & 41-59); (2) conscious and conative behaviour (Pluhar 1995 pp. 249-250); (3) non-rational/instinctive behaviour (Heyes 1998; Williams 1978 p. 284); and (4) no-action (or inability to act) (*infra* fn. 42). These states must be inferred from behavioural/observational studies (Heyes 1998; Ridge 2001).

On this basis, there are important differences with regards to status between the human agent and the human embryo, which culminates in practical and instrumental rationality in the former[45], and which is beyond a mere capacity for sentience (see Bentham 1996 Chapt. XVII para 4; footnote; & Singer 1995).

5.5. Dignity

5.5.1. Dignity and International Human Rights

Regardless of what I have argued regarding moral rights as synonymous with claim rights (in human rights conventions specific to *human agents*), the closest any international agreements have come to a grounding of rights is in 'dignity', and therefore:

> 'Human rights - rights that a person has, not in virtue of any special status or relation to others, but simply in virtue of being human – are grounded in our *status* as human beings, in particular, the *dignity* that attaches to humans simply in virtue of their humanity' (Tasioulas 2002 p. 82).

In the international conventions, dignity is used as the lowest common denominator as regards to the conception between the State and individual and of basic human rights; and accordingly, '...human dignity is the infrastructure on which the modern superstructure of human rights is constructed' (Beyleveld & Brownsword 2001 p. 210). In such a culturally and politically pluralistic world, 'dignity' was a concept that successfully united the Nations together for one common goal (Cassese 2001 p. 358).

The basis for dignity in international law is deliberate. The very concept of rights that these documents are utilising is based on a particular reference to *all human beings*, that functions to perpetuate a policy that demonstrates a concern for the vulnerability of humanity, and protects those that may require protection (and this must include compromised human beings [through mental and ill health etc.], children and the like).

This necessarily corresponds to human beings, and not 'agency', since some human beings are not 'agents', but regardless (and sometimes allegedly) require some form of protection. The particular framework that has developed in the wake of the 'scientific revolution' (originating in the Nazi experiments) is intended to ensure that it is not in the form that could provide a basis for the wrongful or unjust treatment of *human beings* per se, and including those from different cultural, historical and religious backgrounds[46].

However, 'dignity' is a notoriously vague concept, but an oft quoted and relied upon concept when the treatment of human beings is in question. Its present resurgence is partly due to the perceived threat that certain developments in biotechnology pose[47]. But also, its importance as an indisputable value of those human beings that are at the margins of 'personhood' is a common 'conversation stopper' to '...prevent a slide into the relativity of moral pluralism' (Campbell 2000 p. 103)[48].

In international documents, dignity is referred to being inherent in the nature of human beings. However, what has come out of this grounding is uncertainty as to whether *human beings* have rights simply in virtue of having dignity (intrinsic value), or that they have rights because they are necessary to maintain or protect their dignity (instrumental value). The sentiment implicated by 'dignity' is that it is not an insignificant means of protecting human beings that are particularly vulnerable to human rights abuses, and this is an important force in driving forward policies that protect and promote equality within the community.

How should we interpret dignity in these conventions? Should we assume that dignity, as the basis of human rights, either acknowledges each individual as a human being (so indeed encompassing all human beings), or narrowly as only relating to agents (possessing some universal capacity)? If one interprets dignity as a property found in the biological human species, then such documents are open to the charge of

---

[45] For key readings see: Heyes 1998; Hollis 1977; Pluhar 1995; Ridge 2001; Searle 2002; & Zeman 2001.
[46] While the Nazi experiments were '...an aberration in their unparalleled fiendish intensity ...they are also an integral chapter in the [continuing] history of thoughtless, ubiquitous, albeit milder and therefore, barely recognizable [sic.] abuse of human beings for the sake of medical sciences' (Katz 1992 p. 234).
[47] This is not surprising, nor entirely unfounded, in light of the atrocities of the Twentieth Century that were committed in the name of science (see the particularly notorious accounts of the Nazi experiments in Caplan 1992). Gross scientific misconduct was not limited to the Nazi movement; for example see Reverby 2000; and on general human experimentation, see Katz 1992).
[48] '...the notion of dignity plays a very dubious role in contemporary bioethical discourse. It is a slippery and inherently speciesist notion, it has a tendency to stifle argument and debate and encourages the drawing of moral boundaries in the wrong places' (Kuhse 2000 p. 74).

'speciesism' and an arbitrary and unconvincing basis (In Chapter Four I will show that 'dignity' in this sense has not been taken up by the interpretation of the certain courts).

5.5.2. Human Rights, Dignity and Bioethics

Bioethics has brought about a reassertion of the importance of respecting human dignity[49]. In this context, actions are deemed to be contrary to human rights because they call into question (or even harm) the inherent dignity of the human being. In this sense, the bioscientific revolution creates an unprecedented threat to dignity because it jeopardises the perceived integrity of humanity[50]. This may be a fear of the unknown, but possibly is more likely a fear that what changes we make now may influence present, as well as future, generations. Therefore, biotechnological developments must build upon and improve humanity, not fundamentally change nor ultimately destroy the nature of humanity; anything that interferes with this is a violation of the 'natural' moral order of things (Beyleveld & Brownsword 2001 p. 164-165). Thus we have seen the emergence of a 'Dignitarian Alliance' (Brownsword 2003).

Dignity may therefore be seen in two senses. Firstly, as an appeal to preserving what is 'good' in human nature. It does not call for the prevention of acts that may alter the way in which human beings do things, but that developments contribute to the way in which we do things – helping those who cannot achieve legitimate human goals to reach them (e.g. IVF)[51]; help those who are deprived of human capacities to retain, maintain, or recapture them (medicine); or to provide innovative ways for humans to raise the level to what they can attain. But, dignity requires such innovations not to alter our capacities beyond what is seen as particularly 'human'. Dignity is not offended, on this account, because any right has been compromised, or that benefit is outweighed by harms in the final calculation, but because it offends what it is to be 'human' – that all human beings have dignity by no other virtue than being human; and

---

[49] Dignity is explicitly mentioned in the ECHR; the ECHRB; UNESCO's *Universal Declaration of Human Rights and the Human Genome* 1998; and the CFREU.

[50] Lord Alton stated: 'One does not have to believe in the sanctity of human life, or that life begins at fertilisation, to be concerned about the general commodification of life. Every generation is tempted by the seductive and tantalising prospect of universal happiness as a trump over all other values and principles, but human dignity must always be defended against the abuses of scientific techniques' (House of Lords Hansard; January 22, 2001, Col. 28).

[51] It is perhaps surprising that IVF, as a result of embryo research and 'unnatural' conception, is generally accepted, and not associated as being contrary to human dignity.

because of this, certain acts should be constrained as they may harm this core value (Brownsword 2003).

Of course, much of the endeavours of human kind have been against the tide of the 'natural'. If this is nature in the sense of a Darwinian evolution then there is nothing of note to go on, not least because evolution is pressed forward by (sometimes extreme) variation in the nature of things (Dawkins 1998). If 'unnatural' is associated with the 'yuck factor', then this simply does not offer enough incentive rationally to reject unprecedented human interventions. We have been interfering with human evolution ever since we set up social and economic machinery to support, for example, individuals who could not otherwise reproduce.

Labelling something as 'unnatural', and so contrary to 'dignity', may be used as a stop warning about doing something that may have disastrous consequences for human society (Campbell 2000). Perhaps prophesising the future consequences is warranted in prohibiting some endeavours, but this amounts to doing nothing when there is a perceived risk when the goals are ultimately good; many developments have been fraught with risk (development of flight, x-rays, pharmacological intervention), but this should not be interpreted as a resounding 'no' to their (possibly beneficial) pursuance.

So if dignity is not the value implicit in preserving the status quo of humanity, then perhaps we would have more success in a second definition of dignity, as a value that does not stop human endeavour, but reminds us that all human beings have an intrinsic value (expressed as human rights) that is synonymous with their inherent and common heritage of humanity. The problem is that these inalienable[52] and fundamental[53] rights attempt to hold that all 'human beings'[54] have them equally[55] - there is an implicit relationship between 'human beings' and 'human dignity' (Kuhse 2000 p. 61). The justification for this is that all human beings are considered to be 'human beings' (biologically defined) in possession of 'human rights' that derive from a value of 'dignity'. This is most evident in the protection of the human embryo since its

---

[52] '...inherent dignity and of the equal and inalienable rights of all members of the human family...' (UNDHR 1948 *Preamble*).

[53] The '...United Nations have in the Charter reaffirmed their faith in fundamental human rights' (UNDHR 1948 Preamble); and the Council of Europe affirm '...such measures as are necessary to safeguard human dignity and the fundamental rights [in the Convention]' (ECHRB 1997 Preamble).

[54] The term human being is particularly unclear in this usage. The ECHRB decides to '...construe the expression [human being] broadly, covering both connotation of individuality and that of membership of the human race' (Explanatory Report to the ECHRB (draft) (1994) Council of Europe; DIR/JUR (94) 2 Strasbourg, p. 15).

[55] The *Explanatory Report for the ECHRB* (draft) states: '[i]t was nevertheless acknowledged that it was a generally accepted principle that human dignity had to be respected as soon as life began' (ibid. p. 15).

value must rely (in this case) on the explicit and unique human identity as a member of the human species.

This has been difficult to demonstrate philosophically, and in practice to uphold. Indeed, this may have been a contributing factor to why human rights as popular moral protections, have been ineffectual in certain circumstances. There are times when individuals require more or less of a certain right according to specific needs and circumstances. Likewise, there are numerous incidents when a 'human being', biologically defined, does not have or has more of the *same* rights as another biological human being. This latter claim is manifestly incompatible with a belief in the absolute universal human rights of all members of the human species.

One means of evading these criticisms is to defend a position that there are only *prima facie* rights. Thus, all human beings have all *prima facie* rights which can only be over-ruled in *specific circumstances*. In this weaker form, rights serve as an instrumental means to securing equal treatment of human beings. The difficulty with this defence is in the fact that such a position is subjective - conflicts will inevitably arise; and if this is based on equal standing of all human beings, what is the quality of all (some) human beings, and how is this objectively assessed so that it can be resolutely employed?

The answer lies in the metaphysical explanations that demonstrate that not all *biological human beings* are equal. It is not the fact that all human beings have the same values (because they do not), but the same capacities that some human beings have that makes them similar. Consequently, there are human beings that may not have rights, not because they have different values, but because they have different capacities.

5.5.3. Kant and Dignity

Immanuel Kant believed that it was only human beings, *as ends in themselves*, which could be subject to, and were capable of following, moral law (and so guide its actions by maxims).· Therefore, '...the sole condition under which anything can be an end in itself has not merely a relative value – that is, a price – but has intrinsic value – that is, *dignity*' (Kant 1948 p. 96). Thus it is argued that Kant was explicit in stressing the dignity of all human beings by stating, for example, that '...morality, and humanity

so far as it is capable of morality, is the only thing which has dignity' (Kant 1948 pp. 96-97)[56]. Kant also states that:

> Every human being has a legitimate claim to respect from his fellow human beings and is *in turn* bound to respect every other. Humanity itself is a dignity; for a human being cannot be used merely as a means by any human being... but must always be used at the same time as an end. It is just in this that his dignity (personality) consists, by which he raises himself above all other beings in the world that are not human beings and yet can be used, and so over all *things* (Kant 1998 p. 209).

This line on dignity may warrant us to consider that human dignity can be violated even though the transgressed actually experiences no reduction in their dignity[57]. This may require due respect to entities, that although they cannot express their own dignity, as human beings may require others capable of action to accordingly take steps (their duties) towards the protection and promotion of that being's 'rights'. This understanding of Kant has also led some to argue that:

> [e]very living human being shares the inalienable and indisputable value of human dignity due to his or her belief regulated by reason, in short, rationalism ...this [is a] unique property among the entire range of living beings on earth [and therefore] human beings ought always to be treated as ends in themselves and never as mere means towards an end (Oduncu 2003 p. 12)[58].

However, this fails to notice that not every human being is rational (e.g. embryos). Furthermore, there are beings that exist on the earth that are more rational than some human beings (*infra* Chapter Three s. 7.4). But that is not a concern for the 'Dignitarian Alliance', since they are intending to claim that dignity does not rest on any basis of rational agency, but unequivocally on membership to the *human species* and the ability for them to *become human agents* (and this requires a further step regarding *potential agency* discussed in Chapter Three).

Thus, Kant's *Formula of the End in Itself*: 'Act in such a way that you always treat humanity, whether your own person or the person of any other, never simply as a means, but always at the same time as an end' (Kant 1948 p. 91) – is a typical appeal to

---

[56] Gewirth may be similarly misunderstood, because he states that: '...it is because all human beings have dignity that the needs of their agency are eminently worth fulfilling; hence, it is human dignity that provides the ultimate basis of human rights' (Gewirth 1998 p. 160). However, later Gewirth states that such dignity must be viewed in this sense that it is '...*consequent upon* the having of rights and hence is not the *ground* of rights' (ibid. p. 162).

[57] I.e. an embryo cannot experience any loss in 'dignity', but other agents, as rational human beings, can recognise such transgressions themselves when such human beings are treated contrary to 'dignity'. Dignity, in this sense, is a duty led value – that rational humanity has a duty as a whole to respect each other human being because of intrinsic worth (also see Kant: '...we have duties to others, not only as human beings, but also as fellow citizens, and civic duties arise there' (1997 p. 217)).

[58] Cf. Donagan 1982 pp. 664-665; & 1977 pp. 170-171.

dignity and the protection of vulnerable human beings[59]. In this mode, Kahn states that: '...the principle expressed by Immanuel Kant: that of human dignity ...demands that an individual – and I would extend that to read human life – should never be thought of as a means, but always as an end' (Kahn 1997 p. 119).

Kant does relate human dignity to all humanity, but he is really relating it to human beings capable of guided (practical reasoned) action. The attribution of dignity is based on the rational being's autonomy and capacity for self-legislation, and therefore, the precepts cannot apply to all biological human beings, but only to 'persons', which in Kantian terms is a 'being with a will' (Kant 1948 pp. 76-77), or (the non-Kantian term) 'agent'. A human embryo is not ostensibly a 'being with a will', and therefore, the extension of the *Formula of the End in Itself* to such human life is misleading - human beings not capable of agent action cannot have dignity. Therefore, Kahn's interpretation of the principle is not what Kant had in mind, since Kant did not extend the categorical imperative to all 'human life', but instead to the *actions of agents* that would compromise dignity (see Paton 1948 pp. 32-33).

For this reason, Harris has argued that without qualification, such appeals to Kant's 'dignity' are seldom helpful (Harris 1999 p. 67)[60]. We do, and rightly should, use others, as means in certain circumstances. There are two reasons for this. Firstly, there is the provision of a service (we may have no relationship with a service provider, and in procuring that service, we are therefore using him only as a means), or altruistic behaviour, such as blood donation (ibid.). Secondly, there is the conflated protection that would develop as a consequence of the dignity of all human beings. Harris states that '...an abortion performed exclusively to save the life of the mother would also, presumably, be outlawed by this [mis-]understanding of Kant's principle' (ibid. p. 67). Kant's argument therefore should not be used to rule out using certain human beings as means to some 'agent' relative good unless a *potential* to become an agent can be successfully argued to be morally important[61].

---

[59] See Kahn 1997; Novak 2003; & Oduncu 2003.

[60] Kuhse has argued that arguments that attempt to defend the view that dignity is a property of all and only human beings fail because it is too embracing and too exclusive (Kuhse 2000 p. 69). A human embryo that consist of no more than a few cells would be the bearer of dignity whereas primates that demonstrate considerable rationality would be excluded. Thus, arguments that recognise the 'inherent dignity of all members of the human family' may '...lead to the bolstering of some illegitimate, or at least unargued-for claims, in the human sphere, whilst at the same time encouraging blindness as far as the widespread exploitation and mistreatment of animals is concerned' (ibid.).

[61] Lebacqz argues that: 'The embryo (or embryonic tissue) can be considered to have value. It can be cherished. It can be treated not simply as a means to someone else's ends. To the extent that respect for persons requires this general attitude of valuing and the rather vague moral norm of not using another

On this understanding, Beyleveld and Brownsword argue that 'dignity' is respected by acknowledging that all agents have a range of distinctive capacities; such as the capacity for free and purposive action, and those capacities that accompany such choices (such as making informed choices and *real* consent), and that dignity acts in support of individual autonomy (and not as a *constraint* on human action) (Beyleveld & Brownsword 2001 esp. pp. 111-119)[62]. Therefore, far from being a characteristically human value, it is an agent relative value linked exclusively with the autonomy (or '*empowerment*') of the individual and its existential anxiety (of the agent as a bodily and physiologically *vulnerable* being)[63]. In this sense, agents have dignity because of their propensity to act for freely chosen purposes; and it is dignity, as primarily the property by virtue of which one has moral rights (and so dignity as the basis of rights is constituted by the property of being an agent), that allows them to exercise such choices.

On both Kant's and Beyleveld & Brownsword's accounts, dignity is limited to rational beings. Therefore some traditionally 'dignified' beings have been misrepresented as such, because they do not ostensibly have the dignity-relevant capacities that accompany agency. However, in Chapter Three I will contend that 'dignity' may be a terminological means of protecting those beings that are not able to claim moral rights. Instead it is meant as a special protection not of the same type as claim rights (and that is to say that this type of 'dignity' and that Kant and Beyleveld & Brownsword may be different concepts but are using the same word). Our duties to such beings cannot be *perfect* (in the sense of necessarily correlated to moral rights), because such beings cannot have, through the definition of moral right used here, claim rights[64]. And in this sense, it has been noted that:

---

simply as a means to our own ends, respect for persons appears to be able to fit the case of the early embryo or of embryonic tissue (Lebacqz 2001 p. 151). But, as I have argued, and in agreement with Lebacqz, this respect is something different from what Kant had in mind for beings with self-determination or rational will (ibid. p. 152).

[62] '...a person's sense of dignity, of self-worth, is fostered or buttressed when she is in a position to claim rights against other persons ...by virtue of [the] characteristics of his actions, the agent regards himself as having worth and dignity ...If he had no purposes, he would *claim* no rights of agency, nor would he act. And this having of purposes is equal and common to all agents, whether wise or foolish' (Gewirth 1998 pp. 161-171 [my emphasis]).

[63] '...immanent within an autonomy-centred conception of human dignity, there is a dimension of responsibility that must be drawn out – which dimension begins to take shape once individual autonomy is placed in the context of human finitude and vulnerability in which rational agents strive to co-exist ...dignity enjoins ...a degree of humility in the face of uncertainty ...We may strive to be rational but we are not omniscient' (Brownsword 2002 p. 577).

[64] Alastair V. Campbell assumes the middle ground, stating 'dignity ...signifies both the honour and the burden of being human ...[the] honour of being human consists in being a moral agent' (Campbell pp.

> ...appeals to human dignity are not necessarily (unjustifiable) attempts to extend the possession of the basic rights beyond their appropriate bearers, but may be appeals to a different set of considerations all together. While such considerations are, in my opinion, subordinate to the protection of the basic rights, they still merit careful consideration (Beyleveld 1998b p. 337).

'Dignity' may therefore be a protective claim on behalf of certain beings, but this cannot be the *same type* of claim that is made in the case of a moral right. In this sense, 'dignity' may be, on one hand, the basis of agent-centred claim rights, and on the other, some 'dignitarian' value in all human beings. Human 'dignity' in the latter (symbolic) sense may be meant to protect humanity, not agency, because many vulnerable biologically human beings do not qualify as agents.

6. The Limits of Rights

If one could envisage a theoretical world where all rights were absolute (i.e. could not be overridden in *any* circumstances), it would have to be inhabited by beings that never had cause to intentionally infringe, violate or otherwise harm other agents' rights. Furthermore, there would also be no duty to refrain from such actions because there would not be an individual willing to embark upon detrimental actions. Conflicts or rights would also not arise due to unavoidable circumstances and social limitations. Such a community would be devised so that all individuals within the society (voluntarily) acted in accord with the interests of others (positive rights to help); and that external forces would not limit any one being's ability to help or status as a consequence of providing aid. The members of such a world would also have access to information that will allude to the (confident prediction) of the outcomes of all acts. Such a world would therefore also be dependent on non-finite resources and the effects of occurrences in nature.

108-111). But Campbell does not interpret agency in the narrow terms that Kant used. Campbell's argument is that the '...symbolism of respect for all that is human is a potent influence on moral sensitivity' (ibid.). Therefore, '...human dignity is often extended to cover a range of situations ...[where] we accord respect ...But this respect ...must be regarded as an extension (or inflation) of the core concept of human dignity, and so can have moral force only in a weak and generic sense ...the claims from such extensions are not to be compared to the core concept, which is applied solely to conscious beings who are capable of having their rights violated' (Campbell 2000 p. 108).

Of course, we do not live in such a world[65], and therefore we are committed to practical deliberation and consequential foresight: our '...world is of a certain sort, we... may have no choice but to contemplate the [un]avoidable occurrence of the very actions and event whose consideration at an intentional level is absolutely ruled out' (Waldron 1984 p. 16). Furthermore, these are limited to our knowledge and understanding of the world (including never fully knowing all the consequences of a given action), physical limitations (i.e. limited resources); and natural disasters. Ultimately, a given ethical dilemma may result in the evaluator being equally torn between two choices of action, each of which results in harm and equal violation of two (or more) individuals' rights.

Consequentialists strive for the best outcomes – so perhaps in this case the least harm to the least number of citizens (or which creates the greatest aggregate happiness) would be chosen (instead of the implications for each individual separately). The rights-theorist, on the other hand, cannot quantify or calculate the least harm or best outcomes according to the aggregate welfare. Instead any outcomes must be based on the (rights) implications for each individual. Only when different rights are at stake can one action be chosen over another; and then one can make a decision for moral action – and so be able to choose the option that harms the less important right (for example, violate an agent's right to freedom to stop a violation of another's right to life). We are therefore forced to abandon the absolute right, and are committed to *prima facie* rights. It is all too commonplace that individuals are stripped of their status and interests by the actions of others and as a consequence of the natural world. A rights framework therefore creates a situation whereby (morally important) decisions have to be made on empirical study of the available information (which may be false or incomplete), and likely and probability of outcomes to individuals' rights.

With these limitations a rights framework may be shaken by events; but this does not mean that we cannot set out the ideal structure that can withstand, to the best of our capacities, these knocks. Essentially, policies must found systems that attempt to establish all the relevant consequences and the best possible course of action. In any one situation, therefore, rights may be situationally limited or violated by incidents out of our control. The deployment of rights, organised in a hierarchical framework, is

---

[65] 'We are not concerned with ...some never-never ideal land in which all of the differences between persons – in a variety of morally relevant respects – have been erased, but persons as we find them in the actual circumstances found here on earth' (Melden 1977 p. 193).

therefore dependent upon the individuals' needs and society's capabilities. Importantly, mechanisms must be in place to recognise this finitude, and designated to assess allocation, rationing and to attempt to resolve conflicts.

7. The Right-Holder, Duty-Bearer and Justifying Grounds for Rights

So far, we have seen that a person has a moral right when she has '...a claim the recognition of which is called for – not (necessarily) by legal rules – but by a moral principle' (Feinberg 1980 p. 154).

In the first place, a person must be in a position to at least recognise that there may be circumstances where her interests are under threat from other agents or institutions, and therefore that there may be circumstances where she may need to *claim* that such actions are against her interests. Thus, to have a 'right' is to have a claim *to* something and *against* someone, the recognition of which is called for by legal rules, social conduct, and inter-person relations that create the moral society. The recognition of rights by positive law, however, is not necessary and although they are often (or are not) given expression in some form. If the right exists as a moral entity, it does so despite or regardless of the judgement or law. And should the judgement or law go against this right, then that judgement or law is immoral or (interpretatively) wrong[66].

One cannot simply claim *anything*; the claims are to access to important goods that furnish that person's important interests in having, maintaining or accessing basic goods. Likewise, one cannot make a claim against *everyone*. Any particular individual may not be in a position to help; a state or authority may likewise be unable to help; but they must be at least be able to act minimally so that they do not intentionally violate an individual's *negative right*. As a rule, the right has to be held against someone/institution that *can* provide the necessary duty (*infra* fn. 88).

Rights cannot actively exist in isolation to the recognition of the existence of agents – but they are not reliant on the access to, or recognition of, a duty from

---

[66] The Nazi laws (e.g. Law for the *Prevention of Genetically Diseased Offspring* 1933 and the establishment of Genetic Health Courts; the *Nuremberg Laws* 1935; & *Marital Health Laws* 1936) and policies of racial hygiene were given legal effect; they were still, of course, immoral, in that they denied fundamental rights to individuals and groups within society (see Proctor 1992). What is more, there are clearly moral implications for actions that we do outside the recognition of positive law – there are moral rights and duties apart from the law and any legal system, and regardless of the failure of a legislature to provide that right (Bedau 2000 p. 276).

another[67] - the actual existence of other agents is irrelevant to whether rights may or may not be possessed. However, the '...possible existence of other human beings is more than adequate as a basis for talk about right to have a point' (McClosky 1965 p. 118). If one can envisage a situation where access to important goods may be compromised, then one could also envisage that the persons responsible have a duty to stop such actions, whether or not they are actually doing it; but in this case *should they do it*.

Correlative to the right-holder, to be able to claim a right, the duty bearer must be in a position at least to be able to comprehend the circumstances that will entail the fulfilment of that duty. This is an implicit claim, however; in the sense that others may *come to have* a duty to refrain from some action. It is not a right that is claimed against a potential infinite number of individuals in a potentially infinite number of situations.

7.1. A Framework of Morality Based on the Existence of Human Rights: The Indirect Argument to the Principle of Generic Consistency (PGC)[68]

It has been argued here that agents have a claim (or moral right), to those things that are necessary for their ability to be an agent, these things, or 'goods'[69], may be called 'wellbeing'[70] and 'freedom'[71]. This claim is supplemented by holding that all agents should *morally* be treated in similar ways, and this is because all agents are similar in respect to the intrinsic value of their wellbeing and freedom. So unless there is some general and relevant respect in which agents differ that would justify different

---

[67] McClosky gives the example of a hermit on an isolated island having a right to do or have certain things but this is not, due to the circumstances, a right against anyone: 'His rights may give rise to rights against others, but the right – e.g. to live – is not primarily against others' (McClosky 1965 p. 118).

[68] I have made an important decision to not include Gewirth's direct argument to the PGC in the main text (a summary of this argument can be found in Appendix Two). The reason being that, unlike the direct argument, the indirect argument only depends on the existence of human rights as a stating premise, instead of agent action. Although this premise is question begging, I have argued that human rights are acknowledged as a fundamental grounding of European legal policy. This summary of the indirect argument to the PGC is taken from Beyleveld (1996) and Beyleveld & Brownsword (2001) pp. 77-82.

[69] These goods are '...aspects of his individual existence as unique and unrepeatable as is that existence itself ...which, unlike his merit, has *individual* worth' (Vlastos 1984 pp. 56-57).

[70] '...if enjoying 'well-being' is something valuable – and especially intrinsically valuable – then it seems to follow that this is the kind of thing to which one ought to have a right' (Wesserstrom 1964 p. 635; cf. Vlastos 1984 p. 56).

[71] '...under this term [are] not only conscious choices and deliberate decisions but also those subtler modulations and more spontaneous expressions of individual preference which could scarcely be called "choices" of "decisions" without some forcing of the language' (Vlastos 1984 p. 56; cf. Gewirth 1978 pp. 52-53).

treatment, all agents have a right to these goods[72]. If human rights are claim rights, then it must be concluded that there is no difference between agents[73] (if all agents do in fact have equal human rights), and therefore they must all have an equal right to wellbeing and freedom (Feinberg 1964 p. 644).

Melden, however, contends that how can the worth of *A*'s freedom and wellbeing be a ground to derive principles that equate to her own and others equal rights (1977 p. 191)[74]? If it is a *capacity* for freedom and wellbeing (the 'intrinsic worth' that 'some persons have'), how is the move from this made to the right to have them achieved? At best, the framework provides a principle of universalisation – that if we have a good reason to promote *A*'s freedom and wellbeing, then we should also equally promote those of *B* (*infra* section 8.2). We must therefore find out the reason why a person's interests in having something (that she claims), means that they have human rights to them; how can something that one values (or is good) become something that someone ought to have as a right (Feinberg 1964 p. 645)? Furthermore, just because one can see *why* rights are so valuable, we have no reason to commit, without further avowal, that they are *in fact* the only valuable goods (Nelson 1976 p. 146). It may be, for example, also valuable to incorporate wider considerations of social justice, and these impersonal factors may infringe upon individual rights (Young 1978 p. 67): therefore, '...while most people believe that there are such rights, there are in reality no grounds for believing in human rights' (Nielsen 1968 p. 578).

Gewirth states that:

---

[72] Each agent may require more or less of this minimal standard at any given time. In such circumstances it may be justifiable to discriminate *fairly* against that agent who is in less need for the maintenance of the minimal agency than the one in more need (Benn & Peters 1959 p. 108; cf. Melden 1977 p. 193). Therefore we can in proper circumstances treat people differently as long as this is not on any non-moral grounding (and with regards to their basic needs of agency). This point seems to have been misunderstood by Bentham (2002 p. 325-326) (*supra* fn. 18). There are times or circumstances when one individual should be treated differently from another – either because of their possibly temporary capacities (illness or age) (Nielsen 1968 p. 577); or because of what they can safely or competently do without harming themselves or others (the task-specificity of rights) (see Beyleveld & Brownsword 2001 p. 132). However, despite historical or cultural differences between groups of individuals, human rights do not allow different values to treat an agent below that status (and those that do are heavily criticised; see Baden 1992; & Marcus 1993). Cultural or historical factors are not entirely unimportant; they can add to the wellbeing within a society; but they are only defensible when no one individual is unfairly treated with regards to her rights. In such cases, they are secondary to the rights to access to goods necessary for agent freedom and wellbeing.

[73] '...the human worth of all persons is equal, however unequal may be their merit' (Vlastos 1962 p. 45).

[74] Melden concludes: '...we need nothing more than the concept of persons, whose features as the moral agents they are suffice for the possession by them of their fundamental moral rights, features which enable them to join their lives with one another as they go about their affairs' (Melden 1977 p. 231).

> ...human rights are of supreme importance, and are central to all other moral considerations because they are rights of every human being to the necessary conditions of human action, i.e. those conditions that must be fulfilled if human action is to be possible either at all or with general chances of success in achieving the purposes for which humans act (Gewirth 1982a p. 3)[75].

Because of this, Gewirth argues that the categorically necessary requirements of the *Principle of Generic Consistency* (PGC) mean that an agent is concerned with acting to achieve her purposes, and therefore, the necessity of freedom and wellbeing (collectively the *generic features of agency*) for all such purposes also means that she must hold it as imperative that she has rights to them. By virtue of all agents being relevantly similar, she must also recognise that for all other agents this is equally necessary for them to have (generic) rights. (And one must accept that to contradict the PGC is to contradict that they are an agent at all[76]). The non-contingent stringency of this argument has meant that there is a great deal of, sometimes hostile, scepticism to it. Beyleveld & Brownsword therefore advocate that:

> ...unless alternative (dialectically contingent) arguments can be given for employing the PGC as the criterion of moral legal validity, many will not be interested in what the PGC requires for individual actions and social (including legal) rules and practices (2001 p. 77)[77].

There have therefore been, perhaps in an effort to avoid an unnecessary 'trap', and compounding the resentment of those protagonists, notable efforts to present Gewirth's project in a *dialectically*[78] *contingent*[79] (*indirect*) argument, which argues that one is committed to the PGC *not necessarily* because one is a purposive agent, but instead because there are (in a question begging sense) *human rights*. The contingent arguments holds that from a claim by the agent (in the spirit of the dialectical method) that human rights exist, the PGC must follow. And at least one author believes that this

---

[75] Gewirth argues that: 'But may not some humans lack these rights because they are incapable of agency in one way or another? ...This question rests in part on the variant of the dictum that "ought" implies "can," for it assumes that for some person A to have a right to something X, A must be capable of having or doing X... [but some human beings] despite the lesser range of control of which they are proximately capable, [have rights] for they can think, choose (although within narrower limits, and plan)' (Gewirth 1981 pp. 133-134).

[76] 'Any being denying it was a PPA would, in that act, reveal itself to be a PPA' (Beyleveld 1996 p 16 fn.).

[77] But, '...that philosophers are inclined to seek contingent groundings for morality can only be justified on the conviction that the Gewirthian enterprise is unfulfilled' (Beyleveld 1991 p. 3; also see generally Beyleveld 1996).

[78] Dialectical refers to the *method* of using statements or claims made by protagonists or interlocutors and then proceeding to examine what these logically imply. As opposed to an 'assotoric argument' where the conclusion follows from the premises that are not tied to the claims of an interlocutor (Gewirth 1978 pp. 42-47).

[79] A contingent argument is one where the premise(s) or method of inference (i.e. the connection between the premises and the conclusion is not *necessary*) can be denied (ibid.).

argument avoids a hostile reaction because, instead of one being in a position whereby they *cannot* logically reject the premises that Gewirth holds to be rationally undeniable, they are committed to the inference that human rights may in fact exist (Boylan 1999a p. 2). It is clear that human rights, whatever their basis, are of supreme importance in international law, and not least in the EU. And because law is an expression of morality (or so *natural law*[80] affirms), this would be a good place to start in deriving a theory of morality.

A claim right, as understood as a *human right*, is possessed by a human being simply by virtue of being a human agent (who is able to make that claim)[81]. It follows, from the premise that there *are* human rights, that a human being, *qua* human agent, claims that she has human rights, and therefore, all agents' have the same (claim to) human rights. These rights are to have human agent goods, collectively called freedom and wellbeing. Formally, from the claim:

(1) 'I have human rights'[82].

It follows from the definition of human rights that I am asserting:

(1a) 'I am human → I have R-rights'.

The *logical principle of universalisability*[83] now requires me to assent to:

(2) *X* is human → *X* has R-rights,

Which entails:

---

[80] As opposed to the concept of law being *morally neutral* (argued from a *positive law* position); see generally Beyleveld & Brownsword 1994, especially pp. 7-31; & Gewirth 1978 p. 75, 1981 p. 119.
[81] '...where the fact that X is human is *sufficient* to justify the assertion that X has a claim right R, then claim-right R is a human right' (my emphasis; Beyleveld 1996 p. 23).
[82] Or I have a right to do X on the necessary and sufficient grounds that I am human (Beyleveld & Brownsword 2001 p. 79).
[83] '...if some predicate P belongs to some subject S because S has the property Q (where the "because" is that of sufficient reason or condition), then P must also belong to all other subjects S_1, S_2,...,S_n that have Q. If one denies this implication in the case of some subject, such as S_1, that has Q, then one contradicts oneself. For in saying that P belongs to S because S has Q, one is saying that having Q is a sufficient condition of having P; but in denying this in the case of S_1, one is saying that having Q is not a sufficient condition of having P' (Gewirth 1978 p. 105, 1969; also see Appendix 3).

(2a) All human beings have R-rights.

Now, from:

(3) *A* has a right to $y \rightarrow A$ has a right to the *necessary means* to exercise or do *y*;

It follows:

(4) There are *generic features* of agency (action)[84] (GF) (which are necessary means to the exercise of y, whatever y might be),

And it follows that I must assent to:

(5) Whatever A has a right to, A has a right to have the GF.

Thus, it follows from (2a) 'All human beings have rights', that I must assent to:

(6) All human beings have a right to have the GF, whatever R-rights are, and to;

(7) All human beings have a right to have the GF.

However,

(8) Any being granted a claim-right must be capable of exercising it (because 'may' implies 'can' just as much as 'ought' does[85]), and in order to be able to exercise a right a being must be an agent.

It follows that I must assent to:

---

[84] '...precepts require actions; and there are certain invariant features that pertain generically to all actions ...they categorize [sic.] the genus or category of action as a whole, as delimited by moral and other practical precepts ...[and they] provide the necessary content of all action' (Gewirth 1978 p. 25).

[85] '...the "ought"-"can" derivation, which, assuming the familiar principle that "ought" implies "can", argues by contra-position [relation between conditionals of the form 'if *p*, then *q*' and 'if not *p*, then not *q*'] that if some person cannot perform some action, then it is not the case that he ought to perform it' (Gewirth 1982a p. 107; also see Rynin 1957, esp. p. 313; & Tranøy 1972).

(9) All agents have a (claim) right to have the GF. Which, because all agents must therefore have the generic features of agency, is the PGC (see Beyleveld 1996 p. 23):

'Act in accord with the generic rights of your recipients as well as yourself' (Gewirth 1978 p. 135)

7.2. Agency and Human Rights

Truly practical and instrumental rational behaviour[86], together enable the purposive claiming of human rights for important human goods (which are in the agents interests to have if it is to have any success in being a human agent). This resides in a level of rationality that evidences itself as purposeful action. This is the distinguishing factor that separates agents from non-agents, and clearly separates human agents from the human embryo.

One must realise that if I (any agent) has human rights because of the sufficient reason that (I) have claimed them for myself, and then through the *logical principle of universalisablity* (*supra* fn. 83), I (any agent) must be *other-regarding* to human rights. This means that because any agent must regard the fact that she is a human agent is the sufficient reason to claim human rights, then any other human agent must also have the sufficient reason to claim the same human rights. This is implicit in point (8) – '...in order to be able to exercise a right a being must be an agent' and its leading to (9)[87].

It has been argued that the right to freedom and wellbeing could be based upon some other ground more specific than the agent's prudential criterion:

> But is not at all evident why a 'rational agent', whose 'criterion is prudential', must stake his claim to rights to freedom and well-being on the ground of their necessity. Strictly speaking, all that Gewirth's argument shows... is that it would be self-contradictory... for a rational agent, whose criterion is prudential, to refrain from claiming a right to the necessary conditions of action, but not that it would be self-contradictory ...to claim a right on some other ground (Freidman 1981 p 152).

---

[86] Concerning 'what to do' in light of what has been chosen and the best means of achieving it (Richardson 1994 p. 22).

[87] 'The agent's description of himself as a perspective purposive agent is both a necessary and sufficient condition of the justifying reason he must adduce for his claim to have generic rights' (Gewirth 1978 p. 109).

If this is not the case, then it must be demonstrated that agency must be claimed as the sufficient condition for having human rights (and were this not the case then agency *is not* necessary and sufficient to have human rights; if some other ground can be relied upon, then agency may not be relevant and those beings that are not agent may have rights). However, it can be shown, via a *reductio ad absurdum,* that by denying that one has human rights because she is a human agent, the agent denies that she has human rights.

The *Argument from the Sufficiency of Agency* (ASA) (Gewirth 1978 p. 110) (see Appendix Two) shows that if some quality D (i.e. human agency), is necessary and sufficient for having property R (i.e. human rights), then all beings that have D must also have R or otherwise accept that some other quality, S (i.e. species membership) is also (or can be used instead) for having R, which clearly would make D no longer necessary or sufficient. (And remember, I have human rights, not because I am human, but because a claim right is a human right, I would have to accept that I do not have human rights if being human and an agent were not necessary and sufficient). If this was the case, then I could argue that a claim right may be derived for a being that cannot exercise it, and therefore, claim rights would not have to be claimed (i.e. all human beings, including those that cannot act, can have claim rights). Therefore, because denying that it has human rights for the sufficient reason that it is a human agent, requires the agent to assert that it has human rights because it has a property that is not necessarily possessed by all human agents. This would imply that if the agent lacked this property it would not have human rights, which contradicts the previously established statement, made on the basis of its claim to be agent, that it has human rights.

Therefore, if human rights *are* claim rights, only agents capable of claiming a right can have the same capacity to have human rights. Of course, human embryos are human, but they are not capable of exercising such claim rights, and therefore cannot have human rights unless either being human is in fact necessary or becoming an agent will suffice (this is discussed fully in Chapter Three).

7.3. The Application of the PGC

The argument to the PGC shows that from the action basis of agency there is at least a *claim* (in the Hohfeldian meaning) to *prima facie rights*. If the premise that there are human rights is correct (and which I have argued is the case in the EU), then the PGC necessarily follows. Therefore, any policy concerning agent communities must be grounded in, and recognise primarily, that it should protect and promote agent rights. These conventions can therefore only apply to agents, if in fact human rights are their sole grounding.

7.4. The Indirect and Direct Applications of the PGC

Direct applications govern interpersonal conduct, between agent and recipient. The direct application of the PGC requires that its precepts are imposed on the actions of individual agents; the actions are morally right, and the agents fulfil their moral duties when they act in accord with the generic rights of their recipients as well as of themselves.

The *indirect* application of the PGC imposes requirements upon social rules governing multi-agent institution activities (Gewirth 1978 pp. 272-365). The indirect application concerns the legal enforcement and political effectuation of human rights. They are not exclusive of individual interpersonal transactions (such that being illegally detained by the state concerns similar human rights violations as being kidnapped by an individual). A large part of the indirect application consists of the legal protection of individuals from suffering violations of their most important rights by individuals or groups other than those representing the state (so prohibiting certain acts and providing for sanctions and remedies by law). It also constrains the possible actions of the state, and may be used as a means to enforce a general state of affairs where human rights prosper.

Under the latter application, institutions are morally right, and persons acting in accordance with them fulfil their moral duties, when the rules and institutions express or serve to protect or foster the equal freedom and wellbeing of the persons subject to them.

The indirect application of the PGC will define the justification for any policy decisions concerning stem cell research. So for example, if it is true that an embryo, as an agent, has human rights, then the policy will have to reflect this by prohibiting harmful actions directed at human embryos, and thus embryonic stem cell research will be unjustifiable. A policy in this case that does not protect and support the freedom and wellbeing of persons (including embryos) would be contradictory to the premise of the PGC[88].

8. Human Rights and the PGC

The premise of the necessary argument to the PGC is that the agent is capable of claiming a right; if one then also considers the correlativity of rights, then there must also be implicit duties. In both cases, only an agent has the capacities for such actions. Human rights, if they are rights as intended under the PGC, are limited to rational agents.

Although the human rights documents state that human rights are held simply because they are inalienable and fundamental rights of human beings, we must read them as having a dichotomous meaning. Firstly, that the moral status of 'everyone' is indisputable; but only in that it is read so that every agent (which is 'everyone') has human rights. Secondly, that reference to 'human beings' must be embellished by a second meaning that derives a 'proportional' or secondary status to them as opposed to persons (agents). This is discussed in Part One of Chapter Four.

8.1. Non- and Marginal Agents

This is far from the end of the story. It is clear that there are agents (such as 'normal' human adults) and non-agents (e.g. rocks). However, there are increments

---

[88] The *procedural* application of the PGC requires that social rules and institutions operate under the premise that they are established under the free consent of citizens, and that this consent is achieved through certain constitutional procedures. These procedures cannot, however, be limited or biased contradictory to the PGC (Gewirth 1981 p. 140). It could not be the case that one group is constitutionally limited (in freedom) from the benefit and protection of the community. The *instrumental* applications provide that these social rules and institutions are morally right insofar that they operate to promote and protect the wellbeing of all persons (ibid.).

between these two poles, where it is far from clear as to their agent status. Therefore, we have to look carefully at the moral status of *marginal agents* – beings that we cannot conclusively place as either an agent or a non-agent. The ASA showed that being an agent (defined as having purposes that one acts for) is necessary and sufficient for having the generic rights *at all*. Furthermore, the same conditions mean that having the capacities of agency it necessary to have the generic rights *in full*, and is not subject to *any degree* according to the actual (non-moral) abilities of the agent. On the surface then, if *one is not an agent* then one cannot have the generic rights, and therefore there can only be agents and non-agents.

However, Beyleveld argues that because of considerations of abstract ontology[89] to real objects in the world, we cannot be fully confident that something is or is not an agent, and then the *potential* for something to be an agent, cannot be ruled out as being actual agency (Beyleveld 2000b; see Chapter Three).

8.2. Indirect Status and Vicarious Rights

Putting Beyleveld's claim to one side, there is a further way to deploy 'rights' to marginal agents. Vicarious rights are rights 'experienced at second-hand', or held by one person (the agent) as a substitute for another (the marginal or non- agent). Because of the PGC, agents have rights, but these rights may entail 'quasi-rights', on account of the interests of the agent, to a marginal or non-agent. The obvious example of this relationship is in something being owned by an agent, which grants certain rights for that object not to be stolen. However, because we are talking about marginal agents, there are significant considerations to be made here. Specifically, we are talking about the *connection* of the marginal agent *to* others who have intrinsic rights.

Wholly indirect moral status derives from the physical proximity of a being to an agent. So for example, if one harms or 'uses' certain non-agents then this may inadvertently affect actual agents (so perhaps experimenting on an embryo *in utero* may affect the mother). Further indirect status comes from arguments that may wish to limit certain behaviours of actual agents, such as the development of virtues as a generally

---

[89] 'Ontological' is understood to be science of the nature of being; that *existing things belong to different categories*. It refers here to the nature of biological and characteristic existence, and will be used to

good thing (as against brutalisation or cruelty[90]); or to protect the sensitivities of actual agents. In the case of the former, Pluhar argues that such arguments fail on account of the 'slippery slope fallacy':

> ...warning us as they do that humans (at least the 'rational' ones) are threatened by the abuse of nonhumans or of nonrational humans. We humans are outstanding "discriminators". White supremacists who have no difficulty being kind to those of our own ilk while blowing up black churches during services are also not likely to confuse chickens with their fellow cross-burners (Pluhar 1995 p. 91).

It could be considered therefore that certain acts of cruelty may not lead, and indeed may not have anything from a purely *logical* relationship, to do with our treatment of fellow agents. And while it is perhaps clear that one should not do things that upset those around us; especially if they perceive such behaviour as threatening to themselves or loved ones, there may be no such danger if such acts are confined to secrecy and done behind closed doors (Pluhar 1995 p. 102)[91].

Indirect status can also come from the collective waiver of certain rights. In this case, democratic measures would be used to secure certain 'quasi-rights' for non-agents. One could then for example, through the popular will, prescribe 'rights' for embryos; but with the inherent problem that popular will may harm and override the rights of minorities deserving of full moral rights, perhaps at the wilful, but unjustifiable inflation of the 'rights' of non-agents. A society could not, under the PGC, inflate the status of the embryo (if it is not an agent) so that others agents' rights are limited or harmed.

The final possibility to be considered here is that of *property*. The connection between a non- and full agent may be used to describe a property relationship, whereby a particular being or object *belongs* to the agent (but only non-agents can be property, because owning an actual agent would deny certain aspects of freedom and wellbeing under the conditions of, for example, slavery). Furthermore, this would have the possibility of allowing the owner to do as she wanted to her property, and clearly would

---

delineate the different stages of biological development of the human being; each stage comes with a different set of capacities that will be central to its moral status.

[90] Kant's, in *Lectures on Ethics* (c. 1784) states: '...animals are an analogue of humanity, we observe duties to mankind when we observe them as analogues to this, and thus cultivate our duties to humanity ...so if the acts of animals arise out of the same *principium* from which human action spring, and the animal actions are analogues of this, we have duties to animals, in that we thereby promote the cause of humanity [but if] ...a man has his dog shot ...he is by no means in breach of any duty to the dog, since the latter is incapable of judgement... It upsets a man to destroy such a creature for no good reason, and this tenderness is subsequently transferred to man... Thus all duties relating to animals, other beings and things have an indirect reference to our duties towards mankind' (Kant 1997 pp. 212-213).

[91] But secret acts of cruelty may lead to a climate that causes distrust and fear within the community, and through this (physiological) harm may come to individuals.

have far from trivial implications, such as perceived mistreatment or doing as one likes regardless of other-regarding considerations[92].

Conclusion

I have argued that human rights, as an expression of international law, are unsatisfactorily defined, leading to confusion as to their interpretation in difficult cases (specifically the right to life). I have outlined how human rights can be rationally derived from the claim made by an agent that she has human goods that require moral recognition. Human rights are therefore the security that every human individual agent must consider herself to possess if she holds that there are certain goods that are valuable for her vital interests. These individuals have an implicit corresponding duty to the individual making the claim. To have a right, one must be able to claim it, and in doing so, recognise that its existence is under impending or abstract threat; furthermore, that claim can only be placed upon agents capable of having a duty. Although rights do entail duties, the latter are instrumental means of accessing and maintaining her rights, should they become threatened:

> ...the focus lies on each individual *qua* someone whose freedom or well-being is safeguarded by the constraints, rather than on each individual *qua* someone whose latitude to harm his fellows has been limited (Kramer 1998 p. 35).

From the indirect argument to the PGC we are in a position to determine exactly who and who does not have human rights (so potentially clarify some instances where the 'rights' of different sorts of beings conflict with each other) and allowing the logical hierarchical ordering of rights when there are conflicting interests. Importantly, the requirements put upon every agent by the PGC – that human rights must be fostered and cherished above all other moral precepts – and the resulting consequences cannot be evaded (without self-contradiction) '...whenever [an agent] dislikes those effects because of their variable inclinations or ideals' (Gewirth 1982a p. 176). This argument, perhaps more political than philosophical, relies on the fact that these premises attract widespread support and are unlikely to be rejected. The relevancy of this approach for

---

[92] Or supporting the destruction of a mere *human being* (Iglesias 1994). However, treating a biological human being as an object per se cannot be ruled out here (but is discussed in Chapter Three), under the present scheme for deriving the generic rights of agents.

this thesis should be evident. The premise that there are human rights is one that is entrenched in particular as a fundamental basis of policy in the EU. Beyleveld (1996 pp. 23–25) argues that to recognise claim rights to anything requires one to recognise the necessary means of exercising that right, if one is to avoid contradicting oneself. This requires one to grant rights to the generic features of agency as the necessary conditions for exercising any rights irrespective of their specific content. Also, since only agents can meaningfully exercise a right, agents must be the relevant subjects and objects of these rights. Thus, granting human rights (understood as claim rights possessed by virtue of being human) requires one to recognise generic rights to agents. The soundness of this argument turns on the fact that the capacities necessary to exercise rights (to waive the benefits or burdens of rights) and to be a meaningful subject or object of practical precepts are the attributes of agency. Thus to reject this argument would be to reject that there are human rights.

However, there are certain discrepancies in the explicit referral to 'rights'. This is not because of a presupposed flaw in human rights per se – they are not diminished by criticisms of modern-subjectivism, or an illogical right-duty correlation. For this implicit correlative to work, we must be sure in the first place that rights and duties have the same degree of specificity and remove ambiguities in the concept of 'X has a right to Y', which Hohfeld attempted to distinguish[93]. The demarcation of the various rights may help to define exactly what 'right' one is talking about, and so attempt to dispel criticisms of vagueness, and the like. We now have to turn our attention to those beings that are not clearly evident as human agents.

---

[93] For example, the right to free speech may be a general right consisting of many concrete rights – not to be detained, permitted to vote, truthful information, and so on, and including other general rights, perhaps if the free speech pertains to a right to religious freedom; which also correlates to a general duty not to violate that persons free speech, but also a cluster of appropriate and relevant duties to that case – so a duty not to detain, kill, maim, or threaten, and so on. One therefore has *general* rights and *specific* rights. A general right can serve as the foundation of several specific duties; whereas, a specific right can only call on one specific duty.

Chapter Three

Marginal Agents and the Use of Human Embryos in Research

Introduction

Without knowledge of where the likely benefits of stem cell (SC) research will come from, policy makers must decide whether to limit research to non-contentious sources, such as those found in the adult or cord blood or to proceed with the use of human embryos in research. Present progress suggests the prospect that the development of therapeutic applications will be slow, more difficult, and potentially unattainable if the first path is taken (see Chapter One). However, this option would also mean that policy decisions would not be required to justify the destruction and use of human embryos or the prospect of 'therapeutic' cloning. In this case, the alleged 'rights' of embryos would not be an issue, regardless of its disqualification as a normal holder of claim rights[1] (see Chapter Two). While not permitting (or funding) ES research would seem to make the moral deliberations easier in the first instance, the European Union (EU) would have to justify supporting a community where people may suffer because SC therapies came too late or failed to live up to the envisaged applications. Of course, this could happen anyway, even if the more contentious research were permitted.

If we allow the latter embryo research, despite the potential moral hurdles, there has to be some certainty that what is being allowed is not unjustifiable. If we have learned anything from the history of medical research on human beings, it is that we must make every effort not to permit scientific endeavours that put consenting individuals in the way of more harms than the direct benefits to them. Precisely for this reason, if we choose a path that places those outside these parameters in research projects, we must be prepared to state, logically and coherently, that the pursuit of the benefits of SC research is a morally worthwhile and justifiable enterprise. And to do this, we must be able to show that human embryos do not have a moral status that requires *full* protective rights.

---

[1] In the case of the embryo, we must also be talking about specific *embryo* rights, for example, those *basic* rights that prohibit intervention in its continued existence, *nonsubtractive* rights that prohibit

In this Chapter, I will argue that the two properties that may be argued to derive rights for embryos, either being a member of the human species or the potential to become a human agent, do derive a moral status for the human embryo. However, I will also suggest that, while they confer no absolute status (full moral rights), they do require us to treat the embryo as a possible agent. This 'dignity' status may require policies to justify actions that override its existing interests.

1. Dignity and Marginal Agents

Every human agent has human rights because they are able to claim recognition of their important interests; but what else are agents bound to consider as their (explicit non-right claiming) recipients? We are led to believe that those things that are not agents (i.e. not able to claim rights) are not of direct moral concern; or as Kant argued: 'Beings whose existence depends, not on our will, but on nature, have none the less, if they are non-rational beings, only a relative value as means and are consequently called *things*' (Kant 1991 pp. 90-91)[2].

Gewirth argues that because human action is the basis of human rights, no human can evade the context of action, so that:

> In the limiting case of humans who have no abilities of agency at all, they still have rights to life and to any other goods of agency which they are capable of having [*proportionality*]; and insofar as they may recover to the extent of being physically capable of action, they have rights that such *potential* abilities of their agency be protected and fostered (Gewirth 1996 p. 65; my italics).

Thus marginal agents do not have the generic rights in full, because they are not moral agents in the full-fledged sense, but must be considered either as *proportional* or *potential* agents; and the duties that agents are bound to hold towards marginal agents are defined and limited by the nature of the recipient and by the extent of its attainment of agency. The human embryo has no capacities of agency at all, and therefore is discussed here in the context of its *potential* to become an agent, and not on its

---

removal from an environment to continue its development, and *additive* rights that require interventions that allow such development (see Chapter Two s. 5.1).

[2] Hume argues that '...we should be bound by the laws of humanity to give gentle usage to these creatures, but should not, properly speaking, lie under any restraint of justice with regard to them...' (Hume 1975 p. 190). We can restrict our treatment of non- and marginal agents either through vicarious means or a separate set of moral claims altogether from the PGC. But, these other moral protections must be subordinate to the PGC, regardless of any cultural, historical or religious values (Gewirth 1978 pp. 23-25).

proportion of agency (proportionality is discussed in Appendix Three). The human embryo, as a potential agent, '...while of course having no rights to freedom, [will] have such right to well-being as is required for developing its potentialities for growth towards purpose fulfilment' (Gewirth 1978 p. 142). On account that '[p]ersons often learn what morally justified rights they have to some X only by comparing their treatment or holdings as to X with how other persons are treated or have holdings of X' (Gewirth 1996 p. 73): 'In the case of ...subnormal humans, it is their underlying similarity to normal human agents that grounds the attribution of dignity and rights to them' (ibid. p. 66).

Gewirth's reason for asserting the moral importance of marginal agency is because not all beings, or even all human beings, reach or remain constant at this level of rational agency. Marginal agency therefore encompasses those beings that are on the fringe of minimal rationality, approach the level required for full agency, or have temporarily lost that capacity. Agents drift in and out of agency through day to day existence and can be restricted in their capacities by injury or disease. But, they are still agents as long as the conditions of agency are periodically met (cf. Harris 1997). When such human beings do not (temporarily) demonstrate these conditions, their generic rights must also be (temporarily) restricted so that they do not harm themselves or others, with a view to restoring their agency.

However, Gewirth seemingly makes a logical error because under the framework of the *Principle of Generic Consistency* (PGC) (in light of the constraints of the *Argument from the Sufficiency of Agency* (ASA)), agency is both the necessary and sufficient criterion for having human rights in full (*supra* Chapter Two s. 7.2). So if this is the case, then how can anything less than agency provide any other morally relevant conditions to derive human rights? (Even if periodically meeting the criteria is enough to assume agency, the human embryo has not realised any capacities for rational behaviour). The consequence of not accepting a degree of marginal rights is that there will be a radical dichotomy of moral import between agents and mere 'things' (*supra* p. 99 Kant 1991).

It is sometimes argued that all human beings have rights because of their intrinsic dignity. In Chapter Two (s. 5.5), I contended that dignity, as a cornerstone of human rights, is a concept that cannot link the embryo to the possession of moral status through Kant's formulation of the end in itself. This was because his project was associated with the 'being with a will' and her ability to follow autonomously prescriptions of

moral law. Beyleveld and Brownsword, likewise, ground dignity in the agent's autonomy (2001). So in these two cases, dignity is limited to rational agents.

'Quasi-rights' for marginal agents must therefore come from a property that attributes an additional and morally significant capacity. It is this agent-independent capacity that is sometimes referred to as a second account of 'dignity', and is the basis of the 'Dignitarian alliance' movement that attempts to derive a *duty* of protection for the human species, not from the limiting aspect of rationality, but from a homocentric perspective (Brownsword 2003). However, if one wishes to continue to assert that human rights are an agent-centred property, then the human embryo, to have moral consideration, must be considered as having something to do with the *potential* to claim human rights, and these capacities must be a function of attaining full agency.

2. Potentiality

The PGC commits us to regarding agents as our moral recipients, so that policies must promote human rights. This is based on the *Argument from the Sufficiency of Agency* (ASA) and the '...characteristics [that] are deemed necessary or sufficient, on the one hand, for beings to be owed any duties of respect or concern for their interests or welfare, or rights in terms of their interests and welfare, on the other' (Beyleveld 1998a p. 247).

This, however, leads us to consider '...beliefs about the ontological status of the human embryo - its nature, capacities and powers' (ibid.). Because SC are derived at the earliest stages of development, at which point there is little or no cellular commitment (and no *proportional* development), the ontological nature of the embryo is a member of the human species and this at least confers on it the *potential to become an agent*[3].

Potentiality arguments attempt to derive moral consideration for a being that has no means to claim rights for itself. Importantly, they derive obligations on how we treat, what Engelhardt called 'subpersonal human animals'; human beings that under a claim rights framework do not warrant our full moral protection (Engelhardt 1974 p. 217). Our obligations to potential agents depend on a great number of things, which

[3] In chapter one, I outlined the biological ontology of the human embryo. It will become clear that potentiality arguments strongly rely (sometimes incorrectly) on biological observations (see Morgan & Lee 1991 p. 70; Kuhse & Singer 1990 p. 39).

often do not concern the ontological status of the marginal agent (i.e. separate from the human embryo's inability to act or have any intrinsic interests that it is itself aware of) (ibid.).

If potential 'rights' can be considered as *prima facie* and based on something altogether different from, but subordinate to, the requirements of the PGC, then such protections may not be altogether ruled out (Beyleveld 1998b). While one may not rest easy with the notion that the human embryo may be '...an inanimate object [or] a mere animal...', as it stands, it is difficult to consider the embryo as anything near '...a fully developed self-conscious human person' (Engelhardt 1974 p. 218). It is for this reason that having *potential* is argued to be morally significant.

The *Principle of Potentiality* is a broad philosophical concept, but here it is discussed only in the context of the potential of the human embryo to *develop into a moral agent*. Potentiality implicitly refers to the continuity of the embryo/foetus and adult being[4], and any action this disrupts this continuity stops the embryo from becoming that agent, and therefore somehow affects its moral status.

The most publicised activity that compromises the status of the embryo/foetus is abortion. There are, of course, other wholly different factors at play with regards to research and abortion (Engelhardt 1974). For example, in the case of the latter, whatever the potential status of the embryo, there is always a conflict with the status of the mother. In research, there appears to be no such direct or proximate conflict, since the embryo will normally be *in vitro* when considered for research and the rights of the possible beneficiaries of research may come into play. Nevertheless, both actions result in the destruction of a human organism, and in both cases, there are ('full') agents who may benefit from this. Therefore, in both cases, the status of the embryo is an issue.

2.1. The Principle of Potentiality and Inherent Potential

The human embryo can be referred to as a 'potential agent' where the development of the embryo inside the female body is the mere unfolding of, or an

[4] '...an embryo's potentiality refers to the future development of an actual entity that will preserve its identity through this development' (Reichlin 1997 p. 7; fn. 18). This sentence can be broken down into the aspects that make potentiality morally important for the embryo, so that 'future development', 'actual entity', and 'preserve its identity' all become of key importance, and will be central to this discussion.

inherent capacity to develop into an agent (Reichlin 1997 p. 4)[5]. The potential of the *in vitro* embryo, since it cannot become a living foetus unless it is implanted, is somewhat different from this, in that the claim must be that only if the potential agent *is placed into a uterine environment* (or in an artificial womb) that mere unfolding will be possible. The inherent potential may be present, but without the action of external agents, that will never happen (what Reichlin called *passive potential*; 1997 p. 4). Some have argued that deriving cells from parthenotes will circumvent the moral concerns with deriving cells from actual embryos because they are not *potential* agents (they are not 'normal' embryos with same potential to develop); they are 'doomed' from the outset.

If it is morally desirable (or imperative) to actualise potential, then that potential agent must have a protected status. This may be achieved by arguing that the potential being that possesses a property that relates to a potential for *Y* already possesses the same or equal moral significance of actually having *Y*. The potentiality is either a *possibility* for future change to *Y* (so that it is morally imperative that the potential for *Y* is recognised as an internal process alongside an external cause that allows *Y*), or a *probability* that the internal nature of the embryo to become *Y* is, all things being equal, an 'ontological certainty' (Reichlin 1997 p. 2 & 9). Advocates of the principle of potentiality attempt to define this property and its moral relevance with regard to actual existing human agents (often while trying to avoid the pitfalls of the *reductio ad absurdum*[6], so that *all* (abstract) things that can potentially become agents have moral status).

2.2. Potentiality and Human Beings

If all 'human beings' (biologically defined) can have 'human rights', one will have to state that there is a property derived merely from *species membership* that confers a direct status that requires ostensible agents to provide the protections of those

---

[5] Also referred to as a 'strong' or '*active potential*' ('naturally probable potentiality') (Stone 1987; Jacquette 2001). A strong potential is also a potential to *become*, while weak potentiality is a potentiality to *produce* (Buckle 1988).

[6] A method of proving the fallacy of an argument by showing that it leads to an absurd result: i.e. the negation of a proposition *P* is proved by taking *P* as a premise and demonstrating that, in conjunction with previously established premises, a contradiction follows.

rights for those beings that cannot themselves act, and which can override claim rights as the focus of moral concern.

For the purposes of this position, I will sketch a simple basis of 'human rights'. All beings existing with a sufficient level of 'humanness' are human beings[7]. Furthermore, all human beings are granted their own moral status as holders of human rights, because being a human being is the necessary and sufficient property for moral status. Actively moral humans (as opposed to those non-human things which are *non-moral*, and not *immoral*) are considered as 'persons'; those human beings yet to reach this stage of development are potential 'persons' because they will, all things being equal[8], become persons. But because, like persons, they are human beings, they also have human rights. From this position, all human life is protected either from the primacy of the 'sanctity of all human life'[9]; or because every human being, on biological grounds, '...is by nature human, because its parents are human [and that]...[h]umans differ from animals by their nature which specifically causes them to exist as "ens sociale" and as "ens rationale," rather than "ens animale"' (Oduncu 2003 p. 13). Tollefsen states:

> If a human being is an individual with membership in a certain species then any entity may be identified as a human being if it is both an individual living thing, and may be genetically identified as human. Human gametes ...and somatic cells ...are genetically human, but not individual members of a species type. A fertilised egg, on the other hand, is genetically continuous with a recognisable future individual, and genetically distinct from its parent individuals, and thus appears to be a human being from conception (Tollefsen 2001 p. 69).

Therefore, the '...mere membership of humanity creates and preserves the fundamental value of human dignity until death ...the living human embryo is the very first concrete and individual agent in human development, it must [therefore] be regarded as the carrier of implicit and unconditional values' (Oduncu 2003 p. 12; cf.

---

[7] This is normally seen as a genetic criterion that entails membership to the species *Homo sapiens* (see Chapter One). Further definitions of human being may derive from other occurrences in the human experience, such as birth, or as we shall see shortly, the potential to become something else. Often, terms such as 'person' are used to separate these other claims from mere species membership.

[8] See Chapter One fn. 13; this term means that on the assumption that *iff* there is no interference, and the pregnancy is successful, then the embryo will develop to birth. Throughout this chapter, this should be assumed to be the case unless otherwise stated.

[9] See: Ciba Foundation 1986 pp. 197-201; Meyer 2000; Soane 1988; Szawarski 1996 p. 120; & Watt 2000, for defence of this position; and Williams (1986) for a secular argument against this (esp. pp. 192-194). I do not here consider the argument that 'human' is a *single element* that warrants concern, so that '...it would have unpredictable consequences for human society if we began to distinguish between human beings on the basis of the stage of their development' (Mieth 2000 p. 5). Instead, 'human' must be attached to some other value that confers moral status, such as agency (see Markl 2001).

Ford 1988 p. 99). Robert Nozick concurs that species membership must be morally relevant, but fails to give a compelling reason for this:

> Shouldn't only an organism's own individual characteristics matter? ...Normal human beings have various capacities that we think form the basis of the respectful treatment these people are owed. How can someone's merely being a member of the same species be a reason to treat him in certain ways when he so patently lacks those very capacities? (Nozick 1997 p. 307);

This, Nozick admits, '...will smack of "speciesism" ...it makes the species an individual belongs to morally relevant' (ibid.).

From this position, it can be assumed that there are three grounds for moral status: (1) having a potential to *develop* into a full agent; (2) being an *individual continuous* with the agent; and (3) a *genetic member* of the human species. The first two claims, which are here linked to (3), will be addressed separately in the next section. Defending (3) relies on the fact that to have moral rights one only need be a biological human being; and this is not affected by the individual's (non-)status as an agent. It is not necessary to refer to criteria such as 'rational being' or 'agent' as applying to all human beings, since some lack intellectual and mental capabilities or biological properties that are necessary.

Haksar attempts to defend this position as 'Perfectionism', stating that '[s]ome forms of human life are intrinsically (or inherently) inferior to other forms of human life' (1979 p. 1). This *Perfectionist* view sets the foundations of a human egalitarian society, and bypasses moral problems with sub-agent human beings (so as to allow them moral concern) while preventing the membership of non-human animals (that may have greater agent relevant capacities than some human beings).

Therefore:

> ...if the foetus is the same individual as the adult human being that it can develop into, then it is just as sacred as the adult human being that it can develop into, and it is arbitrary to exclude it from the egalitarian club [and this] ...depends upon the nature of the individual, and the nature of the individual is understood dynamically ...in order to answer the question, what sort of entity a particular entity is, in order to understand its nature, we take into account not just the individual's present capacities, dispositions, and so forth, but also his potential (Haksar 1979 p. 96).

The difference between human beings and animals is that human beings have the potential, throughout life, for leading a worthwhile life (ibid. p. 108); and the potential for this derives permanent and equal membership to the 'egalitarian club'. The potential correspondingly derives from the 'nature of an individual' (i.e. which is genetically human). Alan Holland adds, not only are non-human beings distinguished by their

genetic heritage, but also their 'extrinsic relations' with each other (Holland 1991 p. 302). The human embryo is both genetically human and also of human lineage (it has human parents and resides within a human community), and therefore, despite its lack of any 'person' (mental) capacities, the embryo is not a potential human being, but an actual human being.

The '*genetic school*' locates the beginning of human 'personhood' at the beginning of becoming a full *genetically unique individual* – that is, conception. Under such a scheme, potentiality is not strictly necessary, because it is no longer the *potential* that is morally important, but membership of the human species (and those cells that potentially can become human beings – the gametes or even somatic cells – become *potentially* important as *potential human beings*). The human being must therefore only be important as a potential agent because it has (however it is created) the potential to become (through the expression of its genome) a human agent (and in due course join fully the moral community). Thus we are reducing the moral importance of the 'agent' to its genetic make up.

It is true that a human being as a biologically living entity belonging to the human species is present from conception (actually syngamy), but only if one takes human being to mean being genetically consistent with what it is to be a genetic human being (i.e. normally 46 chromosomes)[10]. It comes into being from the moment that a specific species entity exists and regardless of the mode of creation. The moral status of the human embryo therefore relies on nothing more than its living membership to the human species, and the potential resides in the possibility/probability of becoming more than a mere biological human being.

3. Criticisms of Homocentric Approaches to Potentiality

Bernard Williams stated:

> There is of course a greater difference between one species and another, on the whole, than there is between one day's development of an embryo and the next day's development [but to assert speciesistic claims would be an] ...Aristotelian view of life ...in which being ensouled is something all living things have in different forms, depending on the type of life that each thing leads (Ciba Foundation 1986 p. 195).

[10] 'The question of when the life of a human being begins is a biological one, since human beings are rational *animals*; and biology answers it simply and unequivocally: human life begins at conception, when the new being receives the genetic code' (Donagan 1977 p. 83).

The main objection to Perfectionist arguments is that they derive moral significance from morally insignificant attributes; and they are guilty on at least three counts of committing 'speciesism' (Tooley 1998). Firstly, morality under this scheme is no longer based on *following* moral precepts, but the *genetic instructions to become* a being capable of acting upon moral precepts. But the criticism is that there are possible theoretical cases where an essentially non-genetically human being may have moral significance as a present rational being, and therefore have claim (human) rights.

Additionally, and specific to this genetic claim: how much 'human' DNA is human – would an otherwise rational human/other species chimera be human[11] (Wasserman 2003; Zwanziger 2003)? What about those human beings that have radically different DNA (due to spontaneous mutations)? Perhaps it should be borne in mind that the human species is genetically closely related to primates, and there is little genetic difference between species even distantly related; so what makes humans morally different in a genetic sense from our closest ancestors and ostensibly agent-like, the great apes (Jensen-Seaman et al. 2001; Kaessmann & Pääbo 2002)[12]? (Unless of course *it is* this minute difference in DNA between species that is morally significant[13]). There is considerable difference between interspecies individuals (which has been an unjustifiable base of racial/sexual human treatment), which suggests that reliance solely upon (non-moral) species membership is rationally contradictory.

Furthermore, what is the potential moral status of a human skin cell which can be cloned to mirror the development of a fertilised oocyte (Charo 2001; Warren 1973)? And while human gametes may lack moral status (because it is argued they do not have a full genetic complement), a somatic cell does[14]. We also have the peculiar status of the parthenote (see Chapter One s. 6.1.3). While some have argued that human parthenotes are still human beings (and therefore deserve the same status as 'normal' embryos[15]), others have denoted them 'ovumsum', to separate their (apparent) limited

---

[11] Creating a human chimera has already been reported (Leake 2003).
[12]Humans are as much as 99.4% genetically the same as chimps (Wildman et al. 2003; also see Britten 1992).
[13] This is often argued on non-secular grounds; so that human beings are created by God as morally important and unequal to other animals (Iglesias 1984).
[14] I reject arguments that maintain that the embryo has moral status because it is genetically 'unique', since otherwise, by implication, monozygotic twins may lack moral status. Furthermore, gametes are themselves genetically unique, albeit not a complete genetic human being.
[15] 'The same people who were up in arms about doing research on embryos were up in arms about parthenotes …They correlated this with virgin birth' (John Eppig quoted in Weiss 2003 p. 66; cf. Bruce 2002).

developmental potentiality (Nature Editorial 2001). So can it really be considered that the potentiality of somatic cells, or the full genetic complement of the parthenote, confer a status identical to the embryo, that concurrently has the same status as a human agent[16]?

The second objection concerns human relatedness and lineage. If we accept that there may be special family (or species) relationships based on genetics, then we must be prepared to accept that, for example, one should have greater moral obligations to one's biological children than to one's adopted children. This would also unjustifiably accord support for those that hold that their genetic relatedness to one *race* implies granting special moral status to one's fellow race-members (Cavalieri 1998). While it is perfectly reasonable to hold that one perhaps has *special duties* to one's family (but these may be nullified when members disown each other), one cannot treat genetically unrelated individuals with moral contempt or deny their rights because they are unrelated (parental and familiar relationships can be genetically unrelated). We could not justify treating a non-human agent as anything less than an agent just because it was not related to me or the human 'family'. If Holland, and others, are correct, then how should a human agent, much less a human embryo, be treated by an unrelated (non-human) community of agents? To that group, both would be genetically unique and extrinsic to their community – should the two human entities be treated equally as the same (non-) moral beings, or should the human agent be treated as an agent?

Thirdly, the ramifications for taking such a position would be severely (or unjustifiably) restrictive on many activities that are generally supported (IVF or some forms of contraception); differentially supported (embryo research); or at least legally accepted as necessary (abortion) (see Chapter Four). These activities necessarily further an agent's access to their human rights. We would also have special duties to legally dead individuals, because the brain death definition means that the individual is still a biologically living human being (Kovács 1996 p. 225)[17]. If the embryo is morally protected with full rights because of its genetic makeup, the consequence of the strict view would be that it is given a 'super status'.

---

[16] One also has the conjecture that the human embryo is potentially infinite (in its totipotency) or more than one (in its ability to twin) genetic human beings. Does each totipotent cell have human being status? Or does a twinned embryo have less, or two fused cells have more, moral status than one human being?

[17] And what is the difference between the state of brain death and an embryo's existence except for the latter's inherent potential to become something else? After all, they are both biological living human beings with no capacities for agency *at that time*. One should also consider the theoretical cloning of cells from individuals means that any human cell is a potential human being (per zygote).

If one were morally committed to preserve embryonic life at all costs (which would follow from its full status), it would mean that the rights of other human beings (per agents) may have to be sacrificed in certain circumstances. These 'embryo rights' must be more defensible than an agent's rights to wellbeing or freedom, because while agent's rights are fundamental to a purposeful and valued *agent life*, they would be subservient in cases where they are in conflict with those of the *embryo's life* (the conflict inherent in abortion is called to mind). Such a position would call for every human embryo to be implanted and nurtured to full development (Tauer 1997 p. 177).

A more modest position may allow overriding of potential agents' rights in cases of conflict, but then this would mean that the necessary and sufficient status in biological human beings can be compromised by a more 'important' factor[18], and therefore in this case, species membership *is* morally violable and it becomes implausible that there exist uniquely human capacities, with degrees being evident both within and between species (Rachels 1990).

The precepts of the PGC allow one to bypass homocentric arguments, usually on a secular basis, because of the explicit claim that 'agent' does not, and cannot, have any species, race or gender specific claims. Thus claims that attempt to derive equal rights for all human beings, regardless of capacities or stage in development, are bound to fail unless we are also content to grant full rights to other beings of the same capacities or be dismissed as 'speciesistic'.

4. Potential Agents

If it is erroneous to derive rights merely from biological species membership, then one must look to a metaphysical[19] capacity that is not dependent upon this. These capacities reside as (1) having a potential to *develop into a full agent*; and (2) being a human *individual continuous with the agent.* There are three broad means of achieving

---

[18] This is implicit in abortion permissions when the embryo/foetus is granted an intrinsic moral status. There are two broad considerations that allow a termination in such circumstances. One considers that 'abortion ...can be justified ... by viewing [it] ...as a privilege granted to the pregnant woman considering that she is being "used" by the embryo and that she does not have to tolerate this "utilisation" under all circumstances' (Koch 1998 p. 262). The second view argues that whatever the status of the embryo/foetus, it cannot have an equal status to the mother (and therefore cannot make implicit demands), or otherwise endanger her basic rights (which are not necessarily limited to only include 'life') (Brown 2002; Engelhardt 1974 p. 233; Sherwin 1991; Thomson 1971; Warren 2000 p. 222).

[19] I.e. the property that is the *potentiality to become something else,* and not the implications of biology that explain what something is.

a moral status along these lines; firstly, that the potential to be an agent is somehow expressive of actually having the same moral value as being that agent; secondly, that there is an inherent value in being a certain type of object from one's pre- or retrospective agent-centred viewpoint; or thirdly, that potentiality admits of degrees, and thus confers a moral value according to one's proximity to being the thing that has the potential. All three approaches rely on the link between the potential capacities relevant to *being* a marginal agent to *having those capacities* that are accrued in becoming a full agent. So, if the non-agent requires, through its own merit, protection (and this is not entirely based on claims of mere species membership), then it is necessary to locate a *path to agency* that is comparable to the rights ascription to actual agents. The arguments in general claim that any potential agent is entitled to protection *during* the course of its transition or development to agency itself, since it is not an actual agent (for it cannot make claims nor be subject to duties placed upon it)[20].

Membership of the human species is also implicated in this account of moral status, thus Gewirth takes a moderate *Perfectionist* stance that '...since all humans, at least insofar as they are relevant to right-claims, are actual, prospective, or potential agents. No human, then, can evade the context of action...' (Gewirth 1996 p. 13). Gewirth argues that all human beings have some moral status, but because of the dialectical method, those beings incapable of *valuing* their desired purposes, cannot have human rights by the same means as agents. Therefore, although the embryo/foetus warrants some protection, in a case of conflict between the mother and the unborn, the latter automatically comes second (Gewirth 1978 p. 142).

Perhaps, then, the reason why the potential agent has some status is because:

> ...human beings who are not yet agents must possess moral significance for agents for the sufficient reason that they possess the potentiality to become agents. The agent has to attribute to herself dignity by virtue of being an agent [which is] ...a morally and unsurpassable status [and] ...then the agent must see a morally relevant connection between such a [potential] being and herself and her dignity. [However] They do not possess the same moral status as agents for they do not [actually] possess dignity ...It is not possible that agency can possess unsurpassing significance for the agent and in the other case no significance at all. For the agent to judge otherwise would be inconsistent (Steigleder 1998 p. 241-242).

Steigleder's point resides in the ability for some human beings to have rudimentary properties that justify moral consideration which are unique to the potential being. Because of this, an agent must attribute the same dignity in those potential individuals

---

[20] Unless the embryo can make an *implicit claim* on agents to ensure its safe and unrestricted development through to agency.

because it leads to the same basis of the dignity in herself, namely conscious rationality. We cannot therefore unquestionably grant rights to adult human beings and discount 'rights' belonging to the stages of pre-maturity when genetic and biological continuity are maintained. The potential of the embryo therefore lies in its temporal and spatial continuity with the adult being that it can become ((1) above). The metaphysical assumption is that it is important that the embryo *is the same entity* and that the adult individual can be biologically traced back to its own conception ((2) above).

4.1. Potential Agents as Actual Agents

Finnis has argued that the potential agent *actually has* the capacity for agency, even if it dies before ever developing expressive measures of such capacities, and thus it must be assumed that the potential for the human embryo to become a rational *human being* is irrelevant (Finnis 1997). The potential is the *development* of requisite abilities to express one's agency to onlookers, and not the having of an actual ability for agency. Therefore, 'agency' is already present in a dormant or locked-in form, and the potential is merely the ability to ostensibly express this. The 'agency' in some sense is already within the substance of the embryo; the embryo/foetus will not *become* a human person, it already is one. Thus, Noonan argues, '...everyone is a human who is conceived by a human being; ...[and] human beings may not be discriminated by their varying potentials' (Noonan 1968 p. 134). One possible reason for this is that '...there is one substance present throughout the history of the being involved, and, since this being is later rational, the substance itself must be a rational substance *ab initio*' (Engelhardt 1974 p. 223).

So what is the capacity already present in the developing embryo? One argument claims that the potential agent has rights, but not because it can claim rights or have duties, but because it has some sort of *present* interest in having those rights in the future (which it cannot 'know' about until it is somehow sentient):

> ...the fact that an infant's genetic code determines a developmental path which leads, if she follows it to the end, to intrinsic conscious goods (like self-awareness) for her, arguably makes it in her interests to go on living. Death harms her because death deprives her of all the conscious goods it was her biological nature to make herself have (Stone 1995 p. 141 fn. 9)[21].

[21] Similarly see Perrett 2000 p. 192.

Stone argues that a 'strong potentiality' for a being to be become an agent can grant intrinsic rights to that being *at that time* because the potential being has an interest in growing up. He argues that if one relies solely on innate 'interests' actually present from an agent's point of view, one could kill all non- and marginal agents without recourse to moral justification, since they have no actual interest in continued life, but for a 'genetic constitution' that means that such a being has an *actual interest* in achieving this end state:

> ...potentiality makes a difference to what a creature *is* at that time, even if the potentiality is never actualised: if the developmental path determined by a creature's genetic constitution leads to a conscious good for her, the creature has an *actual* interest in growing up. It is true of her at t [time at that moment] that growing up [to be an agent] is a benefit and not growing up a harm. A creature's present interests are relevant to her rights; therefore potentiality matters (Stone 1987 p. 828).

Such advocacy of 'strong' potentiality requires agents to regard this being as a potential ostensible agent with full moral consideration: 'The right to life begins when the harm of death begins, as soon as we get a biologically human creature that can grow up' (Stone 1995 p. 141 fn. 9). Therefore, potentiality grounds the embryo's rights because it '...actually [is] a human being because it already possesses, albeit in undeveloped or immature form, all the capacities or potential that any other human being has' (Finnis 1997 p. 49)[22].

In both cases, the 'interest' lies in a biological nature, which although undeveloped, will inevitably become recognisably actuality[23]. Such 'capacities' may be present in the embryo/foetus despite it being 'unaware' of them; in much the same way that before and after sleeping I am aware of my interests (unlike the embryo), but I also assume an (implicit) interest in my being while I may be unconscious. Therefore one continues to be a person throughout the time when we lack all consciousness, and :

> ...a person continues to survive as long as biological life continues ...A person may cease to be a person and still exist by losing her mental capacities [therefore] ...Psychology is *irrelevant* ...either that organism [non-person] perished when it began to develop a nervous system and was replaced by you, or it continued to exist and is now an adult human being numerically different from you (Olson 1997 pp. 106-108)[24].

But, in contrast, John Harris states:

---

[22] Similarly see Wade 1975 p. 244.
[23] Thus one is defining the spacio-temporal history of a particular organism, and not the total span of its conscious experience (qua agency) (Puccetti 1983).
[24] Similarly see Crosby 1993 p. 415.

> In those states [sleeping] I possess the capacities [agency] which I am temporarily unable to exercise. I have not lost those capacities, for if I had I would have to re-acquire them each morning on waking. The zygote, of course, has yet to acquire any of these capacities (Harris 1997 p. 59).

Harris' point may be countered by two claims: (1) in the terms of the '...expected future, one's potential of awakening' (see Engelhardt 1974 p. 220); and (2) being '...capable of having capacities [may be understood as a] ...nature of a kind whose flourishing involves such valuing, whether or not an individual of such a nature happens to be in a position to exercise those capacities' (Finnis 1997 p. 48). Indeed, at no point does Gewirth's project state that agency *must be expressed* for the possibility of having the capacities of agency; one need only have at least the *disposition* to express ones agency.

Therefore, the argument is that when an agent sleeps, they are, much like an embryo, incapable of valuing, and therefore agency is transient and not a fixed property. If the property is not fixed in the abilities of the actual agent, then such abilities can technically come (and later go) in the embryo.

Crosby concludes that there is no proof that the unconscious sleeper has any different value to the unconscious embryo (so that both are *human beings*):

> We can know, not indeed all we want to know about the embryo, but enough to have the same strong duties towards it which we have towards other human beings whose personhood is self-evident... I am at present embodied in my body in such a way that I have to assume that I was present in it from its very beginning, even before I awoke to consciousness; for I know that there is more to myself as person than my consciousness (Crosby 1993 p. 415).

It therefore is implied that every person is always, and was always, a 'person'. While the individual embryo is a potential rational agent, it is continuous with that agent; thus a 'person' exists as long as its biological life continues, and that a person still exists even when agency is not evident.

4.2. Future or Past Potential Agents

In the previous section, it was implicit that the rational agent has a historical link with the embryo *that it was*, through its genetic and biological relatedness. This meant that the 'substance'[25] that conferred agency in the agent must also be present in the

[25] Called a 'telos' by Wade 1975 p. 244.

embryo. In the present argument, it is instead contended that if the 'substance' of the 'person' is not already present in all developmental stages, then the embryo *becomes a 'person'* some time between conception and maturity.

The emphasis of this second approach resides in the fact that if the potential being does not already have, or is merely unable to express those properties that are normally grounded in the state of agent, then (1) it is the *potential to have that in the future* or (2) *that any agent can recognise the part that the previous stages took in it's development*, that is morally important.

4.2.1. Future Agent[26]

In (1) above, it is claimed that the potential agent has rights because that human being has a natural and innate ability to become an agent. This has been referred to as the 'Strict Potentiality Criterion' (SPC):

> All and only those creatures who either actually or potentially possess C [capacities for agency] (that is, who either have C now or would come to have C in the natural course of events) are moral persons now (Feinberg 1986 p. 266).

Instead of viewing the embryo from the point of fact that potentiality is not actuality, 'rights' exist at time *t1*, not because that being does not have those capacities (C) at a given time but will, all things being equal, at *t2*. In the same way as when an actual agent is sleeping; those capacities for agency may not be present at *t1*, but they will be in the future, as long as nothing intervenes to frustrate this: the '...salient potential, albeit non-actual' moral interests and rights are of value, because at '...an early stage of development [human embryos] do not actually have the capacity for pain or pleasure [or conscious rationality], they will soon enough, if nature is allowed to follow its course... [this is why protagonists] ...suppose that potentiality but not yet actuality sentient fetuses [sic] have a moral right to life...' (Jacquette 2001 p. 82-83). All human embryos have the same kind of potential – to become a human agent.

---

[26] This argument is related to the arguments of futureality. The significant difference is that stem cell research results in the non-viability of the embryo. Because futureality views the moral status of the future being *as that being it will become* as important at that time, the research embryo, unless it is viable and implanted, has no future. Up to reaching the morally significant moral status attained at a point in the future, there is no morally relevant being, only a future being of moral importance (see Appendix Four).

Therefore, potentiality arguments of this kind hold that what is important is that a potential being can *become* a rational agent; but in this case: 'The potentiality of the fetus [sic] to become an adult is not a passive potency [potential], which is neutral to the future; nor a specifiable active potentiality, which is a very "iffy" promise; but is an active natural potentiality or tendency, which is a guarantee of the future as far as the agent is concerned' (Wade 1975 p. 245). Thus, the potential agent has a future (at *t2*) set and fixed in the active potentiality. The potentiality is already present (in the genome); furthermore, there is no learning involved (in the way that a medical student is a potential doctor). This argument follows the agent-centred rights frameworks, but importantly, also allows the derivation of rights for those beings that *become* agents. Such potentiality does not concern being presently and minimally conscious or the capacities of rationality which allow one to realise one's own future values, and furthermore, the potential agent does not have to value its past and present existence. In this strict sense, it is the natural tendency to *become* a 'full' agent that is key to understanding its present moral status.

Thus the intrinsic unfolding of the potential inherent within the biology of the embryo may provide it with a 'future-like-ours', where 'typical' embryos have a right to life (Marquis 2001 p. 363; & Marquis 1989). Marquis argues that killing any particular being (not necessarily biologically human; 2001 p. 190-191) that has a propensity to become an agent (i.e. a life of value), has the effect of depriving that being of those things that they value presently, in the past and in the future. From this it can be extrapolated that the embryo can have a *value of a future-like-ours*, even though that embryo cannot at that time actually give expression to that value (ibid. pp. 198-202). The ability for the embryo to have a certain type of future means that it should it not be destroyed at that time (ibid. p. 103), because having a future itself is sufficient to create the strong presumption that killing is seriously wrong (ibid. p. 195).

4.2.2. Past Agent

An alternative to the potential to *be something in the future* would be to look back to the potential being from the actual agent's retrospective viewpoint. From this position, an agent can realise the link between different stages of its own development, and can therefore appreciate that there was a time when it was an embryo and later, a

foetus, just as it was once an infant, and that all of these overlapping statuses are intrinsically associated. It makes no sense, the argument claims, to view the ultimate status of agency as unrelated to previous states of existence. Since one's identity can be located in each previous stage.

From the position of rational agency, one can see that it is good, indeed, essential for my present agency, that no one experimented to the detriment of the embryo that became me. Therefore, the embryo represents '...an individual who *would* benefit, even though that individual... does not now exist' (Hare 1997 p. 10). The potential that that embryo had at the time of its existence is a potential to become an agent. The status of agency is a value in itself, and it is alleged that any agent can deduce the value of its own previous marginal status. A potential being also must have the same value as a present agent asserting its own rights (perhaps the inability to value at that time is the same as an agent in the event of its temporary unconsciousness). Therefore, development is a:

> ...mere alteration of something that already exists. Just as my present organism has a reasonable claim (at least!) to be diachronically identical with a certain foetus existing before my birth, this foetus has a reasonable claim to being identical with a certain embryo that existed months earlier, and the embryo a reasonable claim to being identical with a zygote that existed still earlier. Since we (people) are identical with our present organisms, we once existed as zygotes (Carter 1982 p. 94).

4.3. Potentiality in Degrees[27]

This account of potentiality does not argue that any potential is strictly and equally morally relevant for all remotely potential agents. In the first argument above, potentiality expressed the view that the actual 'person' was always present in the developing being, regardless of the abilities of that being at any given stage to express

---

[27] The Principle of Proportionality (as the gradual attainment of actual agent capacities) is linked to this theory. However, it is clear that the embryo and foetus have different ontological capacities, and therefore it seems logical to accord them at least some different status. Proportionality in this sense protects certain human life from being treated as merely things, but limits full moral protection in cases where its status is in conflict with that of an agent(s) (Gillespie 1977 p. 241). The embryo, at the time when it is required for stem cell research lacks any ostensible proportional properties of agency, and for this reason, is not wholly relevant. This theory may be linked to potential, because while *X* is not *Y* if it only has the potential to *produce*, if *X* maintains its identity with *Y* so that it is *becoming*, then the difference is only that of time, and while becoming *Y*, it has a proportion of *Y* (Evans 2001 p. 65). Proportional agents may also be potential agents - such beings differ in their potential in proportion of having the capacities of agency, nevertheless, all thing being equal, they can develop into full agents (Perrett 2000 pp. 188-189). The important distinction is, however, that morally significant marginal agents of this type *have* a degree of *Y*, not a *potential* degree of *Y* (see Appendix Three).

that capacity. Therefore, all potential beings are equally morally significant to the end state. In the two formulations of the second argument, the fact that the potential agent would become an agent (as per (1) above; *supra* s. 4.2 p. 114), or that as an agent one can recognise its past existence ((2) above; ibid.), also meant that prior states of existence were of moral equivalence.

This third argument does not assert that at all times there is such an entity that deserves the same status as each proceeding one, but that there are degrees that approach the end state, and each degree, however, requires a different understanding of potential. So, the human zygote, if given the right conditions and permitted to develop, will, at each consecutive developmental stage, have an increasing proximate potential to become an agent. At each consecutive stage, different requirements are necessary to realise its potential, but at some point, the potential to be come an agent grounds a moral status equal to that end status.

The point at which this occurs is an empirical matter. So, while from the moment of fertilisation the being will have the ability to become an agent because it is 'biologically programmed' (presented above, as the second argument headed *Potential Agents as Actual Agents*; s 4.1 p. 111) to that end. However, the degrees of potential mean that there are different *types* of potential. Its main value is in that it formally claims to avoid criticisms of the *reductio ad absurdum*, so that not everything has a morally significant potential (i.e. unlike everything [that is/can be] biologically programmed), and even though that non-moral 'thing' may nonetheless have a potential to become something else.

The difference can be illustrated in that gametes have *less* potential than the embryo: the gametes are a *potential human being*, while the embryo is a *potential agent*. For gametes to become embryos, they have to be somehow brought together; this is an *additional* action on the part of another, which is unlike the embryo, which merely has to be left alone to realise its potential[28]. The human embryo, on this account, is more proximate to a human being, which is concurrently more proximate to an agent than mere gametes. Thus, the property that confers the potentiality for normal embryo development is of moral importance (since no other thing can become be a human agent – gametes can only become a human embryo). Making this distinction also fixes a

---

[28] A similar argument is used to nullify the claim that every somatic cell is a potential person by employing CNR. In this case, outside agency is required to create the 'specific kind of process' (cloning) to produce a human being (Mori 1998 p. 53; Wendler 1999 p. 36).

'line' that what can be done to a human embryo is different from that can be done to human gametes or non-human embryos (Campbell 2001 p. 44; Szawarski 1996 p. 122-123; Tauer 1997 p. 173; Wreen 1986 p. 24).

As a result, there is a clear attempt to avoid the rejoinder that anything can potentially become anything – only things with a 'strong' potential (the potential to *become*, or a 'naturally probable potentiality') can become something of moral significance (as opposed to those things that have a 'weak' potential). So, a 'strong' potential is attributed to the embryo, while 'weak' potential is afforded to the human gametes (Buckle 1990, 1988; Jacquette 2001 p. 84). The individual embryo maintains an identity with the individual agent – both spatially and temporarily. Without the earlier, the later does not exist, and the embryo has the '...power possessed by an entity to undergo changes which are changes to *itself*' (Buckle 1990 p. 95). Gametes therefore have only the potential to *produce*, or a 'merely logical possible potential' (ibid. p. 93). Therefore:

> The fact that sperm and ova have the potential for combining, and thus forming the zygote – which is a potential person – doesn't make them potential persons. Rather, the sperm has an active potency to fertilise the ovum, and the ovum a passive potency or potentiality to become fertilized [sic.]. The entity thus created, the zygote, has an active potentiality to become a person, and thus is a potential person (Wreen 1986 p. 18).

The embryo requires no additional 'parts' to become the agent (unlike the two parts that are the gametes that combine), and the implication of additional or separate parts suggests that there is not continuity of identity.

Protagonists of the strong potential of the embryo status claim that the potential for *X* exists given the absences of interference on the one hand, or on the other, at most modest assistance; and that the entity would *probably* acquire *X* at some time in the future (Pluhar 1977 p. 160). The potential for *X* resides in '...something we expect to happen' (Jacquette 2001 p. 84); and as long as there is not a fatal accident or deliberate interference, nothing more need occur.

Up to now, it has been taken for granted that the moral entity, as a potential agent, occurs at the point of 'fertilisation'. The embryo, although merely a potential agent, is proximate enough to that end state to be accorded the same status as the agent. Along these lines, the primacy of the human species can also be asserted, because other non-human beings, regardless of the proportion to being an agent, are not potential agents, because they cannot actually become full agents (as opposed to human beings). Once

the potential for agency confers a being with moral status (but still a potential agent), it makes no difference about the subsequent level of potential; essentially, those differences are in *degree* rather than in *kind* (Feinberg 1986 p. 267).

But, others have argued that the embryo is potentially many human beings until twinning can no longer occur (once the primitive streak has formed) (Evans 1996; Lockwood 1995), because before this '...development of the embryo has not proceeded to a point where such an individual comes into existence [so there is not] any individual whose interests are (directly) adversely affected by the non-development of this potential' (Lockwood 1997 p. 19)[29]. Therefore embryos before this point can be used in research.

However, this argument also implies the claim that if degrees of potential can be located between the gametes and embryo, then there are surely different degrees of potential in other states of affairs. This means that a certain type of embryo has no moral status, and can be used in research as long as these conditions are met. Thus, the 'strong' potential of the human embryo can consist of a subset, for example the *in utero* and *in vitro* embryo (and indeed, of the latter there may be separate claims on those to be implanted, those that remain after IVF treatment, and those specifically created for research) (Koch 1998; Schroten 1998)[30]. This liberal interpretation of potential may account for the observation that '...potentiality admits of several degrees: potentialities are more remote and indeterminate when the goal is more distant, and more proximate and determinate when the goal is nearer' (Mori 1998 p. 52).

But this seems a difficult argument to maintain, because essentially all embryos are the same *thing*[31], in the same way that all human beings are genetic members of the human species, or all agents have the same necessary and sufficient conditions of agency. Indeed, similar arguments are used to separate the intention behind creating an embryo. But whether created in a fertility programme or specifically for research, it is argued that the thing is the same, and there are no degrees of moral relevance (Leaston

---

[29] But see Crosby 1993 (p. 410); Howsepian 1997; & Munthe 2001 (p. 385-386) for arguments that defend the position that divisibility of the embryo does not necessarily rule out moral status.
[30] Koch (1998) argues that IVF spare embryos are '"...doomed to die" ...[therefore] in-vitro embryos have a lower status [because of] "reduced potentiality"' (p. 262).
[31] See the unsuccessful challenge to the UK's Human Fertilisation and Embryology Act 1990 in 2001. The 'Pro-life Alliance' failed in contending that a cloned embryo was a *different type* of embryo to that created by *in vitro* fertilisation (*infra* Chapter Four Part Two s. 5).

1998; Tauer 1997; Wolpert 2001[32]). The ontology of all embryos at a comparable developmental stage must be the same or otherwise accept that the status of the embryo is dependent on other factors, such as agent intention:

> To suggest that the moral status of an embryo depends on the nature and intent of the activity within which it is conceived seems intuitively absurd ...[if one] ...makes use of the Kantian dictum that we ought never to treat others merely as means to our own ends ...then if the preimplantation embryo [is the]...the sort of entity to which the Kantian maxim properly applies, then no destructive research with [any type of embryo] would be permissible (Tauer 1997 p. 175-177).

Once we start accepting evaluative degrees of categorisation one can create a climate where subjective claims can be vindicated, and these are often related, for example, to unjustified attempt to delineate the status of different human sexes, races or cultures.

5. Criticisms of the Argument for Potential for Agency

Potentiality is often dismissed because we do not often describe things as being that thing that it will naturally become; we do not consider viable acorns are oak trees[33] (and do not treat the two entities as the *same* things) (Williams 1986 p. 192; cf. Evans & Evans 1996 p. 222). It is argued that the things are fundamentally different, requiring a different attitude. Proponents of the potentiality argument who distance themselves (although perhaps not far enough) from the 'genetic school', claim that there is a teleological concept that refers to the embryo/foetus becoming an agent through an inherent ability or inner principle that it possesses or, retrospectively, that every agent was once an embryo/foetus and therefore must accept the value in this. So why would an agent necessarily be inconsistent if she claimed that a potential agent had a different and lesser status than herself?

I have already dismissed arguments that rely on human species membership. So these latter arguments must only be interpreted as being employed to construct moral consideration for the embryo as a potential agent, and not merely a potential *human* agent. However, the important factor to be borne in mind in these arguments is that:

---

[32] Wolpert argues that if there is an intrinsic and worthwhile value in IVF treatment (regardless that embryos are created and necessarily destroyed), then one should non-contradictorily accept that creating embryos for stem cell research may also have real value and therefore be a worthwhile pursuit (2001).
[33] See Thomson 1971 p. 48.

> Being a mere potential agent is not a necessary property possessed by agents. It is not even a contingent property of agents. In fact, it is a property that cannot possibly be possessed by agents. If one is an agent then one is not a mere potential agent and if one is a mere potential agent then one is not an agent (Beyleveld 2000b p. 68).

From this, the potential to be an agent does not accord the same moral treatment as *being* that agent. A potential agent must be considered as a different type of 'thing' from an agent – and it is therefore consistent that the embryo has a different status from an agent.

If this was not the case, then practical assertions would require us to go to absurd and dangerous lengths. Some forms of contraception would be prohibited because they stopped the embryo from continued development, furthermore every embryo, including those created through IVF, would have an equal 'right' to have its developmental path realised, and therefore would have to be implanted within a uterine environment. Abortion, even at the earliest stages, would be prohibited; and states would have to favour policies that asserted that it would be equally morally wrong to destroy a fertilised human egg, as it would be to kill an adult human being[34]. Although writers may wish to affirm that potential beings deserve some moral concern, if that concern amounts to anything like that due to agents, then to have any moral concern surely must protect that being per se.

So, the problem with these potentiality arguments is that they can lead to 'moral absurdities' (McGinn 1992). An acorn does not have as much (aesthetic or sentimental) worth as a fully-grown oak tree, simply because (more often than not) it is a different thing of value. Nevertheless, the seed that the tree grows from has the innate potential to become a tree. If potentiality were to ground rights to human embryos on a comparable level to agents, then there would be certain things that could not be done to them; but then this would either unduly inflate the status of mere potential agents, or devalue those rights that are due to actual agents.

Furthermore, these rights could be extended to gametes (they are potential agents and undoubtedly living cells of human origin and genetically unique; Mori 1998 p. 44) and clonable somatic cells by virtue of their human potentiality. The oocyte *itself is capable* of early embryonic development; before it ceases to develop, it is the same as

---

[34] 'If it is true that the life of the human being begins once fertilisation of the ovum is complete, then to deliberately prevent its implantation in the uterus is to end a life that has already begun, not to prevent one from starting' (Beasley 1996 p. 90).

the potential embryo that will continue to develop[35]. Therefore, potentiality arguments have adapted to be acquiescent to the opinion that, although embryos may command distinct and separate considerations, these are not the same moral precepts as those directed at agents.

5.1. The Continuity and Ontology of the Embryo

It is evident that any agent's present existence was dependent upon the existence of a previous embryonic stage. But it is also true to say that the same agent also relied on the existence of her parents, and their respective gametes that were successfully brought together and then allowed to develop in the uterine environment. The natural continuum of life is dependent on the actions and biological relations of previous entities, and it is an extravagant claim to assert that all those entities have a moral status that derives from any agent's present interests. This *reductio ad absurdum* argument suggests that although an agent is dependent on previous entities, it is absurd to inflate the moral inferences that can be shaped; not only is it illogical to derive a strict moral status for a dead ancestor[36], much as it is for the gametes that derived the embryo (all as discrete entities from the agent), but also it is entirely possible that one can be discontinuous with one's biological past-'self' (Dawson 1990 pp. 48-49). For example, how can monozygotic twins be continuous with one embryo? Can they *both* be the *same* embryo? How can the divisible embryo be a potential agent, when it is potentially many agents (each totipotent cell of the early blastocyst can become an embryo in itself), no agent[37], or a hydatiform mole (non-embryonic cell mass)?

Austin stated:

> The whole egg certainly becomes the embryo, and the whole fetus [sic] becomes the child, but the whole embryo does not become the fetus [sic] – only a small fraction of the embryo is thus involved, the rest of it continuing as the placenta and other auxiliary structures (Austin 1989 pp. 17-18).

---

[35] Indeed, as Harris points out: 'This possibility [of parthenogenesis] shows that the human egg is an individual of the human species if the embryo is, for they both contain within the one individual all that is necessary for continuous growth' (Harris 1992 p. 35).

[36] It may be possible to circumvent having *any* parents because reportedly both male and female gametes have been derived from embryonic stem cells *in vitro* (Clarke 2003; Hübner et al. 2003; Sample 2003).

[37] Only 50 to 60 percent of all conceptions advance beyond 20 weeks of gestation; 75 percent represent a failure in implantation (i.e. before the 14th day) (Norwitz et al. 2001). It is argued, however, that the fact that few embryos survive under 'optimal' conditions is not an excuse for affirmatively destroying them (Charo 2001 p. 84).

We can infer from Austin that if the early embryo had rights, then the placenta (and any of the cells in the embryo) would deserve equal rights (but only before it becomes the placenta, because once it does, it cannot be a potential agent, unless it can be 'reprogrammed')[38]. For this reason, the 'product of conception' is sometimes described as a structure from which the embryo proper and supporting tissues develop (Szawarski 1996 pp. 124-126); fertilisation results in a 'conceptus' that begins the process of embryogeneis, but is also part of a larger project that supports the development of the designated embryonic cells (Mori 1998 pp. 48-49). Therefore, an individual mass of cells alone cannot be considered to constitute an individual life, although those cells are human and living (Evans 1996)[39] and for this reason, Thomson states that the concept of the 'individual' cannot be applied to the embryo as it does to the adult (Thomson 2001 pp. 16-17).

Thus, there is a distinct possibility that the embryo that I came from was potentially not 'me'. I only become 'me' once there was a discrete and continuous entity with my being. From biological observations, it is held that twinning or segmentation (division of the embryo into more than one discrete embryos) implies that there is not a continuous being, and therefore the being before this time (sometimes called the 'pre-' or 'pro-' embryo) cannot merit full moral concern (Dawson 1990; Mori 1998 p. 45; Olson 1997 pp. 104-105; 182)[40]. Such an argument can deny an embryo 'rights' up to around the fourteenth day, since if gametes cannot have rights due to their separate existence - they are not on the same path as the nature of the embryo – the embryo cannot have an existence as one, two, and theoretically limitless, identities (Stone 1987). Furthermore, the existence, and moral status, of the twined organisms

---

[38]Subsequent to the cells commitment, the placenta may be regarded an *organ* of the human embryo/foetus that is discarded at birth.

[39] Holland argues that the '...collection of pieces which lie on the watch-repairer's bench is surely the same individual watch as the one I sent off for repairs' (1991 p. 304). But I would contend that these bits can be used to repair other watches, much as the totipotent cell can be removed from the embryo and be introduced to a second to constitute a chimera.

[40] Twinning is countered by arguing that the first 'twin' gives 'birth' to the second twin in a form of 'asexual reproduction' (Crosby 1993 p. 410; see Mori 1998 pp. 46-47). But then, all human cells can also give 'birth' through cloning! The *Transitivity of Identity* (see below) theory shows that there is a special kind of entity capable of development present in the conceptus – while all totipotent cells can become individuals (of the same kind), they cannot all be individuals within the conceptus. The conceptus itself can become one (or more) individuals (none of which would be the same [identical] entity as the original conceptus), but likewise, the conceptus cannot already be more than one individual – since what would happen to all these beings if only one being develops? The conceptus , while being this type of entity, is neither one or many individuals, but potentially can be coaxed towards each outcome.

could only come into being after the division of the original cell mass into two viable embryos (Fisher 1994)[41]. Therefore:

> ...the "embryo" as a continuous entity could be traced back only as far as the primitive streak stage ...and the "embryo" that develops from fertilisation onwards is a different entity, which includes and gives rise to the "embryo" that grows into the foetus and neonate but is in no way coextensive with it (McLaren 1986 p. 14)[42].

Can one argue that that the potential agent *becomes* an agent at a point of regional or committed development, because at least now it is possible to discern the point at which a genetically unique human being comes into existence (Baumgartner 2002)? If one argues that genetic uniqueness is essential for moral status, then those beings that would not be unique (twins or clones) would somehow have less moral significance, and there are grounds for not believing this to be so (Dawkins 1998 pp. 63-64; cf. Tooley 1999): '...*genetic uniqueness* is not equivalent to *somatic* (or *bodily*) *uniqueness*' (Mori 1998 p. 42).

So what about the existence of a discrete entity as the means for deriving moral status? It is argued that a human embryo has a 'developmental path' (full genetic complement), determined by its nature to become a human adult (Stone 1994 p. 819). Therefore there is a *prima facie* duty to all beings not to deprive them of their conscious goods which it is their (unconscious) nature to realise. Yet such embryonic entities cannot realise their *own* interests (or many interests in each totipotent cell!), since they are not presently consciousness or even proximately conscious (Pluhar 1977 p. 166).

What about the question that because a potential organism may cease to exist if that potential is never realised, it has an interest in continued existence (*future of value*)? Firstly, this does not provide a moral imperative for all potentialities to be realised. Although a living being may change (i.e. to realise its potential) in order to persist, it is entirely possible for a potential to be put indefinitely on hold (in this case by freezing the embryo). That potential presumably continues but will often be remotely actualised, depending on the fate of the (if ever) thawed embryo. More to the point, because of this

---

[41] Finnis has argued that 'The specification of embryonic tissue into embryoblast and trophoblast, and the development of the latter into the placenta and related tissue, is nether more nor less than the development of an organ *of the embryo*, an organ which it will discard at birth. The division of an embryo into twins or triplets is simply a change from one individual into two...' (Finnis 1997 pp. 46-47; cf. Howsepian 1997). But conversely, the placenta may also be seen as a 'sibling', since equally and before this point the cells could be separated into more than one embryo, and which cell become which dedicated structure seems to be indiscernible. Harris adds: 'It does not follow that the egg, say, is necessarily the same individual as the adult it eventually becomes, any more than the zygote could logically be the same individual as each of the twins it becomes, if it twins' (Harris 1997 p. 58).

impending expiration, there is no corresponding requirement on any one individual to preserve the potential to ensure eventual *actuality* (Savulescu 2002 p. 133).

Secondly, Mark Brown is apt to point out that this future of value must still be a 'potential future of value' since the embryo is unable to self-represent this view (Brown 2000). The future existence of the embryo still then hangs in the balance of the potential events that lead to it enjoying its own interests/future[43]. Being an agent is indeed, on these descriptions, important and valuable for that agent, but how can not being an agent ever be valuable to the potential agent?

In the end, these arguments fail because one cannot infer conclusions from as yet unresolved premises, and this is based on the *transitivity of identity* (Holland 1991 p. 307; Stalnaker 1975 esp. p. 173). Perret (2000) argues that logically, one cannot infer a conclusion from a premise that itself depends upon a prior premise, and from which the conclusion is dependent on both (A > B > C cannot infer A > C). But, he does claim that if a=b, and a=c, then one can rely upon b=c. Therefore the morally important potentiality lies in B > C (*strong potential* for C); while A > B is at most a *weak* potential for C. This means that:

If the sperm (Ai) and egg unite (Aii) (Ai + Aii = A) than there will be an embryo (B);

If the embryo (B) is not impeded, it can become an agent (C);

B has a strong potential[44] to C;

A cannot become (weak potential[45]) C, without first becoming B.

---

[42] Similarly see Evans 1996 p. 78.

[43] In a reply to Brown, Marquis states that '...the self-represented future of value account might be preferred to the potential future of value account for reasons of gender equity. This is because the wrongness of abortion would impose burdens on women that it would not impose on men and one might argue that choosing an account of the wrongness of killing that imposes burdens on one gender, but not the other, is unjust' (2001 p. 366). While it is certainly true that females have a greater burden when it comes to violations of reproductive rights, this does not mean that you can pick and choose according to a desired outcome. Surely such a conclusion would, on Marquis' own terms, be 'unjust' to embryos?

[44] Or 'naturally probable potentiality' (Jacquette 2001 p. 79). In this scheme, B > C is also termed an *active* potential, because B has an inherent capacity to become C. A consists of two parts that require bringing together by external agents, which is interpreted as a *passive* potential (see Reichlin 1997; & Aristotle 1998 pp. 131-134). Of course, B > C also requires the actions (and inaction) of external agents. The natural tendency for B > C also fails to reject a possible natural tendency for B to fail to become C (or become C_1, C_2, ..., C_n).

[45] 'Merely Logically possible potentiality' (Jacquette 2001 p. 79; Reichlin 1997)

Although this does address the *reductio ad absurdum* problem (i.e. only B's can become C's, so no A's have a potential for C, or at most a weak potential), it does not tell us why B to C is a morally important step[46]. Certainly, from A one cannot infer C, at least without the intermediate step of B. But although one cannot infer A > C (see Stalnaker 1975 p. 173), A is required for B, which in turn is required for C (and A in this scheme has a strong potential for B!). This does not mean that B is more morally important than A, and indeed, A is necessary for C regardless of its proximity to it[47]. While one could substitute A1 (CNR) for A (fertilisation) and still have B, B could also become B1 (hyditaform mole), B2 (embryo1 & embryo2) etc., so that the scheme can result in having no moral significance for C (because you may have C1 [two agents] or C2 [no agents]. If B > C was morally imperative, then the steps from A > B would also become equally imperative, thus ruling out any steps that attempt to hinder this development.

Is it, therefore, not necessarily a natural path of all embryos to become agents? The mother and others in proximate contact must refrain from certain actions, and indeed want that embryo to come to term. (If it is an *in vitro* embryo, it must be implanted). Through our modification of behaviour, there is a greater chance of the embryo developing to agency, but then these actions are mingled with the path of the embryo. Stopping the gametes from coming together is not 'killing' an individual. But this can equally be applied to later stages if you can show that no one (person or agent)

---

[46] There are a number of arguments to defend this position with regards to the embryo (B) and person (C). For example, the step from B > C represents only a minimum degree of human intervention (Wreen 1986 p. 22); that B is a potential C and an actual thing that will normally develop into C (see Perrett 2000); that destroying B is stopping C from existing at all and at any time (Wreen 1986 p. 21); B *shares* the nature of a *future* C (there is an 'inherent tendency' to develop the capacities of C which is present in all Bs); and that B is the 'very beginning of actualisation', and thus must be treated as C (see Reichlin 1997 p. 23). All three arguments assume that unlike the gametes, the embryo is a potential, if not actual 'person'. But as we have seen, it is unlikely that the embryo is in fact any sort of 'person' in any individual sense, and that potential capacities are not *presently present in any measurable, ontological or empirical way* (the same potential must also be present in the somatic cell that is used in the [theoretical] creation of a cloned embryo - if this is not the case, then it must be present only in the [enucleated] oocyte and so actually in the cytoplasm, since sperm play no part in cloning). Furthermore, the parthenote must also have this potential because '[t]he sense in which the embryo is already what it will be is the project which it contains: it has all the information needed in order to accomplish the person it is' (Reichlin 1997 p. 16)). If it is not, then the *process* of forming the zygote *activates* (whether this is through syngamy of both sex gametes or the electric current in CNR and parthenogenesis) the moral status within the oocyte. The capacities for agency must also be present in the placenta and other support tissues (but is subsequently lost, only to be re-established in cloning!).

[47] What about those embryo that do not have a natural path to agency, so that B does not lead to C? Those, for instance, that have faulty or mutated genomes; or the majority of embryos that fail in conception and pregnancy (Singer & Dawson 1990). Furthermore, there is no status difference between types of embryo, because an *in utero* embryo that is to be willingly aborted does not necessarily have

is present. Therefore, Pluhar comments that if we violate a potential being's right to life by not allowing them to become an agent, then contraception, and also abstinence, may be construed as 'murder', in the sense that 'someone's' right to life is violated (Pluhar 1995 p. 112).

This seems true on two counts; that the gametes are potential agents (arguably less than an embryo), but also that stopping an embryo from becoming can be effected by stopping the union of gametes. After all, the move from embryo to agent is also reliant on fertilisation. Wreen argued that '...in some sense the sperm and ovum do seem to provide the basis for the existence of an actual person, and that because of their potentialities. And both are, as seems important in this context, direct or approximate causes of the existence of an actual person' (Wreen 1986 p. 18). But the emphasis on actual person (per embryo) accords far too much inherent moral status to the embryonic cells. One may assert that there is a different potential between a gamete and an embryo (through the process of fertilisation), but then there is also a different potential between the embryo and a foetus (implantation or neural development); and there is also a difference between an 'individual' and a 'person' (qua agent).

Therefore, the early stages of the embryo's development do not count as part of the agent's existence, in the same way that its life does not exist as many entities. I would have not existed if I had been aborted; but then I would not have existed had the embryos of my sibling fused with mine (unless we would be both present, and if a human embryos and mouse embryos were fused to form a chimera, would both a human and a mouse be present?[48]). Furthermore, where would I be if my sibling split to become both me and him prior to that event? (Did he perish in the split, giving rise to two new individuals?). What about further back? If the gametes that fused to become me had not done so, then likewise I would not have existed. So are those gametes 'me' existing as separate entities? What about if my parents had not decided to have a child? Or my mother never met my father? One must therefore consider the potential agent's moral status in its actual capacities.

---

more potential than an *in vitro* IVF embryo. Indeed, if the *in vitro* embryo is part of a parent's willing participation in an active IVF programme, then there is a chance that that embryo has a greater potential.

[48] Scientists have purportedly succeeded in creating genetically male/female human embryos (Hutchinson 2003) and human/rabbit embryos (Chen et al. 2003).

5.2. Agents were Once Embryos?

Wreen asks, if '...it would have been o.k. [sic.] to kill me in the womb while I was a mere potential person, [why would it]...not [be] o.k. [sic.] to do so now, when I am an actual person' (Wreen 1986 p. 24); because killing an embryo *in utero* has the same effect for that agent as killing her presently? After all, it is only '...one step back in the creature's life' (Wreen 1986 p. 35), and surely a determinate action such as killing would deny its continued existence as a single living individual; and killing the embryo would mean, as I exist presently, a loss of my present interests (cf. Holland 1991 pp. 305-306; & Reichlin 1997 p. 6). Thus, although I may never have existed, I presently do, and this means that I should at least extend moral concern to beings that are proximate to my present existence. And this is the same for every agent, and therefore every potential agent.

It is my opinion, however, that any embryo's existence cannot be continued merely for the sake of a future agent. The argument to be made in support of this rests on the fact that I do (or would not exist). And from this it is difficult to hold that any embryo has the same 'rights' as the agent that it will become. The discrete entity that was the embryo, and that I can link to my present existence, no longer exists (unless either I was always present as that embryo or that embryo somehow presently exists concurrently to my present agent status). Still, if that embryo was destroyed, then presently I would not exist, and nor would the embryo, and subsequently there would be nothing to extend 'rights' to. All embryos that are destroyed could have been agents, and those agents (if existing) would have had a (present) interest in the embryo's continued existence. The fact is, however, that if the embryo is destroyed, the agent is not in existence[49]. There are no conscious interests, and therefore these 'rights by extension' are nothing like actual agent-centred rights. I cannot account for the dialectical needs of an embryo, since: '[n]one of us knows, not because we have forgotten ...but because our conscious personal lives had not begun yet' (Puccetti 1983 p. 172). And a peculiar consequence of accepting the arguments from past existence is revealed by Kovács: if his parents had used contraception on the night that 'he' was conceived, then he would not have existed (1996 p. 242). To avoid this, one would now have to prohibit contraception, and furthermore, every possible human being must

---

[49] There is a special case here for those agents that do come to being have an interest in the embryo not being harmed so that the harm transcends to the *future* agent (*supra* fn. 26).

somehow be born or otherwise deny any future agent her existence. While undoubtedly my history *can* be traced back to the existence of an embryo, if that embryo never existed, then I would have *never* existed, and would never be in the position to have any thoughts of my previous existence.

5.3. The Primary Moral Status of the Agent

I have shown that the potentiality arguments cannot demonstrate why it categorically follows that being a mere potential agent, as such, confers any intrinsic moral status. However, the PGC commits one to establishing (in the practicalities of the real world) at what point the agent comes to exist. It is clear that the rational nature of the agent is where the line has to be drawn if we are committed to claim rights (and thus the equal moral status of agents); and if one considers what is biologically present in gametes, then it is evident that they have no more capacities for agency than a zygote or multi-celled embryo. Thus contraception, early abortion, and research do not deny the entities destroyed in question any rights to any different degree[50]. But, we have to put some worth in the embryo otherwise there would be no agent to be of our concern. But then without further clarification (perhaps that being an embryo is a necessary condition for being an agent), one is speculating on *potential* abilities and the corresponding potential moral status; and more often than not, these abilities are being imposed as *more important* that actual agent rights (i.e. rights to freedom and wellbeing).

Having said that, whilst we should remember that agents are the primary subjects of our moral concern, we should not then blatantly disregard the separate value of marginal agents (in fact I will argue that there are metaphysical reasons why this should not be so). We should be content for now to assert Parfit's suggestion that mere loss (or gain) of numerical identity with the 'original being' does not involve a morally important loss (or gain) of identity (1987 pp. 261-266). As long as there is a being in existence, then that is the being that we should concern ourselves with; and the PGC

---

[50] Kovács (1996 p. 236) argues that if brain-death is a legally accepted limit to human life, then why should more stringent principles exist at the beginning of life? If one asserted the same embryo protection to the dead, then one would have to wait some time after brain-death (the 'death' of every somatic cell) before removing life saving organs. I would add that the removal of organs for the benefit of others could be favourably compared with the use of embryos in research for the benefit of others.

categorically claims that we should promote the generic needs, and therefore human rights, of agency.

Biological events in agent development do not support the claims made by those who wish to protect the embryo, since they only help to confirm that potentially there are many possible outcomes in the development to agency. Furthermore, while a particular organism may have a spatio-temporal connection with the embryo, this does not, or should not affect the agent's rights as a being of conscious experience. This is because bodily continuity and/or individuality are not sufficient conditions of one's personal identity as an agent, and therefore for the ascription of rights, because being an agent (not a potential agent), are necessary (and sufficient) for having the generic rights (see Puccetti 1983).

In conclusion, the agent is of primary moral concern, and for this reason potentiality as a self-validating condition must fail. There are two reasons for this. Firstly, that *potentiality is not actuality*, and secondly, the inference from the *Argument from the Sufficiency of Agency* (ASA).

5.3.1. Potentiality is not Actuality

It is argued that *mere* potentiality cannot be morally relevant because a being's rights at a certain time depend on the being's properties *at that time*; properties that the being has yet to actualise cannot matter in a morally relevant way and cannot serve as a surrogate for actuality (see Beyleveld 2000a; Beyleveld & Pattinson 2000; Feinberg 1980). If a being has full moral status by virtue of being an agent, then potential agents only have potential moral status, not actual moral status. The problem is however, that one must make metaphysical assumptions as to at which stage of development potentiality *becomes actuality*. This is the point when the necessary and sufficient capacities of agency are present; when a given being is capable of reflecting upon the needs of her agency. This can only be known by the agent, and external onlookers will find it difficult to grade the potential for, and actual, states. These objections are important when the criterion for moral significance is the possession of specific capacities to logically claim rights for oneself. The *potential to claim* rights should not be confused with full attainment of the capacities *to actually claim*, and attempts to *link*

potentiality and full moral significance obscure the importance of *being able to claim, through its own actions, the generic rights*.

A capacity for agency is set at a threshold that is necessary and sufficient for full rights and this is exactly the same for any being where those conditions are met, regardless of status, culture, species or race. A recognition potential for this moral value would skew the necessary conditions so that one could start to value other strictly non-moral capacities. Harris correspondingly argues:

> ...an individual either possesses a capacity or she does not... Finnis's understanding of capacities allows him to say that an individual *possesses* a capacity which she never *acquires* nor has the *power to exercise*. On the Finnis understanding, a zygote *actually* has the capacity for self-awareness and reasoning, even if it dies before ever developing either of these capacities (Harris 1997 p. 58).

The human embryo has merely the biological potential to become an agent – this cannot mean that the embryo is an agent (it may never become one!). It cannot claim or waive its rights, nor can it respond to the duties placed upon it – for if it could then it would *be* an agent, and not a *potential* one. The embryo may actualise its inherent 'telos' (which gametes apparently lack) (Wade 1975 p. 244; cf. Coors 2002), but this sense of actualisation will lack any 'intentionality'; it is a mere unfolding of biological potential, and the potential to act resides in a set of genetic instructions (and this is what arguments that attempt to disassociate *action* from morality rest upon - but then I have also argued that it is a moral fallacy to attribute one's genes with a significant moral weight).

5.3.2 The Argument from the Sufficiency of Agency

If there is a means of extending 'rights' to merely potential agents then it will contradict that there are necessary and sufficient capacities for agency, and therefore contradict the *Argument from the Sufficiency of Agency* (ASA):

> ...having the generic capacities of agency to the degree needed to be an agent is not only necessary (and sufficient) to have the generic rights in full (so that agents with the generic capacities of agency to degrees greater than that needed to be an agent cannot, thereby, acquire the generic rights to a greater extent), it is *necessary to have any generic rights at all* (Beyleveld 2000b p. 66).

If there is moral significance in disregarding the necessary and sufficient capacities for agency, then beings not reaching the previous rational level may have actual 'rights'. But asserting this means that if the ASA states that which is necessary and sufficient for claim rights, then anything less, such as the potential for the necessary and sufficient capacitates, is not enough to have actual rights – only the potential to have such rights. Having the degree needed to be an agent is not only necessary (and sufficient) for agency, but it is necessary to have any generic rights at all. The two reasons for this are that (1) no agent can thereby acquire the generic rights to a greater extent than is needed to be an agent (egoist claim); and (2) human rights, as claim rights, require the agent to value their needs for their own sakes, and to be able to freely waive the benefit of a right (Beyleveld & Brownsword 2001 pp. 117-119). Therefore: (1) no agent can *potentially* claim the generic rights to a greater extent; and (2) potential agents cannot value or waive the generic rights with its present capabilities.

However, this may also mean that the sleeping agent does not have the same rights, because the unconscious agent does not fulfil the necessary and sufficient conditions of agency. But, unlike the embryo, the sleeping agent's capacities are '...concrete and real in the sense of being based upon the past development of a full-blown human person' (Engelhardt 1974 p. 200)[51]. The sleeping person, unlike the potential agent, has a functional and fully developed neuronal capacity that facilitates agency; and this is what confers the ability to claim rights. Even if the sleeping agent never wakes up (but has the same internal potential to wake up) then those capacities that were evident before sleep may still be present. In this sense the potential of the agent is 'locked-in'; it is there but is not at that time being expressed.

The ASA means that anything below this level cannot have rights. On this account, the embryo cannot possess the abilities at that time to have a personally rational claim to the access of necessary goods, thus cannot be construed to need them for its continued agency. Aleksandar Jokic stated that embryos are more like those things which we traditionally ascribe no rights to (Jokic 2001). As it develops it becomes more like what it is to be an agent and the necessary capacities start to emerge.

---

[51] One can argue that sleeping agents have rights insofar that they will wake to the extent of being physically capable of action. Embryos do not 'wake' to their agency, their agency after all was never ostensibly present (but as we shall see, this cannot be ruled out altogether). In this sense, '[a]t most, the fetus [sic] is an animal with great promise of becoming more than just an animal' (Engelhardt 1974 p. 220); but that, inasmuch as *X* is merely a potential *Y*, then it stands to reason that *X* is not *Y* (Engelhardt 1986 p. 111).

On this account, we do appreciate that children are sufficiently like adults to have at least some (all basic) rights. We may even describe the late foetus as being proximate to an agent (but only because of its proximity to the newborn). But it is now evident that the argument is moving away from mere potential to possess something, and towards the idea that these beings have some of the capacities of agency, and this in itself may ground at least some moral significance[52].

6. Interim Conclusion

It is apparent that as long as any moral framework is committed to claim rights, the human embryo cannot have the same status as an agent. Metaphysical observations do not, in themselves, suggest any further obligations to potential, proportional or future relations of an entity to the agent and state, because such life does not have any actual capacities for agency.

There is, however, one final factor to take into account regarding the status of such a being. That is that we cannot be sure of any ontological facts about marginal agency, and therefore the chance that we may be wrong should be taken seriously in a search for valid moral precept.

7. Precautionality

The *Principle of Precautionality* derives from the uncertainty as to the ontological status of the embryo. This means that because of the embryo's *potential* to become an agent, we cannot entirely discount the possibility that that it is already an agent. On this basis, its *non-status* as an ostensible agent, becomes a *marginal agent* status[53].

---

[52] See Appendix Three.

[53] Meaning, not the same status as an ostensible agent, since it lacks purposiveness and voluntariness in its actions (the generic feature of action common to all ostensible agents; Gewirth 1978 pp. 26-28) altogether; but a marginal status, because of additional reasoning that means a status above a non-agent.

7.1. The Dichotomy between Rational Action and Mere Motion

Agents can perceive the necessary conditions of their agency. These are subjective values, but derive from the objective (own) understanding that they are purposive beings. The subjective determinate is how societies should be constructed to foster and nurture important agent rights. This consists of agent experiences and discoveries, and is based on metaphysical realism. Thomas Hobbes, in the introduction to *Leviathan* describes the difference between '*Man*' and 'artificiall life':

> For seeing life is but a motion of Limbs, the beginning whereof is in some principall part within; why may we not say, that all *Automata* (Engines that move themselves by springs and wheeles as doth a watch) have an artificiall life? For what is the *Heart*, but a *Spring*; and the *Nerves*, but so many *Strings*; and the *Joynts*, but so many *Wheeles*, giving motion to the whole Body, such as was intended by the Artificer? *Art* goes yet further, imitating that Rationall and most excellent worke of Nature, *Man* (Hobbes 1985 p. 81).

Hobbes, realising that one could not know for certain that another being was not an 'Automaton', made the assumption that 'Man' was distinct in its 'Nature' from other entities. From this, he proposed his thesis regarding the rational person ('agent') within – '...that great LEVIATHAN called a COMMON-WEALTH, or STATE' (ibid. p. 81).

Thus human beings are capable of existing within a rational community; and in doing so, they must be capable of being subject to moral laws, and realising that all similar beings are also part of this community. Therefore:

> ...whosoever looketh into himself, and considereth what he doth, when he does *think, opine, reason, hope, fear,* &c, and upon what grounds; he shall thereby read and know, what are the thoughts, and Passions of all other men, upon the like occasions (ibid. p. 82).

However, this is not a clear case of limiting rationality only to human beings, and there are certainly reasons to be prudent regarding the Hobbesian prejudiced view of the categorically superior status of the class of human being. It is not 'Man(kind)' that can conceive and act according to natural laws, but 'agents' – and it is the agent that must look into himself to attribute ostensible agency to other entities. This must be based on empirical observations of the 'thoughts' and 'Passions' of other ostensible agents as individual entities, and not any assumption on the primacy of human beings. Through personal experiences and the sciences, we can determine that as far as one can tell, purposive action is not a part of the properties of the human embryo; and it is arbitrary to assume the moral superiority of all human beings on any other basis.

David Hume shares this view:

> ...no truth appears to me more evident, than that beasts are endow'd with thought and reason as well as men ...'Tis evident, that *sympathy*, or the communication of passions, takes place among animals, no less than among men (1978 pp. 176-398).

Although, he concludes, that regardless of human beings and animals sharing similar biological components, human beings alone are '...susceptible ...of the pleasures or pains of the imagination' (Hume 1978 p. 397); or as Hobbes argued, capable of following moral laws or precepts. How then should we treat this alleged difference in moral capacities with regards to the human embryo[54]?

7.2. The Principle of Precautionality

Uncertainty in the moral status of certain beings requires us to adopt a precautionary policy in our treatment of them. This is because the PGC requires considerations of applying it to the abstract ontology of real objects in the real world, which compels all agents to treat all other agents in a morally regarding way and regardless of any non-moral considerations (Beyleveld & Brownsword 2001 p. 119). Therefore:

> Where X is an ostensible agent, the metaphysical possibility that X might not be an agent, is to be wholly discounted, and X's display of the characteristics and behaviour expected of an agent is to be taken as sufficient evidence that X is an agent (Beyleveld 2000a p. 465).

This is because the capacities for agency for the most part are mental capacities that cannot be observed directly in other beings. Therefore, all beings that demonstrate similar characteristics to 'normal' human adults must be regarded as agents (from the argument from analogy[55]). The *Principle of Precaution* adds:

> If there is no way of knowing whether or not X has property P, then, insofar as it is possible to do so, X must be assumed to have property P if the consequences of erring in presuming that X does not have P are worse than those of erring in presuming that X has P (and X must be assumed to not have P if the consequences of erring in presuming that X has P are worse than those of assuming that X does not have P) (Beyleveld 2000a p. 465).

---

[54] It could be contended that this does not matter, and animals, like human beings, can feel pain and pleasure through their shared sentient capacities (see Bentham 1996 p. 284; in footnote).

[55] I know that I am an agent, and so if *X* acts like me (or with the characteristics and behaviour that I expect of an agent) based on my reflections as an agent; then I must assume that this is sufficient for *X* to be an agent.

Those beings that ostensibly lack agent capacities should not be immediately discounted and confined to a non- or marginal agent status[56]. The doubt about the status of these beings asks the question as to whether they are actual ostensible agents. Beyleveld (with Pattinson 2000; & Brownsword 2001) has shown that:

> ...the best I (any agent) can do, when trying to determine whether or not some other being 'X' is an agent, is to construct a model of the characteristics and behaviour to be expected of an agent, and test X's characteristics and behaviour against it (Beyleveld & Pattinson 2000 p. 40).

That this is 'the best' that can be done rests on the problem of 'other minds'. Agency is not a generalisation about the empirical world, but a function of the characteristics that beings must be supposed to have if they are to be regarded as rational subjects (qua agent), and therefore as objects of practical moral prescription. This means that agency essentially derives from mental capacities that form the ostensible characteristics and behaviour. This is based on the assumption that I know that I am an agent because I have direct access to my mental state, but I do not have a similar access to other beings' mental states (qua 'minds'). Therefore, a being that is in notable biology, characteristics and behaviour an ostensible agent, may equally be an automaton (qua Hobbes), and there is no definitive *proof* in either case (regardless of Hobbes' statement). We therefore have to find a way to detect or infer agency in other beings.

The question of 'other minds' was of notable concern to Descartes[57]. However, we do not need to show that other minds may or may not exist, or that entities may or may not be, *living machines* that lack mental processes for the time being[58]. The essential problem for the status of the embryo is that it seems to lack any agent relevant capacities, but in this we cannot be sure. However, merely because one cannot enter the

---

[56] For example, patients have been known to recover consciousness after being diagnosed as being in a persistent/permanent vegetative state (PVS) (Jennett 2002; Kampfl et al. 1998; Zeman 1997; 2001). The vegetative state is described by the presence of 'wakefulness', but 'awareness' is absent (Bernat 2002; Giacino 2002; Zeman 2001). Likewise, a child's capacities of 'agent' rationality is often not dissimilar to that of whales, dolphins, and great apes, who also show evidence of having a high degree of capacity for agency (See Bekoff 1998; D'Amato & Chopra 1991; Glennon 1990).

[57] Descartes 1993; also see: Williams 1978; Wilson 1969.

[58] I can deny (and therefore question the practical application of the PGC) that there are any other agents at all in the world without contradicting that I am an agent. Beyleveld & Brownsword offer a response to this: (1) such a position would be virtually impossible to sustain in practice; (2) it would be irrational for me to deny that there are any other agents other than myself; (3) the denial of the application of the PGC to other ostensible agents would not place the PGC at any disadvantage with any other moral theory; and (4) one is mistaken if Gewirth's project does not show that I am categorically required to grant the generic rights to any creatures other than myself (2001 pp. 120-121; also see Beyleveld & Pattinson 2000 pp. 41-43).

'mind' of another[59], we should not assume that no other mind exists. This position is virtually impossible to sustain in practice because one must make assumptions of the nature of the world around us (Beyleveld & Pattinson 2000). The *Principle of Precautionality* addresses this solipsistic[60] assertion by showing that:

> ...the propositions 'X is an agent' and 'X is not an agent' are on par with respect to an ability to demonstrate *the truth* of either. However, it needs to be appreciated that these propositions are not on a par *morally*. If I (any agent) mistakenly presume X to be an agent, then, although this will lead me (mistakenly) to have to restrict my exercise of my rights to some extent, I do not deny my (or any other agent's) status as a rights holder. But, if I mistakenly presume X not to be an agent, then I deny that X (an agent) is a rights holder (Beyleveld & Pattinson 2000 p. 42).

In the second case, the prospect of denying an agent its due rights are far worse than taking the first precautionary route; the risk of possibly violating the PGC should be intentionally avoided at all possible costs. Therefore, there are necessary reasons to prescribe upon those entities *A* that do act, behave, or have mental and biological capacities similar to me an ostensible agent status. If I can detect elements of agency in entity *B* (so I might be interacting with an agent, but am less sure than before), I should also assume agency to be present. However, if I am in a situation where I have to prioritise the status of one of either *A* or *B*, then I should favour the more likely agent.

From this I can (and necessarily should) assume the agency of all 'normal' adult humans. Where then does this leave other marginal agents that either satisfy some capacities of agency to the full but lack others, or show all capacities but to a lesser or greater degree?

7.3. Potentiality Under Precaution

In the abstract, the possibility that the embryo is not an agent cannot be discounted entirely. Therefore:

> Apparent partial agents are owed duties of protection by agents in proportion to the degree to which they approach being ostensible agents – not *qua* partial agents – but *qua* possible agents (Beyleveld & Brownsword 2001 p. 123).

---

[59] This is not a dissimilar point to that of Thomas Nagel in: 'What is it like to be a Bat?' (1974). We can only assume to know about human consciousness, but what about 'bat consciousness', or for that matter the consciousness of an embryo?

In this regard, the more like an agent a being is, the more likelihood that it is an agent; and on its own, we should not treat such a being as a proportional agent, but an actual agent. We must take the same care when evaluating apparent *potential* agents:

> ...because any evidence that a creature is a potential agent increases the probability that it is an agent, creatures that appear to be potential agents must be granted some intrinsic moral status (Beyleveld 2000a p. 464).

Thus, precautionality requires us to take the consequences of potentiality (as an 'element' of empirical evidence) more seriously. Potentiality here means the potentiality to express itself as an agent, not to become an agent, and therefore, 'mere potential' means that the potential agent may be an actual *possible* agent that does not exhibit in full the behaviour expected of an agent. However, the being is either choosing not to express itself as an agent or, and more likely, is being held back by something, so that it cannot express itself as an agent, and may be a 'locked-in agent'[61] (Beyleveld quoted in Dettweiler & Thiem 2000 p. 311). Precautionary reasoning imposes duties on agents to allow potential agents to develop this potential. This reasoning applies equally to all beings for which there is evidence that they are potential agents.

There are difficulties with this approach since we cannot be sure that the evidence that is presented is actually evidently of agency. On the one hand, the evidence of agent relevant behaviour may be programmed behaviour requiring and demonstrating no capacity for agency (Boden 1990; Hauser 1993; Searle 1984 pp. 32-35). On the other hand, the evidence (or lack of evidence) that denotes a proportion of 'full' agency may actually be non-representative of the being's actual capacities for agency, and we may conflate or deflate the moral status of such beings unjustifiably.

Therefore, my duties of protection to ostensible marginal agents that are more probably agents should take precedence over partial agents who are less probably agents. Policies should therefore take more care to protect foetuses than embryos, and preferentially protect children over foetuses. The distinction between these three categories is empirical evidence of their similarity to agents in action and form[62]. On

---

[60] The view that only oneself exists and that there is not reasonable (or at least sceptical) evidence that other beings have a conscious life because the only inference that can be made is directly from observed behaviour.

[61] Some conditions similar to PVS are described as a type of 'locked-in syndrome' (Giacino 2002).

[62] 'Form' includes the development of a nervous system and brain that are central to the characteristics of the agent. In the three categories the nervous system develops (from non-existent) to an ever more complex level approaching that of a full agent.

these grounds, the embryo deserves moral consideration, although the failure for it to display itself as an ostensible agent is likely due to there being present no neuronal capacity, and therefore there is no evidence that the embryo is anything beyond a collection of integrated cells with a potential to be something else.

The precautionary principle to be adopted here is not to state that there is uncertainty in the matter of agency per se (that we are uncertain that *any* agent is *actually* an agent; Evans & Evans 1996 p. 222). Rather, because we cannot be sure *of the status of the embryo*, we must affirm a certain level of justification in what we do to it. Evans and Evans rightly point out:

> ...we rarely enjoy absolute certainty about anything in this world and human action is judged morally in light of this fact. A person is judged for his actions on the basis of what it is responsible to believe is the case in any given situation, not on the basis of what is absolutely and demonstrably certain (Evans & Evans 1996 p. 222).

On a precautionary (practical) basis, ostensible agents should be treated as though they *are* agents. All beings that show marginal characteristics or capabilities of agency likewise are assumed to be actual agents. However, when in conflict with those in the former category (or in any action that may affect them), and because there are degrees to being a marginal agent, one must take account of the evidence of their approach to agency. This does not mean that it is always wrong to harm such a being, but this must be in line with the prevailing rights of more likely agents, and those circumstances that determine one's actions must be justifiably reasoned. In the case of the human embryo, an individual researcher's actions must be reconciled on the available facts. So because a human embryo may be an agent, the act of research must be justified on the grounds that the research (because it overrides the embryo's marginal status) is necessary to benefit more likely agents.

7.4. Agent Relevant Capacities

In Chapter Two, s. 5.4, I argued that claim rights could only be attributed to rational agents. Now, we have to at least accept the possibility that a potential agent is an actual agent, which must be based on the (evidential) likelihood that the embryo can implicitly 'claim' rights. The evidence of this is deduced by comparison with known agent relevant capacities. The clearest evidence of agency would be the rational

interaction with others. However, there are degrees of behaviour (which may be indicative of agency) and this obviously has implications for our treatment of non-human animals[63]. Beyleveld & Brownsword describe the key biological stages of agent capacities (2001 pp. 123-124). At the base of their categorisation is *simple patterned behaviour* that is connected by neuronal interfaces directly to the senses. All animals have sensations to environmental stimuli; but those animals confined to this level are lacking in any leaning or reflective capacities. This is at most where the embryo would qualify[64].

From this it is clear that the 'behaviour' of the embryo offers little of the agent relevant capacities that provides us reason to consider its intrinsic moral status. We view other beings' capacities for moral agency on a day-to-day basis; and these observations are based on analogy with what is expected of an agent. Confirmed agent status provides additional constraints on our treatment of beings regarding their rights and autonomy, and where there is uncertainty, we employ 'tests' of verification (e.g. in questions of competency and consent; see Brazier 2003 Chapter 5 esp. p. 123). Fundamentally, these observations rest on the theoretical test to assess by questioning[65] the rational capacities (existence of 'other minds') of prospective agents (Turing 1950)[66]. The result is that if a target entity contains elements of characteristics and

---

[63] This can be summarised in the following: (1) some human beings lack agency (i.e. the human embryo); (2) some animals evidently show rational behaviour, therefore from the *argument from analogy* (see Allen 1998; Duhrssen 1960 p. 212) some animals may be agents (i.e. demonstrate *human* action, behaviour and imitation; see Cantalupo & Hopkins 2001; D'Amato & Chopra 1991; Glennon 1990; Hauser et al. 2002; Metsuzawa 2003; Ramus et al. 2000; Whiten et al. 1999). Therefore, (3) it is inconsistent to argue that the human embryo has rights when non-human animals cannot (such as that claimed in Tauer 1985 p. 261) or claim that there is a capacity limited only to humans; (see Carruthers 1989; Descartes 1970 p. 251; Herder 1966). Therefore, (4) all agents have to be assumed to be agents on their *present powers* which may be inferred from speech and behaviour (Bekoff 1998; Locke 1975; Putman 1964; but see on the problems of behaviourism: Heyes 1998; Nagel 1974; Wittgenstein 1969 (p. 46) & 1980 (p. 27e II-143-31e II-161)).

[64] Increasing complexity would indicate: (1) beings that are capable of being minimally perceptual, such as motivation by 'feeling' or 'desire'. Such beings may show practical rationality but they are not, as far as we can tell, valuing the purposes that they are motivated by (Scruton 2000 p. 10); (2) behaviour that displays intelligence and a capacity to learn by experience. This invokes fulfilment of an appetite, but requires not just a response or *conditioning* to the perceived situation, but also a *belief* about it and; (3) behaviour that exhibits practical and instrumental rationality (problem solving that involves making choices that are appropriately motivated by its own beliefs, and the capacity for inference and generalisation). This purposiveness (intentional action for some end or purpose that constitutes the reason for acting; Gewirth 1978 p. 27) demonstrates a higher cogitative state which resides in value guided behaviour that is characteristic of agency.

[65] 'The question and answer method seems to be suitable for introducing almost any one of the fields of human endeavour which we wish to include' (Turing 1950 p. 435).

[66] Alan Turing argued that if a tester could not tell the difference between two candidate agents (he used a human person and a computer), it would be logically arbitrary to deny that either candidate was rationally inferior to the other. If you knew that only one was an agent, but could not tell which one, then you must at least accept the possibility that both were (possible) agents. This test essentially detects the presence

behaviour that one expects of an agent, we have no basis to doubt, and indeed reason to assert, that it has a mind and a corresponding status as an agent.

Thus human adults that act and behave as rational agents should be considered as such. Those things that possess such capacities to a lesser extent, such as human children, also are agents (because they sometimes act like agents). As we progress further away from the human adult yardstick, however, doubts creep in, especially when the human element is replaced by something 'non-human'. There may be a reason for this. Human agency is the only criterion that I, or any other human agent, has to compare with other ostensible agents. But the assumption of human agency requires addressing, since assuming human agency limits moral worth to a human component. The definition of agency (there is no subjective element separate from rationality), however, contends that such an assumption cannot be made (Bekoff 1998; Jamieson 1998; Puccetti 1983).

If any entity can demonstrate an element(s) of agency, through language or behaviour, then we have to entertain the possibility that such a being is an agent (and we could even grade such evidence to the degrees of agency)[67]. Thus we could presuppose that we have a test for accrediting the categories of *agent*, *marginal agent*, or *non-agent* status to candidate entities. We do not have to set up the test each time we are in doubt, but we do have to take the logic from the test however and take careful account of the presuppositions that follow from the test parameters. The minimal standards for agency may become a fairly subjective evaluation, and will be based on a being's ability to interact with objects in the real world (and not abstract rationality), and in a way that is indistinguishable from a human agent.

---

and basis of 'artificial (or non-human) intelligence' (ibid.). Intelligence equivocates to agency – but not in the sense that one has to be good at chess, only that one has to act in a non-contradictory manner to moral precepts. What we are asking from a Turing machine is to do what a human candidate can do – we have no reason to ask more of it just because it is a machine. So if the test *is* enough to show that we can infer that a human being has a mind, then by the same token it must be enough for us to infer, on the same grounds, that the machine (or anything else) has a mind (qua agency). Additionally, the candidates are kept out of sight of the tester, so that no judgement would be biased by what the candidate looked like. On this point, Locke stated: 'For I presume 'tis not the *Idea* of a thinking or rational Being alone, that makes the *Idea* of a *Man* in most Peoples Senses; but of a Body so and so shaped joined to it…' (Locke 1975 Book II; Chap. XXVII, 9 pp. 334-335; cf. Putman 1964 p. 691).

[67] Based on criteria (from question/answer tests through to the observance of indistinguishable agent behaviour) that increasingly requires the tester to reject her scepticism as to the agent status of the target being (Harnad 2000).

7.4.1. The Turing Hierarchy and Biological Agency

The first thing to note is that the test involves inherent uncertainty – thus we are committed to the principle of precautionality – since no test can *confirm* that a being has a mind. Hobbes argued that on the basis of what he observed, only human life could have rationality; Locke however, was at least prepared to acknowledge that rationality was not limited to the human species[68]. Secondly, the test is not a revolution in mind reading, but a formal means to evaluate situations in which one confronts other beings that may require our moral concern[69].

There are two possibilities of determining the presence of the capacities of a rational mind (as a function of the Turing test), and a positive outcome must denote moral concern (qua agent). Puccetti uses an example of how one would find out if an apparently abandoned house is occupied (as an analogy of the presence of a mind); one may knock on the door (analogous to the use of language) or watch the house to see if there are signs of activity (analogous to behavioural observations) (1983 p. 179).

The former course is not open to inquiries regarding the embryo, so instead we must look at behaviour (and the properties that allow behaviour). These are all absent in the embryo; so is there any property that the embryo has then that may denote the presence of agency? There are possibly two: (1) its potential to become an agent and; (2) its membership of the human species. I have already argued that potentiality as a separate consideration necessarily fails. It must however be taken seriously as evidence of agency when coupled with precautionalty. I have also argued that species membership cannot be considered by itself to confer any moral status. However, there is a further element to this latter conjecture, also when it is aligned with precautionary reasoning.

---

[68] In recounting a story concerning a talking parrot, Locke wrote: '...whether if this *Parrot*, and all of its kind, had always talked ...they would not have passed for a race of *rational Animals*, but yet whether for all that, they would have been allowed to be Men and not *Parrots*?' (Locke 1975 Book II; Chap. XXVII, 9 pp. 334-335).

7.5. Dignity and Precaution

If agency is subject to precaution on the basis of agent relevant capacities, how should we treat the human embryo? It is clear that the embryo has no capacity for ostensible agency. Furthermore, unlike an *unconscious* human being, none of the embryo's existence (as far as we can tell) is wrapped up in a memory of its origins, and at no point was a 'certain' agent observed by any onlooker. It is only under its *potential to become something else* that any moral status can rest.

'Dignity' under this scheme may be a justified claim that *human marginal agents* require special consideration when assessing their 'quasi-rights', because *only* human beings (as far as we can tell) can (potentially) become ostensible agents (and therefore is the *only potential agent*). Potentiality therefore acts as supporting evidence that the embryo is an actual agent – but regardless, it cannot be *proved* (either way) that the human embryo is such a being[70]. Therefore, on the premise that its agency cannot be ruled out, that even if the embryo cannot have full rights, scepticism either way must compel one to at least have *good reasons* for its 'quasi-rights' to be violated.

No member of another species, as far as we know, can be an ostensible agent. Therefore, this 'dignity' claim becomes *species specific*. If any other member of a species was shown to be an agent, then on its own merit, it should be considered as an agent. Unless this characteristic was typical of that species, other members would either be non- or marginal agents. However, if another species was shown to become certain ostensible agents (perhaps great apes were proved to have equivalent agent capacities to human beings), then that species would have 'human' (or 'agent species' dignity).

This does not mean that only one member of a species needs to be rationally autonomous for the whole species to be granted dignity (and when that individual dies then that species would return to non-dignity status)[71]. Precaution under the PGC requires us to recognise ostensible agency in any individual in its own right, and due to

---

[69] Indeed, we are generally guided in our everyday life by tests lest stringent than those considerations embodies in the Turing test (Hauser 1993).

[70] It would in fact be contradictory to hold a (speciesistic) view that children's behaviour expresses mindfulness and embryos and foetus have some claim to rights solely on the basis of their 'humanness'; and all the while the behaviour of primates is akin to the movements of wind-up toys. This would be inconsistent with the observation that embryos have no agent capacities, while primates (etc.) are *at least equivalent* to children in their behaviour.

[71] Because we do not know of any other species with consciousness, then why should we promote the consciousness of this *one non-human individual* (Albritton 1964 p. 693)? But then we don't *know* that any other human being is conscious either, so why assume the same for the human species?

species membership, marginal agents that are potential agents may have dignity[72] - *iff* it was not atypical (i.e. there were good reasons to believe) for that species to become ostensible agents.

There are two potential problems with this theory. Firstly, human beings (*Homo sapiens*) are the only species capable (as far as we know) of both being agents and non-agents and therefore under this scheme they may possess what could be termed both 'positive' and 'negative dignity'. This means that an agent that is human also has dignity, and this results in a positive effect on a human's moral status (so human agents are more likely agents than non-human agents are in a hierarchical scheme). But this must also mean that non-human agents must have a negative value that deflates the status of its agency.

However, if positive dignity is added weight to human marginal agents, then why should there therefore be negative dignity that takes moral weight away from such beings? In the case of the latter, if a being is an ostensible agent, then it is treated as such. Any marginal non-human agent would likewise be treated according to its actual marginal status. On account of precautionality, the human embryo will have dignity because they are biologically human, and that this is a capacity which is remotely linked to its potential for human agency.

Secondly, is the 'species border problem'. It could be argued that serious genetic anomalies would strip human marginal agents of their 'dignity', and hence their moral status (because they allegedly are not genetically human). But this would not be the case, because such beings would actually be a marginal agent (only if they were not full agents) in respect to precautionality (under proportionality), and would deserve 'quasi-rights', as would any other marginal agent. A genetically non-human embryo (unlike a human embryo) cannot become an agent, but only, in the case of some species, a marginal agent.

Therefore, there may be two different types of 'dignity'. Firstly, it may be deployed as an inherent property of autonomous agents which is designed to protect the

---

[72] If one embryo human foetus was shown to be a full agent then this would pay heed to our previous precautions. However, if a computer were able to pass the Turing test it would have marginal agency. But there is no reason why other machines should be considered as precautionary agent with dignity since the 'species' does not demonstrate agency as a normal matter of course. The difference resides in the ascription of 'dignity' to other agents and marginal agents. While such a being has marginal agency, this would not have any bearing on other machines because it is evident that other machines, such as a toaster, are not agents, but connections and wires with programmes built in. The machines cannot have 'dignity' in the way that the human species does, although a super computer may have dignity in the way that an autonomous agent does.

decision making capacities of those subjects. It is a prescription of the PGC, in this sense to allow an agent's autonomy to make decisions, rather than to protect human life per se, that any act that intentionally ends such a life will contravene 'dignity'.

However, secondly, it could be taken to be something separate to this, and instead, a potential/proportional capacity only found in human beings. In this case, *human dignity* may have a separate moral consideration. It is not, however, a claim that exercising one's autonomy should be a function of maintaining (or recognising) the intrinsic (or primary) value of human life (cf. Finnis 1997 pp. 33-34). The PGC and precautionary reasoning requires us to regard human living beings as precautionary agents (to differing degrees depending on the developmental status at that time) unless there are more important considerations according to the PGC (and in such carefully defined cases it may be perfectly *moral* to terminate a human life on the grounds of protecting agent-centred dignity). Therefore, all human life has worth (as precautionary agents), but our moral duties must be prescribed by the agent-centred PGC. The important caveat is that agents, on account of being autonomous beings, can choose to waive their rights (and dignity[73]) should they so choose.

Therefore, we cannot as agents arbitrarily, or without justification, end human life. However, and in light of our limited knowledge, it is evident that not all human life is equivocal with *human agency*, on account of not all human life having the capacities of agency per se. But there is the possibility that such expression is present, but remains unexpressed until further development[74]. Animal behaviour studies, at a minimum, demonstrate that certain animals cannot be regarded as 'mindless', and certainly above some standards traditionally reserved for the uniquely human[75]. Therefore, agents may have a duty to recognise the possibility that certain other non-human animals may have rights[76]; and certainly entertain the observation that these

---

[73] Under the PGC there are no duties to oneself; but compare this with Kant (see this comparison being made in Beyleveld & Brownsword 2001 pp. 98-110).

[74] This is particularly a pertinent point with regards to later foetuses, young children and patients with forms of 'locked-in' syndromes. In these cases, it is not at all certain that the being is aware of her agency, or able to express that agency if it is present.

[75] And this may be a tradition set in our familiarity with the human species, and it should be noted that the same has been true for the treatment of humans by humans, and the '...foundational philosophy for genocide and enslavement ...[because of the] pseudo-rationalization [sic.] that the victims are less than human' (D'Amato & Chopra 1991 p. 26; cf. Jamieson 1998 p. 93; Sapontzis 1981; Wasserman 2003; Zwanziger 2003).

[76] These rights are not 'human right', because the animals we are talking about, such as whales or primates have no need for those rights particular to humans beings. The rights that animals may have are *basic* rights, such as to life and freedom from torture. However, additive and non-subtractive rights as they are generally understood, are for promoting purely human interests (e.g. education & clothing etc.).

animals are '...more animate than corporations, more communicative than infants and mentally enfeebled persons, more communal than the society of nations, and perhaps more intelligent than the smartest human being' (D'Amato & Chopra 1991 p. 51).

Therefore, a scale (if lines must be drawn[77]) can be constructed along which we place entities according to their likeness to human agents (including potential to become human agents). At one end is a non-agent (a rock), and at the other is an agent ('normal' adult human being). We must then compare the target being's ontology with these two reference point. It becomes clear that the status of certain beings at a particular time falls closer either one or the other. These are the various temporal and spatial forms of marginal agent. The human embryo is more like a non-agent than a full agent. However, dignity, as a property of the *human embryo*, must be taken as evidence that it is more like an agent than a *non-human* embryo. This paves the way for the 'special status' of the human embryo in research (i.e above tissues and some animals). Therefore, in the case of embryonic stem cell research, we must weigh the precautionary status of the embryo against that of agents claiming access to promising research.

7.6. The Moral Status of the Human Embryo and the Justification for Deriving Human Embryonic Stem Cells

Because the basis for agency is an abstract categorisation based on ontological and empirical evidence of the real world, it is necessary to proceed with caution when we encounter and intend harmful acts to marginal agents and non-agents. Such evidence is open to a degree of subjectivism, and while some beings can be certainly categorised as non-agents (such as plants), other beings, in this case those that have a potential to attain agency, must not be treated arbitrarily, and at least the possibility that they actually are ostensible agents requires conditional treatment. Under the *Principle of Precautionality* there is very little evidence of agent capacities in the human embryo. It is genetically human (but not necessarily genetically unique or an individual) and has

---

[77] Line drawing may be notoriously subjective, and it is perhaps better to evaluate each *individual being* with regard to its *individual characteristics*. This is because the non-speciesism position makes it impossible to use groups (species) membership as the sole criterion for choosing which individuals should be used in various types of research (Bekoff 1998 p. 271). Of course, such a view can in practice

the potential to develop into an agent. There is no behaviour. Despite claims that the embryo controls and influences the pregnancy, these are only biological cues. Furthermore, phylogenetic relatedness plays *no direct* role in determining moral status, although under precaution it may add weight as 'dignity'.

The *Principle of Precautionality* commits one to the criterion that it is more damaging to treat an ostensible agent as though it was not an agent, than to treat a marginal agent as though it were an agent (causing the least probable harm). One should treat both as 'agents' when considered as separate entities, and as long as they are not brought into conflict. Therefore, marginal agents should be treated as though they are ostensible agents unless there are more important requirements of the PGC. Where there are two marginal agents to consider, Z and X, then:

> If my doing y to Z is more likely to cause harm h to Z than my doing y to X (and I cannot avoid doing y to one of Z or X) then I ought to do y to X rather than to Z (Beyleveld 2000a p. 466).

Therefore, it is morally better to derive stem cells from 3 day-old human embryos (as a marginal agent there is very little chance of harm) than from a human foetus, because harm is more likely to occur to the latter (because it has more proportionally developed the characteristics expected of agency, the more seriously we must take the possibility it is an agent; which means the more probable that harm may occur). (This also corresponds to the present scientific evidence that ES cells hold a greater prospect for therapeutic application than foetal stem cells; see Appendix One s. 1).

The embryo/foetus develops through stages of human genetic uniqueness, potentiality for individual development, sentience, brain activity and degrees of cognitive development. Separately, and in that order, they warrant increasing increments of moral concern. Taken together they form a convincing argument for agent status, but one that is short of full agent capacities (i.e. rational behaviour). 'Dignity' informs the debate by stating that although it may be far fetched that having a human genetic constitution is *evidence* of agency, this cannot be ruled out altogether.

For these reasons, the human embryo has a status above that of mere tissue. Firstly, because precautionary reasoning commits us to uncertainty with regards to the possession of the capacities of the generic features of agency (and the ostensible display of those capacities at that time is not morally relevant) and, secondly, because the

---

be difficult to interpret in law (for example, at the attempts to delineate human embryo research from other human research in the *Warnock Report*; Warnock 1985).

human embryo is more likely to be a 'locked-in-agent' than an embryo of another species or a somatic cell.

The embryo's moral status therefore allows derogation on account that it is morally better to presume falsely a being to be an agent, rather than to assume that a being is not when it is. Policies should follow this dictum, but only in the case that no harm comes to a more likely agent. There are two means of implementing this. Firstly, one can attempt to preserve some of the primacy in the moral superiority of human beings[78]. However, on my account, it would be contradictory to '...seriously maintain that dogs, cats, sheep, cattle, pigs, or chickens consciously think to themselves ...the experiences of all these creatures [are of] the nonconscious variety' (Carruthers 1989 p. 265) because there is at least the possibility that they have consciousness[79], and in rejecting this, one would have to at least forgo rights to human beings of equivalence to animals of a similar cognitive ability. (And realistically, if one wants to grant rights to human embryos then there is an argument to grant similar rights to all entities with a degree of rationality above that of cells!).

Secondly, the status of the human embryo should not be discounted entirely (on account of its potential), but on the same grounds, it cannot be accorded full moral rights as those of an ostensible agent, despite its belonging to the human species. As the embryo approaches being an ostensible agent (through the foetal stages), its potential to express itself as an ostensible agent becomes more apparent (through characteristic biology and behaviour). Where there are conflicts of interests between an ostensible agent and a marginal agent, and the likelihood of harm can be prevented to one of them, then priority must be given to the status of (and benefits to) the more likely agent.

This is open to empirical determinants, and ultimately will be a subjective evaluation. But, if stem cell research offers realistic benefits (as I have argued) then the agent-centred goods that may derive from this are a justification for overriding the marginal agent's status. Furthermore, on the above principle, it is better to derive human embryonic stem cells than from any other source because of the limitations of

---

[78] '...although we cannot be certain that no animals are conscious, we can say that it is most unlikely that any of them are' (Kennedy 1992 p. 31).

[79] However, this must be rejected because the PGC acknowledges at least the possibility that some forms of human life are comparable to equivalents in the non-human sphere (because agent is without any gender, race or species relevance). Therefore, our treatment of certain animals, as well as some restrictive provisions on human research, requires redress to account for their equal assessment under precautionalty (Jamieson 1998 p. 95).

the therapeutic applications of animal cells (i.e. species biological incompatibility and species-specific diseases).

The ontological uncertainty in the status of the embryo must be transferred and reflected in research policies (Ruyter 1996 pp. 182-183). There are two possible outcomes: (1) any doubt should be translated into an obligation (or a 'default position') to treat the embryo as a person from conception, at least as a *prima facie* reason to prohibit research (Tollefsen 2001 p. 75). In embryo research, we are denying one human being's existence so those ostensible agents can benefit from the *possible therapeutic benefits*. These may not turn out to be actual benefits. Therefore, the favourable position for the quasi-rights of embryos means that direct harms to agents should be prioritised (permissive abortion policies), but that mere speculation regarding research benefits (and alternatives).

Alternatively, (2) if policies are committed to promote the more likely agents' human rights, then on the balance of probabilities, not prioritising (the more probable) agent's freedom and wellbeing would be a more serious harm. In cases of conflict between a marginal and an ostensible agent, the resolution must go the way of the latter and therefore, the actual and undecided benefits of embryo research should be promoted to best serve the generic rights of ostensible agent(s) (and protesting individuals can waive their rights to access to this research).

The weight of evidence presented in Chapter One pointed towards supporting the second of these positions (or at least a 'dual track' approach pursuing all avenues of research); and is vindicated in the position that in principle policies do not require an absolute ascription of rights to beings of a (clearly) uncertain agent status (discussed in part one of Chapter Four). However, because of the uncertainty, we have to be forthcoming with the justification of our acts. In effect, the benefits of denying access to research that benefit agent-relevant goods would have to be outweighed by the prescription of rights to marginal agents, and as already discussed, this is not possible. Thus the prescription of precaution allows for careful assessment of this balance of research benefits over the marginal status of the human embryo.

The precaution/dignity framework does not distinguish between *types* of embryo, nor how these embryos came to be, since they are all equally *marginal agents of the same type*; and as such have the same moral status (discussed in Chapter Five). Considerations of futureality would not count since the derivation of stem cells would result in the subsequent non-viability of the embryo (see Appendix Four).

Conclusion

This chapter has argued that the use of the human embryo in medical research is possible because it is not ostensibly an agent. Stem cell research is possible on potential agents as long as it is justifiable on the grounds that there is no less probable agent to use, and that it is conditional upon attaining some agent centred good. If these conditions were not met, then the marginal status of the embryo would be harmed as a direct violation of its (marginal) status. For the research to proceed, one must incorporate institutional measures intrinsic to research policy to assess the likely benefits.

These measures should recognise the possibility that the embryo is an agent, and therefore restrict unlimited and unregulated use. This does not mean that research should be *a priori* prohibited, because the benefits that may derive from research represent a realistic opportunity to foster and promote more probable agent rights. Instead, policies must be directed by measures that do not treat the embryo as merely human tissue (because it has a marginal status above that of tissue), but accords it a status that invokes regulatory parameters, but which ultimately requires permissive research policies.

In the next chapter I will outline national and international measures in light of this conclusion, and determine whether such regulations promote agent-centred rights, unjustifiably bolster the rights of the embryo to the detriment of real agents, or deflate those rights of agents to protect an (illusionary) moral protection of the embryo.

Chapter Four

European Union Law and Policy on Stem Cell Research

Introduction

This chapter will describe present paradigms in European Union (EU) policy, concentrating on the alleged status of the embryo in international and Member State policies in stem cell (SC) and embryo research. This will be required to assess the necessity and possibility of implementing a harmonised EU policy on SC research. I have proposed that the mainstay of a harmonised international policy (if it is needed) will require the commitment to an already established framework of human rights (see Chapter Two). However, the possibility of implementing a SC policy should be philosophically formalised in line with the *Principle of Generic Consistency* (PGC). This thesis deals primarily with 'first order' ethical issues (the possibility of research and the implications for the derivation of cells from different sources). Here it may be necessary to reiterate that issues related to 'second order' issues (such as use of post-isolated cells, demand and supply of oocytes, patents, and the like) cannot be discussed in the thesis due to limitations of space. In the context of international regulation, especially in the EU, questions are presently confined to the status of the embryo in research. Within National borders, where embryo research may have been regulated for some time, the debate has begun to move on to these secondary issues. Notwithstanding this, these issues may have been underplayed in a number of national and international reports (Brownsword 2002 p. 583; also see Holm 2002).

In the first part of this chapter, I will confine the discussion to human rights as conceived in the regional conventions; the *European Convention on Human Rights* (ECHR), the *European Convention on Human Rights and Biomedicine* (ECHRB) and *Treaty Establishing the European Community*[1], to show how national commitments to human rights are expressed in line with international influence.

I will argue that the formal commitment to human rights as a whole is set in a sometimes contradictory framework. Embryonic research involves protocols that do not benefit the research subject directly; *in vitro* research results in the destruction of the

[1] See Chapter Two fn. 2.

subject. But, the right to life of the human embryo is not guaranteed in Community law. This being the case, it is not surprising that the majority of member states allow some form of embryonic research.

The second part of this chapter focuses on the present and prospective national law and policy in the individual Member States. I will explicitly address the status of embryo research and the influence this may have on harmonisation in SC research. This will demonstrate an increasing acceptance of regulated embryonic SC research, and that within national policies, there is remarkable similarity in research limits (whether in permissible or prohibited research) and that this may offer a means to Community harmonisation. The purpose of this will be to set up, in the next chapter, the grounds for a harmonised SC policy.

Part One: Interpreting the Right to Life in the European Union

1. The Right to Life, Abortion and Embryo Research in the European Union

In Chapter Two it was argued that international law is an explicit vehicle for human rights, but that a common underlying basis of this framework is an implicit grounding in 'dignity' reserved for all biological human beings (section 6.5.2). I argued that this may lead to an ad hoc interpretation of rights in dealing with conflicts between different ontological states of human development. I also argued that the true understanding of the moral right lies in a Hohfeldian claim right. This claim right leads to an agent-centred basis of morality, and this was developed through the Gewirthian concept of the will claim right, ultimately arguing for the *Principle of Generic Consistency* (PGC) as a supreme principle of morality (Chapt 2 s. 2 and 8.1).

In Chapter Three, I argued that Beyleveld's (1998a; and with others) argument for the *Precautionary Principle* could grant 'quasi-rights' for marginal agents (section 7) (Beyleveld & Brownsword 2001; Beyleveld & Pattinson 2000). While these rights cannot be as important as (will) claim rights, they could protect marginal agents to the degree that justification would be required to override its marginal status.

This framework will be used for grounding an EU policy based on the need and possibility of a harmonised policy on SC research. The purpose of this first part to Chapter Four is to highlight the present inherent problems of EU harmonised legislation and policy, and this is clearly evident in the derivation of the right to life.

1.1. International Law, Dignity and the Right to Life

The right to life in the European[2] context allegedly derives from the:

---

[2] Likewise, the UN states its commitment to '...fundamental human rights, in the dignity and worth of the human person... [and that] All human beings are born free and equal in dignity and rights [therefore] ...Everyone has the right to life' (Preamble, Article 1 & Article 3; UDHR 1948). The body of the UN that may influence this discussion is the United Nations *Educational, Scientific and Cultural Organisation's* (UNESCO) *International Bioethics Committee.* Particularly see the *Universal Declaration on the Human Genome and Human Rights* 1997 (UDHG). The UDHG states that to promote in principle, guidelines '...*emphasizing* [sic.] that such research [on the human genome] should fully respect human dignity, freedom and human rights' (Preamble).

> ...measures as are necessary to safeguard human dignity and the fundamental rights and freedoms of the individual...[and to] protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine (ECHRB 1997 Preamble & Article 1).

The EU is in the process of establishing a framework so that the 'Enjoyment of these rights entails responsibilities and duties with regard to other persons, to the human community and to future generations... Human dignity is inviolable [and] It must be respected and protected... Everyone has the right to life' (*Preamble*, Article 1 & 2 CFREU)[3].

While dignity has a prominent status, I have argued that 'dignity', as an *inviolable* value, is not an absolute basis for human moral status. Furthermore, this is recognised implicitly in the Conventions of Europe, because the act of procuring an abortion, that deprives the unborn of its rights, is permissible in all but one state[4]. Additionally, legal deprivation of life in emergency and certain other sanctioned situations, including euthanasia in Belgium and The Netherlands[5], and, importantly, embryo research is possible.

Embryo research is presently permissible under certain circumstances in all but three member states[6]. Like abortion, this act necessarily destroys the embryo's prospect for development, but in the case of abortion, most states accept that in cases of conflict of the right to life of the pregnant woman and the unborn, the former must prevail. Although the embryo/foetus has its rights restricted by those of the mother, there is a gradual transition of the weight of the embryo/foetus's *prima facie* rights as it develops. These rights never reach 'full' moral status until birth (or viability). In the case of research, it must be that the benefits that (may) follow from research can outweigh any status of the embryo.

---

[3] 'Dignity' is also stated in Article 6 of the *Treaty of the European Union* (1997); and Article 7 of the *Sixth Community Framework Programme for Research, Technological Development and Demonstration Activities* (1998-2002); The 6th Framework Programme concerning the creation of the European Research Area (2002-2006) states that 'Fundamental ethical principles are to be respected ...including the protection of human dignity and human life...' (Official Journal (OJ) L232 of 29.8.2002 p. 4).

[4] See Appendix Five.

[5] In *Pretty* v. *United Kingdom* (application number 2346/02 (2002) 35 EHRR 1) the ECHR was unwilling to assess the admissibility of whether the '...failure to acknowledge a right to die under the Convention would place those countries which do permit assisted suicide in breach of the Convention. [therefore] It is not for the Court in this case to attempt to assess whether or not the state of law in any other country fails to protect the right to life' (para 41).

[6] Note that Germany allows the import of ES cells. Only Italy is likely to enact totally prohibitive legislation (Ireland has a de facto ban) (This is discussed further below).

The 'dignity' of all human beings cannot therefore be understood under these legal terms (except in Ireland[7]), as an absolute value in all biological 'human beings'; because not all human beings (as a species concept) have a right to life. In interpreting international documents, such the ECHRB, we must therefore be dealing with a distinction between 'everyone'[8] and 'human beings'[9]. If these documents are proclaiming the rights of all human beings (on account of their intrinsic dignity) then they are immediately in conflict with all states that allow abortion or embryo research. However, if they can be read to protect the *rights* of *persons* and ensure 'respect' (or some other value) for *human beings*, this problem maybe circumvented. This 'dignity status' may therefore be recognised as two separate values: (1) '...a generally accepted principle that human dignity and the identity of the human being had to be respected as soon as life began' (Explanatory Report to the ECHRB 1997 *infra* fn. 8 para. 19); and (2) 'everyone' which only refers to a 'person-status' grounded in some form of (restrictive) capacities; thus allowing, in limiting circumstances, the termination and instrumentalisation of biological human life.

But even in the levels of higher 'personhood' there are exceptions to the absolute value of life: such as emergencies to the state, self-defence, attempting to enforce legal detention, the 'just war' (non-consenting loss of life), and euthanasia (consenting). Furthermore, if human dignity represented an absolute value in all human beings, then certain '...autonomous choices of women (to terminate pregnancies) must be measured for their legitimacy against not only the general regime protecting human rights [of 'everyone'], but also against the special dignity-based regime protecting such early human life' (Beyleveld & Brownsword 2001 pp. 32-33).

---

[7] Article 40.3.3 of the Constitution states: 'The State acknowledges the right to life of the unborn and, with due regard to the equal right to the life of the mother, guarantees in its laws to defend and vindicate that right'.

[8] 'The Convention does not define the term "everyone" ...In the absence of a unanimous agreement on the definition of these terms ...it was decided to allow domestic law to define them for the purposes of the application of the present Convention' (*Explanatory Report to 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* (1997); DIR/JUR (97) 5, Council of Europe, Strasbourg, para 18).

[9] 'The Convention also uses the expression "human being" to state the necessity to protect the dignity and identity of all human beings' (ibid. para 19).

1.2. Rights in Research from Rights in Abortion

Stem cell research highlights further the tension between stages of human existence. At one end, there is the moral status of the human embryo, and at the other are the potential benefactors of the research. To address this conflict we must look at the obligations of the targets of human rights (public authorities) under the ECHR; the CFREU; and with specific regards to embryo research, the ECHRB.

Within Europe, the *legal* right to life has been addressed in the context of abortion. Here the various institutions have been rather unwilling to state where the right to life begins. In *Paton* v. *British Pregnancy Advisory Service Trusties*[10] the father of an unborn child sought to prevent an abortion. The domestic court ruled that:

> The foetus cannot, in English law, in my view, have a right of its own at least until it is born and has a separate existence from its mother (p. 279).

On appeal to Strasbourg, the European Commission ruled that there had been no breach of Article 2, stating:

> ...both the general usage of the term 'everyone' in the Convention... and the context in which this term is employed in Article 2... tend to support the view that it does not include the unborn... the life of the foetus is intimately connected with, and cannot be regarded in isolation from, the life of the pregnant woman. If Article 2 were held to cover the foetus and its protection under Article 2 were, in the absence of any express limitations, seen as absolute, an abortion would have to be considered as prohibited even where the continuance of the pregnancy would involve serious risk to the life of the pregnant woman. This would mean that the unborn life of the foetus would be regarded as of higher value than the life of the pregnant woman. The 'right to life' of a person already born would thus be considered as subject not only to the express limitations mentioned in [Article 2(2)], but also to a further implied limitation[11].

If it is argued that the right to life is fundamental and absolute; no derogation is permitted from the provisions of the concept (such as that defined by Article 2 of the ECHR). But this fails to recognise that if no conditions are asserted of this kind, the right to life can be derogated from in exceptional circumstances. If the embryo were drawn under the Act, then termination of pregnancy would be contrary to any alleged principle of non-derogation from the right to life (except in exceptional circumstances); but no authoritative legal position has been held on this ground (except in notable attempts made in Ireland; see below).

---

[10] [1979] 1 Q.B. 276 at 279.

[11] *Paton* v. *United Kingdom* (1980) E.H.R.R. 408, paragraph 9, 18 & 19; cf. Application No. 8416/79, *X* v *United Kingdom*, admissibility decision of 13 May 1980, 19 *Decisions and Reports of the European Commission of Human Rights* (D & R) 244.

The Commission's ruling in *Paton* stated that the term 'everyone' did not extend to the unborn, but went on to consider whether protection of 'life' could be interpreted as including 'unborn life'. They considered two interpretations: firstly, whether Article 2 did not apply at all to unborn children; and secondly, that Article 2 recognised the right to life of the unborn, but was subject to certain limitations (in this case that of the mother). In the end, the Commission rather side-stepped any conclusive judgement, instead holding that an interpretation of the right to life of the unborn:

> ...would be contrary to the object and purpose of the Convention. It notes that, already at the time of the signature of the Convention ...all High Contracting Parties, with one possible exception, permitted abortion when necessary to save the life of the mother and that, in the meanwhile, the national law on termination of pregnancy has shown a tendency towards further liberalisation [and that] ...Article 2(1) is subject to an implied limitation justifying termination of a pregnancy in its early stages in order to protect the life and health of the woman at that stage (*supra*. fn. 11 para 20)[12].

While the Commission did not adopt a position on whether the right to life under the Convention extends to the unborn, if the right extends to the unborn, the right is not absolute.

In *Attorney General of Ireland* v. *X and Others*[13], the Irish Attorney General declared that the right to life of the unborn was non-derogatable under the restraints of the Irish Constitution, regardless of the conditions of free movement and access to services protected by the Treaty on European Union (1992)[14]. It was clear, however, that the ECJ and the European Court of Human Rights (under the ECHR) would not permit such a restricted position. In the case of the former, the ECJ held that the judgement of the Attorney General was contrary to the Treaty. Therefore abortion was a legal service in those states that permitted it, and that information about and free movement between states was permissible to procure that service[15]. In the *Well-woman*

---

[12] 'It finds that the authorisation, by the United Kingdom authorities, of the abortion complained of is compatible with Article 2(1), first sentence because, if one assumes that this provision applies at the initial stage of the pregnancy, the abortion is covered by an implied limitation, protecting the life and health of the woman at that stage, of the 'right to life' of the foetus' *(supra* fn. 11 para 23).

[13] [1992] I.R. 1; [1992] I.L.R.M. 401.

[14] The Irish complaint was made under the Eight Amendment of the Irish Constitution (40.3.3) and was protected under the Maastricht Treaty by Protocol No. 7 (annexed to the Treaty on European Community 1992; but not reproduced in the present Consolidated Text 2002). It states: 'Nothing in the Treaty of the European Union or the Treaties establishing the European Communities, or in the Treaties and Acts modifying or implementing those Treaties, shall affect the application of Ireland of Article 40.3.3'. Subsequent to the *X* case, and after a campaign to have the Protocol deleted, a 'Solemn Declaration' was made to considerably dilute the said Protocol (Murphy 1994).

[15] The ECJ held: '1. Medical termination of pregnancy, performed in accordance with the law of the State in which it is carried out, constitutes a service within the meaning of Article 60 of the Treaty; 2. It is not

case[16], the European Court of Human Rights held that the claim that assisting clients to procure abortions infringed the Irish Constitution, violated Article 10 which guaranteed freedom of expression[17].

With regards to embryo research, if one takes the view that the right to life could not apply to the unborn per se, then there would be little to stand in the way of destructive experiments and investigations. However, the restrictive position of an implied limitation on the right to life of the embryo requires one to address the actual limitation, if research is legitimate under international law. The interpretation of case law cannot allude to how the right to life of the embryo should be construed in destructive research; this is because the case law explicitly addresses the embryo in abortion. But perhaps with the continuing and explicit liberalisation of embryo research and the pluralistic nature of Europe, it should not be decided either way explicitly by the courts; and thus leave each state, as is presently the case, to legislate as it sees fit. However, as I will show, this is tending not to be the case, with increasing pressure being placed on legislative authorities within Europe to adjudicate on the matter. The first means that may force the legislative hand is through the ECHRB and the Council of Europe; the second is by restrictive Directives being placed before the European Community.

1.3. The European Convention on Human Rights and Biomedicine (ECHRB) 1997

The Council of Europe's ECHRB is an instrument that covers most areas in medicine. The Convention is expressly intended as a moral and legal model to create

---

contrary to Community law for a Member State in which medical termination of pregnancy is forbidden to prohibit ...distributing information about the identity and location of clinics in another Member State where voluntary termination of pregnancy is lawfully carried out and the means of communicating with those clinics, where the clinics in question have no involvement in the distribution of the said information' (*The Society for the Protection of Unborn Children Ireland Ltd* v *Stephen Grogan and others*; C-159/90; 4 October 1991).

[16] *Open Door Counselling Ltd* v *Ireland* (A/246) (1993) 15 E.H.R.R. 244. Also see the history of this case: *Attorney General ex rel. Society for the Protection of Unborn Children (Ireland) Limited* v. *Open Door Counselling Limited and the Dublin Well-Woman Centre Limited* [1988] 2 C.M.L.R. 443. *Open Door Counselling Ltd* v *Ireland* (A/246), (1992) 14 E.H.R.R. CD131 (Eur Comm HR); *Open Door Counselling Ltd* v *Ireland* (A/246), (1993) 15 E.H.R.R. 244.

[17] It is a salient point that in both cases the right to life of the unborn (an alleged absolute right) was overridden by traditionally weaker *prima facie* rights – freedom of movement and to information, and freedom of expression. These latter rights are linked to the having and expression of individual autonomy; and so perhaps here we are seeing the already prevalent emphasis on the primacy of agent autonomy over arguments that protect the sanctity of all human life.

international minimal standard within an agreed framework, but is not intended as an instrument to be directly applied to state medical affairs. For this reason, the Convention can appear ambiguous; but then this was arguably necessary to gain widespread consensus among the states of Europe, leaving individual states where necessary to interpret the rights and principles set out therein with precision and clarity and according to national values (Romeo-Casabona 2002 p. 561). It is couched in the rather imprecise terms and principles of protecting 'dignity', 'identity' and 'integrity' of the 'human being'. With regards to Member States, only Austria, Belgium, Germany, Ireland and the UK have so far not acceded to it. It has been signed by the other Community states, but with binding effect in Denmark, Greece, Portugal, and Spain. The Convention has been supplemented by two additional protocols concerning human cloning (2001)[18] and transplantation of organs and tissues of human origin (open to signature 2002).

A separate reading between 'person' and 'human being' is further supported in that *most* articles in the ECHRB must be read in context with the Convention (i.e. human dignity and rights)[19]. This is emphasised in that:

> Parties to this Convention shall protect the dignity and identity of *all human beings* and guarantee *everyone*, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine (my emphasis, Article 1).

But, while this is *central* to Articles 15[20], 17[21] and 21[22], it is not mentioned *explicitly* in Article 18, concerning human embryo research (paragraphs 115 & 116 of the Explanatory Report; *supra* fn. 8):

---

[18] *Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings* (Paris, 12.I.1998).

[19] 'The concept of the human being has been used because of its general character. The concept of human dignity, which is also highlighted, constitutes the essential value to be upheld. It is at the basis of *most* of the values emphasised in the Convention' (my emphasis; Explanatory Report; *supra* fn. 8 para 9). Later, the Report states that: 'The whole Convention, the aim of which is to protect human rights and dignity, is inspired by the principle of the *primacy* of the human being, and *all* its articles must be interpreted in this light' (my emphasis; ibid.). This suggests that the Convention should be interpreted as raising the protected status of the human species as a whole, but it does not mean that acts could be taken that are based in the values of the human being, but which may affect certain levels of that value.

[20] 'In medical research it is limited by the fundamental rights of individuals expressed, in particular, by the provisions of the Convention and by other legal provisions which protect the human being (ibid. para 96).

[21] 'The rule prohibiting the carrying out of the research against the wish of the subject reflects concern ...for the autonomy and dignity of the person in all circumstances, even if the person is considered legally incapable of giving consent' (ibid. para 106). 'Article 17 lays down a more stringent requirement for research without direct benefit to persons incapable of giving consent ...Indeed, it is only in respecting

> Article 18 – Research on embryos *in vitro*[23]
> (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

There would seem to be therefore, two levels of protection available to legislators – that for persons included as 'everyone', and a lower level for 'human beings' not qualifying for the former[24].

The wording of Article 18 implies a number of salient points. Firstly, authorisation or prohibition of embryo research rests with the state; but then however the state wishes to treat the embryo, this must be secured by legal provision, and that minimally; where research is authorised, there must be a legal guarantee that *some* ('adequate') protection is in place.

Secondly, the Convention expressly forbids signatory states from creating embryos specifically for research, thus implicitly limiting *in vitro* research to supernumerary embryos created as a result of fertility treatment. The Convention does not expressly mention any further limitations, and this may be implied to acknowledge a more or less restrictive approach by individual states[25] (Romeo-Casabona 2002 p. 561).

From this one can assume two implicit intentions in the Article. Firstly, one must acknowledge that embryo research is *not prohibited* by the Convention. Research is permitted on embryos created for fertility purposes (by *whatever means*) and which remain after treatment, for *whatever reason*, but only when it is accorded *adequate protection* by legislative procedure. But, since the only prohibition lies in creating an embryo explicitly for research, one may imply that it is not prohibited to create an embryo specifically for treatment (including IVF *and* SC treatment)? If this is the case, then can embryos be created for the explicit reason of SC treatment (but *not* research)? Romeo-Casabona therefore argues that:

---

these conditions that such research may be carried out without constituting an instrumentalisation of these persons contrary to their dignity' (ibid. para 111).

[22] Concerning *Article 21 - Prohibition of financial gain*: 'This article applies the principle of human dignity' (ibid. para 131).

[23] This explicitly suggests that *in utero* research is not permitted by the Convention; and therefore attempts to delineate the *in vitro* embryo and research, from the *in utero* embryo and abortion. In this way, the Convention can avoid declaring a position with regards to abortion.

[24] And this suggests that 'dignity' is not the grounding of human rights, because while all 'human beings' have 'dignity', not all have 'human rights'. Therefore, 'dignity' in this sense is not meant to apply only to rational beings, but to all biological human beings; see Chapter Two s. 5.5.

[25] For example, there is no mention of common limitations such as ethical review, research aims, limits on gestation age of the embryo, or storage restrictions.

> [a]ccording to this interpretation, we could consider that the European Convention has put the interest of the embryo above collective interests (such as the promotion of research), but that it has placed the human embryo's interests below that of a given individual's health and life (Romeo-Casabona 2002 p. 561).

Thirdly, the fact that the human embryo is given its own Article, outside those dedicated to the protection of 'everyone', Reuter argues, would warrant us to read those provisions as applying to 'everyone' as covering individual or persons, and not life in general, and which would exclude the embryo (Reuter 2000 p. 186). In agreement, Lebech states:

> Considering the widespread use of legal abortion, and the legal provisions for pre-implantation diagnosis and the freezing of embryos, the term "everybody" is not intended to include human embryos (Lebech 1997 p. 20).

Thus 'everyone' and the 'human embryo' are furnished with an inherent set of somewhat different 'rights', in the same way that the ECHR treats 'everyone' and 'human being' as separate moral beings – and thereby offering a means to different degrees of legal protection (in this case, research versus rights to life (or in the ECHR the rights of autonomous choice [of agents] versus right to life [of all human beings]). Taken together, they obviously cannot support an absolute right to life, since research is permissible under the legislation of nation states.

The only demand of the ECHRB is a prohibition of the creation of embryos for research (which would rule out therapeutic cloning techniques only for research; but then cloning for reproductive aims is prohibited by the Additional Protocol). The *Additional Protocol on cloning*[26], in light of this reading, arguably *allows* therapeutic cloning that does not use *embryonic cells*, stating that it:

> ...does not take a specific stand on the admissibility of cloning cells and tissue for research purposes resulting in medical applications. However, it can be said that cloning as a biomedical technique is an important tool for the development of medicine, especially for the development of new therapies. The provisions in this Protocol shall not be understood as prohibiting cloning techniques in cell biology (Explanatory Report [to the Addiction Protocol] (1998) Council of Europe, Strasbourg, ETS no. 168, para 4).

The *Hellenic National Bioethics Commission* argues that the Additional Protocol should be taken to mean that *therapeutic cloning* is exempt from a general prohibition

---

[26] 'Any intervention seeking to create a human being genetically identical to another human being, whether living or dead, is prohibited. ...For the purpose of this article, the term human being "genetically identical" to another human being means a human being sharing with another the same nuclear gene set' (Article 2; *supra* fn. 18).

(personal correspondence 8/9/03). In effect, the Protocol intends to ban reproductive cloning but is unwilling to place a blanket ban on therapeutic cloning.

This becomes confusing, because, firstly, creation of embryos for research is prohibited (under Article 18.2 of the ECHRB); secondly, the cloning of an identical human being is prohibited under the Additional Protocol. However, research is permitted on embryos *in vitro* (presumably those created for IVF treatment only) under the ECHRB (Article 18.1), and so is cloning research (as a technique) that does not involve human embryos. The 'Dolly' technique would not use any human embryos, but would create one. Scientists are therefore creating a human being (which is prohibited) but using a technique that is explicitly permitted. The Protocol states that cloning involving human embryos '...should be examined in the protocol on embryo protection', and therefore is subject to Article 18.2, forbidding the act of creating embryos specifically for research. If the technique is permissible, but the consequences are not, then one has to take precedence, unless the cloning technique produces something non-human[27]. Under the ECHRB, it would be likely that the explicit prohibition of creating embryos would take precedence for research only, and that creation for therapy would be possible.

The difference of opinion in the perceived status of the embryo has led to a number of states being unwilling to sign the Convention and Protocol. The implicit difference in status between persons and human beings can be used as a warrant for establishing a considerable practical difference in treatment of the two categories. Although the Convention does not even mention the right to life of *anyone specifically*, we could conclude that the rights it does mention separately from Article 18 apply differently to the human embryo. Additionally, the Convention is setting a minimal standard (in this case prohibiting the creation or research embryos) while allowing for stricter national regulation. The problem arises for states that have less stringent regulations however, as acceding to the Convention would supersede those permissions[28].

---

[27] This would be an unlikely reading. The UK has declared that because cloning by Cell Nuclear Replacement (CNR or the 'Dolly' technique) was unknown at date of Human Fertilisation and Embryology Act 1990, a purposive approach necessitated the conclusion that an embryo produced by CNR should be within scope of regulation (*infra* section 5).

[28] A state can submit and register a reservation with the European Council with regards to the creation of specific research embryos – and this has been proposed by the *Swedish Committee on Genetic Integrity* to the Swedish parliament (SCGI 2003).

1.4. The Margin of Appreciation, The Principle of Subsidiarity and the Principle of Proportionality

The argument therefore, is to allow the ECHR and EU law to leave the issue of embryo research to the states' discretion. International law could therefore be unwilling to demand prohibitive *in vitro* research by each state, and instead each state can legislate as it sees fit. But accordingly as a compromise, the state must recognise an adequate protection.

While this suggest a 'gradualist' position on the part of the international authorities with regard to embryos' moral status, so that *in utero* embryos have a higher moral status to *in vitro* embryos (which conveniently also mirrors most states' position with regards to abortion; but see Gethmann 2002 p. 2), it also undermines effective regional supervision of a clearly important and contentious issue. Because while it is willing to state that one course of action should not be pursued (i.e. creating embryos), it in effect turns a blind eye to the regulation of effective *in vitro* research within Europe.

There are potential problems with regards to this position, in that without taking a stand, it leaves important questions as to the legislative position of the states. But additionally, the Community is also unwilling to sanction any restrictive measures with the consequences for women's rights and potentially beneficial research that would be severely, and certainly in the case of the former, unjustifiably restricted. And so these issues are presently in the main determined by the state's political conscience.

The *Margin of Appreciation* is an implicit doctrine within the Council of Europe that has developed from the case law emanating from the ECHR: '...the doctrine stands for the notion that the authorities of each state party to the European Convention ought to be allowed a certain discretion in implementing the standards enshrined in the Convention' (Gross & Aoláin 2001 p. 626). It gives the flexibility needed to avoid damaging confrontations between the Court and European states over their respective spheres of authority and enables the Court to balance the sovereignty of contracting parties with their obligations under the Convention.

However, detractors have pointed out that the Courts have been reluctant to take responsibility over precedents in complex and sensitive cases, thus weakening the Court's authority with regards to the actions of national governments. (This also means that observers are often left to guess the real reasons for a judgement that it has left to a

state to decide). It is also argued that the doctrine is fraught with moral and cultural relativism which runs contrary to any notion of universal human rights.

The EU operates similarly, in that:

> In areas which do not fall within its exclusive competence, the Community shall take action in accordance with the principle of subsidiarity, only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale or effects of the proposed action, be better achieved by the Community (Art 5 of the Treaty of the EU 2002).

Furthermore, the *Principle of Proportionality* defines the intensity of the action that the Community should take. Every proposed measure must be scrutinised to see whether it could do its job in a way that would be less obtrusive or burdensome to member states (Dashwood 1996). Thus the powers of the Community are limited and its law-making competence is conferred to further specific objects: in the case of stem cell research, the most relevant policy where the EU may intervene is in *Public Health* (Article 152)[29]. SC come under the Article as 'substances of human origin' (Art. 4(a)). However, while the Community should adopt 'incentive measures designed to protect and improve human health', this '[*excludes*] ...any harmonisation of the laws and regulations of the member states' (Art. 4(c)).

This may be read as the EU having no law-making powers to introduce harmonised regulations, but may offer incentives along those lines. These incentives may be important for promoting a Community wide policy on public health. The question is whether the Community has any competency to enforce restrictive measures.

1.5. The Legal Limits of 'Life'

The question of whether human beings can be used as research subjects has truly haunting connotations. And indeed, wide respect for human rights and the never to be repeated experiments of Nazi Germany (among others) led to universal acceptance of an absolute value in autonomy and consent in human research. Special care was taken to ensure that those who were vulnerable to exploitation were protected from experimental research. And here lies the conflict between those who consider the human embryo to be at the furthest extremities of what is 'human' (and therefore lacks the absolute value

---

[29] See Appendix Six s. 2.

in that), and those that holds that 'human is what is born human' (Reuter 2000 p. 181), the deviation from which is entirely unacceptable.

The majority policy on abortion within the EU is unwilling to endorse the latter camp (with the exception of Ireland); instead the right to life of the embryo/foetus must be secondary to the mother's right. Limitations are put on the autonomy of the mother to demonstrate that the states are also not inclined to sanction a policy of *laissez-faire* with regards to some levels of 'human life'; but continuing liberation of abortion policy demonstrates that the embryo has a far from absolute value in life. Thus the *X* case, along with *Paton*, demonstrated that the EU was, under its own law and that of the Council of Europe, unwilling to make the right to life an absolute right, and thus allowed derogation to that right in the case of abortion. So if the unborn lack the full right to life, as any other human being, how does this reflect upon its substantive claim to 'life'?

The jury is still out concerning EU agreement on this matter. A human embryo can be considered as 'human life' within individual states, but the protection that flows from this is open to interpretation. This is not as damaging to EU policy as it first seems, however, since the derogatable nature of the right to life of the unborn is also reflected in the fact that the right to life of the unborn can be derogated from in certain circumstances, as stated in 2(a) of the ECHR: 'Everyone's right to life shall be protected by law'. Although the right to life is '...one of the most fundamental provisions in the Convention'[30], derogation is permitted under '(2) Deprivation of life shall not be regarded as inflicted in contravention of this Article when it results from the use of force which is no more than absolutely necessary: (a) in defence of any person from unlawful violence[31]; (b) in order to effect a lawful arrest or prevent the escape of a person lawfully detained; (c) in action lawfully taken for the purposes of quelling a riot or insurrection' and Article 15 '...in respect of deaths resulting from times of war' and '...public emergency threatening the life of the nation'.

---

[30] *McCann* v. *United Kingdom* (1996) 21 E.H.R.R. 97 para. 147. The Judgement also stated that: 'The Court's approach to the interpretation of Article 2 must be guided by the fact that the object and purpose of the Convention as an instrument for the protection of individual human beings requires that its provisions be interpreted and applied so as to make its safeguards practical and effective' (para 146). 'It must also be borne in mind that, as a provision which not only safeguards the right to life but sets out the circumstances when the deprivation of life may be justified, Article 2 ranks as one of the most fundamental provisions in the Convention - indeed one which, in peacetime, admits of no derogation under Article 15 ...As such, its provisions must be strictly construed' (para 147).

[31] It could it be argued that the mother is protecting herself from 'violence' on account of the embryo, but since I have previously argued that duties are only due from agents, it is unlikely that the embryo has any duties in this sense, and therefore cannot be considered under the remit of the ECHR.

What is more, the right to life is only *protected* by the law, which means that the state's obligations reside in a duty to refrain from unlawful killing; to investigate suspicious deaths, and in certain circumstances, a positive obligation to take steps to prevent *avoidable* loss of life (see Ovey & White 2002 pp. 42-57).

Though the test for derogation may be very high (and indeed perhaps fully effective in peacetime) (Black-Branch 2001), it is nonetheless by explanation not absolute. Black-Branch continues that because the right to life has an 'autonomous meaning' in the ECHR, then individual states cannot express their commitment to its enforcement in any less measure than that which is dictated by the European Court (ibid. p 33). Thus the right to life must be '...strictly construed'[32], and therefore 'life' means 'life' but with the restrictions placed upon it by those of the European Court (see Article 2(2) of the ECHR; Article 18 of the ECHRB; and the *X & Paton* cases). And as we have seen, the Courts are unwilling to assert an absolute right, and are keen to emphasise, if nothing more, that the rights of the unborn cannot supersede the mother's.

Thus the list of circumstances of derogation to the right to life is maintained in a number of ways, which tends to suggest that the right to life of the embryo in Europe is not absolute. It is arguably not the purpose of the Conventions to ensure the continuance of *all human life* regardless of the circumstances.

2. Conclusion to Part One

The means to make exceptions to the absolute applications of the right to life and the embryo's non-absolute status under the ECHRB, would seem to be underlying justification for embryo research in states where it is permitted. The derogateable right to life of the unborn, which can be extrapolated from abortion cases, therefore exists as baseline political defence. It is clear that, although in most states the embryo has either no or very little legal status before the law regarding abortion, additional reasons are required to enter it into destructive research. The two main positions derive from firstly, a Cartesian tradition that grounds a moral value in either being or being able to become a rational entity; the second from the biological nature of all human beings, which is undeniable from conception. And, as I argued in Chapter Three, this also

---

[32] *Supra.* fn. 30.

might be the reasoning behind claim rights. Clearly, any protection for the embryo must come from a second, subservient value particular *to* all human beings.

However, there is a fundamental difference between abortion and embryo research, since although both result in the destruction of the human embryo, only the former is implicated with the pregnant mother and therefore the intimate potential conflict of rights. Research, on the other hand, concerns potential benefactors in the abstract, so those who may gain as a consequence of the research are not directly linked to the status, and therefore alleged rights, of the embryo; and conversely, would not be directly affected by a raised status for embryos in research. While in the case of the latter, reasons may be found that necessitate the destruction of the embryo/foetus (such as the 'risk' of harm to the mother or unborn); one has to look elsewhere for the justification for destroying the same being, but *in vitro*. And so while these attempts to derive right for the embryo are less prevalent in abortion legislation (so, for example, regardless of the *potential* rights of the embryo, the mother has actual rights), in the research arena, they come to the fore. It comes down to whether the potential or actual rights of the embryo can or cannot be superseded by the interests of others (which I argued in Chapter Four).

On the one hand, in practice the limitations placed on the right to life of the embryo by legal (and therefore arguably moral[33]) norms in abortion allows a route which policies can take to justify destructive research using human embryos for the benefit of human 'persons'[34]. In the same way that contracting states enjoy discretion with regards to abortion, then regulated research likewise would not go beyond its discretion in this sensitive area[35]. On the other hand, states that do allow abortion (and those that don't) can prohibit research regardless of the alleged indirect benefit to others; they can recognise that the difference between abortion and research are fundamental to restrictive and permissive legislation.

---

[33] It is not the place of this thesis to address the arguments for and against abortion per se, although these debates inevitably resonate in discussions for and against embryo research. It has been the point of this section to highlight the legal differences in approaches to abortion to demonstrate that unless the right to life of all human beings in non-derogatable, then there is an underlying justification for states to pursue policies in embryo research. This section should be read in conjunction with Chapter Three, so that the marginal status of the embryo and the status of EU law, together permit a limited use of the embryo in research.

[34] 'Persons' recognised as legal agents, and therefore rights holders.

[35] Indeed, the *Explanatory Report* to the ECHRB states: 'The article [18] does not take a stand on the admissibility of the principle of research on *in vitro* embryos' (*supra* fn. 8 para. 116). But have countries, like the UK, gone beyond their discretion by allowing the creation of embryos for research, which is expressly prohibited by the ECHRB (and is a reason why the UK has failed to sign the Convention)?

Part Two: Present and Future Policy in the European Union

1. National Regulation and Policy

The status of the embryo in research is balanced implicitly between the relationship of the mother and unborn in abortion, and the benefit of research. If states allow research, this must be on the grounds that the embryo does not have an absolute right to life, which is supported by EU law, that provides for a derogation of life when it is justified for a significant benefit (or to avoid significant harm). Those states that do not allow research must align themselves with a right to life when separated from the context of the mother, and maintain that this life is to be fully supported when considered in isolation. When taken in relation to the mother, all states with regard to abortion, regardless take a gradualist view of increasing protection concurrent with gestational age, with little status being derived for the early embryo (e.g. the use of some forms of contraception and the implicit encouragement of early, rather than late abortions). Accordingly, I will now look in detail at the legal protection of the embryo in research within the European Community.

1.1. Empirical Research

Much of the following information was gleaned from direct contact with the relevant policy groups in respective countries. This thesis was intended not only to argue for a framework of human rights and its application in policies on SC research, but also to attempt to integrate this theory into the EU research policy. It is evident that divergent views exist in the EU with regards to the status of the embryo and SC research policies. However, with attempts to increase the co-operation between member states, and possible benefits from a harmonised policy, and harms that could come from conflicting agendas, it would be prudent to identify where the individual states stand on the issue of research.

Much is changing in the states' policies as new SC developments put stress upon the moral decision-makers. An initial task was therefore to identify the National governmental advisory committees to expose early policy moves. Although it may take

time for this advice to filter in to national legislation, early identification could hint as to the policy directions of Member States. It is of course entirely possible that the advice given to national governments would be ignored or altered as more information is obtained (this is discussed in Chapter Five).

1.1.1. Methodology

It is evident that there are a number of committees in each state that have different levels of advisory competency. It was also clear that obtaining an up-to-date list of active committees would be difficult and that monetary restraints in the research would create language barriers (such as translations of relevant reports). Nevertheless, a number of groups were identified and their *moral* position on stem cell research was sought. This would identify and be used as a *pragmatic guide* to the future of SC research policy in that state.

The identification of advisory groups was achieved on an ad hoc or 'paper-chase' basis through the available literature and the internet. The main advisory groups and their subject competency were easily identifiable (for example, each state generally had a permanently standing national 'ethics' committee); and these groups often had links to further identifiable and relevant groups. There were a number of other groups that seemed to have competency in government advice and possibly SC research issues, and these groups were contacted 'blindly'. Established EU research networks were also identified, and these often also gave links to potentially relevant groups.

A number of reports (or summaries) were available in English in hard copy or on the internet. In addition, a questionnaire was designed to get up-to-date opinions and to locate further advisory documents (see Appendix Seven). It would not have been possible to translate any non-English language reports. If no official document were readily available for a particular group, the questionnaire would allow groups to state their considered future policy advice. Again, because of monetary restraints, the questionnaire was translated only into French[36] and only allow responses in English and French.

---

[36] By the University of Bristol Language Centre, 30/32 Tyndall's Park Road Bristol, BS8 1PY, UK.

The documents obtained were used for qualitative data of the advisory bodies' positions. The method was to review the reports and identify and summarise the positions and any qualifications attached to them. The documents and reports were generally formatted in a way that clearly stated the position of that group with regards to the issues raised by stem cell research. These views (normally stated as an 'opinion' or 'recommendations') could then be juxtaposed with other groups' positions and the present national regulatory framework. Of the opinions received, it was evident that in the main the ethical considerations were concentrated, and often solely confined to, the derivation of cells in the context of embryo research (mainly the moral status of the embryo, the use of 'spare' and creating embryos for research, and therapeutic cloning; and there was little discussion of cord blood and somatically derived SC). There was evidently little concern (at present) for secondary issues (although there was some national referral to national cell banks and the commercialisation of embryos). There was particularly little stated on international regulation and harmonisation of SC research (except explicitly where the opinion dealt with the import of embryonic stem cells). The details of the opinions will be stated below[37].

The design of the questionnaire was primarily that if an official opinion was publicly available, then there was no need to fill out the questionnaire. The group could either send a copy of the report or opinion, or direct one to where it was obtainable (usually from their web-site). The public opinion would be the means of ascertaining the groups' position and the advice that would be forthcoming to government and policy makers. The remainder of the questionnaire attempted to get the position of the group despite not having published any official position (perhaps if one was forthcoming).

1.1.2. Results

Of 114 questionnaires sent, 26 responses were received[38] (full details are in Appendix Eight s. 1). Of these responses, 8 stated that they had no competency in this

---

[37] This may suggest some bias in the responses because they focused primarily on the status of the embryo, the nature of which cannot be investigated here (Oppenheim 1993 pp. 106-107). There are further problems in the use of mail questionnaires, none of which can be ruled out as influential in this study. Perhaps the most pressing is that there is no means of confirming who responded – was it one person's view, or, as intended, the formal opinion of the entire advisory group (Moser & Kalton 1993 p. 261).

[38] 11 out of 15 Member states were represented: Belgium (4 responses); Denmark (5); Finland (2); France (1); Germany (2); Greece (1); Italy (1); Luxembourg (1); Netherlands (2); Sweden (3); & UK (4). There

field or were not forthcoming with any relevant information[39]; 14 sent either a copy of, or details to obtain, their opinion[40]; and one stated that they were planning to address the issue, but had not done so yet[41]. Three were forthcoming in answering the questionnaire only[42]. Additionally, nine reports were available via the internet but were not notified to me by contact with the relevant group[43]. Of the opinions obtained, 14 were government appointed/directly associated and so may reflect a significant persuasive opinion to national policy[44]. Legal and policy documents were obtained from the internet or the available literature and news reports, but are only summarised here in section 3[45]. Although no European wide groups were contacted directly, the various institutions of the Council of Europe, European Community (European

---

were no responses from Austria, Ireland, Portugal or Spain. Where a formal opinion was expressed (in report form either through personal correspondence or other means [internet or literature]), citations will be made in the text to the full references in the bibliography. A list (and summary) of all responses can be found in Appendix Eight s. 1. A full list of all the groups that were sent the questionnaire is in Appendix Eight s. 3. Where a response was in the form of a letter/email or questionnaire, or the opinion is generally not available in the public domain, the in text citation will state 'personal correspondence' and the date received.

[39] Belgium Association of Bioethics (Belgium); Den Centrale Videnskabsetiske Komite (Danish Central Scientific Ethical Committee) (Denmark); Forskningsstyrelsen (Danish Research Agency) (Denmark); Ministry of the Interior and Health (Denmark); National Advisory Board on Research Ethics (formally the National Research Ethics Council) (Finland); Centre national de la recherche scientifique (CNRS) (National Centre for Scientific Research) - CNRS Committee on Ethics for the Sciences (COMETS) & Comitié d'Ethique de CNRS (France); Genteknikämnden (Swedish Gene Technology Advisory Board) (Sweden); & Ministry of Health and Social Affairs (Sweden).

[40] ad hoc Committee on Genetic Technology (CGT) (Ministry of Interior and Health) (Denmark); Danish Council of Ethics (DCE) (Denmark); Deutsche Forschungsgemeinschaft (DFG) (Germany); Nationaler Ethikrat (German National Ethics Council) (NEC) (Germany); Εθνική Επιτροπή Βιοηθικής (Hellenic National Bioethics Commission) (HNBC) (Greece); Comitato nazionale per la bioetica (National Bioethics Committee) (CNB) (Italy); Gezondheidsraad (Health Council of the Netherlands) (HCN) (Netherlands); Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands); Kommittén om genetisk integritet (Committee on Genetic Integrity) (CGI) (Sweden); Statens Medicinsk-Etiska Råd (Swedish National Council on Medical Ethics) (SMER) (Sweden); Medical Research Council (MRC) (UK); Nuffield Council on Bioethics (NCB) (UK); The Royal Society (UK); & The Wellcome Trust (UK).

[41] The Ministere de la Sante (Luxembourg) has requested an Opinion from the Commission consultative national d'éthique pur les sciences de la vie et de la santé (National Ethics Committee for the Life Sciences).

[42] Comite Consultatif de Bioethique (CCB) (Belgium); Fonds voor Wetenschappelijk Onderzoek – Vlaanderen (Fund for Scientific Research – Flanders) (FWO) (Belgium); & Valtakunnallinen terveydenhuollon eettinen neuvottelukunta (National Advisory Board on Health Care Ethics) (ETENE) (Finland).

[43] Die Bioethikkommission (Austrian Bioethics Commission) (ABC) (Austria); National Consultative Ethics Committee for Health and Life Sciences (CCNE) (France); Enquete-Kommission (EK) (Germany); Rathenau Institute (Netherlands); National Commission of Human Reproduction (NCHAR) (Spain); Advisory Committee on Ethics (ACE) (Spain); Swedish Research Council (SRC) (Sweden); Department of Health (DoH) (UK); & House of Lords Select Committee (Sel. Com.) (UK).

[44] National ethics/ad hoc governmental committees in the above are underlined (and so have direct advisory roles to the Government).

[45] Unless otherwise stated, this information comes from CBDI 2001; CE 1998; Gratton 2002; Hansen 2001; MacKeller 1997; Rendtorff & Kemp 2000a, b; & Schenker 1997.

Parliament and European Commission), and others, had published various opinions and projects which were readily available[46].

The response was not very high[47] (23%), and this may make the sample unreliable in showing any pattern in policy direction[48]. There are two possible reasons for the low response. Firstly, the groups were 'cold' contacted. Their contact details were either found through published literature, project reports[49] or the internet. Many groups and government web-sites were linked to national and international bodies that had a bioethics element. Some of these groups could therefore not have competence in the field of SC research, or not made (either not intending to or not within their remit) public any formal opinions (so chose not to answer). Secondly, some of the groups may no longer exist. The reasoning being that some committees are created ad hoc to address and resolve specific issues.

It was evident that if no report was available, then the contacted groups were generally unwilling to state any opinion (perhaps understandably because they may have not formally addressed the issues). However, with the already published reports on the internet and in journals, I was able to gain a fairly good picture of the Fifteen Member states' policy with regards to stem cell research[50].

2. The Legal Situation in the European Union

The regulation of biosciences at both national and international levels in the EU is complicated. This is because firstly, the states have developed the legal and political

---

[46] Directorate General for Research (various projects funded by the European Parliament, Commission and Council); European Group on Ethics in Science and New Technologies (EGE) (European Commission); European Science Foundation (ESF); European Society of Human Reproduction and Embryology (ESHRE); International Federation of Gynaecology and Obstetrics (FIGO); Interacademy Panel (IAP); Nordic Committee on Bioethics (NorCB) (2001); & Steering Committee on Bioethics (CDBI) (Council of Europe) (See Appendix Eight s. 2).

[47] This perhaps should not be unexpected (see Moser & Kalton 1993 pp. 262-268; & Oppenheim 1993 pp. 102-103).

[48] And with no results, such as that from Austria, among others, it is impossible to identify any policy moves, and one must rely on information from other sources. However, it should be noted that I obtained opinions from all national advisory groups (Appendix Eight s. 3).

[49] Rendtorff & Kemp 2000a, b; (the BIO-MED-II Research Project 1985-1998 European Commission); Gratton 2002 (European Commission/ EGE); Hansen 2001; and the ESF at www.esf.org.

[50] This research was limited to, in the main, *unofficial* translations of the relevant documents, to English. A number of English formatted documents were available, as were news reports of relevant policy and legal reforms.

oversight at a different pace and often from vastly different cultural persuasions. Often, this development is over time and is influenced by local and international developments.

The following table (see over) outlines the main legal and policy positions of the member states (up to date 29th October 2003). The table is not intended to be a detailed account of the Member States' law, but to highlight four principal areas of policy in the EU at the national level: (1) permissive regulatory policy at the national level; (2) permissive movement at the EU level; (3) member states with regard to restrictive research policies and; (4) recent moves to restrict EU state research in this field. These policies also reflect the sliding scale from little or no regulation, to comprehensive and detailed legislation, with regards to embryo research (and by implication, embryo stem cell research, if this is seen as a legitimate research purpose).

Country	Year of Law	Permissible Types of Embryo in Research			Cloning		ES Cell Research	14-Day Limit	Imp./ Exp.	Ethical Review/ Reg. Body
		Spare Embryo	*Create by IVF*	*Chi.*	*Th.*	*Rep.*				
Member States with Permissive Policies										
Denmark	1997[51,a]	Yes[52]	Yes[53]	No	No	No	No[54]	Yes	U[55]	Yes
Finland	1999[56]	Yes[57]	No	No	Yes[58]	No	Yes[59]	Yes	U	Yes
Nether-lands	2002[60]	Yes[61]	No[62]	Yes[63]	No[64]	No	Yes	Yes	U	Yes
Sweden	1982[65]	Yes[66]	No	No	No[67]	No	Yes[68]	Yes	U	Yes
UK	1990; 2000; 2001[69]	Yes[70]	Yes	No	Yes	No	Yes	Yes	U	Yes

[51] *Act on Medically Assisted Procreation.*
[52] Improving either the success or efficiency of IVF treatment, hereditary disease or preimplantation diagnosis (CVK *personal correspondence* 8/11/02; DCE 2002 p. 41).
[53] There is continuing debate as to the legal position of specific research embryos, with some arguing that the creation of embryos for research into the cause and treatment of disease is possible (Rendtorff & Kemp 2000a p. 167).
[54] Unless for the stated purposes (DCE 2002 p. 40).
[55] Using imported ES cells is possible for purposes additional to those stated in the Act (CGT *personal correspondence* 24/11/02; Gratton 2002 p. 14).
[56] *Medical Research Act.* An English translation of the Act can be found in the *Bulletin of Medical Ethics*, February 2000, pp. 7-11.
[57] Research is permitted for the purpose of '...intervention in the integrity of a ...human embryo ...for the purposes of increasing knowledge of the causes, symptoms, diagnosis, treatment and prevention of disease or the nature of disease in general' (s. 2).
[58] The term 'embryo' covers only *in vitro* embryos and is described as 'a living group of cells resulting from fertilisation not implanted in a woman's body' (s. 2(2)). Therefore, it is unlikely that CNR, on account of not strictly being *fertilisation*, is covered by the Act.
[59] Hovatta 2002; NABHCE *personal correspondence* 20/12/02.
[60] *The Embryos Bill*: available at: http://www.minvws.nl/english/document.html?folder=441&page=13442 (accessed October 2003).
[61] As long as research will lead to new insights in the field of medical sciences and those insights cannot be obtained by other methods.
[62] Section 24 (a) of the Embryo Bill bans the creation of human embryos 'specifically for research purposes or for purposes other than the induction of a pregnancy'. However, under section 33(2), this ban will lapse no later than 5 years from the inception of the Bill (and presumably will be re-enforceable if deemed necessary). Specifically, embryos may be created for research when 'culturing of embryonic cells intended for transplantation...' (s. 9(1((a)) and 'research' (s. 9.1(b)) aimed at 'new insights in the field of medical science' (s. 10(a)): infertility, artificial reproduction techniques, congenital disease and transplant medicine and which can only be performed by making use of specific research embryos (s. 11).
[63] Under Article 25(b) a chimera can be created but cannot be kept for more than 14 days or implanted.
[64] The provisions concerning creating IVF embryos for research (*supra* fn. 62) also applied to therapeutic cloning.
[65] *Law on Measures for Purposes of Research and Treatment Involving Fertilised Human Ova* (No. 115).
[66] The research projects must be carried out for purposes of either improving infertility treatments, contraceptive methods, or to develop the knowledge of the embryonic development and the causes of defects.
[67] Although the Act refers to the fertilised ovum, which in CNR, does not occur (*supra* fn. 38).
[68] As SC research elucidates mechanisms for cell differentiation, it was deemed to fall within the third category of authorised research projects (to develop knowledge of the embryonic development and the causes of defects) (SRC 2001).
[69] *Human Fertilisation and Embryology Act*; *Human Fertilisation and Embryology (Research Purposes) Regulations; & Human Reproductive Cloning Act.*

Member States Moving to Permissive Policies/Proposed Legislation *(Note: embryo research is presently possible by default in Belgium and Greece; and prohibited in France and Spain)*										
Belgium	2002[71]	Yes[72]	Yes	No	U	No	Yes	Yes	U	Yes
Greece	2000[a,b]	Yes[73]	Yes[74]	U	Yes	No	Yes	Yes	U	Yes
Luxem-bourg	1998	Yes[75]	No	No	No	No	Yes	Yes	U	Yes
France	2002[76]	Yes[77]	No	No	No	No	Yes[78]	No[79]	Yes	Yes
Spain	2003[a,b,80]	Yes[81]	No	U	No	No	Yes	Yes	No[82]	Yes

[70] Research is permitted for promoting advances in the treatment of infertility; increasing knowledge about the causes of congenital disease; increasing knowledge about the causes of miscarriages; developing more effective techniques of contraception; developing methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation, or for such other purposes as may be specified in regulations (Schedule 2 s. (2)). In 2000, three further purposes were added by regulations: increasing knowledge about the development of embryos; increasing knowledge about serious disease; or enabling any such knowledge to be applied in developing treatments for serious disease.

[71] Bill on the Protection of Embryos 1999; Law No. 2-695. Cordis News 2003; Available at: http://dbs.cordis.lu/cgi-bin/srchidadb?CALLER=NHP_EN_NEWS&ACTION=D&SESSION=&RCN=EN_RCN_ID:20094 (accessed October 2003). The Belgian legislation is available in French at: http://www1.dekamer.be/FLWB/pdf/49/1122/49K1122001.pdf (accessed October 2003) (also see Wert et al. 2002 p. 85; European Commission 2003a).

[72] For the therapeutic purposes or for the advancement of the understanding of infertility, sterility, organ or tissue transplants, congenital or genetic diseases or cancer; and only if an alternative method of research would not be as effective.

[73] Creating embryos may be possible for therapeutic purposes.

[74] Provided they are created for *therapeutic* purposes (HNBC 2002; Rendtorff & Kemp 2000a pp. 190-191).

[75] Research having a medical purpose (Ministère de Santé *personal correspondence*; 24/9/03).

[76] The 1994 Bioethics laws provide for their revision and re-examination by parliament every five years (Article 21 of law 94-654). Because of delays in the legislative calendar, the proposal for the revision of the Bioethics laws was only adopted by the French National Assembly in January 2002 (Gratton 2002; also see Merchant 1996; Viville & Nisand 1997).

[77] Research on embryos and ES cells is permitted only for medical purposes and when there is no alternative method.

[78] *Supra* fn. 29.

[79] A seven-day limit is imposed.

[80] See Martinez 1996 for details of 1988 law. A new law, dated October 2003, updates the 1988 law; *infra* s. 3.2.5. (Bosch 2003c).

[81] Until the law takes effect, *any embryos up to 14 days, and regardless of how long they have been frozen*, can be used explicitly for SC research. These embryos will remain available for donation to another couple for 5 years, at which point they will be transferred for storage and research to a National Centre. Likewise, if the parents, or the mother, are unknown and/or an informed consent has not been provided within a year, embryos will remain available for donation to other couples for up to 4 years, then be transferred for research. After the law takes effect, all 'spare' embryos will remain frozen 'throughout the full fertility period of the woman' (Bosch 2003a, c). After this point the embryos may be available for research.

[82] It is forbidden by law to trade, import or export human embryos as well as their cells (Matthiessen-Guyader 2003 p. 39).

Member States with Existing Prohibitive Policies										
Austria	1992[83]	No	No	No	No	No	No	N/A	NC[84]	N/A
Germany	1990[85]; 2002[86]	No	No	No	No	No	No	N/A	Yes[87]	Yes[88]
Ireland	1999[89]	No[90]	No	No	No	No	No	N/A	U	N/A
States Moving to Prohibitive Policies/Proposed Legislation *(Note: In both Italy and Portugal, embryo research is permitted in exceptional circumstances and after ethical review)*										
Italy	1999[91]	No	No	No	No	No	No	N/A	No	N/A
Portugal	1998[a,b]	No	No	No	No	No	No	N/A	U	N/A

Notes:
Chi. = Creating human chimeras; ***Th.*** = Therapeutic cloning;
Rep. = Reproductive cloning; **Imp./ Exp.** = Import or export of embryonic stem cells;
[a] = entered into force the European Convention on Human Rights and Biomedicine (ECHRB): Denmark & Greece: 1999; Spain & Portugal: 2000;
[b] = entered into force the Additional Protocol to the ECHRB on cloning; Greece: 1999; Spain & Portugal: 2001
NC = Not clear from the available literature;
U = Unspecified in relevant law or available literature.

[83] *Act on Procreative Medicine.*
[84] The 1992 Act does not explicitly cover research on human embryonic stem cells, therefore the legal situation is unclear. It is generally agreed that embryonic stem cell research is forbidden, since the derivation of ES cells destroys the embryo which is contrary to the Act. However, there are questions as to the legality of the import of ES cells (although it appears that law would allow such import), and discussion regarding authorisation is ongoing (Gratton 2002).
[85] *Embryo Protection Act*; Gesets zum Schutz von Embryonen [Embryonenschutzgesets] (13 December). English translation in *Bulletin of Medical Ethics* December 1990 p. 9-11. Also see Honnefelder 2002.
[86] The *Stem Cell Act* ('Bill Guaranteeing Embryo Protection in the Context of Importation and Use of Human Embryonic Stem Cells'; 'Stammzellgesetz' – StZG) 2002 (An unofficial translation of the Act appears in Oduncu 2003),
[87] The Act will '...principally forbid the import and use of embryonic stem cells' (1(1)), but 'defines the conditions on which the import and the use of embryonic SC are exceptionally permitted' (1(2)).
[88] Importation of pluripotent cell lines is permitted into the operative area of the law when the *Central Ethics Committee for Stem Cell Research* (s. 8), is convinced that the cells have been derived in accordance with the law *of that country* (s. 4(2)(a)) and before January 1, 2002; that the cells have been derived from IVF embryos created for the purpose, but not used in, fertility treatment (s. 4(2)(b)); and that there is not financial agreement between the derivation of the cells and their subsequent import (s. 4(2)(c)). Research is permitted, under section 5, for 'high priority basic research' and enhancing 'medical knowledge and skills while developing diagnostic, preventative or therapeutic procedures applicable to humans'. The research has to be necessary and unachievable by any other means.
[89] 1937; amended 1999; 40.3(3), 8th Amendment: available at: http://193.178.1.117/upload/publications/297.pdf (accessed September 2003). Article 40, paragraph 3(3) of the Constitution expressly prohibits research on embryos (see Appendix Five; also see Murphy 1994).
[90] Any 'surplus' embryos must be implanted in the cervix where they are unlikely to develop (Madden 1998).
[91] See Lorenzi 2002; Simini 1999; & Wert et al. 2002 p. 85. In 2004, the Senate of the Government passed the assisted reproduction law, which will come into force later that year. The law makes illegal to freeze or destroy any human embryos in the course of research (Clarke 2003; Turone 2004).

3. The Advisory Position in the European Union

The advisory position of each state in the following is given in more detail than the previous legislative measures. This shows (1) the present reasoning behind legislative measures and policies and; (2) offers hints to future policy reforms.

3.1. Permissive Research

3.1.1. Denmark

A minority of the *Danish Council of Ethics* (DCE) has stated that therapeutic cloning is ethically justified, as long substantial benefits are available for treating disease. A majority, however, recommend that the creation of embryos solely for research by any method should remain forbidden since there is no pressing need at present (because treating disease is only a theoretical possibility). ES cell research should be permitted, but confined to 'spare' IVF embryos; stating that ES research is necessary in order to promote the development of SC therapy (DCE 2002 p. 33).

Accordingly, the *Committee on Gene Technology* (CGT) stated that research on embryonic stem cells and therapeutic research would not be supported under present Danish legislation (CGT 2002). Should a political decision be made to pursue such research purposes, then the present Act on Medically Assisted Procreation would require amending. Pursuant to this, the *Central Scientific-Ethical Committee of Denmark* (CVK) has stated that substantial legislation on stem cells, gene therapy and gene diagnosis is planned (personal correspondence 8/11/02). This includes an intention to build a National 'Bio-bank'[92].

The *Nordic Committee on Bioethics* (NorCB), established under the Nordic Council (representing the Parliaments of Denmark, Finland and Sweden, among others), recommended that:

> ...most of the members of the Nordic Committee on Bioethics ...shared the opinion that...:

---

[92] The *Central Vindenskabsetiske Komite* (CVK) is a sub-committee of the *Danish Research Agency* (see Appendix Eight fn. 11). The Bio-Bank is currently under consideration by a task group of representatives of the Ministry of Interior and Health, the Ministry of Science, Technology and Innovation, and the Ministry of Justice.

> The use of stem cells, derived from human spare embryos produced for *in vitro* fertilization [sic.] but no more needed, was considered acceptable until day 14 of embryonal development. The provision must be the high quality of the research proposal and accept and [sic.] by an independent ethics committee. Special concern should be put on the free and informed consent from the donating couple.
>
> The creation of human embryos solely for research purposes seemed not necessary at the present stage of research...
>
> The potential future advantage of the technique of transferring somatic cell nuclei into an enucleated ovum to yield transplantable cell lines immunologically compatible with a patient donating the nucleus was clearly recognized [sic.]. Still, the therapeutic perspectives of this technique seemed very remote and the "slippery slope" possibilities to reproductive cloning are to be seen, even if legally prohibited. Therefore, at this stage of embryonic stem cell research and waiting for more definite results on the potential of using adult stem cells it was felt that use of the somatic cell nuclear transfer technique in humans should not be allowed in the Nordic countries (2001).

3.1.2. Finland

At present there are no publicly available advisory positions on SC research (NABHCE personal correspondence 20/12/03). However, Finland is a member of the NorCB, and as such implicitly endorses those views (*supra* s. 3.1.1).

3.1.3. The Netherlands

The Netherlands is only the second country as of this time to have enacted legislation aimed at specifically regulating SC research (as opposed to reforming or interpreting the restrictions of previous legislation; the other is the UK). The *Explanatory Memorandum*[93] to the Bill addresses the recommendations of various advisory and non-governmental bodies. It is explicit in responding to the *Health Council of the Netherlands* recommendations, and demonstrates how advisory body opinions are accounted for (but not always agreed to) in policy decisions.

The *Health Council of the Netherlands* (HCN) recommended that government should permit ES cell research by legislation. In 1998, a Report by the Council questioned the necessity of prohibiting the creation of embryos for purposes other than inducing a pregnancy (Dondorp 2002). Accordingly, the Committee considered that it would be acceptable for embryos to be created for research, but only when such

research cannot be carried out using surplus embryos (and subject to a proviso on the ECHRB) (HCN 1998 p. 14). They argued that '...while a given value should be assigned to the embryo (by virtue of which it deserves respect), this value is relative and can be overridden when other, more imperative interests are involved' (HCN 1998 p. 12).

In the Report *Stem Cells for Tissue Repair* (2002) the committee was of the opinion that:

> [regarding spare embryos] ...existing cell lines provide insufficient options for research into cell therapy and that Dutch researchers should be able to contribute to the isolation of new cell lines from embryos left over from IVF procedures (chapt. 6 p. 57) [because of the] ...embryo's relative right to protection ...the committee believes that ...the use of spare embryos for this important scientific research is both acceptable and permissible. It would be inconsistent to give the go-ahead to research with embryos in relation to reproductive technology while prohibiting the isolation of embryonic stem cells aimed at the development of cell therapy, under circumstances in which no equivalent alternative is available (p. 58).
>
> [regarding creating embryos for research] ...because there are no alternatives ...the Committee feels that the legal option of generating embryos specifically for scientific research should remain open (s. 5) in the interests of acquiring important new knowledge ...that cannot be obtained by any other means ...The committee considers that, in ethical terms, the distinction between conducting research on spare embryos and creating embryos specifically for the purpose of research is comparatively small (p. 58).
>
> [regarding cloning]...The committee takes the view that cell nuclear transfers in human ova are appropriate if research using spare embryos leads to usable forms of cell therapy, while the alternatives are either less usable or totally unusable. However, the committee sees no forceful reason to make cell nuclear transfer into enucleated ova legally possible (by lifting the moratorium contained in the Embryo Bill). The development of stem cell therapy still requires a great deal of preliminary research ...The committee feels that, for the time being, such research can and must be carried out using stem cells from spare embryos ...in the view of the committee, this right to protection cannot be used to make a convincing *a priori* objection to the creation of such an embryo by means of cell nuclear transfer (p. 59).

The *Netherlands Organisation for Health Research and Development* (ZonMw), as a member of the *European Science Foundation*, take the same view as given in ESF's *Human Stem Cell Research: Scientific Uncertainties and Ethical Dilemmas* (2002) (personal correspondence 12/12/02). Specifically, there should not necessarily be restrictions on the specific creation of embryos by any means for research (see Appendix Eight s. 2).

---

[93] Available at: http://www.minvws.nl/english/document.html?folder=441&page=13441 (accessed October 2003).

3.1.4. Sweden

The *Swedish National Council of Medical Ethics* (SMER) has stated that embryonic stem cell research was not contrary to the 1991 Law (SMER 2002). They supported ES cell research on the condition that each individual project should be ethically reviewed under public scrutiny (particularly since 'adult' stem cells had clear limitations; ibid. s. 4.2). The creation of research embryos was rejected for the present, as was CNR (but that in the case of these latter opinions, developments should be kept under review, but that no ban should be introduced to Swedish law).

Contrary to the SMER, the *Swedish Research Council* (SRC) (Ritter 2001; SRC 2001) and the *National Council of Science* (Solbakk 2002) stated that therapeutic cloning was ethically defensible because of the prospect for major long-term advances in treating diseases, and called on the government to review legislation to allow the procedure[94].

The SRC added that any CNR research must be licensed and monitored by a national authority, and research should be permissible if there are no other ways of attaining 'equivalent results'. However, creating IVF embryos specifically for research was not necessary. If the project is judged to be necessary for the advancement of SC research, embryos that have been previously frozen may be used for research and providing that their storage is to be terminated (legal period of five years). Reproductive cloning should be prohibited by legislation. The SRC judges the commercialisation of embryos and stem cells to be incompatible with ethical research and recommends that it should be established as a criminal offence.

The *Committee on Genetic Integrity* (SCGI) was asked for its option on stem cell research by the Swedish parliament. They published their report in January 2003 (SCGI 2003). In it they stated that a general prohibition against producing fertilised eggs for research purposes should not be ruled out (p. 14). Instead, research should be permitted under ethical review and on a case-by-case basis[95]. Additionally, on the same grounds, therapeutic cloning should not be exclusively prohibited (p. 15).

The government will also be influenced by the opinions of the NorBC (*supra* s. 3.1.1).

---

[94] Sweden has signed the ECHRB and Additional Protocol and therefore may be obliged to make a reservation in respect of Article 18(2) of the Convention before ratification in order to be able to legalise therapeutic cloning (SRC 2001).

[95] And indeed, called for a reservation with respect to Article 18(2) of the ECHRB.

3.1.5. United Kingdom

The question of the right to life of the embryo was initially stated in the *Warnock Report* (1985). In that report it is stated that:

> ...though the human embryo is entitled to some added measure of respect beyond that accorded to other animal subjects, that respect cannot be absolute, and may be weighed against the benefits arising from research (11.15) ...the embryo of the human species ought to have a special status (11.17; Warnock 1985).

From this statement of moral ideology came the 1990 Act and the restrictions therein. Importantly, research could be permitted by virtue of a licence if the research could be demonstrated to be lawful under the restrictions and purposes stated by the Act and necessary.

In 1998 the *Human Genetics Advisory Commission/ Human Fertilisation and Embryology Authority* (HGAC/HFEA) published a joint report on '*Cloning Issues in Reproduction, Science and Medicine*'. The Report noticed that under the present regulations the production of embryo by CNR would be legal as long as it was licensed by the HFEA and for one of the conditions laid down in the Act (5.2). However, CNR would probably not apply to these purposes, and likely therapeutic advances would only be forthcoming if the procedure were used for the production of cell lines for the purpose of cellular tissue therapy (5.3). They therefore recommended that new regulations should be specified to take account of these developments (9.3).

The 'Donaldson Report' (DoH 2000) was the first step in implementing the recommendations of the Joint Report. The Group was asked to undertake an assessment of the anticipated benefits of new areas of research using human embryos, the risks and the alternatives and, in the light of that assessment, to advise whether these new areas of research should be permitted.

The Expert Group concluded that:

> ...the proposed new research uses to develop treatments for diseased tissues and organs did not raise fundamentally different ethical issues from the research uses currently permitted under the Human Fertilisation and Embryology Act 1990... The potential benefits of the research justified the use of such embryos as a source of stem cells at this early stage of their development (para 27).

Therefore, in their recommendations, the Group stated that research using embryos (whether created by *in vitro* fertilisation or CNR) to increase understanding about

human disease and disorders and their cell based treatments should be permitted, subject to the controls in the 1990 Act (rec. 1). Furthermore, in licensing any research using embryos created by CNR, the HFEA should satisfy itself that there are no other means of meeting the objectives of the research (rec. 2). The Report also asked for a number of substantive and procedural controls to be placed upon research in this area[96].

The Report was fully supported by the Government[97] in Command Paper 4833 and in 2000 the House of Commons voted in favour of implementing the Report's recommendations and culminated in the resulting 2001 Regulations[98]. They were subsequently accepted by the House of Lords on the proviso that a Select Committee was established concurrently to review the issues connected with human cloning and stem cell research arising from the Regulations[99]. The *House of Lords Select Committee* (Sel Com. 2002) released its report in February 2002, and reaffirmed that the potential benefits to science and medicine from experimentation on embryos (cloned, IVF surplus and specifically created) outweighed the ethical objections. It rejected claims that developments in adult SC research have made research on embryos unnecessary and concluded that research on ES cells should be allowed to take place under the strict conditions of the 1990 Act and 2001 Regulations. The Select Committee called upon the UK Government to keep the necessity of using SC derived from embryos – cloned or otherwise – under review, and to take measures to establish a public ES cell bank.

---

[96] Some were already imposed by the 1990 Act, and therefore highlighted by the Report (Capps 2003; See section 33, pp. 10–11, of the Report).

[97] The report was welcomed by the *Medical Research Council* (MRC) (Press Release (MRC/45) 16 August 2000), *Royal Society* (RS 2000), and the *Wellcome Trust* (WT 2000) at: http://www.wellcome.ac.uk/en/1/awtvispolstm.html (accused October 2003). The Nuffield Council on Bioethics (NCB 2000) agreed with the extension of the permitted uses of embryos under the 1990 Act, but stated: 'While there is sufficient and appropriate donated embryos from IVF treatment for use in research, we consider that there are no compelling reasons to allow additional embryos to be created merely to increase the number of embryos available for ES research or therapy' (para. 27). The Report does argue, however, that the use of 'SCNT [CNR] for the derivation of stem cells offers such significant potential medical benefits that research for such purposes should be licensed' (para 34-38).

[98] After a lengthy government debate; House of Commons Hansard: 17th November 2000; 19th December 2000; & 29th November 2001.

[99] House of Lords Hansard: 22nd January 2001; 26th November; & 5th December.

3.2. States Moving Towards Permissive Policies

3.2.1. Belgium

The proposal for the new legislation is in principle supported by the *Fonds voor Wetenschappelijk Onderzoek – Vlaanderen* (National Fund for Scientific Research – Flanders) (FWO), although no formal opinion has been made yet (personal correspondence 7/10/2002).

The *Belgium National Consultative Bioethics Committee* (CBC) has not published any opinion on stem cell research as of yet (personal correspondence 26/3/03).

3.2.2. Greece

The proposed law has been commented on by the *Hellenic National Bioethics Commission* (HNBC)[100]. These are the closest documents that may indicate the future policy of the Greek government (personal correspondence 8/9/03).

Embryo research should be conducted under the provisions of the ECHRB that generally allows research under specified conditions on embryos *in vitro*. They consider that further clarification is needed concerning the conditions for embryo research and SC derivation. One point of clarification involves CNR, since most members of Commission consider that embryo production for therapeutic purposes via CNR and derivation of SC from such embryos should not be precluded, on the condition that there is no alternative. The Commission has argued that this may be exempt from the ECHRB and Additional Protocol prohibitions[101].

---

[100] HNBC: Comments on the Draft Bill Concerning Medically Assisted Human Reproduction, 31 October 2002: http://www.bioethics.gr/images/draftbillen.pdf; Report on the Use of Stem Cells in Biomedical Research and Clinical Medicine (from HNBC; personal correspondence 8/9/03); Recommendation on the Use of Stem Cells in Biomedical Research and Clinical Medicine (2001; from HNBC; personal correspondence 8/9/03).

[101] 'It is noted that article 18 of the Convention ...prohibits generally embryo production for research purposes. However, since therapeutic intervention cannot be applied –even on an experimental phase- without research being carried out previously, it seems that article 18 prohibits embryo production for therapeutic purposes as well. It is however stressed in the Additional Protocol to this Convention (where explicitly it is prohibited embryo production via cloning for reproduction purposes) that "some cloning techniques themselves may contribute to scientific knowledge and its medical application". Based on this, the Commission (by majority) reckons that therapeutic cloning is exempted from the general prohibition of article 18' (HNBC 2001 section 7).

3.2.3. France

In the National Consultative Ethics Committee for Health and Life Science's (CCNE) *Opinion On the Preliminary Draft Revision of the Laws on Bioethics* (No. 67, January 18 2001), it was argued that the '...embryo or foetus has the status of a potential human being who must command universal respect' (Part 1, para. 1). Accordingly, producing human embryos by IVF for research purposes should remain prohibited, but the Committee is in favour of opening up regulated possibilities of research on 'spare' embryos which are no longer included in a parental project and with the agreement of the donating couple. Embryos used in research cannot be subsequently implanted nor can IVF treatment projects be used as a means to 'stock up' on 'spare' embryos to be used in later research (Bousingen 2001; Butler 2000).

The Committee is split on therapeutic cloning. There is a majority that favours the controlled authorisation to engage in CNR research, arguing that: '[s]hould early results [on CNR] confirm expectations [it would be] ...in contradiction with inappropriate legislation [i.e. a complete ban] and in circumstances which may not provide the necessary safeguards ...making France dependent on research abroad ...and without having had any say in the ethical rules ...[therefore] the creation of the APEGH [Agence de la procréation, de l'embryologie et de la génétique humaines] ...[will] examine each research protocol on its merits ...[and should] ensure adequate safeguards...' (2001 Part 1 *Position favourable to legalising therapeutic cloning*).

3.2.4. Luxembourg

The *National Consultative Ethics Committee for Life and Health Sciences* (NCEC) has been asked for an opinion on stem cell research (Gratton 2002 p. 43-44).

3.2.5. Spain

There are two main advisory groups in Spain. Firstly, the Report of the *National Commission of Human Assisted Reproduction* (NCHAR). This Report, *Reproducción Humana Asistida* (1998) was only recognised by the Health Ministry in 2003. It

recommends an amendment of the 1988 law to allow researchers to obtain stem cells from embryos stored for more than 5 years[102].

The second Report was released in February 2003, by the *Advisory Committee on Ethics* (ACE), which was created in 2002 to advise the Ministry of Science and Technology. The Report, *Stem Cell Research* (2003), supports research on previously frozen and spare embryos crated as a consequence of IVF treatment. (This Report contains the main elements of the new law)[103].

The Report stated that '...the early embryo has a value and is worthy of special respect, but that this value may be weighed against other values' (Recommendation 4). Furthermore, '[t]aking into account the possible negative effect of prolonged freezing [of IVF] embryos, as well as their possible destruction after expiry of the legal time limit, the Committee recommends that, as an alternative to the destruction of the surplus embryos, these may be used to obtain embryonic stem cells' (Rec. 5). It is '...desirable to promote the donation of these embryos to the couples that need them for purposes of reproduction' (Rec. 7); and that the '...creation of human embryos for specific purposes of generating stem cells for research is not recommended' (Rec. 9). They also press for a national ethical review committee, consent of the donating couples, the research aims at relieving 'human suffering', and applications only from experienced research groups.

The *Observatory on Bioethics and Law* (OBL), based in Barcelona, supports the production of human embryonic stem cells for therapeutic research (Holden 2003). This view is also supported by the *Andalusian State government* (as well as some others) (ibid.). The research must be ethically reviewed and not aim at reproductive goals. Therapeutic cloning should also be permitted along with creating specific research embryos when 'spare' embryos are not suitable.

3.3. The European Union and Permissive Regulation

The European Commission's *European Group on Ethics in Science and New Technologies* (EGE), stated that:

---

[102] Available in Spanish at: http://www.msc.es/salud/epidemiologia/ies/repro_asistida/resumen_anual.htm (accessed October 2003).
[103] Available in English at: http://www.fecyt.es/publi_comite.asp (assessed October 2003).

> The human embryo, whatever the moral or legal status conferred upon it in the different European cultures and ethical approaches, deserves legal protection. Even if taking into account the continuity of human life, this protection ought to be reinforced as the embryo and the fetus [sic.] develop ...It results from the aforementioned principles, that, in the scope of European research programmes, the question of research on the human embryo has to be approached, not only with regard to the respect for fundamental ethical principles, common to all Member States, but equally taking into consideration diverse philosophical and ethical conceptions, expressed through the practices and the national regulations in force in this field (EGE 1998 para 2.6).

Now while this isn't outright support for embryo research, the EGE are keen not to enforce their will upon Member States, and only to forbid those activities that are condemned by a majority (but not unanimously). So that '...because of a lack of consensus, it would be inappropriate to impose one exclusive moral code' (EGE 1998 para 2.4). Therefore, embryo research is permissible (with caveats) but should fall within the competence of national legislation and ensuring national ethical review (ibid. 1998a para 2.3; EGE 2000 para 2.6). Accordingly, funding from the EU '...should not a priori exclude human embryo research' (EGE 1998a para 2.8); but ensuring that 'systematic ethical evaluation' exists at Community level (ibid. 1998 para 2.9; 2000 paras 2.8 & 2.13, in additional to the aforementioned national ethical review (1998 para 2.10).

Restrictions should exist on the implantation of embryos used in research (ibid. para 2.7). The prohibition on the creation of research embryos by IVF (and limiting research to 'spare' embryos) should be accepted by all Member States, but the Opinion adds, '...the creation of embryos by cell nuclear transfer for research on stem cell therapy would be *premature*' (my emphasis; EGE 2000 para 2.7), and thus not ruling out such a prospect in the future. Research funded by the EU should be free from commercial interests and widely and freely disseminated to the Community (ibid. paras 2.8 & 2.17).

The International Bioethics Committee (IBC) of UNESCO likewise endorses the view that research is possible within national borders (as a matter of national conscience), as long as there is a state sponsored regulatory system and is assessed by an appropriate ethics committee (McCall Smith & Revel 2001).

The view that both embryonic and CNR research for therapeutic goals should go ahead for medical research is endorsed by the *European Science Foundation* (ESF 2002). They state that there should be efforts made to create legislative frameworks in all European countries to deal with the science. It states that '...it is particularly important that adequate funds are made available from public bodies to the scientific

community outside the commercial sector to keep pace with [stem cell] development. It is essential for public confidence that the views of independent scientists are available for the development of national policies' (rec. 9).

FIGO (*International Federation of Gynaecology and Obstetrics*) is of the opinion that embryonic research is ethically justifiable for the purpose of human health up to 14 days from fertilisation. Furthermore, the research must be necessary, with consent of both parents, under ethical scrutiny, and subsequent to research should not be implanted. They did not rule out therapeutic cloning or the creation of specific research embryos (FIGO 1990; & 1997).

The *European Society of Human Reproduction and Embryology* (ESHRE) has stated that 'pre-implantation' embryos can be used in research but should not subsequently be used to achieve a pregnancy. The creation of embryos is not ruled out as long as the same results cannot be achieved through the use of supernumerary embryos (ESHRE 2001; 2002). In all research, consent from the gamete donors should be sought. The 14-day limit should remain but only because it would be difficult to find an acceptable limit subsequent to this. They state that this limit may have to be re-evaluated in the future (ESHRE 2001).

It is notable that none of these groups rule out therapeutic cloning per se, instead recommending to monitor developments (also see the IAP 2003, representing seven EU national academies of science).

3.4. Prohibiting Research

3.4.1. Austria

The *Austrian Bioethics Commission* (ABC) was established at the Federal Chancellery in June 2001. In its *Opinion of the Bioethics Commission on the Issue of Stem Cell Research in the Context of the EU's Sixth Framework Programme for Research, Technological Development and Demonstration Activities as a Contribution Towards the Realization [sic.] of the European Research Arena (2002-200)*[104], it stated by a majority, that '...until further notice, ...[imported] stem cell lines may be used

[104] Available at: www.bka.gv.at/bka/bioethik; see ABC 2002; European Commission 2003a p 40.

which have already existed before a given date'. However, only cell lines that have been derived from surplus IVF embryo created for medically assisted procreation can be imported. The research must be necessary and no alternatives exist, furthermore, the cells cannot be purchased and informed consent of the donor is necessary. They also recommend the setting up of an independent interdisciplinary commission to evaluate and peer-review the research and to ensure that results are published[105] (*Position A* of the Report p. 3). The minority argued that any ES cell research would promote a demand for, and social acceptance of, specific research embryos and divert funds away from other sources of cells (*Position B* p. 4), and therefore should be prohibited.

The Commission called for an exclusion of EU funding for the creation of research embryos and the derivation of ES cells by any means (para 8). The Commission has argued that Austria should ratify the ECHRB so that international minimal standards for trans-border medical activities are observed, and to dissuade the migration of international research projects not permitted in other countries, to those areas where there is a low level of legal protection.

In 2003, the Commission published an *Interim Report on so-called Reproductive Cloning*...(for full title see Appendix Eight fn. 3) which calls for a *permanent* ban on reproductive cloning; however, states that '...at the same time, it would have to be clearly evident from the formulation that this ban involves a deterrent measure from which no assessment can be derived about so called therapeutic cloning' (ABC 2003).

3.4.2. Germany

The *Deutsche Forschungsgemeinschaft* (DFG) has stated that there is no justification for excluding from funding research using imported ES cells produced legally in other countries as long as an independent ethics committee is established to review all work on imported ES cells[106] (DFG 2000; Heinemann & Honnefelder 2002). The change of policy resulted from an application in 1999 to import ES cells for

---

[105] The Report pointed out that restrictions should also take into account future developments to account for loopholes and the validity of technical prohibitions.

[106] The DFG stated under legal advice, that any government employee is committed to German law anywhere in the world, and as such would break the 2002 Act if they participate in laboratory work where new SC lines are derived or used (unless they take an official leave of absence) (Vogel 2003). Their position in a 1999 report was that any ES cell research was contrary to human dignity (Oduncu 2003 p. 6).

research and doubts about the scientific quality of them, and because ES cell lines were not totipotent, but pluripotent, and therefore not subject to the Act. Furthermore, the potential benefit to patients and the exclusion of scientists in this research could no longer be justified. The DFG went as far to state that in the future creation of ES cells by German scientists should not be ruled out and therefore recommended German researchers could in principle generate their own cell lines from surplus embryos for a period of five years. This view is supported by the *German Research Society* (Siang 2001).

The *National Ethics Council* (NEC) (Nationaler Ethikrat) was set up by the Government in 2001. In 2001 the NEC published interim recommendations (with a view to a full appraisal in the future), where a majority broadly supported the new legislation, in that the import of ES cells be permitted for a limited period and subject to strict conditions. They maintained the sentiment of the 1990 Act, by stating that '[f]rom this point on, the criteria of potentiality[107], identity[108] and continuity[109] in particular are satisfied, and with them all the essential prerequisites for existence as a human being are fulfilled' (NEC 2003 p. 74).

The German *Enquete Kommission* (EK) objected to the import of cells for research on the grounds that the utilisation of ES cells could not be distinguished from the destruction of the embryo (EK 2001). However, because of the conditions of the right to freedom of research, recommended an in-principle ban that could be relaxed under exceptional circumstances.

3.4.3. Ireland

There is no legislation dealing with SC research in Ireland. However, a *Commission on Assisted Human Reproduction* was established by the Department of Health and Children in 2000 in order to '...prepare a report on the possible approaches to the regulation of all aspects of assisted human reproduction and the social, ethical and

---

[107] '...the embryo already possesses the real capacity to develop into a born human being' (NEC 2003 p. 74).

[108] '...one and the same living organism is involved from the beginning' (ibid.). This is regardless of twinning, because: 'there is no question of the relevant criterion not being met: it is in fact met twice over' (ibid.).

[109] '...from this moment on and throughout all phases of human existence right up to death, a process is in hand whereby any other discontinuity could not but appear arbitrary' (ibid.).

legal factors to be taken into account in determining public policy in this area'. The *Royal Irish Academy*, at the request of the Department of Enterprise, Trade and Employment, recently established the *Irish Council for Bioethics*. It has not given any opinion yet.

3.5. States Moving to a Prohibitive Policy

3.5.1. Italy

The *Comitato Nazionale per la Bioethia* (National Bioethics Committee) (CNB) has addressed the issue of stem cell research in a number of Opinions, the most relevant being the *Opinion of the CNB on the Therapeutic use of Stem Cells* (2000). 'Part' of Committee considers that:

> ...it [is] ethically legitimate to derive stem cells for therapeutic purposes from embryos that it is no longer possible to implant ...on the condition that they are wittingly [sic.] donated by the woman or the couples concerned (section 31).

This should be subject to case-by-case review as to the 'suitability for' and 'impossibility of' implantation. Others in the Committee argue that the using of even supernumerary cryopreserved embryos is contrary to human 'dignity', and therefore cannot be ethically supported. The committee is likewise split on the legitimacy of CNR; some argue that without any alternatives, this may offer 'therapeutic results of great significance'. Regardless, Italy is set to implement highly restrictive legislation in reproductive medicine (*supra* fn. 91).

3.5.2. Portugal

The *National Council on Ethics and Life Sciences* (CNEVC) stated that the European Convention's prohibition of cloning should be understood as only referring to *reproductive* cloning; and did not give an opinion of *therapeutic* cloning (Wert et al. 2002 p. 87). In additional opinions[110], it considered that research on embryos is not

[110] *Report-Opinion 3/CNECV/93 on Medically-Assisted Reproduction*, issued on 1 February 1993; Report-Opinion 15/CNECV/95 *on Experimentation on the Human Embryo*, issued on 4 October 1995; &

ethically acceptable with regard to the special status of the embryo. In its 1995 Opinion, it stipulates that '...it is seriously illicit to conduct upon the embryo experimentation from which it will not benefit and which, on the contrary, will lead to its destruction' (since any embryo subjected to experimentation may not be implanted in the uterus). The Council grounds its position on Article 24 of the Portuguese Constitution that establishes the inviolability of human life. Consequently, as it seems impossible to deny the existence of a new human life in the embryo, the embryo cannot be the object of any experimentation that leads, or might lead, to its destruction.

Although the CNEVC does not adopt a specific definition of the embryo, it mentions in its 1995 Report that the real start of a new human life is at syngamy (precisely when two pro-nuclei fuse). Therefore, '...there are no objections to the utilisation, for experimental purposes, of activated oocytes (parthenotes); nor, though with some reserve, to the recourse to fertilised oocytes, so long as the fusion of the pro-nuclei (syngamy) has not yet taken place'.

The CNEVC recommends avoiding the creation of surplus embryos and therefore called for the elaboration of a specific regulation on medically assisted procreation and on the status of the embryo to avoid the legal limbo resulting from the absence of legislation. The Council stated that '...the cloning of human beings, because of the problems it raises concerning the dignity of the human person, the equilibrium of the human species and life in society, is ethically unacceptable and must be prohibited' (1997). No distinction is made between reproductive and therapeutic cloning (Gratton 2002 pp. 50-51).

The National Council mentioned the issue of human stem cells in its 1999 annual report, but has since disbanded due to the expiry of its mandate.

3.6. The European Union and the Prohibition of Research

There are two sources of pressure being applied to explicitly permissive Member States. I have already dealt with one of these, which was the influence that the ECHRB was exerting on those states that permit the creation of research embryos (*supra* s. 1.3). It is clear that certain elements of the Council of Europe have been keen to severely

---

Opinion 21/CNECV/97 *on the Ethical Implications of Cloning*, issued on 1 April 1997 (details in Portuguese at: http://www.cnecv.gov.pt/; accessed January 2003).

limit embryo research practices on the European continent[111]. While in the ECHRB there are limits only on providing 'adequate protection' and to refrain from creating specific research embryos, earlier efforts had gone some way further; and the Convention is therefore a watered down compromise to gain wide acceptance.

The second source can be found within the EU itself, where there has been considerable opposition to policies permissive to embryo research – accordingly, the UK's stance on therapeutic cloning has been called an 'anti-European initiative' (Tajani 2001). The European Parliament (EP) requested in a Resolution that the members of the British Parliament reject the UK government's proposals to allow research into therapeutic cloning[112]. This resolution was approved, but was ultimately ineffectual, and was the last in a 'series' of resolutions aiming to prohibit all human cloning on the grounds that:

> ...human rights and respect for human dignity and human life must be the constant aim of political legislative activity (para 1 of the Resolution) ...[and that] 'therapeutic' cloning ...irreversibly [crosses] a boundary in research norms and [is] contrary to public policy as adopted by the European Union (para 2).

In the same Resolution, the EP called for the introduction of '...artificial insemination techniques that do not produce an excess number of embryos in order to avoid generating superfluous embryos' (para 7). This opinion reflects the implicit ideology that no embryos should be created by IVF unless they will be used in reproductive projects (and not stored without an intention to implant at some stage). Thus the claim is to phase out the existence of 'spare' embryos that can be used in research. In effect, this is a call to put a stop to embryonic research, since the creation

---

[111] It has in the past stated that it intends to '...forbid any creation of human embryos by fertilisation *in vitro* for the purposes of research during their life or after death' (para A (iii)); and that '...research on viable human embryos [and] ...experimentation on living human embryos, whether viable of not' should be banned (A(iv); Recommendation 1046 (1986) *on the use of human embryos and foetuses for diagnostic, therapeutic, scientific, industrial and commercial purposes*). More recently, the Council of Europe has stated that '...the human embryo, though displaying successive phases in its development which are designated by different terms (zygote, morula, blastula, pre-implantation embryo or pre-embryo, embryo, foetus), displays also a progressive differentiation as an organism and none the less maintains a continuous biological and genetic identity [and reiterates that] ...research on living embryos must be prohibited, particularly ...if the embryo is viable ...[and the] intentional creation and/or keeping alive of embryos or foetuses whether *in vitro* or *in utero* for any scientific research purpose ...shall be prohibited (para 21) ..."viable" embryos shall be understood to mean embryos which are free of biological characteristics likely to prevent their development; however, the non-viability of human embryos and foetuses shall be determined solely by objective biological criteria based on the embryo's intrinsic defects (para 25) (Recommendation 1100 (1989) *on the use of human embryos and foetuses in scientific research*).

[112] Human Cloning: B5-0710, 0751, 0753 and 0764/2000; European Parliament Resolution on Cloning.

of specific research embryos is prohibited by the ECHRB (and is directly referenced in the Resolution).

It is perhaps not surprising that this statement appears in a resolution condemning the intentions of the UK legislative framework, since the UK is also at present the only Community state to explicitly permit the creation of specific research embryos by any means. The statement fails to realise however, that the creating of 'excess' embryos is necessary for IVF treatment to achieve a general chance of success (so that more than one cycle can be undertaken) and to minimise medical harm to the mother (since the process of superovulation may not be without risks and probably should not repeated if possible[113]). The practice also allows for repeated cycles of treatment without undergoing IVF procedures repeatedly. If embryo research is to continue by any means (and it is clear that elements of the EP do not want this), then it will require a supply of embryos; by attempting to discourage the creation of spare embryos and banning the creation of research embryos, the EP is effectively enforcing its will that no research of this kind should take place.

3.6.1. The Directive on setting standards of quality and safety for the donation, procurement, testing, processing storage, and distribution of human tissues and cells[114]

This Directive was initially proposed in June 2003, stating that its aim was to: 'establish European Community legislation setting standards for the quality and safety of tissues and cell of human origin used for clinical application in the human body' (COM(2002) 319 final; p. 13); but:

> ...does not interfere with decisions made by Member States concerning the use or non-use of any specific cell type of human cells, including ...embryonic stem cells [and] ...this Directive does *not interfere* with the provisions of Member States defining the legal term of "person" or "individual" (COM(2002) 319 final Recital 7; my emphasis).

---

[113] Such as ovarian hyperstimulation syndrome (OHSS). In about 1-2% of cases hyperstimulation is severe and complications require urgent hospital admission to monitor progress, control pain and in some very serious cases, termination of pregnancy. Complications associated with severe OHHS include blood clotting disorders, kidney damage and twisted ovary (ovarian torsion); (D'Angelo & Amso 2002; Hughes 2003; Tucker 1996).

[114] Details of the initial proposal for the Directive, and the subsequent two amended texts can be found in Appendix Six.

But it called for measures necessary to protect human health and fundamental rights. (And as I have argued, this must apply to born human beings).

In its presentation to the European Parliament, Recital 7 was amended to sanction measures to prohibit creating human embryos solely for research purposes or to supply stem cells. It also prohibits the import of cells created in this way into the EU (Liese 2003a Amendment 8; see Appendix Six). The Report was passed by 321 votes against 89 (57 abstentions) (Liese 2003b)[115].

This attempt to make the Community responsible for ethical conduct of research in Member states is a significant step for the decision making procedures in Brussels; it shows signs that creating research embryos specifically for research and therapeutic cloning are not actions that the EU wishes to sanction[116]. (This flies in the face of the UK's position on embryo research, and if implemented would have precedence over national law. This would put a stop to SC research as presently regulated in the UK [and will affect those states that either intend to or have not ruled out creating embryos specifically for research either by IVF or CNR]. It is therefore more in line with policies of those states in not *presently* or intending not to allow creation of research embryos; see Watson 2003)[117].

This will be an important vote for the EP and European Commission[118] and Council of Ministers when it reaches each respectively in the procedural process[119]; not least because it interferes with state sovereignty and the *principle of subsidiarity*. It also infers that the Community is better placed to make such provisions rather than individual states (*principle of proportionality*).

The Amended Proposal (COM(2003) 340) as the latest draft from the Commission, rejected the EP amendments, but added to the original draft that the Directive allows prohibition of certain types of cell derivation (i.e. ES cells), but:

---

[115] Where the original text of the Directive did not lay down restrictions on the definition of 'person' and 'individual', the Liese Report was criticised as enforcing '...draconian new laws to restrict research on embryonic stem cells and on cloning of cells to create tissues for transplant' (Coghlan 2003).

[116] In response to the Liese Report, the *European Economic and Social Committee* stated that although the application of ES cells should come under the proposed Directive (4), it proposed restricting '...the concept of the donor to living or deceased individuals for the time being, as the use of foetal or embryonic elements of human origin is liable to generate ethical debates or controversies in individual member states, which would be difficult to manage in the Union context' (6.5.2; OJ C85/44 2003).

[117] Søren Holm article concerns the separate matter that these discussions are taking place without public or scholarly input (2003).

[118] Up to now, the Commission has taken a less restrictive view, and only considered that the creation of embryos by CNR for research on stem cell therapy was premature at present (EGE 1998).

[119] See Appendix Six s. 3.

> If any Member State takes such a decision, the reason for which must be made publicly available, the ban may also be extended to imports of cells or tissues of such kinds [and where research is permitted the] ...Directive will require the application of all provisions necessary to protect human health and guarantee respect for fundamental human rights. Moreover, this Directive does not interfere with the provisions of Member States defining the legal term "person" or "persons".

This clearly shows that the Commission is unwilling to implement the prohibitions desired by the EP, and supports the view of the EGE that:

> It is not only legally difficult to seek harmonisation of national laws at Community level, but because of lack of consensus, it would be inappropriate to impose one exclusive moral code (1998 2.4).

Furthermore, the Commission endorses the view that the Community should not interfere with ethical positions within Member sates, as long as minimal regulations are present[120].

3.6.2. The Sixth Framework Programme

In addition to the restrictions of the Directive, there have been similar controversies regarding EU monetary support for ES cell research. In 2001, the '*Fiori Report*' attempted to persuade the European Parliament (EP) that:

> Research on adult stem cells constitutes a promising and ethically acceptable alternative to the use of stem cells from human embryos; ...research on adult stem cells must be accorded unconditional priority (sec. AI)... All research that is contrary to human dignity must be prohibited (para 3)... [therefore, the Report] ...Calls for a ban of any activities which ...make use of embryonic stem cells or of human embryos where the embryo was created *in vitro* for any other purpose than bringing about a pregnancy (IV; 54(d)) [and]...Reaffirms... its position that the most effective and creditable way of combating human cloning is to exclude the possibility both of therapeutic cloning and of reproductive cloning of human beings (IV; 60) (Fiori 2001a).

While the Report has no effect on research within national borders, it was nevertheless rejected by 316 votes to 37 (with 47 abstentions) (Fiori 2001b). The Report was reported to have been rejected because an amendment to allow therapeutic cloning was added. This, according to Fiori, contradicted the sentiment of the Report[121], and accordingly, those who opposed embryonic and cloning research, as well as those that were pro, voted against the final text (Schiermeier 2001). This seems to signal that members of the EP do not wish to rule out altogether (by rejecting the Report) the

---

[120] Also see Recital 15 of the Commission proposal (Appendix Six), which states that the ECHRB lays down minimal requirements only, which can be exceeded by Member states should they wish.
[121] Fiori's Report was based on '...respect for human dignity and the sanctity of life' (Fiori 2001c).

potential benefits of embryonic stem cell research. Regardless, the Directorate General for Research (Directorate A) maintains that (a minority, it would seem) of the EP '...believes that any form of embryo research is permissible only if the aim is the direct and otherwise unattainable benefit of the embryo and mother concerned' (Schmidt 2000 p. 1). This rules out stem cell research on the grounds that the '...founding basis [of human rights in] respect for the individual, for the equality of human beings, human dignity and the dignity of human life' (Schmidt p. 1)[122].

The European Commission were subsequently asked to prepare guidelines and in the interim, the Sixth Framework budget contained a one-year moratorium on ES cell research funding (Bosch 2002a; European Commission 2003a p. 4). During this time, funding will only be allocated for already existing ES cell lines. Holding back funding would not legally stop states from continuing research, but it would serve as a symbolic statement of contempt and may significantly hinder European community research collaboration.

The Commission's subsequent guidelines allow the use of EU funding to derive embryonic stem cell lines from supernumerary embryos that were created only before the 27th June 2002[123] as a result of medically-assisted IVF designed to induce a pregnancy and are no longer to be used for that purpose (European Commission 2003a, full version: 2003c). Furthermore, research could only be funded in states that allow such research; it has to be registered with a new EU body for transparent and timely availability of findings (a regulatory committee); it has to be necessary and only permitted where there are no alternatives, and subsequent to national or local level review. Therapeutic cloning is ruled out, as (implicitly) would be creating human chimeras. Their argument for these restrictions is that, while AS cells and ES cells have both advantages and limitations (and therefore in light of current state of knowledge *new* ES cell lines are required), the EU has a role in contributing responsible stem cell science while advancing this science for the benefits of patients (European Commission 2003c). This framework is intended to *encourage research on certain ES cell lines*, on the conditions that it optimises the use of existing ES cell lines, minimises duplication, and ensures that new ES cell lines will only be created where necessary (European Commission 2003d).

---

[122] Austria, Germany, and Ireland called for no EU finding to be directed at ES cell research (CEU 2003 p. 94).

[123] Both Italy and Portugal supported this cut off date (European Commission 2003a pp. 94-95).

The matter has now passed to the Council of the EU (CEU). They have preliminarily stated that creating an embryo solely for the purpose of research or for SC procurement, including CNR, are 'no-go areas', and will not be funded. They did not address the date imposed by the Commission (CEU 2003). A final decision is expected from the EP and CEU sometime at the end of 2003.

3.6.3. International Restrictions

I have argued that under the ECHR and the EU, the right to life cannot be absolute, and that embryo research draws on principles that are not wholly different from those involved in abortion, some kinds of contraception and IVF. Therefore, the Courts may likewise be unwilling to interpret life in the more restrictive context. If such rules are passed by the collective bodies of the EU, then any derogation from the right to life (through creating specific embryos) may be in contravention of the Convention and Treaty (via the Directive); thus those states that permit embryo research on these grounds will be faced with complex legal battles[124]. It thus seems far more reasonable to allow a *Margin of Appreciation* and *Principle of Subsidiarity* in such difficult issues that are far from settled within the EU.

The Commission has made this point through its *European Group on Ethics and New Technologies to the European Commission* (EGE). The EGE emphasises the self-determination of individual states, but called for a common consensus on issues that concern the Community as a whole[125]. The danger is that while restricting funding should not affect state legislatures and policy, the aforementioned Directive will. It seems that in this case the EU will be flexing its legal powers (with regard to individual government individuals who are against such research) to forbid research that is predominantly supported by the democratic view of individual states.

---

[124] For example, if it is illegal to create specific research embryos, then will it be in question that creating specific embryos for fertility (which are then selectively reduced or aborted) under the same pretext?
[125] With regard to the Directive, it has been argued that '...the European Parliament has backed a cynical manipulation of the legislative process by a small minority who want to overturn the rights of individual member states to make their own democratic decisions' (Lord May of Oxford quoted in BBC News 2003a).

4. Common Values

The life sciences and medicine are internationalised because legal decisions in one state do have effects on other states because of the phenomenon of 'bio-tourism', the 'brain-drain', and globalisation (most evidently shown by the EU's demarcation of significant funds for health research). This is particularly evident in the EU as the states converge on a common goal, and this is increasingly more important with the enlarging of the Community. In Chapter Five I will outline the benefits and problems of a harmonised EU policy and discuss whether agreement can ever be found and if there is any realistic benefits in continuing along the lines of a EU position of stem cell research.

The first stage is to identify the general arguments found in the EU. These can be considered as one of three positions: 'pro-life'; 'pro-choice' and 'gradualist'. The positions not surprisingly have often been evident in abortion debates, but likewise can be applied to the embryo research controversy.

The 'pro-life' argument can be argued along the lines that: 'The embryo-foetus has full moral status, equal to that of any adult human, from the moment of conception' (Beyleveld 2000b p. 59). This terminology transforms, in respect of SC research, to the full rights that are indicative of the 'life' of the embryo as a biological human being and potential agent *in vitro*; the status of the embryo because of this deserves a positive duty on agents to preserve its existence and to nurture its future development. This transpires as a positive right that the embryo must be aided in this development (as well as not hindered) (McGee & Caplan 2003).

The 'pro-choice' position considers that '[t]he embryo-foetus has no intrinsic moral status (i.e., no moral status solely by virtue of its own characteristics). Such status is only acquired at birth or even beyond and, when acquired, is acquired to the full extent possible. Until then, any moral status the embryo-foetus has is derived indirectly from the moral status of those with moral status [i.e. the mother]' (Beyleveld 2000b p. 59). Again, of course, this terminology is explicitly restricted to the status and rights of the mother (as an agent) over that of the embryo. So, in SC research, 'pro-choice' should really apply to the rights of agents to have access (should they wish) to the medical benefit that may be forthcoming from destructive research.

The 'gradualist' approach is based upon principles such as stricter conditions on abortion as gestation increases, with full status only at birth, and that the rights of the

mother to physical and mental health override those of the embryo/foetus[126]. This view is epitomised by the general paradigm set by national abortion legislation in the member states. All states allow fairly unrestricted termination at the early stages, which becomes increasingly more restricted through gestation, ultimately culminating in a maximal cut off point, but even here abortion is permitted to save the life of the mother (Appendix Five).

The therapeutic prospects with regard to the derivation and use of ES cells has appeared to instigate or catalyse the introduction of less restrictive policies and regulations concerning research with supernumerary embryos, at least in the majority of countries. The exceptions are those countries that have gone further to allow the creating of research embryos and CNR (UK and possibly Belgium & Sweden (although a legal loophole already exists); the Netherlands possibly in future regulation). It is evident that many advisory groups have gone further than government action in either supporting these positions or at least not ruling them out altogether (e.g. the Austrian ABC argued that import should be permitted, while the government intends to ban it).

It has been relatively uncommon for states to create *de novo* (possibly Italy and Portugal) or continue with restrictive legislation (Austria & Ireland). Germany has taken a unique stand in attempting to separate the act (which is explicitly prohibited) from the use of embryonic stem cells.

While there are undoubtedly convergent policies (both in the permitted and non-permitted use of stem cells), there is a real uncertainty with regards to the applicability and achievement of a harmonised policy. Most divergence resides with issues of ES cell research and the status of human embryos (and indeed, issues regarding other sources of stem cells are remarkably similar and may well be suitable for harmonisation in an EU policy).

4.1. Common Ground in Permissive Regulation

Common ground for widely accepted minimum standards and legal harmonisation is evident and the most consistent issues of agreement are issues which attract an almost

---

[126] The HNBC stated that 'We adopt the point of view of the gradual moral status for the human embryo' (personal correspondence 8/9/03). This view has likewise been endorsed in Denmark (Rendtorff & Kemp 2000a p. 270); and the Netherlands (ibid.; & HCN 1998 p. 55).

universal condemnation. States both within and external to the EU have rejected any possibility of permitting these activities, such as reproductive cloning, regardless of the beneficial goals, either explicitly or implicitly in national law or international customary Conventions[127]. Where there is a legal void in this matter, states are implementing or intending to implement unequivocal prohibitions.

Where research on human embryos is permitted, it is applicable only to those situated *in vitro*. Of those permissive states with specific embryo research legislation, only the Netherlands specifically mentions SC research. In the remaining states, SC research has been incorporated or interpreted in general restrictions[128]. Not all Member States have explicit laws concerning *in vitro* embryo research when research is nevertheless practised[129], although most of those without are in the process of enacting specific regulations[130]. In light of recent developments in SC research, there are moves in some countries to modify existing prohibitive legislation to more permissive position[131].

Common limitations that directly affect SC research are that the research should be based on non-commercialisation principles; time limits on the maintenance of embryonic life[132]; time limits of 'cryopreservation'; and prohibitions on cloning[133]. Furthermore, all research should be reviewed by an appropriate ethics committee that deems the research to be necessary and unattainable by any other means[134]. Research is limited to 'spare' IVF embryos in the main[135]; and explicit consent must be gained from

---

[127] See Siddle 2001.

[128] Denmark, Finland, Spain and Sweden have used previous law to encompass SC research. The UK used existing provisions to implicitly allow SC research; indeed, without explanation, it would not be at all clear that the amendments to the 1990 Act were designed to facilitate SC research, including CNR (Brownsword 2003 p. 36).

[129] Belgium, Greece, Italy, & Portugal.

[130] Belgium; Luxembourg; & Greece.

[131] France.

[132] All states that allow embryonic research either explicitly (Denmark, Finland, Netherlands; Spain; Sweden & UK) or implicitly (Belgium; Greece) limit the time for research up to 14 days with the exception of France, that has a 7 day limit.

[133] All states either explicitly by regulation (France; Netherlands; UK), or implicitly prohibit reproductive cloning. Only the UK explicitly allows therapeutic cloning. Belgium has not ruled out therapeutic cloning in future legislation. The Netherlands has a 5-year prohibiting moratorium on therapeutic cloning. Sweden may implicitly allow therapeutic cloning through a legal loophole.

[134] Belgium (proposed); Denmark; Finland; Netherlands; Spain, Sweden; & UK.

[135] This limitation is intrinsically linked to IVF fertility treatment, which unintentionally, but inevitably results in supernumerary embryos being created and frozen (either for use in subsequent treatment cycles or after treatment). These embryos can be kept indefinitely, donated to other couples, destroyed, or used in research. Presently, only the UK allows the creation of specific research embryos (by any means); and Denmark in exceptional circumstances (but not for SC research); Belgium has not ruled out creating embryos for research in the proposed law. The Netherlands has a 5-year moratorium. Finland and Sweden explicitly prohibit the creation of research embryos, but along with Spain, allow research on

the donating couple[136]. Furthermore, no embryo previously used in research can be later introduced into a woman for gestation[137]. There is also general agreement on the permitted purposes of research; normally it is limited to health related issues (human-centred medical benefit), and includes IVF technology[138], increasing knowledge concerning the physiology and pathology of human reproduction[139], transplantation medicine[140]; and diagnosing genetic disorders[141]. A number of states have extended the permitted purposes (unless they were already included) to investigations for the diagnosis and treatment of disease[142].

In the countries that prohibit research, there has been exploitation of a contingency (or loophole) to allow research on imported embryonic stem cells[143].

4.2. Common Ground in Restrictive Regulation

As mentioned, there has been a universal rejection of human reproductive cloning. In the field of SC research there has been some agreement of common restrictions. In those states where IVF treatment is permitted, but embryonic research is restricted, there are common limitations on the creation and storage of embryos for this sole purpose. However, 'spare' embryos will inevitably be created, and the only option for these states is to store them indefinitely, allow donation to other reproductive projects or destroy them.

It is interesting that in most states where embryo research is prohibited, no efforts are permitted to optimise treatment (through embryo research), and therefore reduce the number of 'spare' embryos that must be created. The only present exception is France,

---

donated IVF embryos created, and not required, in a previous fertility project. The Spanish law has the unique position of freezing IVF embryos for the full period of the fertility of the woman. It is not clear whether after this point they can be used in research. The Netherlands is the sole state to permit the creation of human/animal chimeras.

[136] Belgium (proposed); France; Greece (proposed); Netherlands; Spain; Sweden & UK. (Information not shown).

[137] Exceptionally, and if there is no damage to the embryo, it can be implanted on the grounds that it will benefit the embryo or mother; Belgium (proposed); Denmark; & Netherlands. (Information not shown).

[138] Belgium (proposed); Denmark; France (exceptionally); Netherlands; Sweden; & UK.

[139] Belgium (proposed); France (exceptionally); Netherlands; & UK.

[140] Belgium (proposed); Netherlands.

[141] Belgium (proposed); Netherlands; & Sweden.

[142] Belgium (proposed); Finland; Netherlands; Sweden; & UK. Finland permits research into any medical investigation that is necessary and cannot be achieved by any other means.

where investigations can be conducted that would optimise IVF treatment. Indeed, Ireland enforces the condition that a maximum of three embryos can be implanted to the uterus and any others to the cervix, where they are unlikely to implant and indeed will normally cease development (Madden 1998)[144]. This practice ensures that no embryos are frozen and available for future use or are available for research[145].

The common background to prohibitive states is that the embryo has a primary interest in not being destroyed in research (and it would seem that these interests are begrudgingly subservient only to the interests of the mother). Additionally, these member states are keen to emphasise the limits of embryonic stem cells and to favourably promote scientific developments with regards to other sources.

4.3. Advisory Opinions in the European Union

The advisory position in the EU can be roughly divided into five groups (these are general opinions that do not take into account the various further restrictions). The first majority group have stated that embryonic research is ethically possible using spare embryos from IVF treatment, those created through IVF specifically for research and by CNR[146]. The main caveat added is that the latter two practices, although in principle defensible, should be subject to a moratorium for now. Secondly, are those that support the use of 'spare' embryos and the creation of CNR embryos for research (normally pending on future developments), but not to create further IVF embryos specifically for research[147]. They in the main argue that while sufficient 'spare' embryos exist, there is no imperative to create any more (but again, cloning should be subject to a moratorium).

---

[143] France & Germany. Denmark explicitly permits the import of embryonic stem cells. The position in Austria is unclear, and although the import of EC cells is supported by the Austrian Bioethics Committee, the government has been apparently more restrictive.

[144] But may cause an ectopic pregnancy which is potentially life-threatening condition (see DaCosta et al. 2002; Jaswal et al. 2002; Lasker & Toedler 2003; Van de Meerssche et al. 1995).

[145] McGee & Caplan have argued that this may be seen as granting a '…super status that outweighs the needs of others in the human community' – because having to recognise a right to be implanted or for unimpeded maturation must override those rights of the mother, and forsakes any recognised positive rights to exiting persons – such as the right to be protected from intentional harm or access to treatments (2003 pp. 152-153).

[146] FIGO (Europe); ESF (Europe); ESHRE (Europe); HCN & ZonMw (both Netherlands); NCS & SCGI (both Sweden); OBC (Spain); DoH, Sel Com., RS, & WT (all UK) (total 12). The IAP (international) supports CNR for therapeutic purposes.

[147] CCNE (France); HNBC (Greece); SRC (Sweden); & NCB (UK) (4).

The third group only advises using 'spare' IVF embryos[148]. There is a small element within this group that considers that creating embryos by CNR for research should not be ruled out in the future. The fourth group only sanction the import of embryonic stem cells under restrictions[149]. Some have expressed the opinion that in exceptional circumstances, less strict restrictions should be implemented. There is only one group that expresses the fifth and final opinion, that no embryonic research can be ethically sanctioned[150].

4.4. The Basis of Disagreement

The main area of stem cell research divergence is in the derivation and research on using embryos and is based on the fundamental status of the human embryo. It is clear that deep-set values towards the positive status embryo cannot be reconciled where the research subject is destroyed. Likewise, those that weigh any (or no status) of the embryo against the perceived benefits of research cannot regard its immature human form as worth preserving in light of therapeutic benefits.

One basis of disagreement as to the status of the embryo in research is that of the actual basis of human moral status. Human value may derive from the 'sanctity of human life'; 'human dignity'; avoidance of socially undesirable endeavours (or practical and legal issues, such as those associated with 'slippery slopes'); and agency (or the primacy of autonomy). All four of these claims have been reconciled with defending and promoting fundamental human rights. I have argued that the first criterion cannot be successfully and purely applied to the notion of human rights unless one commits the illogical contradictions inherent in 'speciesism' – attaching moral significance to something that has no moral basis of justification for having such significance. Furthermore, attaching weight to the biological species through potentiality arguments leads to incoherent and contradictions in human rights doctrine. I have also claimed that human dignity, derived from autonomy and espousing human rights, cannot be applied to those beings that are not agents, unless one sees it as the human element of precautionality. But even this cannot protect the moral status of the human embryo to

---

[148] DCE (Denmark); EP (Euro Parl.); EGE (European Comission); DFG (Germany); CNB (Italy); NorCB; NCHAR (Spain); ACE (Spain); & SNMC (Sweden) (9).
[149] ABC (Aust); DFG, EK, & NEC (all Germany) (4).

the full extent proclaimed by pro-life camps. It is only the last criterion that sets the necessary basis for human rights, and I have argued that only purposeful and valuing agents can have rights. Therefore the embryo fails as a legitimate holder of intrinsic rights, unless there is some other value subordinate to the PGC.

When the *gradualist* position is identified, there is dissent over what can be done to those embryos involved in research (but not generally at what stage since the 14-day limit is unilaterally promoted). The most controversial difference derives from the acceptance of creating specific research embryos and the application of cell nuclear replacement techniques. Some see the prohibition as more a pragmatic position – that while 'spare' embryos exist, then there is no necessary justification to create more (but conversely, some who hold this position allow for the creation of CNR embryos but not IVF embryos). Others argue that if one is allowed to research on IVF 'spare' embryos, then why shouldn't embryo research be permitted per se, since all embryos are the same sort of thing.

The necessity criterion either explicitly or implicitly held in the permissive camps has been dealt with in two ways. Firstly, that a moratorium is put in place (per Netherlands) to compulsorily assess future prospects. The second (per UK) is to appoint powers to an authority that will only allow research that is considered important enough to allow these fringe permissions. If the research can be done with 'spare' rather than creating specific research embryos, and then the latter cannot be justified.

5. Common Difficulties in Stem Cell Policy

Three problems have come to the fore in this analysis. Firstly, it is evident that in attempts to establish comprehensive legislative framework, there has been no foresight into future developments, and as a consequence, (1) loopholes have opened and; (2) previously restrictive measures have hampered policy liberalisation. This can lead to confusing, and sometimes contradictory positions on fundamental principles regarding embryo research. Firstly, the interpretation of legislative measures. In the UK, the 1990 Act was challenged because it does not cover *cloned* embryos. It was argued that such embryos are not covered by the explicit wording of the 1990 Act which concerns

---

[150] CNEVC (Port).

itself with an 'embryo where fertilisation is complete... [and includes] an egg in the process of fertilisation' (1(1) (a) & (b)). The case ultimately failed[151] on the grounds that the protection of live human embryos outside the body under the definition of the Act was subject to licence by the HFEA and cloning by CNR was unknown at date of statute. The Court took a purposive approach that necessitated a conclusion that embryos produced by CNR should be within scope of regulation and that therefore, CNR was covered by statute and not absolutely prohibited.

With regards the second difficulty, it is evident that in the case of Denmark (national legislation; DCE 2002 p. 40) and Greece (in signing the ECHRB and Additional Protocol), their hands are somewhat tied with regards to allowing certain aspects of SC research since they are not permitted to allow creating embryos for research or therapeutic cloning. This can also affect restrictive moves, since unlike Denmark, who appeared to have foreseen the prospect of the 'Dolly' technique being used in reproductive cloning (prohibiting in section 28 of the 1997 law), the UK, although banning some forms of cloning, had to rush through legislation to specifically prohibit for this purpose. In foresight of this problem, states like Sweden intend to make reservations in respect of Article 18(2) before enforcing the ECHRB to allow therapeutic cloning (SCGI 2003; SRC 2001). (The Netherlands has already made a reservation with regards to the Additional Protocol; stating that 'human being' can only include human beings already born, and not embryos[152]). Greece, on the other hand, intends to negotiate the problem by arguing that creating embryos for treatment is not prohibited by the Convention.

This demonstrates the difficulty that can arise when interpreting the exact terminology of an Act or Convention. We may see similar contentions with terminology such as 'serious disease' found in the 2001 regulations (Brownsword 2002 pp. 579-580). With regards to creating genetically identical individuals, because clones are not identical, there is already concern in certain Member States that national regulation may not cover the explicit difference between *types* of embryo creation (*supra* Finland fn. 59; & Sweden fn. 68).

---

[151] *R (on the application of Quintavalle) v Secretary of State for Health* [2001] EWHC Admin 918, [2001] 4 All ER 1013; *R. (on the application of Quintavalle) v Secretary of State for Health* [2002] EWCA Civ 29, [2002] 2 WLR 550; *R. (on the application of Quintavalle) v Secretary of State for Health* [2003] UKHL 13.

[152] Declaration made with respect to treaty No. 168 (Additional Protocol) 29th April 1998.

The second problem is that national policies cannot rely on guaranteeing that cells have been derived on a scientific or ethical basis required for that state (this is evident in any policy that allows the import of cells but prohibits national derivation). Using the UK as an illustration, there are two primary concerns. The UK stem cell bank[153] will provide a repository for donated cell lines, and supply fully characterised cell lines for use in research in the UK and abroad. These will be established under regulated conditions and made available in order to promote fundamental research and to deliver banks of SC lines to be used for production of human therapeutic materials. The Bank will store SC from national and international sources, as long as they are obtained legally (including from other countries) and supply the cells for research uses (again, as long as they are used under the regulatory conditions at least as stringent as those in the UK). The problem is that the Bank is publicly committed to promoting ethically acceptable cell lines for use in equally sound research. The problems start however, when there are requests from other countries out of the HFEA's scope or when cells are deposited from less regulated sources.

Thirdly, there is a concern as to the exact nature of Member States' moral discussion in the context of Community law. In the UK, the embryo has a 'special status', it is by no means entirely clear how this can be interpreted. If this does amount to having human rights (but I have argued that it cannot) then under Community law a 'correct' interpretation should be read as limiting actions that harm its human rights, and not only in research, but also IVF and abortion. It is clear that the EU is unwilling to make decisions about the status of the embryo, but if that changed so that Community Directives took a more restrictive interpretation, then there may be difficulties ahead for the Member States that offer less than absolute human rights.

Conclusion

It is evident that there are significant areas of agreement in international stem cell research. While much of this is implicit and no formal agreements are in place for embryo research there are fundamental disparities in the status of the embryo, disagreement on common guidelines, and standards and goals remain elusive; with a

---

[153] Created under the remit of the National Institute for Biological Standards and Control (http://www.nibsc.ac.uk; accessed October 2003).

harmonised framework liable to restrict certain states' accepted practice or to offend restrictive states.

There seems to be fairly straightforward agreement with regards to the advisory bodies. However, it is evident that these expressed opinions often disagree with their state legislation. In such cases, it is apparent that there are new policies being discussed, although in some cases, this is not in line with those opinions.

In the next chapter, I will argue the main points for and against a harmonised framework, and propose a moral grounding for minimal standards based on the PGC. This will be juxtaposed with the opinions of advisory bodies and state legislation and policy.

Chapter Five

Conclusions for the Grounding of an European Stem Cell Policy

Introduction

In this concluding chapter I will suggest how the European Union (EU) should regulate embryonic stem (ES) cell research. In the first part I will argue that a common policy is *necessary*, since the EU is committed to promoting public health within the Member States and encouraging minimal standards of scientific and ethical research.

A harmonised policy must adopt one of the three prevalent positions within the EU regarding the status of the embryo, which have been termed in the context of abortion as 'pro-life', 'pro-choice' and 'gradualist' (Chapter Four Part Two s. 4). These views are based on fundamental beliefs about the embryo and its relationship with other agents, and therefore they have also been prominent in the discussions regarding a harmonised stem cell (SC) research policy within the Community. Because of the framework that I have defended, this policy should be guided by either of the latter two positions, because a 'pro-life' view would unjustifiably inflate the status of the embryo as a possessor of human rights, or deflate that of existing agents. However, a pro-embryo-research position would be in direct conflict with those states with restrictive policies, and it is this issue that will be addressed in the second part of this chapter. In this final part, it will not be possible to discuss the *practical* deployment of any harmonised policy because of limitations of space. Instead I will concentrate on the macro-establishment of a research policy (i.e. on basic agreement of policy grounding), and specifically the status of the embryo as a *primary* concern of the Member States[1].

There are two substantial questions to be considered: (1) whether ES cell research can be permitted based solely on the status of the embryo and; (2) what precepts a harmonised policy should reflect if research is permitted to proceed.

---

[1] Some have identified the status of the embryo as a *primary* stage of discussion, while other concerns regarding the application of research and therapy as *secondary* (Resnik 2002). This does not mean that the latter are any less important and have be dealt with elsewhere (see Cohen 2000; Lo et al. 2003; McLean 2001; Nilsson & Rose 1999).

Part One

The European Union and the Grounding of a Harmonised Policy

1. Introduction

In part one of this Chapter, I will look at the reasoning behind attempting to establish a harmonised policy in the regulation of embryonic stem cell research. Because I have argued (in Chapter One) that it is necessary for embryonic stem cell research to be pursued, here I argue that it follows that the EU therefore has a role in supporting medical progress towards public health goals, and this should mean that it supports stem cell research, which I have argued, should contain elements of embryo research. This grounding is then deployed in Part Two to recommend that the EU, if it is unwilling to actively support embryo research (or at least certain aspects), it should at least refrain from offering a paternalistic policy in restricting state research, and instead should encourage minimal state regulation.

1.1. State of the Art Research and Medical Progress

In Chapter One, I made the case for what the House of Lord's called a 'dual track' approach to ES and AS cell research (Sel Com. 2002 para 3.16.). This is based on two reasoned arguments: (1) the probable benefits of SC research to medical research are considerable and; (2) there is overwhelming evidence at this time that points to using all derivative cell lines for continued scientific progress towards therapeutic applications. Of course, it is one thing to say that a certain line of research is necessary, but quite another to allow researchers to cross that line if it is contrary to defensible moral norms. This thesis is concerned with the EU, and therefore one would have to identify the moral values that guide research activities within this international Community.

1.2. Moral Norms in the European Union

The overarching moral norms that exist in the EU were identified in Chapter Four and in the following I will unpack the policy that must accordingly follow. I have argued that firstly, although human rights and dignity are ever-present tools of regulation in the EU, they lack philosophical exactitude. So, secondly, I have defended the Hohfeldian explanation of rights to identify their exact philosophical nature, which is that *moral* rights are those which can be *claimed*. This was followed by Gewirth's argument that claim rights are only those requirements that serve the important needs of human agents (the Principle of Generic Consistency; PGC) (see Chapter 2 s. 7.1).

The PGC limited human rights to humans that have a minimal capacity for rational agency. This meant that embryos, because they lack any ostensible features of agency, may be used in research because they lack any moral status (the Argument from the Sufficiency of Agency (ASA); Chapter Two s. 7.2). But there is an important caveat, because although the embryo cannot have a moral status *only* on the grounds of potentiality, through precautionary reasoning (Chapter Three s. 7), they should be granted *some moral status* (as an unlikely, but possible agent).

So a human embryo could have 'quasi-rights' on its own account, and this means that one is not free to do as one wants with such entities. The guiding rule was that research could be sanctioned if there was some agent-centred benefit to be gained; therefore, the status of the embryo determines not only what one can do to the embryo, but also what one should not do.

In Part Two of Chapter Four, I outlined the national and Community laws and policies on SC and embryo research. This present chapter argues that these policies reflect one of two principal goals: (1) promotion of medical benefits in ES cell research and; (2) protection of the embryo. These aims are closely linked by three arguments that respectively state: (a) (1) overrides (2) (because (1) is necessary and there are no alternatives); (b) (1) does not override (2) (because there are alternatives) and; (c) (1) cannot override (2) (because of the status of the embryo). These arguments have respectively guided states that have either prohibitive or permissive policies in embryo research to promoting either (1) or (2).

I argued that position (c) was not morally defensible, not only because the embryo could *only* have 'quasi-rights' with respect to actual agents, but also because permissive abortion rules mean that the rights of the embryo could be practically overridden when

there are agent-centred moral imperatives that should be recognised (Chapter Four Part One). The embryo, as human life, could only at most have a limited status, and any attempts to protect the embryo (undertaken from the 'pro-life' position) would unjustifiably inflate the status of the embryo or deflate that of human agents; and in practical measures may harm the agent by denying its actual (human) rights.

1.3. The Role of the European Community

In the context of SC research, the European Community has two roles: to promote progress in public health through medical research[2], and to maintain research standards with regards to scientific practices and ethical limits (norms)[3]. Ultimately, the involvement of the EU institutions should only be required when they are better placed than Member States to achieve these goals (*Principle of Subsidiarity*), and where they do act, such action should be in proportion to the necessity for their involvement (*Principle of Proportion*) (Dashwood 1996; Chapter Four Part One s. 1.4). There are two means by which that this may be achieved. First is the investment of Community funds in scientific research (the so-called *Framework Programmes*) and secondly, through Community regulations (Directives) that are binding on Member States.

1.4. Reasons for a Harmonised European Policy

The main reason for harmonised legislation in Europe is that it can benefit matters of public health. Consolidating research through infrastructure support and funding can build a framework that encourages the Community's international competitiveness (through research progress and investment, and in countering the international 'brain

---

[2] 'Community action, which shall complement national policies, shall be directed towards improving human health, preventing human illness and disease, and obviating sources of danger to human health ...by promoting research into their causes ...and their prevention' (Public Health Article 152 (Title XIII) Consolidated Version of the Treaty Establishing the European Community; para 1). Under the Framework Six Programme (FP6), priority 1: *Life Sciences, Genomics, and Biotechnology for Health,* section i, it is stated that '...research will focus on ...development and testing of new preventative and therapeutic tools ...in particular stem cell therapies' (OJ L 294 2002 p. 10).

[3] In light of the FP6 and SC research, the Community '...shall contribute to the achievement of the objectives referred to in this article through adopting: (a) measures setting high standards of quality and safety of organs and substances of human origin' (*supra* fn. 2 Article 152 para 4).

drain', but more importantly, supporting the Community's commitments to progress in public health[4]. Pivotal to this is what the Community is permitted to fund, either through policy (i.e. targeted areas of research or excluding contentious research) or Community law, which is centred on the common aims of the Member States.

Evans & Evans (1996) argue that there may arise problems when, because of the geographical closeness of the European Community, there is a chance of legal inconsistency within bio/medico-legal laws, especially with the conditions of free movement. Transposing these concerns to embryo research may pose similar problems, and may include the maintenance of donor anonymity and consent with the import and export of research embryos and ES cells.

Furthermore, ethical and scientific standards might not be maintained. The ethical derivation of SCs (according to one state) must be carefully monitored by those states wishing to import these cells. In addition to the Member States that have no present legislation, prospective EU states, such as the Czech Republic (which has begun ES cell research) (Abbott 2003), Cyprus and Malta have no specific regulations (European Commission 2003a). States that adopt a prohibitive stance on embryo research within their borders, but nevertheless allow the import of ES cells, require that imported cells are obtained under prescribed circumstances, and these standards can only be maintained throughout Europe if harmonised legislation is evident. A major concern is the *scientific* quality of cells imported into a state (Heinemann & Honenfelder 2002)[5]. There may also be 'race to the bottom' of regulatory control because restrictions in one country may allow (contentious) research to be deregulated or funded in another (Capps 2003; also see: Bosch 2003b; Hellemans 2001; Ssemakula 2002).

Policies may resolve nothing in banning certain practices in one country if the practitioners and researchers can develop them elsewhere. Jacques Chirac stated that in this '...age of globalisation ...unscrupulous laboratories carry out premature testing of new molecules on poor and helpless populations ...the trade in organs and tissues gives rise to a shameful form of trafficking. These abuses constitute a challenge to the universal conscience'[6]. The potential of practitioners, scientists and biotech firms to

---

[4] See: http://www.cordis.lu/en/home.html, (accessed October 2003) for details on the European programme of research and the Frameworks of Community research funding.

[5] Scientific collaboration may aid consolidated efforts to minimise duplication of research projects and competition, and aid progress and the sharing of biological material and reagents; both of which may achieve standardised research (Hagan 2003).

[6] BBC News 2003 available at: http://news.bbc.co.uk/go/pr/fr/-/1/hi/sci/tech/2792497.stm (accessed October 2003).

relocate to countries in which particular kinds of research or practices are less restricted, to avoid specific prohibitions that operate within particular member states (Evans & Evans 1996), or to benefit from lenient research environments (Friedli 2003; Young 2002), is not only a 'drain' on national infrastructure, but also can act as a magnet to perhaps unscrupulous activities.

The opposite problem is that where research or practice *is* regulated or prohibited, medical services or practitioners may not be in the position to offer the best possible health care because they are either refraining from, or being prohibited from, using the latest or superior medical advances because they are derived from, or involve embryo research. Therefore, patients may only be able to obtain certain services from other states either because they are prohibited in their own state or superior in another, leaving them open to possible exploitation from unregulated and scientifically or ethically dubious practices[7].

Where there is no regulation, IVF and embryo research is often self-regulated by professional codes of practice (MacKellar 1997; Rendtorff & Kemp 2000a). Prohibitive regulations in other states may drive research to these less restrictive countries or underground in that state where it escapes the scrutiny of public control (Evans & Evans 1996 p. 223). Furthermore, while 'soft' law (self-regulation) does have its benefits, such that it can adapt to developments (a problem evident in the UK HFE Act 1990 and its outdated prohibition on reproductive cloning; *infra* s. 5), this type of regulation is not open to effective scrutiny (Johnson 1998 p. 1771) or the public input from democratic policy implementation of legislative measures.

The point is that there is a strong incentive to establish minimal standards, while accepting that there is cultural pluralism inherent within Europe. There has been published support for implementing minimal restrictions on embryo research. Both the Commission's EGE and UNESCO's *International Bioethics Committee* have pressed home the idea that regulation should be sponsored in every state, but that this should be local to that state (EGE 2000 paras 2.3 & 2.6; McCall Smith & Revel 2001 p. 13). Where no national legislation exists, the EU should take the lead in promoting full

---

[7] 'Tourism' to procure 'biotechnological' interventions creates the situation whereby a service that is considered morally problematic in one state, is available in another (per Diane Blood and her request for sperm to be collected from her dead husband; she was able to take the sperm abroad where insemination was legal; see MacKeller 1998; The Times February 7 1997; [1996] 3 C.M.L.R. 921; [1997] 2 C.M.L.R. 591). In the *Blood* case it was deemed illegal for a state to prevent access to an illegal service in that state in another country where it is not (cf. *Well-woman*; *Open Door Counselling; & Grogan* Chapter Four s 1.2).

public consideration of the issues in that state (Wood 1999 p. 8). Therefore encouraging policy debate and promoting legislation on accepted and tested paradigms. The *Steering Committee on Bioethics* (SCBI) (Council of Europe) maintained that it would not acknowledge or respect the fundamental choices made by different countries where opinion diverges, if one will was enforced; however, common agreements should be built upon to ensure 'proper conditions' for this research (SCBI 2003 p. 37).

The argument is that the EU can be instrumental in setting a broad consensus and can establish tangible limits that are likely to be followed by existing and new states (Nielsen 1996). This harmonised legislation, at the least at the national level, can have a *norm-setting function*, thus declaring minimal values and interests, providing (international) *sanctions,* and have a *declarative* function. The influence of national deliberations of other nations, given the globalisation of research, economies and dispersion of information through the internet and media, has implications for the ways in which the provision of health care is structured, organised, and conducted in one nation beyond its national borders.

Policy discussions can force neighbouring countries to keep up with scientific, ethical and legislative progress in biotechnology, and to promote debates as to their national policy and legislative measures. A *laissez-faire* attitude may be encouraged were the institutions of the EU not to enforce these measures (Capps 2003), furthermore, where no regulations exits, knowledge and deployment of EU support may *encourage* the timely formalisation and implementation of appropriate regulations (Evans & Evans 1996 p. 209).

1.5. Reasons Against Harmonised European Policy

Those states that prohibit or promote research rely on the scientific findings and the reports of advisory bodies that gather and express opinions on the comparable potential of alternative sources. These reports are influenced by the national opinion regarding the status of the embryo, and then may be acted upon depending on the political nature of the then government. This reflects the position of that state, and clearly is not reflective of the EU as a whole. It is all too evident that Community institutions cannot judge the universal position, but regardless can implement unfair restrictions, or refrain from getting involved when necessary; and for this reason it is

often argued that states should legislate according to (their) principles (norms), and in light of cultural pluralism.

The argument is that the moral position of any one state should not be enforced upon another. Not only would a harmonised policy disregard national plurality, but also on such a macro scale, local cultures are likely to be ignored, forgotten or lost. International policies may be magnetised towards one ideology, and this may be entirely contrary to either the macro or micro-cultures of individual state. In states with permissive legislation, it is evident that there is often a more secular society, and often this expresses a positive attitude to embryo research (Lyall et al. 1995). The opposite is evident in predominately Catholic states (but notice the exception of Spain). By imposing one will, it not only confers possibly unacceptable EU legislative or funding measures, but also offends national values and culture.

Furthermore, imposing or encouraging minimal standards also risks 'harmonisation downwards' (Nielsen 1996 p. 33). The reason for this is that standards imposed may have to be broad and perhaps vague, and this means states are tempted to only implement these minimal measures, instead of more reasonable measures. These minimal standards may unjustifiably (or unintentionally) enlarge or deflate the protected status of the embryo according to the national position; and furthermore, harmonised legislation can be (politically) exaggerated or underplayed when there are such extremes of opinion.

In the case of the status of the embryo, states objecting to research may not welcome the free movement of persons out of its restrictive borders to obtain services to which the majority (in that state) objects. (It makes a nonsense of having prohibitive rules). This is typified by the procurement of abortion service outside Ireland and the *Blood* case (*supra* fn. 7). Additionally, if universal norms are too restrictive for a certain state (and where the act is widely supported; for example, embryo research in the UK[8]), then an underground demand may develop. It is clear that where opinions on issues such as this differ greatly, it is unjustified in imposing one will.

Finally, in setting these minimal standards, states become committed to a certain intentional ideology, for example, there are states that have previously signed the ECHRB, but now are limited by its restrictions. (Greece, which has ratified the Convention, seems to want to attempt to circumvent the prohibition on creating

---

[8] See Alder et al. 1986; & MORI poll 8th April 2003 at: http://www.mori.com/polls/2003/amrc.shtml (accessed October 2003).

embryos for research, to argue that this does not forbid creation for therapy; indeed IVF creates embryos for therapy!). Harmonised legislation can set political and legal 'bright lines' to prohibit certain universally rejected actions, such as reproductive cloning. But, because these lines are sometimes difficult to set (i.e. disagreement concerning the limit on the age of research embryos at 14 days; Warnock 1985 pp. 65-66; & Ciba Foundation 1986 p. 196), they must stick to a clear delineation between acceptable and unacceptable practices (which is far from clear between the Member States), and these agreed limits should be unambiguous (which again would be difficult between distinct ideologies).

2. Harmonisation: Yes or No?

While non-harmonisation may be an easier option, considering that the discrepancies in SC research alternatives divides opinion, and while disagreement as to the fundamental status of the embryo remains, minimal standards would: (1) provide a means to promote public health by allocating funds to ethically reviewed and necessary research; (2) set standards for the imminent entrance of new states; (3) establish minimal standards to counter the negative implications of cross border research and movement, including minimal ethical and scientific standards in the export and import of cells and; (4) the establish common rules for procedure and arbitration, such as those evident in the enforcement of Community and Council of Europe law.

Particular to SC research, however, there are further important benefits, such as the means to establish Community Stem Cell Banks. Scientific harmonisation of research findings and progress would have benefits in: (a) setting and maintaining scientific standards of derivation, characterisation and evaluation of the cells (to enable the comparison and classification of existing and future cell lines); (b) ensuring that research is necessary (for important medical benefits) and not duplicated; and (c) providing a means of monitoring, evaluation, and access to research findings (and allow a means of validating research claims) across the Community.

For a comprehensive framework to be effective, it would be necessary to facilitate dedicated stem cell research institutions. Following the UK's experience[9], this may be

[9] See Chapter Four Part Two s. 5.

achieved through the establishment of a Community stem cell bank that can act as a repository and registry for SC and that acts as a central facility for communication and organisation between that national research frameworks, and to order and distribute information (including to non-specific stem cell research institutions) (Zerhouni 2003). Such an institution would clearly benefit from universal standards of scientific research and reporting.

Harmonised measures and the establishment of a central depository would facilitate the import and export of ethically sound (according to minimal standards) ES cells to those states that only permit the import of previously isolated cells. These states can be guaranteed that the cell lines are derived under minimal constraints if all Member States are subject to the same ethical standards. Furthermore, it can be ensured that the researchers can be isolated from, and in no way complicit in, the derivation of ES cells lines. The cell lines will already exist and were deposited by research unrelated to that now required by the request (Robertson 2003 pp. 125-126).

3. Conclusion to Part One

I have argued that on balance, a harmonised policy would be beneficial and make progress in public health commitments. This would be better than doing nothing (unless states can be trusted to implement self-regulation, which has so far been lacking). The problem is how can regulations be placed in restricting and funding research where there is a great deal of disagreement, and in light of the concerns regarding the imposition upon cultural sovereignty?

Part Two

Establishing a Moral Grounding for a European Stem Cell Research Policy

1. Introduction

The argument that harmonisation is necessary for progress in Community public health policies presents a number of problems. The main consideration is whether that policy can be anti- or pro-embryo research and not alienate or unduly restrict Member States; and this latter concern drives one towards a non-harmonised policy (Beyleveld & Pattinson 2001 p. 66).

Taking either of the first two positions, it is likely that a European incentive will be enforced upon dissenting Member States, resulting in the rejection or the reluctant agreement of these nations to harmonised policies. If states agree on harmonised goals, it will either enforce the primary status of *all human beings* in research, or benefit shared visions of *human agent* health and flourishing (McLean 2001 p. 201). I have argued that harmonisation would be beneficial for progress in public health, which would concurrently require investments and support for ES cell research; and implicit in this claim is a pro-embryo research sentiment. Of course, this view, and any harmonised policy based upon it, will create ethical counter-claims that remain unacceptable for significant segments of the European Community, and therefore this implicitly supports Beyleveld & Pattinson's (2001) argument for a non-harmonised position in research.

2. Prohibitive or Permissive Regulation?

I have argued that (1) human rights are an accepted basis of Community policy; (2) the priority of human rights must be primarily reflected in the freedom and wellbeing of agents (and is reflected in the actions of the EU) and; (3) the majority view in the EU was to allow at least some ES cell research. Furthermore, there is evidence of public support for embryo research within the EU (*supra* fn. 8; Bionews 2003). This, as

well as providing benefits to Community solidarity and research competitiveness, has the effect of implicitly pushing towards an argument for permissive harmonisation. With the progression towards more permissive legislation in the majority of states, restrictive measures could be seen as curtailing human freedom and rights, which is particularly evident in the (permissive stance on the) free-movement of citizens within the EU to procure services that may not be available in her own state. It is only on the former ground that a harmonised policy could be coherently formed, because enforcing a prohibitive stance would be to concede that there is no room for cultural sovereignty, either for national beliefs or on the basis of democratic consensus (Beyleveld & Pattinson 2001 p. 69). This would also be a paternalistic position for the EU to take, which would go against its designated involvement in matters of national interest. States that do desire a more restrictive legislative environment can do so on their own accord, and without enforcing international measures; of course, they are faced with the prospect of citizens procuring services outside their jurisdiction.

This progression towards permission can be described accordingly (support for various components are hierarchically ordered, with the most agreed upon first; the reader should refer to explicit prohibitions/permissions to the table in Chapter Four Part Two s. 2):

(1) The cloning of *in vitro* embryos for *reproductive* purposes is forbidden;

(2) The *creation of embryos for IVF* fertility treatment is permitted;

(3) Research on *ES cells* is permitted (either derived in that county or imported);

(4) The use of *supernumerary* embryos in research from (2) is permitted;

(5) The *cloning of embryos for research* is strictly forbidden;

(6) The *creation of embryos for research* is forbidden;

(7) The use of embryos in research is *strictly forbidden*;

(8) The creation of chimeras for *research* is permissible.

Embryo research is generally accepted on certain conditions (4); most commonly on embryos that are surplus to a reproductive project (4). Only two states explicitly forbid embryo research (7), while one of these allows import of ES cells (3). It is explicit in one state, and a future possibility in others, that the creation of embryo for research can include both IVF and cloning techniques for research and therapeutic purposes. These

latter states are more sympathetic for the creating of embryos by cloning than by IVF because of the potential *therapeutic* application. Only one state allows the creation of chimeras (all others that mention this research prohibit it); but then this state also has a moratorium on creating embryos (by any means) for research.

Those in the anti-embryo research camp, I imagine, would not support pro-research measures regardless of the benefits for the Community; either because they are convinced that the research is unnecessary from a scientific point of fact, or because the fundamental status of the human embryo rules out its use in research. The framework stated in this thesis contradicts this position; because not only is the research *necessary* for stated goals, these views cannot be concurrent with the majority of Member State policy developments. This is based on supporting progress in the treatment of individuals affected by disease and injury, and that the status of the embryo can be overridden in justified circumstances. How, then, is a policy to reconcile these extreme poles to be achieved?

3. The Moral Basis for a Harmonised Policy

In this section I will argue that a harmonised policy based on permission may be established on 'trust' and 'respect', that although allowing research, treats the embryo as having value above that of mere tissue, and also requires the necessity for research to be assessed.

3.1. The Role of Advisory Bodies

Public trust can be maximised by providing for informed and public debate. This can primarily be achieved through political and public interest groups addressing the salient issues. It is evident that within the EU there is a fundamental reliance in ethical debate that is centred upon national and international governmental and non-governmental 'ethics' groups, committees, and commissions, that I have collectively termed 'advisory bodies'. The main two types are parliamentary appointed (but parliamentary independent) *standing* or *ad hoc* committees (Rogers & Bousingen 1995 p.185), and established and independent interest groups. The policy function of such

groups is in the main to help prepare parliamentary processes to be organised as rationally as possible (Friele 2003); supplying the available evidence by review of evidence or interview, and then reporting to the government of that time, generally with a consensus view (it is not uncommon for dissenting views to be included; e.g. see Warnock 1985).

National ethics committees have an important purpose, in that they expose (through expert membership and gathering first hand evidence), and then state options, based on a (supposedly) sound understanding of the scientific and medical implications. They also facilitate transparency and public access to the debates, serve as an interface between public authorities, the scientific community and the public, and can (independently) influence government policies or prepare the grounding for legislation.

These committees serve an important moral function, in that they facilitate the discussion of available evidence and dissemination of knowledge to justify certain actions against the 'quasi-rights' of the embryo in research. The importance of this is that new knowledge may change the *necessity* for research (i.e. that ES cell research is no longer necessary or that AS cell research is not progressing). This is required for the practical implementation of the PGC, since harm to the embryo's status can only occur when there is a realistic benefit to a more likely agent and that there is no other way to attain this benefit by using a less likely agent. The message to be taken from this is that review does not stop with the opinion of the national advisory bodies, and therefore policies should reflect this fact by demanding consistent ethical review and scientific monitoring of progress in the field, that also provides up to date transparency to the public and politicians.

In my analysis of the various national advisory bodies within the EU, it was evident that they contain a wide spectrum of membership (so called 'expert' and lay members[10]). Their opinions served as a means of outlining *proposals* of general policy. They cannot be *assumed* to be representative of the government at that time[11], although they may be an expression of national opinion[12] - although these Advisory Groups are not without their potential faults (see Friele 2003; Mongoven 2003; & Spielman 2003),

---

[10] See reports referenced in Appendix Eight.
[11] But see for example, see the UK Government's endorsement (Department of Health. 2000. *Government Response to the Recommendations made in the Chief Medical Officer's Expert Group Report*. Cm 4833) of the 'Donaldson Report' (DoH 2000); and the Netherlands HCN (Chapter Four Part Two s. 3.1).
[12] For example, The 'Donaldson Report', like the majority of UK consultation documents, invited and received input from public and representative and interest groups (Campbell, A. V. personal communication).

they are illustrative[13], if not definitive, of national opinion in issues of biotechnology and biomedicine.

It was evident in the opinions of these bodies that there was a general environment of support for the liberalisation in SC research with regards to the human embryo, which often coincided with liberalisation of present or prospective state legislation. For this reason, I have argued that the consensus, but by no means universal opinion within the EU, is for the promotion of limited and strictly regulated embryo research for the purpose of SC research.

3.2. Consensus in the European Union?

I have argued that it is extremely unlikely that the human embryo is an agent, and therefore has direct moral *claim* rights. Instead, the risk that it may be an agent is to be judged so that it becomes a matter of agent responsibility to assess proposed actions that harm any *precautionary rights*. It is this basis that any possible consensus in the Community on SC research should reflect. Of course, there are those within the Community who would not accept this conclusion (probably) on non-secular grounds. There may therefore be two means of attaining agreement on embryo research, through mechanisms of *trust*, inherent in the functioning of advisory bodies, and respect. One may be able to *persuade* those of the anti-embryo-research position that research can be justified for realistic benefits[14]. The problem with this view is that where states do allow activities that remove the right to life of the embryo, this is because of an unavoidable compromise, and not necessarily for *realistic benefits* (in allowing abortion), or wilfully forsaking the status of the embryo. In research, the compromise would be in accepting the possible benefits of research, which would denote a departure from the status of the embryo – this is an implicit acceptance that the embryo's status

---

[13] In my research it was evident that the opinions of advisory bodies were influential on political moves.

[14] Dworkin argues that it is rarely expressed in any policy that abortion is prohibited in all cases, and that it is possible in the case where the life of the mother is in peril. So as Dworkin points out: '...this exception is also inconsistent with any belief that a fetus [sic.] is a person with a right to life [it is therefore] ...morally justifiable for a third party, even a doctor, to kill one innocent person to save another' (Dworkin 1995 p. 32). Policies that reflect this position may then also apply it to embryo research, in that research is possible when there is good reason to believe that it is necessary to cure life-threatening or severely debilitating disease (Siegel 2001 p. 179). Most states do not take this strict view of abortion, so it is arguable that this interpretation in not necessary, therefore research may be justified where there is a possibility of medical benefits, including therapy and basic research.

(which is allegedly the same as an agent) can be sacrificed for potential research benefits.

Instead, the position proposed here, is that having grounded the moral legitimacy of SC research in the PGC, research can be permitted utilising human embryos, not necessarily because they cannot be harmed in destructive research (because they cannot be validly held to have claim rights), but because precaution requires us to check our unrestricted use of them. Justification comes from the necessary use of embryos in promoting agent rights through progress in public health measures, and this allows the Community to override the embryo's marginal status in pursuance of this.

Those that are of the opinion that the embryo has full rights will not condone this; but then enforcing an opposite rule may harm others' generic rights (to freedom and wellbeing), and so may be contrary to the premise of the PGC. Furthermore, policy harmonisation can only be achieved in this latter way by restricting the status of agents, while unjustifiably sustaining the rights of the embryo. Without alienating states with prohibitive legislation entirely, a policy would have to based upon agreement[15] within the Community that such research will be permitted, but only on account of the perceived necessity for the proposed research, which in turn, is based on a case by case evaluation.

Necessity has to be based on the health benefits to agent wellbeing. Importantly, the science may become obsolete or *unnecessary* if developments in other fields fulfil their promise. Furthermore, stem cell banks may mean that further derivation is not required from human embryos. For this reason, the evaluation, as far as possible must be guided through universal and transparent access to developments. Trust in the regulation of ES cell research must be facilitated by an attitude of informing, and explaining when necessary, to those in disagreement, the current state of art. This may promote confidence, and perhaps support, in that the research is necessary for defined therapeutic goals and is strictly controlled for these purposes *only*, and indeed should dissuade misinformation and disinformation (O'Neill 2002)[16]. Furthermore, this would

---

[15] See Locke 1988 esp. pp. 113-117. Agreement would be based on trust through effective modes of public debate and political openness and transparency.

[16] Dissident opinions may be the result of different terminology. For example, most state and international definitions of 'embryo' differ when one is given (see Maienschein 2003). Recent confusion over the meanings of 'reproductive' and 'therapeutic' cloning has been evident in the press. Furthermore, the anti- and pro research lobbies have declared the benefits of taking each route, while it is clearly evident that it is scientifically unjustified to declare any one sources of SC as either sufficient or superior. The two positions should be tempered in their desire to promote their own stance by thorough and proper science, and truthful dissemination to politicians, policy makers and the public. As Solter stated, there is

require that the regulation is flexible to accommodate developments, because the necessity for research may change.

4. The Status of the Human Embryo in Research Policy

4.1. The Human Embryo and Precautionary Reasoning

Because the possibility that the human embryo may be an actual agent, agents must take violation of its status seriously. This means that a *justification* using a needs-calculus is required for anything done to the embryo that is not in its interests (Beyleveld 2000b p. 76). Precautionary reasoning could 'give us pause' to evaluate options. One outcome may be that policies become ultra-conservative and therefore prohibit ES cell research (see Glannon 2002), because:

> Where an activity raises threats of harm [to biological human beings] ...precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically ... In this context the proponent of an activity, rather than the public bears the burden of proof (Ashford et al. 1998)[17].

But then Harris & Holm argue, during this 'pause' thousands would continue to die from possible treatable disease (2002 p. 356). This failure to promote research now therefore causes harm to agents' freedom and wellbeing – harm that could be avoided if research is permitted[18].

Furthermore, the human embryo (as a human being) does not have the same status as an agent, so precaution must be argued differently than that previously stated. In this case: *Where an activity raises a threat to the human embryo, precautionary measures should be taken to ensure that the activity is justified in the sense of promoting or*

---

a '...flurry of mindless publicity, mostly from individuals who are ignorant of the biology involved and who have not taken the time to become informed or reflect ...[and they are] coming up with ...near-sighted and hasty decisions' (Solter 2001 p. 24). Likewise, pro-embryo researchers are also accused of 'inflated language' (Fletcher 2001 p. 64; cf. Kahn 2002). It is true that there is a substantive gap between discovery and cure, but then this is not an argument against ES cell research per se – it is a call to recognise the inflated claims on both sides (Shannon 2001 p. 181).

[17] This *Principle of Precaution* is directed towards the uncertainty in the application of agricultural bioengineering, and given the uncertainty, some politicians and activists are insisting on caution first in the use of this technology.

[18] Embryo research has been separated from abortion because the 'embryo's existence threatens no one' (Fletcher 2001 p. 63). My point would reject such a claim, because raising the embryo status so that research would not be possible would harm other agents through denial of IVF treatment (which would have to be rejected as well), but also the envisaged benefits of ES cell research.

defending an agent-centred good. In this context the proponent of an activity bears the burden of proof.

In the context of ES cell research, the available evidence verifies that there is (compelling) proof that there are realistic benefits, and that alternatives may not be as readily available or applicable. This is a rational deduction from the available evidence and is subject to modification; but then not having certainty does not mean that precaution should go the other way. This would place the status of the embryo above considerations of agent-centred human rights. The essential justification is that research is possible on the basis of the embryo's status alone, and as long as the research is necessary for a more likely moral agent-centred benefit. However, it is still the case that the seriousness of overriding the embryo's status, based on a needs calculus of the benefits of overriding that status, requires an acknowledgement of the decisions that compel policies to do so, and this may transpire as degrees of 'respect'[19].

Therefore, agents (and communities) must be willing to impose duties upon themselves to protect the embryo in line with the need-calculus of agent/marginal agent goods, and they are waiving their generic rights when then impose duties on themselves that are stronger than the needs-calculus requires (Beyleveld 2000b). The difficulty, as Beyleveld acknowledges, is that because of the practical and theoretical requirements of formulating a needs-calculus (for example, no community can know the full outcomes

---

[19] Steinbock states that, while embryo research is acceptable in principle, many policy bodies have argued for a principle of respect (2001 p. 28). Callahan sees this view as incoherent, because one cannot both 'respect' an embryo and also condone its dismemberment in research (2001; 1995). Respect is not a function of 'esteem' or 'etiquette'; it is about translating moral duties into 'protectability' (Baylis 2001 p. 53); thus 'respecting' what one destroys is an attempt to 'rationalize [sic.] the killing of embryos' (ibid. p. 54). Baylis argues that commonly destroying embryos does not mean that destroying embryo for research readily transforms to a morally acceptable action (ibid. 2001 p. 55). But then not only abortion, but IVF treatment would also be immoral. IVF inevitably creates supernumerary embryos. These could be donated to other couples, but failing that, all would have to be implanted (with the additional threat to the mother's rights) or frozen indefinitely. If Baylis wishes to assert that abortion involves a conflict between the maternal and embryo rights (ibid.), then I would point to the competing interests of couples wishing access to IVF or potential medical therapies (and not necessarily the rights of scientists to do research), then the embryos status is being inflated above that of the wellbeing and freedom of agents. Baylis argues that couples should not have the option of discarding unwanted embryos, and they should either be donated to other couples or the number of embryos limited (ibid. p. 56). This is unacceptable because couples could not enter into IVF programmes unless they agreed to the forced donation of their embryos or the prospect of more than necessary cycles of ooctye collection, fertilisation and implantation, probably increasing the cost of IVF treatment (limiting those further which can have access) and potentially putting the mother at more than necessary emotional and physical discomfort. Those who argue for a policy of respect do not believe that the embryo has the same status as other agents, because if 'respect' was the same for both, then it would indeed be incoherent to deny a moral status to one, while at the same time grounding a full moral status of the other; therefore, the embryo has no intrinsic status (so one could do what one wanted; or to '...kill embryos and not feel bad about it' (Steinbock 2001 p. 28)), but that 'respect' may mean: (1) acknowledging the status of other agents in the donation of their gametes and embryo for research and; (2) respect for other agents' sensitivities (Parens 2001 p. 43).

or have all the available evidence, in making any decision), there is legitimate scope for disagreement, and therefore policies should attempt to specify as precisely as possible the limits of possible discretion (ibid.). However, this disagreement must acknowledge the basic import that the embryo has an inferior moral status to that of born human beings for it to be even considered in this calculus.

Pressing ahead with limitless and unregulated research may be sign of an uncaring community, which may signal or cause a climate of distrust within that community, to the detriment of human rights. Therefore, respect for others' sensitivities is a necessary component of any public policy. It is therefore necessary to limit some actions that may go too far in offending the minority group (Roche & Grodin 2000 p. 138).

4.2. Types of Embryo and their Use in Research

Despite a marginal agent's status not being comparable to actual agents, regardless of the benefits, there are still certain actions that are not possible or acceptable. For example, research may be restricted in the use of reproductive cloning or creating chimeras, regardless of the possible benefits to human health. If the human embryo is not given an absolute status, and research is possible, then restrictions may be likewise placed on the type of embryo used or the research that can be legitimately pursued. The reasons for this may be that, although research per se can be accepted, there are certain acts that policy makers are unwilling to condone, either because the possibility of medical benefits do not warrant certain lines of enquiry; or because certain acts would offend any 'respect' one has for the embryo (*supra* fn. 19).

4.2.1. The 14-day Limit

Most states follow the paradigm that was set by the Warnock Report that there should be a 14-day limit on research. There has been a great deal of controversy regarding this line drawing. For instance, Edwards argued that some research requires only 5 day development, while other worthwhile research needs to be done at a later stage, and therefore, 14 days is arbitrary (Ciba Foundation 1986 p. 195). While there is little difference between a 14-day old embryo and a 15-day old embryo, a line has to be

drawn somewhere (this line is allegedly influenced by the proportion of development towards agency). On this basis, the 14-day limit is generally considered as a 'bright line' (only France differs from this where research is permitted, using instead a 7-day limit).

ES research requires embryos at around the 5-6 days of development. Therefore, the 14-day limit is unnecessarily lenient. However, on the necessity for a cut off point, ad hoc discussions cannot set a common denominator to which everyone can subscribe, and also addresses those critiques that show redress to the slippery slope argument. The status of the embryo changes as it progresses to the foetal stages (as it becomes a proportional and not potential agent), but as pointed out by many anti-embryo research positions, this is a gradual transition with no point whereby moral status is attained (this is clearly seen in the 'transition' from a viable foetus to a born human being).

But then without a point of change, no decisions could be made, and the avoidance of not making a decision may itself be a harmful act (Williams 1986 p. 190). It may be easier to consider a cut-off slope, rather than a cut-off point (Pluhar 1977 p. 166), and this inevitably has to accommodate a 'point' (indeed, the Warnock Report considered the point at 17 days or more, but decided on an earlier date as a consensus that errs on the side of caution; Warnock 1985 pp. 65-66); in consideration of ES cell research, this point can be set at 14 days, not least because of convention, and perhaps only because there exists a degree of agreement (rather than through scientific need or biological facts) (see Ruyter 1996 p. 184).

4.2.2. A Distinction between the Creation of Embryos Specifically for Research and the use of Supernumerary Embryos

Embryo research policies that allow destructive research will often make a distinction between the use of embryos based entirely on the intention of their creation. Commonly, research is restricted, so that without attributing an inflated value to the embryo, only spare embryos should be used in research (see Roche & Grodin 2000 p. 138) (i.e. there is no scientific imperative to create research embryos). The argument rests on the assumption the spare embryos exists as a consequence of the generally accepted practice of fertility treatment, and rather than destroy or indefinitely freeze

such embryos (or implement irresponsible policies such as implantation of all embryos), at least some good can come from research (Annas 2000 p. 374)[20].

However, there is no ontological difference between the embryos created for research or those intended for, but not used in reproduction; and in both circumstances the embryo will inevitably be destroyed[21]. (What if therapy from ES research is forthcoming – would a distinction *then* be made between IVF therapy?). If respect drives this assumption, then once again the status of the embryo is being inflated above the status of agents whose generic rights may be benefited by such research[22].

4.2.3. A Distinction between Different Types of Embryo and their use in Destructive Research

Three types of research embryo are often distinguished between; those created through IVF or cloning techniques, and artificial parthenotes. Using IVF embryos in research is not uncommon in the EU, and is at least implicitly endorsed by all states that practice IVF for fertility treatment, since research was necessary to develop this treatment; though they may wish to distance themselves from this.

However, I have also argued that there is no difference between the types of embryo, except that the latter two at present have no developmental prospect. The cloned embryo, if implanted, will normally spontaneously abort (regardless, there is still a consensus that these embryos should not be implanted). The assumption, where a

---

[20] Annas argues that '...the ethical basis for this compromise is that such embryos were created for the *legitimate purpose* of procreation' (2000 p. 374). If this purpose is legitimate (and creating embryos for research is not), then surely it is the purpose of the creation that makes it legitimate or not, and if procreation is legitimate, then how can any research be likewise? Surely, the ethical decision, if Annas is correct, is to implant all embryos or to attempt to donate those embryos to other couples.

[21] A further aspect of this interpretation is that limiting research to spare embryos, on the one hand, limits the embryos donated for research only to those women who seek fertility treatment, and this may lead to coercion on these woman to donate embryos (Ruyter 1996 p. 187); on the other hand, allowing the creation of embryos specifically for research will not only open up donation of oocytes from other sources, but may also drive a market for the donation.

[22] There are also practical considerations, such as the inevitable availability of *spare* embryos created in fertility treatment. Some countries do not allow the creation of spare embryos and instead insist that all embryos are implanted. Furthermore, as IVF technology improves (through research where it is possible!), the number of spare embryos will fall. Some types of research (studying the process of fertilisation or development) and treatment may require the creation of embryos (i.e. therapeutic cloning). One must also look at the reason why embryos may be surplus, because if they are defective, the derived cells may also be defective or atypical of ES cells (Pickering et al. 2003). But, if these cells are used to derive further cell lines (thus potentially circumscribing the need to derive any more cells from the embryo), these lines themselves may also be therapeutically useless.

distinction is made, is that of necessity. This is evident in advisory positions that advocate a reluctance to prohibit therapeutic cloning per se, but argue that creating embryos for research is at present unnecessary (this is often also argued along with establishing a difference between therapy and research in using created embryos; which is implicit within the ECHRB).

Parthenotes have not been covered in any regulatory or policy documents, so it is unclear whether the 'non-embryonic' status derived by some would be endorsed. If, as appears to be the case, human parthenotes are not capable of continued development, then there may be a case for arguing that they have *no potential* developmental properties, and therefore, are less likely agents than 'normal' human embryos. There may be a case for arguing that they have less moral status, and should be prioritised in usage in embryo research.

We also find objection to creating cloned and human/animal chimeras for research. These embryos, like any IVF embryo, are still *potentially* human beings or human-animal beings. (I will not consider their status as *agents* if taken to term). If these embryos are *created for research* and *destroyed* in the course of the research, then they are only potential agents, like any other embryo.

Some states have argued that non-viable embryos may be considered for research. This has two problems, firstly, traditionally (i.e. not suitable for implantation because of defects; see Zoloth 2001 p. 227) non-viable embryos may not be suitable for research because of the very defects that make them non-viable (*supra* fn. 22). The second problem is that non-viable embryos may also include those embryos frozen with no prospect of being implanted (perhaps because the donating couple cannot be contacted for their consent to donate; or, as is the case in Spain, that embryos subsequent to the legal requirement of five year storage, become technically non-viable since they must now be legally destroyed). Thus such embryos are only 'non-viable' because the intention of implanting them is technically compromised by some other consideration.

All the EU institutions and the Member States, in one way or another, see the types of embryo as deserving a different status. The UK is the most lenient in this, prohibiting only the creation of, and research using, chimeras. But isn't a chimeric embryo the same as a cloned embryo? – and if therapeutic cloning can be permitted as long as reproductive cloning is explicitly prohibited, then can't the same happen for *reproductive chimeras*? Thus, in this case, 'embryos' do have different moral status (part of which is based on the intention behind creating 'embryos'). However, there is

no ontological difference between different types, and certainly between IVF embryos created for different reasons. There is therefore no reason why such embryos should have a different moral status, and therefore be treated differently in research policies. Indeed, cloned or chimeric embryo would look no different from an IVF embryo, but may have different properties, which makes them more or less suitable (or necessary) to certain research protocols.

I argue that the use of any type of embryo is morally supportable, as long as the criteria given are met regarding the *justification* of their use – if they are used in research, they are *actually* research 'tools', albeit with a status above that of mere tissue (or any other non-agent)[23] (DeWitt 2002; Karpowicz 2003; Kobayashi 2003)[24].

4.2.4. A Distinction as to what Research is Permitted

With the advent of realistic medical benefits from embryo research evident in the form of SC derivation, most states are keen to pursue such research, but are also determined to place restrictions on it; embryo research therefore is not ethically and *a priori* unjustified. Limiting the permissible research is normally an attempt to show respect for the 'embryo' (*supra* fn. 19). I would argue that a different approach to the permissible limits of research might be that research is limited by agent-centred benefits that can override the embryo's marginal status.

Thus one may place restrictions that reflect this justification; for example the research cannot be achieved by any other means and that it is a realistic agent benefit. Of course, the benefits of ES cell research may be distant, and basic research is a more immediate prospect. But then if this is considered as a first step in the ultimate goal of therapeutic applications, then this may also be permitted.

The main concern for a legislative measure is ensuring that the law is precise in its specification of what is permitted. In Part Two of Chapter Four, s. 5, I noted that embryo research regulations have been subject to interpretation or lack of foresight, and

---

[23] There are interesting issues here regarding the agent status of chimeric born entities; especially since they may not be genetically human(?). My argument from *precautionality* remains however, that if the entity is an agent, then it has such a status regardless of its genotype (Chapter Four s. 7). The precautionality-'dignity' argument may also mean that an embryonic chimera considered as not being genetically human, could not have 'species dignity' (ibid. s. 7. 5).

this has led to activities being either intentionally or unintentionally (un)regulated. This has to be addressed in two ways: expressing precise legislation (based on present knowledge and probable progress), and allowing a degree of policy interpretation (which can reasonably be accomplished by a central regulatory/licensing authority).

5. The Basis of a Harmonised Policy

I have highlighted three positions throughout this thesis: (1) embryo research is *a priori* unjustifiable; (2) embryo research is unnecessary; and (3) embryo research is permissible (I have added certain limits based on the proportion of benefit to be attained to agent freedom and wellbeing).

I have argued that there is no difference in the status of the embryo regardless of its intention or means of creation (bearing in mind that any research embryo used in SC research will be destroyed in the course of that research, could not be implanted [because it would become non-viable], and *that* embryo would not exist more than a few days from creation [unless frozen]). Therefore, if an embryo can be justifiably used in research, it is regardless of the type of embryo[25]. It is what a thing is (and the status this derives) that matters (and not the condition in which they are created).

I therefore believe that embryo research can be morally justified because of the agent-centred benefits that may be developed. There are realistic benefits to agent health through new or more effective treatment, providing basic developmental knowledge (benefiting IVF and embryogenesis) and drug development, and possibly combating the chronic shortage of organs and tissues for transplant. This ideology is based on a specific account of human rights, and an imperative to ensure measures that have a realistic chance to reduce suffering and promote wellbeing. Furthermore, there are reasons for creating different types of embryo or utilising a non-human supply of oocytes (e.g. creating research embryos allows one to study that process itself, which may be impossible if the embryos are intended for implantation).

---

[24] Unless scientists are eager to begin bringing these chimeras to term; but then stem cell research is not intended for this purpose, so regulations should only highlight the possible dangers of this (inadvertent) slip (Cohen 2003); and not the concerns of *reproductive* intentions (Johnston 2003).

[25] Should supernumerary embryos become scarce, it may become practice to fertilise more embryos than is necessary for the fertility treatment. In such circumstances it would be difficult to see how oversight bodies would be able to discern the *intentions* of the creation of the embryo; the moral status of children is not determined or a function of the parents' intention at the time of conception (Parens 2001 p. 44).

Of course, one could proceed from a separate set of beliefs that follow from human rights, which is based on a (separate) interpretation of the society that one wishes to create. These often-decisive beliefs have indeed shaped Member States' policies (Parens 2001 p. 41). Here, I will consider only three bases that are implicit in certain EU states. These are that the prohibition of all embryo research is justified because: (1) that there is an overriding commitment to not using human life in research (possibly as a relic of the Nazis' human experiments policy); (2) non-secular arguments that preserve the sanctity of life doctrine and; (3) secular argument that maintain that the '...devaluation of humans at the commencement of life encourages a policy of sacrificing the vulnerable that could ultimately put other humans at risk, such as those with disabilities and the aged, through a new eugenics or euthanasia' (Young 2000; also see Beyleveld & Pattinson 2001 p. 67).

If these beliefs that suggest a prohibitive policy are informative to the discussion, then they should demonstrate why such a stance protects or promotes the subjects of human rights. They must maintain therefore, that the denial of certain individual rights can be justified, by either a paternalistic or freedom limiting policy. I do not believe that either view can conclusively demonstrate that the suffering or flourishing of human rights can take second place to such societal concerns. The fear of history repeating itself can be countered by measures that ensure that it does not; the Nazi crimes were a very specific and massive kind – today, it would surely be a case of locating group/individual crimes, that would not threaten a nation (or the EU) in the same way. (Or at least in a way that permitting embryo research, which are arguably human beings, would threaten or override other human agent benefits). Such measures must still be based on promoting an equal status in the human embryo, which would put human agents in the way of harm to their human rights – and treating embryos in such a way (as Young (2000) does argue) would compromise the effectiveness of human rights as protections to human agents. (Indeed, I would argue that it is wrong to think that these agents have a status that is comparable to embryos, because to do such would inevitably deny human rights!).

These arguments should not be entirely dismissed, because they can inform the debate (but should not dictate). To deny access to possibly exceptional medical progress because of history, or an over inflated status, would itself be contrary to human rights (Baschetti 2001), likewise, to argue that 'slippery slope' arguments should prohibit possibly beneficial actions, because it legitimises or sets an unavoidable

progression to immoral acts, seems unnecessarily cautious when there are other imperatives (here, public health) to realise (*supra* Chapter 1 fn. 35).

The argument for 'respect' is an expression of the requirement for a justification for doing certain actions (*supra* fn. 19). This justification does not rule out using embryos in important medical research, but does make frivolous or trivial research unjustifiable. The research must be seen as necessary and have an element of a pressing need. Without this, one may view unscrupulous researchers proposing unnecessary projects as being contemptuous to those who oppose such research per se. ES cell research is seen as (presently) necessary and the medical benefits (possibly) significant and (probably) unreachable by other means[26]. This cannot mean that policy makers *know* what results will be forthcoming from ES research, or that AS research may ascend to be necessary. So it is essential that policies should assess the available evidence, the goals of the research, likely benefits or prospect of significant progress, the necessary means and the possible alternatives. This can only be possible through mechanisms of pro-active review, so that these prospects and progress can be assessed.

6. Policy Options: The Proposed Directive[27] and the Sixth Framework Programme (FP6)

Tony McGleenan has identified twelve possible policy options for action for a European policy in SC research (McGleenan 2000 pp. 8-9). These can be grouped into three categories: (1) prohibiting embryo research and derivatives within the Community; (2) restrictions upon research within the Community; or (3) regulating research and funding within the Community. Of course, a fourth option would be to do nothing, but because the EU has a *duty* to public health, I would argue that this option would impede significant benefits to that end; and would correspond to a breach of responsibility on the part of the EU (i.e. it has a responsibility to promote public health

---

[26] And this may include research that is not normally sanctioned, such as creating specific research embryos or using therapeutic cloning, because these may be the only means of attaining some aspects of progress. (Indeed, some national laws and advisory documents have not ruled out certain aspect of research a priori and this may be an argument for moratoriums on certain research applications).

[27] *Proposal for a European Parliament and Council Directive on setting standards of quality and safety for the donation, procurement, testing, processing storage, and distribution of human tissues and cells*: see Appendix Six and Chapter Four Part Two s. 3.6.1.

unless it is either not placed to help – which it is not – or would be acting contrary to human rights if it did act).

In order to assess the validity of these policy options, one has to juxtapose them with: (1) the framework that I outlined in Chapters Two and Three and; (2) the function of the Community and national sovereignty (Chapter Four). It should be remembered that these policy measures are being debated in the Directive (Appendix Six) *intentionally* designated to set the highest scientific standards for use and research involving human tissues and cells (which is concerned with promoting the public health policy under Article 152) and to protect public health and guarantee respect for fundamental human rights (Recital 7), and this must only apply to human persons. Likewise, under FP6, EU research is to be maximised, explicitly including SC research. So, the EU/Member States are not unaware of their responsibilities to public health.

Any policy that unjustifiably inflates the status of the embryo must be rejected unless it is based on the grounds that there are no good (or immoral) reasons to pursue such research (based on the benefits to agents) – I have maintained that there are no such reasons. Furthermore, one should be careful of insisting upon irrational compromises – specifically, it seems arbitrary to insist on a cut off date after which ES cells cannot be derived as has been argued in the Sixth Framework Programme[28].

However, the EU is not attempting to rule out prohibiting embryo research per se – and this is in line with my argument that such research is necessary. So, perhaps certain restrictions could be placed on Community research that attempts to recognise common goals? This is arguably the intention of the amendments made in the *Liese Report* (2003) which restricted named research activities. The problem with these restrictions is that they again make arbitrary claims about the type of embryo[29], and enforce strict restrictions on state sovereignty (and overstep EU policy influence). The Community could restrict some types of research, but only if based on 'respect', and not based on applying a separate status to either different intentions or 'types' of embryo. The research that is prohibited would have to be that which cannot reasonably be expected (or is necessary) to derive benefit to more likely agents (i.e. medical progress).

---

[28] Indeed, the European Commission (2003b) states that only these embryos are destined to be destroyed! – what about embryos created for fertility after this point?

[29] The amendments failed to recognised that it is highly contestable whether the embryo does come under the meaning of an EU citizen, and certainly, the constraints of the Liese Report imply that the embryo has a status above that granted by many states (see the Opinion of the European Economic and Social Committee 2002 in Appendix Six).

The most important message from the Liese Report was that alternatives, being less controversial than ES cell research, should be specifically promoted (2003 p. 11). However, this fails to recognise that using ES cells may be controversial, but is accepted by most Member States, and therefore, embryo research is, in the majority at least, not condemned per se. I have argued that benefits may be more forthcoming from ES cell research, which includes therapeutic cloning applications (see Zoloth 2001 p. 228), and while some states may prohibit the creation of embryo for research and therapeutic cloning, others do not, or have not (legislatively) blocked such measures indefinitely. Evoking the *Principal of Subsidiarity*, the Liese Report states that it '...is normal practice for Member States to be able to set more stringent standards than those laid down by Community directives' (2003 p. 10), surely then, if the states do wish to ban such research (and arguably it would be more efficient for this to happen at the national level under the *principal of proportionality*), then minimal standards should reflect common goals (such as scientific standards and ethical review), and not the more controversial (and not universally supported) issues.

Therefore I will argue that (1) the EU should encourage minimal standards and; (2) should fund research according to promoting public health (based on minimal standards and according to national and international authority regulation).

6.1. The Majority Position

There is a tendency towards more permissive embryo research within the EU, and therefore, it would be inappropriate for the EU institutions to promote a more restrictive position (as is being attempted)[30]. The Treaties of the EU are designed to drive the Member States towards a common goal, but this is tempered by the *Principle of Subsidiarity* and *Proportionality* (or the Council of Europe's *Margin of Appreciation*). These principles are an attempt to fend off the tendency of Community law to creep into areas reserved for national sovereignty. The essential basis of Community legislative competency is in involving itself in issues that have trans-national aspects and which cannot satisfactorily regulated by the actions of member states. Community action

[30] In addition to those Member States that have permissive legislation, Estonia (Embryo Protection and Artificial Fertilisation Act 1997), Hungary (Act on Health Care 1997), Latvia (Law on Reproductive and Sexual Health 2002), and Slovenia (Law on Medically Assisted Reproduction 1997) permit regulated

should only be preferred to member state action if this will bring demonstrable advantages to the *Community* (see Dashwood 1996 on EU policy). I have argued that there are benefits to harmonised policy, and therefore, that this should follow the majority view.

The message explicit in the above EU/Council of Europe principles is that international policy should only override national sovereignty when either there are benefits to the European Community as a whole, or that the states' actions would not be sufficient in any action[31]. The minority claim by anti-ES cell research groups that the EU should not fund, or even restrict research, should be disregarded. The reason for this is that the funds that the EU has at its disposal are European funds, meaning that member states may not attach conditions to their contributions in an effort to circumvent European decisions (Gruss 2003). Arguing otherwise would go against the present EU position; that it has no direct influence either in internal state issues or the regulation of medicine or research that do not have common market measures in mind (EGE 2000 para 1.14).

6.2. The Minority Position

States that wish to continue or enact more restrictive measures should be aware that they might be denying citizens access to promising therapy. Community law again has no place in dictating the democratic decisions of Member States, even when a minority view is expressed (i.e. not ruling against the restrictive actions of a state) - should therapeutic benefits be forthcoming from ES cell research, there would be no sense in the EU enforcing these benefits upon states. But it may become the case that citizens within prohibitive borders wish access to the medical treatments. This may be dealt with along the lines of the Irish abortion controversy, whereby individuals can procure an abortion ex-state according to the rules of free movement and service provision. Additionally, states could 'label' therapies derived from embryo research (Burton 2003) (would this be made clear in IVF treatment also?).

---

embryo research; only Poland and the Slovak Republic seem to prohibit embryo research (see European Commission 2003a).

[31] The Treaty of the European Union states that the Community does not have legislative competence in the fields of research and medicine, and therefore this implied that protection of the embryo in research

A far deeper concern would be states' 'conscience', and that a state may prohibit research that demonstrate significant public health/medical benefits (Capps 2003). The state would then have to make a discussion whether to allow the benefits or continue the prohibition, and deny citizens access to such research. These citizens would be denied the possibility of benefits because of the restrictive view that a state prescribes to (EFBTG 2001 p. 6). In the case of free movement, the danger is that only well-off citizens may be able to travel to receive possible therapies, so that certain individuals within the EU will be deprived of any medical benefits deriving from this research. An alternative way to look at this is that in allowing liberal research, one would *place* patients into a situation where their welfare would depend upon using therapies developed under possibly immoral or dubious circumstances – the same clearly applies to IVF treatment[32].

Should benefits be forthcoming from ES cell research, would prohibiting citizens from accessing those benefits be a matter of state conscience? If a State legitimately prohibits research (from the position that human beings, regardless of the biological stage of development, cannot be used in any research that is not a benefit to *that* subject), one may be able to in principle draw parallels with the post-War use of research ordered by the Nazi party in Germany in the 1930s and 1940s. In both cases there is an arguable medical benefit to be gained[33]. In the latter case, for some, the use of the documentation after the event cannot be morally justified, or at least is deeply disturbing (Greene 1992; Green 2002). However, should the benefits of SC research be realised, then those countries that at present take a prohibitive position will have to make a conscientious decision as to whether to endorse the benefits from fundamentally reprehensible research. It may be perceived as hypocritical for that State should it decide to take advantage of the beneficial effects of such research.

---

falls within the competence of national legislation (as is the case of medically assisted procreation and voluntary interruption of pregnancy) (EGE 1998 para 2.3).

[32] The main point to realise here is that some immoral acts, such as the Nazi experiments, may have led to modern (and beneficial) medical applications (*infra* fn. 33). But that this differs from the question here because I have argued that embryos, unlike those harmed in the Nazi experiments, do not have the same status, and therefore the act is only immoral if an agent's human rights are harmed; or a marginal agents quasi rights are *unjustifiably* harmed.

[33] In the case of Nazi data see Freeman (1992). If one does not conclude that the US's air and space superiority is a benefit (which was significantly enhanced by the use of Nazi records and scientists in the US), then there are certainly benefits to be found in examples of the use of records in cold-water survival and other medical therapy advances. Particularly in Germany and Austria and subsequent to the War, there existed a corruption to the development of science directly from the Nazi experiments. This was particularly evident in the unwilling association of scientists with genetic and human research (see Capps 2003; Weale 2001).

This is clearly demonstrated in IVF and fertility treatment (which Beyleveld & Pattinson have called 'hypocritical' 2001 p. 69; also see EFBTG 2001 p. 6). While all states allow provision for this treatment, there are some states that prohibit research and the freezing of embryos. This is not only a contradictory position (since IVF was developed through embryo research) but also dangerous (and expensive) to the woman involved, because embryos cannot be frozen, they must be implanted (where they will perish anyway, if they do not cause an ectopic pregnancy). Additionally, embryo research would possibly remove the need in the future for embryo freezing, because it would make the procedure more efficient. It is also argued that embryo research in IVF treatment is needed because of unknown risks in the procedure; arguably, if a nation offers a service, they may have a duty to ensure that it is of the highest safety standards (Connor 2003; Hardy et al. 2002; Henderson 2003)[34].

Prohibitive states may also lose out due to scientific prestige and investment affecting the economic status of states (Beyleveld & Pattinson 2001 p. 69). Permissive states could likewise benefit from this by implementing liberal regulations to attract research that perhaps would not be possible in some permissive states. This is a concern for those new states entering the EU, some of which at present have no regulations at all.

In Chapter Two, I argued that if a framework was morally sound as a supreme principle (s. 2.1) (I have argued that human rights, if they exist, must be interpreted as claim rights, which necessarily limited them to agents), then policies must reflect this, regardless of (national) values or interests (see s. 3.2). This means that states that limit stem cell research entirely on the status of the embryo (i.e. it has human rights), must re-evaluate their restrictive policies, or argue that the status of the embryo resides in vicarious reasoning, and this must presumably be based on the democratic consensus of that state (Chapter Two s. 8.2). On this basis, it would be unjustifiably paternalistic to prohibit both embryo research and free movement of citizens to permissive states (e.g. for potentially life-saving treatment). This reasoning equally applies to EU policy, so as long as the requisite systems of review are present, then there is no justification to enforce a prohibitive stance. Indeed, the purpose of the EU should be to encourage systems of review and not to unjustifiably limit state sovereignty.

---

[34] Tauer (2001) argues that if communities are to practice reproductive technologies, then they have a *responsibility* to ensure that they are proved efficient and that harms are minimised by providing for regulated embryo research.

7. International Competency

The international attitude to embryo research seems to point towards minimal standards, such as those repeatedly detailed here. If these are in place, then it seems that regulation *is* being sufficiently achieved by the member states (because the state is doing what is asked of it). Furthermore, there can be few advantages of prohibiting research *a priori* unless protecting the sentimentality of the minority states is preferable, or the defence of the quasi-rights of the embryo presents an advantage itself, because the embryo deserves such protection (i.e. in the same way that it is an advantage to protect the human rights of born human beings). Briefly turning to abortion, there can be little gained by protecting the embryo in the earliest stages of life, because such abortions are preferable to later ones, and should be implicitly preferred if the unborn has any moral status (where the principle of proportion may come to bear). In the case of embryo research, likewise there can be little to be achieved by having a status that derives full protection unless research is not preferable to the pseudo-status of the embryo. As I have argued here, embryo research does present realistic benefits and a justification does exist that places advantages firmly with the prospect of medical benefits.

But when these offend other member state's interests, does the EU or Council of Europe have a place to act? The Council of Europe can only act in instances of human rights abuses, under the ECHR, and this does not apply to the human embryo. If the ECHRB were to be enforced, then those states that allow the creation of embryos specifically for research would be in breach of Article 18(2).

Action by the EU would be highly contestable, since the envisaged medical benefits may both benefit individuals and the European Community as a whole in progress. Furthermore, under its policy on Public Health, it is highly doubtful whether there is any precedent for the EU to intervene (*Principle of Subsidiarity*). Because of the majority consensus, it would be more damaging to involve the European Courts in enforcing minority opinions (*Principle of Proportionality*). These principles should only be invoked if the Community considers that a harmonised approach is required for effective co-operation and co-ordination; with most states enacting legislation on their own initiative (and this seems to be in line with minimal standards), then there is little to sanction EU action, unless the Community felt that the embryo was being unjustifiably

harmed. The common movements towards permissive legislation seem to suggest that this is not the case[35].

The reason for a harmonised policy is mainly to ensure that whatever regulation there is, is put under public control, rather than allow states to either have very low standards or adopt a *laissez-faire* attitude. Additionally, there are issues of the large amounts of funding available in the EU for research and the nature of international borders, whereby citizens are free to transgress national jurisdictions.

8. An EU Framework: Ethical and Scientific Harmonisation

A harmonised framework must therefore promote public health within the Community, and this can be best served through a generally permissive position. Community regulation should: (1) set *precise* minimal legislative standards of protecting human rights and 'respecting' the embryo; (2) ensure a system that reviews research according to necessity and; (3) ensures public access and accountability for research findings (where appropriate).

This will: (a) protect human rights on points of agreement (it may also be possible to regulate techniques that are not contrary to the PGC but are commonly held to be unacceptable at present; as long as the restrictions themselves do not contravene the precepts of the PGC) and; (b) *promote* the more popular opinion in areas of disagreement. These standards cannot be strictly enforced (or prohibited within the community) unless they are clearly contrary to the primacy of human rights, but measures should be made to minimise, or at least discuss in the public arena, those acts which cause controversy.

For example, embryo research can go ahead under a common human rights framework (as I have defended) but that Community institutions should monitor the effectiveness (as compared with other less contentious sources of research material), prospects and developments, and review the necessity for research on a case by case basis. Furthermore, research findings should be made transparent and accessible to other researchers to minimise the need for further embryo destruction.

---

[35] It is perhaps important to note that if the embryo does come under the proposed Directive, then creation of specific research embryos may indeed be prohibited under Article 18(2) of the ECHRB, which is evoked by the European Economic and Social Committee with regards to human donors (see Appendix Six). (The EESC does not, however, include the human embryo under s. 6.5.2).

One area of significant disparity is 'therapeutic' cloning research. Presently, only the UK permits such research, which is converse to the majority community view. This does not however mean that the UK should be forced to rescind their view, because creating and using embryos for research is not contrary to the PGC as long as the research is scientifically reviewed to be necessary for some agent-centred benefit. The EU may decide that it cannot fund such research; it may prefer to divert expertise and resources to maximising the development of less controversial research. If the research became redundant for good purposes, then the UK would self-impose a prohibition on such research. If the research is evidently beneficial, then the EU can, should it deem necessary, pursue its own research agenda with the use of cloning. However, while the benefits are unclear, it may be prudent to place a moratorium on Community research funding.

8.1. Possible Structure of an European Union Harmonised Policy

It is clear that any harmonisation would be based more on achieving practical benefits, rather than reaching any general theoretical agreement on the status of the embryo. However, due to limited space, the implementation of practical measures can only be briefly mentioned here. European research programmes should concentrate on areas that clearly benefit from European-level collaboration (RS 2000). They should also promote the interests of the Community as a whole, and not attempt to restrict national endeavours unless they contradict fundamental human rights[36].

Because of the plurality within the EU, it is unlikely that a uniform and maximum coverage could be achieved. Instead, policy should concentrate on areas of convergence, such as non-commercialisation of the embryo, limits on the maintenance of in vitro embryonic life, and precise prohibitions covering reproductive cloning, hybrids, chimeras and the like – it should morally promote the highest levels of scientific research standards[37]. The Community should include basic measures of

---

[36] This is evident in the Directive on the *Legal Protection of Biotechnological Inventions* (98/44/EC) which regulated the patenting of research within the Community, but does not comment explicitly on the type of research that can be conducted in each Member state (Busquin 2000).

[37] Clearly, there is great benefit for the Community, if it involves itself with issues of pure science, and this is evident in the proposed Directive, which in it original draft form, only took a stance on promoting these high scientific standards. Arguably, this is not the place to add opinions on moral issues, although this is potentially a considerable future part of this Directive.

regulation and encourage minimal regulation in each state (and this is an important initiative to be sponsored by the Community). There are broad areas of consensus, and these should be emphasised in *international* harmonisation to promote public health (Nielsen 1996; Evans & Evans 1996). Research that satisfies these common standards should be eligible for research funding from the EU (with other caveats; these should be 'low' in the sense of out-rightly prohibiting, and of expressly regulating, a narrow range of practices which are generally acknowledged to be controversial in a sense which is relevant to the public interests; Evans & Evans 1996 p. 214). This leaves individual states free to exceed the threshold or not, should they so choose[38].

For a harmonised framework to operate there is a need to agree on scientific evaluation and reporting. The easiest means of achieving this in the EU would be for a central organisation to assess, store and disseminate scientific findings for research that it funds on an equitable basis. This, like the UK's stem-cell bank, could also be a depository for SCs, allowing access to the biological materials, as well as ethical and scientific review and monitoring. Cell lines should be fully characterised to allow appropriate access to scientists (instead of the situation in the US where cell lines are held back because of a lack of specification and characterisation; Holden & Vogel 2002b; Kennedy 2003). The lines should be standardised so that means of derivation, isolation, and culture can be uniform and comparable (Zerhouni 2003). Training should also be provided to facilitate uniform collection and use of cells that are issued or deposited.

The areas of divergence cannot be dealt with at an international level without imposing upon sovereign interests. While there are clear differences (for example, concerning therapeutic cloning and the creation of research embryos), there are also differences in the research purposes and requisite medical benefits. It would be better

---

[38] Under the Public Health of the *Community Policies* no state is prohibited from '...maintaining or introducing more stringent protective measures' (Title XIII: Public Health; Article 152; *Consolidated Version of the Treaty Establishing the European Community*; Part 3: Community Policies, 4(a)). Evans & Evans argue that harmonisation should be on a permissive, rather than prohibitive approach, so that what is not specifically forbidden it is assumed to be permitted (1996 p. 241). This has the benefit of ensuring that states with permissive policies are not bound by a harmonised EU policy, and which prohibitive states can exceed, should they wish. This has the limitation of not having any remit to prohibit those acts (such as reproductive cloning) that are generally rejected. I would argue that the EU institutions should not have a *laissez-fair* attitude with such acts, and instead should ensure that such acts are flagged as contentious and unjustified, unless they are subject to national oversight (thus ensuring that at a minimum these acts are discussed and appropriately regulated). Essentially, the implicit claim is that if a state is willing to sanction an act that is not covered by the EU policy, then national review and public transparency should be in place to highlight the state's intentions.

for states to regulate such matters themselves, because interference by the Community (with its divergent views) may well confuse the matter.

National and international review is necessary to: (1) ensure that research is in line with national standards; and (2) at the ethical level, agreeable to international standards. The reason for this is that if national regulations are to be set at a minimal level according to Community requirements, then the Community needs to be confident that these standards are met through its own review mechanisms. But also, additional measures may be applied within national borders, and this will require its own review mechanism; furthermore, there may be salient issues specific to national or international agendas, and these should be supervised accordingly. Both levels of review will ensure that cells used in national and international contexts (import and export) are of the highest standard.

One could favour the directing of funds for AS cell research towards those member states opposed to ES research. The problem would be, however, that there might be equally favourable research in AS cells in states that are also amenable to ES research. SC research not only involves important ethical questions regarding the status of the embryo and social questions associated with medical care (public health), but because of its link to embryo research, it also converges with several other areas of public sensitive research, namely those related to reproduction (Cohen 2001 p. 209), cloning and gene therapy.

There are benefits for Community policy, not only in the benefit to public health but also of the special influence international review can offer. If the EU is to fund ES cell research, the review should find it necessary and the most effective form of research, as judged against feasible alternatives. If less contentious alternatives are not forthcoming, the EU should direct funding to spare embryos (most agreed upon) and parthenotes (if they prove useful in this research) before considering creating embryos. Furthermore, there are issues what such research should promote. Clearly, basic science will be the immediate research goal, but after that, rare disorders (which have been traditionally short of industry funding; Bonatta 2002; Saha & Saha 2000; Terry et al. 2001) may be concentrated on (as the EU is not primarily concerned, and may counteract primary funding in moneymaking research). It should also be convinced that there is a realistic and medical benefit in the research.

Conclusion

The discussions regarding harmonisation on a European stem cell research policy have focused on the status of the embryo and the reasons for or against using it in research (both scientific and moral). From these debates, there is the suggestion that because of the lack of conformity in opinions, a compromise policy supporting both views is nigh on impossible to achieve. The question that I have attempted to address here, therefore, is whether it would be unjustifiable to enforce any one particular will, if it could be argued that such measures would benefit the Community policy on public health.

I have argued that there are good reasons to create a harmonised stem cell research environment in the EU; and furthermore, that harmonisation should take an overall permissive stance in allowing embryo research for this purpose. However, because of the plurality of opinions in the EU, a *compromise* position should be assumed. This is in line with the *gradualist* position (although I do not comment here on later foetal development), rather than the other positions of 'pro-life' (because the embryo does *not* deserve full rights at the 6th day of development); or 'pro-choice' (because there should be minimal restrictions and not a limitless choice).

The overriding principle is that if research is directed towards realistic benefits and is necessary (on a needs-calculus analysis), then the precautionary status of the embryo can be overridden. The balance is achieved by: (1) measures that 'respect' the embryo; (2) promoting minimal legislative standards in Member States and; (3) directing funds towards only those research protocols that are agreed upon by the majority. This does not mean that member states cannot go beyond these minimal standards or that certain acts should *a priori* be prohibited.

Harmonisation should ensure that a common moral consensus (norms) is attained (i.e. human rights). But, this would mean that human rights, as defined here, *cannot* apply to the human embryo (which would impact upon abortion legislation). Furthermore, as a practical measure, precise terminology (learning from other attempts to legislate in this field) should be used in future legislation, to avoid the already evident loopholes. This should all be directed at providing minimal standards that provide a regulatory environment within the Community for progress in public health through therapeutic stem cell applications.

The difficult case is the creation of an embryo (by any means) specifically for research, which, although not a research practice that is universally condoned, is supported in the minority. This act attracts widespread condemnation, but I have argued that it does not violate the status of the embryo. Furthermore, this research may benefit ES cell research progress.

I have argued that prohibitions that are based on a rejection of certain types of research given the status of the embryo have no philosophical basis. So should these acts be banned on the basis of 'respect'? This should consist of the elements of respect that ensures that human embryos have a status above that of mere tissue (which the precautionary status demands). But again, banning research on this ground when there are benefits to be gleaned therefrom would erroneously inflate the precautionary principle. If the EU takes its role seriously, it cannot enforce restrictions that are not within its competence (and therefore should invoke the *principle of subsidiarity*).

The easiest means of dealing with this discrepancy in creating minimal standards and acknowledging prohibitive positions, is to appreciate (indeed demand as part of the minimal standards) that states have their own means of ethically judging such research and the criteria detailed in this thesis. Accordingly, the principle of subsidiary/margin of appreciation should allow such states to proceed. This would be a key role of the EU policy – to promote such review mechanisms (which would be in line with the principle of proportionality, which provides that states are better placed to regulate national legislation in controversial areas). Indeed, it is clear that where such research does occur, extensive ethical discussions have taken place within that state. Furthermore, the EU should then take measures that are within its field of competence, namely within its duty to promote public health. In light of this, the EU should fund research that accords with the majority view (accepting that embryo research is not to be rejected per se) and therefore should introduce a regulatory authority to oversee funding and monitor progress, in order to assess the necessity for research.

Conclusion

The debate on embryo research is vital to the discussions regarding harmonisation of European policies in stem cell research given: (1) the benefits that may derive from stem cell research; (2) questions regarding the necessity use of embryos in research and; (3) the status of the human embryo and its relation to other agents. In Chapter One I argued for a 'dual track' approach to both ES and AS cell research. This has given rise to the suggestion that even if a harmonised policy is necessary for the promotion of public health in the Community (as I argued in Chapter Five), it would either be too difficult to achieve, or would unjustifiably infringe upon Member State sovereignty. Such opposition is guided by the two most prominent positions, anti- and pro- embryo research, which are central to the acceptance of the benefits of this research in any particular member state.

I have argued to the contrary, from the premise that the EU derives moral norms from human rights, which are expressed in national and international law. From this premise, I argued that human rights are in fact claim rights, and the nature of claim rights, as rights protecting the important needs of agents, means that they can only properly be held, and held equally and to the fullest extent, by human agents. This thesis does not claim that there is a common morality that should be accepted by all; instead, I claim that there is a rational account of human rights and human agency, which should be accepted given the indisputable adherence to the notion of human rights in Community law and policy. This fundamental reliance should lead the Community to resolve its differences, and as a whole to guide its actions, specifically with regard to the human embryo, in line with the PGC. Again, this is not based on a consensus view, although it does follow from a rational understanding of human rights. Therefore, in Part One of Chapter Four, I argued that the EU's legal resolutions with regards to the issue of abortion could be interpreted as supporting the precepts of the PGC. This meant that non-agents could not be considered the claimants of human rights, and accordingly I rejected the argument that 'dignity' (properly understood as an agent-centred value) could protect the embryo, because it should be understood as a value only applicable to agents.

Therefore, the human embryo, lacking the necessary and sufficient capacities of agency, could not have human rights and could be used in destructive research, despite

arguments emphasising its value as a *human being* or a *potential* agent. However, such research should be restrained in two ways (discussed in Chapter Three). Firstly, the human embryo should be considered as a (precautionary) marginal agent, because its agency cannot be ruled out entirely based on ontological evidence; and this may be a form of 'dignity' specific to human beings because of their tendency (as a species) for (potentially) acquiring the capacities of agency. Thus, policies that may place the human embryo in the way of harm must include a needs-benefit calculus based solely on its intrinsic status. The needs-benefits calculus is based on the proposed benefits to actual agents, but progress to this goal cannot be permitted to proceed unchecked; accordingly, thought should be given to the necessity for, and alternatives to controversial research. Secondly, unimpeded research would likely infringe upon others' sentimentalities, and therefore 'respect' may function to curb certain actions – researchers would not be permitted to do as they wish, but would be subject to the same review mechanisms as for the embryo's precautionary status. As such, it is permissible to pursue research that is necessary and that cannot be achieved by any comparable alternative.

Clearly, opposition will persist from anti-embryo research groups as to the use of human embryos in research in stem cell research, even if there are good reasons for using them and there is no available alternative (or less likely agent, on which research could be conducted). However, I argued that this is a minority view, at least as expressed within the policies of Member States (in Chapter Four), and therefore the progress of research should be permitted (or at least not prohibited by Community measures since this would be overly paternalistic). Furthermore, a fully centralised regulatory framework would be too restrictive in prohibiting certain state-sanctioned activities (namely therapeutic cloning and creating chimeras), and therefore minimal measures would bring certain Community-wide benefits while not overstepping the legislative competence of the EU. Significantly, this would not prevent those states that wish to from implementing more restrictive measures, as long as those states realised that free movement of citizens within the Community might allow them to procure the potentially beneficial therapies from more liberal states. Moreover, generally supported aspects of embryonic stem cell research should have Community backing in pursuance of (beneficial) public health goals.

Those acts that are not acceptable (to a majority) in an EU policy (such as therapeutic cloning and chimera research), should not be prohibited out of hand.

Instead, the EU should ensure that such matters are publicly disclosed and discussed; and therefore should a state wish to promote such research, it should proceed according to democratic consensus (and at least public regulatory oversight).

There are, it was argued, three pivotal and practical roles for the institutions of the EU that would assist in the provision of public health and future legislative discussions (Chapter Five). Firstly, the Community *should allocate funding* for embryo research and stem cell projects that will benefit the Community and its role in promoting public health measures. This would require, secondly, *minimal standards* to be enforced (or at least encouraged) in Member States (and those states joining) so that trans-national activities can be overseen (such as import and export) and research can be assessed and funds allocated to accord with generally accepted practices. Finally, *ethical review* would be necessary at a national and international level to ensure compliance with state and Community law, and to provide the means to assess the necessity for and alternative means of undertaking such research.

Although there are other issues worthy of investigation, instead I have concentrated on *primary* issues regarding stem cell research, where the predominant debate in the EU concerns the status of the embryo. This thesis offers a framework that grounds an ethical, harmonised Community policy on embryo research; however, further work is necessary in order to address *secondary* issues that will affect the Community, such as patents and possible exploitation of vulnerable populations. These may be solvable through incorporating issues of concern into the framework that I have argued for here, but the precise nature of the theoretic and practical implications of this proposal will require further work.

Bibliography

Abbott, A. 2003. Czech Stem-Cell Work Tightens Calls for EU ruling. *Nature* 424: 602.

Abkowitz, J.L. 2002. Can Human Hematopoietic Stem Cells Become Skin, Gut, or Liver Cells? *New England Journal of Medicine* 346: 770-772.

Albritton, R. 1964. Mere Robots and Others: Comments. *Journal of Philosophy* 61: 691-694.

Advisory Committee on Ethics of Scientific and Technical Research (ACE). 2003. *Report: Stem Cell Research*. Ministry of Science and Technology/ State Office for Scientific and Technological Policy; Madrid: Spain.

Alder, E.M., Baird, D.T., Lees, M.M., Lincoln, D.W., Loudon, N.B. and Templeton, A.A. 1986. Attitudes of Woman of Reproductive Age to *In Vitro* Fertilization and Embryo Research. *Journal of Biosocial Science* 18: 155-167.

Alexy, R. 2002. *A Theory of Constitutional Rights,* Oxford: Oxford University Press.

Alison, M.R., Poulsom, R., Forbes, S. and Wright, N.A. 2002. An Introduction to Stem Cells. *Journal of Pathology* 197: 419-423.

Alison, M.R., Poulsom, R., Jeffery, R., Dhillon, A.P., Quaglia, A., Jacon, J., Novelli, M., Prentice, G., Williamson, J. and Wright, N.A. 2000. Hepatocytes from Non-Hepatic Adult Stem Cells. *Nature* 406: 257-257.

Alison, M.R., Poulsom, R., Otto, W.R., Vig, P., Brittan, M., Direkze, N.C., Preston, S.L. and Wright, N.A. 2003. Plastic Adult Stem Cells: Will they Graduate from the School of Hard Knocks? *Journal of Cell Science* 116: 599-603.

Allen, C. 1998. The Discovery of Animal Consciousness: An Optimistic Assessment. *Journal of Agriculture and Environmental Ethics* 10: 217-225.

Almeida-Porada, G., Porada, C. and Zanjani, E.D. 2001. Adult Stem Cell Plasticity and Methods of Detection. *Review of Clinical and Experimental Hematology* 5: 26-40.

Alnajjar, G. 2001. Human Rights in Crisis Situations: The Case of Kuwait after Occupation. *Human Rights Quarterly* 23: 188-209.

Alvarez-Dolando, M., Pardal, R., Garcia-Verdugo, J.M., Fike, J.R., Lee, H.O., Pfeffer, K., Lois, C., Morrison, S.J. and Alvarez-Buylla, A. 2003. Fusion of Bone-Marrow-Derived Cells with Purkinje Neurons, Cardiomyocytes and Hepatocytes. *Nature*

Advanced Online Publication, published online 12 October 2003; doi:10.1038/nature02069.

Amit, M., Carpenter, M.K., Inokuma, M.S., Chiu, C.P., Harris, C.P., Waknitz, M.A., Itskovitz-Eldor, J. and Thomson, J.A. 2000. Clonally Derived Human Embryonic Stem Cell Lines Maintain Pluripotency and Proliferative Potential for Prolonged Periods of Culture. *Developmental Biology* 227: 271-278.

Anderson, D.J., Gage, F.H. and Weissman, I.L. 2001. Can Stem Cells Cross Lineage Boundaries? *Nature Medicine* 7: 393-395.

Annas, G.J. 1999. Waste and Longing - The Legal Status of Placental-Blood Banking. *New England Journal of Medicine* 340: 1521-1524.

Annas, G.J. 2000. Ulysses and the Fate of Frozen Embryos- Reproduction, Research, or Destruction . *Legal Issues in Medicine* 343: 373-376.

Antoniou, M. 2001. Embryonic Stem Cell Research: The Case Against... *Nature Medicine* 7: 397-399.

Aristotle. 1998. *The Nicomachean Ethics*, Oxford: Oxford University Press.

Ashford, N.A., Barret, K., Bernstein, A., Costanza, R., Costner, P., Cranor, C., deFur, P., Geiser, K, Jordan, A. King, A. Kirschenmann, F. Lester, S. Maret, S. M'Gonigle, M. Montague, P. Myers, J. P. Jones, A. O'Brien, M. Ozonoff, D. Regal, P. Resor, P. Robinson, F. Schettler, T. Smith, T. Sperling, K. Steingraber, S. Takvorian, D. Tickner, J. Moltke, K. Wahlstrom, B. and Warledo, J. 1998. *Wingspread Statement on the Precautionary Principle.* Available at: http://www.gdrc.org/u-gov/precaution-3.html (accessed: September 2003)

Austin, C.R. 1989. *Human Embryos*, Oxford: Oxford University Press.

Austrian Bioethics Commission (ABC). 2003. *Interim Report on so-called Reproductive Cloning with Regard to a Detailed Opinion on the Application of Human Cloning, Embryo Protection and Embryo Research, Preimplantation Diagnosis as well as Additional Issues Concerning Reproductive Medicine.* Decision of the Bioethics Commission at the Federal Chancellery of 12 February. Vienna: Austria.

Austrian Bioethics Commission (ABC). 2002. *Opinion of the Bioethics Commission on the Issues of Stem Cell research in the Context of the EU's Sixth Framework Programme for Research, Technological Development and Demonstration Activities as a*

Contribution towards the Realization of the European Research Area. Decision of the Bioethics Commission at the Federal Chancellery of 3 April and 8 May. Vienna: Austria.

Baden, S. 1992. *The Position of Women in Islamic Countries: Possibilities, Constraints and Strategies for Change*. Bridge: Development - Gender: Report Prepared for the Special Programme WID, Netherlands Ministry for Foreign Affairs: Report No. 4. Institute of Development Studies, Brighton: United Kingdom.

Bagheri, M.M., Burd, L., Martsolf, J.T. and Klug, M. 1998. Fetal Alcohol Syndrome: Maternal and Neonatal Characteristics. *Journal of Perinatal Medicine* G.26: 263-269.

Bain, G., Kitchens, D., Yao, M., Huettner, J.E. and Gottlieb, D.I. 1995. Embryonic Stem Cells Express Neuronal Properties *In Vitro*. *Developmental Biology* 168: 342-357.

Barberi, T., Klivenyi, P., Calingasan, N.Y., Lee, H., Kawamata, H., Loonam, K., Perrier, A.L., Bruses, J., Rubio, M.E., Topf, N., Tabar, V., Harrison, N.L., Beal, M.F., Moore, M.A.S. and Studer, L. 2003. Neural Subtype Specification of Fertilization and Nuclear Transfer Embryonic Stem Cells and Application in Parkinsonian Mice. *Nature Biotechnology (Online)* 21: September.

Baschetti, R. 2001. Use of Stem Cells in Creation of Embryos. *Lancet* 358: 2078.

Baumgartner, F. 2002. Human Embryos: Potential Humans? *Science* 296: 1967.

Baylis, F. 2001. Human Embryonic Stem Cell Research: Comments on the NBAC Report. In: Holland, S., Lebacqz, K. and Zoloth, L., (Eds.) *The Human Embryonic Stem Cell Debate: Science, Ethics and Public Policy*. Cambridge, Massachusetts: Massachusetts Institute of Technology. pp. 51-60.

BBC News Online. 2001. Tissue Transplant Advance. 23 February.

BBC News Online. 2002. GM Cells Help Fight Cancer. 28 October.

BBC News Online. 2003a. MEPs Vote to Ban Stem Cell Research. 10 April.

BBC News Online. 2003b Mouse Cloned to Cure Parkinson's. 21 September.

Beasley, S. 1996. Contraception and the Moral Status of the Early Human Embryo. In: Evans, D., (Ed.) *Conceiving the Embryo: Ethics, Law and Practice in Human Embryology*, The Hague, The Netherlands: Kluwer law International. pp. 89-118.

Bedau, H.A. 2000. 'Anarchical Fallacies': Bentham's Attack on Human Rights. *Human Rights Quarterly* 22: 261-279.

Bekoff, M. .1998. Deep Ethology, Animal Rights, and the Great Ape/Animal Project: Resisting Speciesism and Expanding the Community of Equals. *Journal of Agricultural and Environmental Ethics* 10: 269-296.

Benatar, D. and Benatar, M. 2001. A Pain in the Fetus: Towards Ending Confusion About Fetal Pain. *Bioethics* 15: 57-76.

Ben-Zeev, A. 1982. Who is a Rational Agent? *Canadian Journal of Philosophy* 12: 647-661.

Benn, S.I. and Peters, R.S. 1959. *Social Principles and the Democratic State*, London: HarperCollins Publishers.

Bentham, J. 1996. *An Introduction to the Principles of Morals and Legislation*, Oxford: Clarendon Press.

Bentham, J. 2002. Nonsense Upon Stilts, or Pandora's Box Opened, or The French Declaration of Rights Prefixed to the Constitution of 1791 Laid Open and Exposed - With a Comparative Sketch of What has been done on the same Subject in the Constitution of 1795, and a Sample of Citizen Sieyès. In: Schofield, P., Pease-Watkin, C. and Blamires, C., (Eds.) *The Collected Works of Jeremy Bentham: Rights, Representation, and Reform - Nonsense Upon Stilts and Other Writings on the French Revolution*, Oxford: Clarendon Press. pp. 318-401.

Bernat, J.L. 2002. Questions Remaining about the Minimally Conscious State. *Neurology* 58: 337-338.

Beyleveld, D. 1991. *The Dialectical Necessity of Morality: An Analysis and Defence of Alan Gewirth's Argument to the Principle of Generic Consistency*, Chicago: Chicago University Press.

Beyleveld, D. 1995. The Concept of a Human Right and Incorporation of the European Convention on Human Rights. *Public Law* Winter: 577-598.

Beyleveld, D. 1996. Legal Theory and Dialectically Contingent Justifications for the Principle of Generic Consistency. *Ratio Juris* 9: 15-41.

Beyleveld, D. 1998a. The Moral and Legal Status of the Human Embryo. In: Hildt, E. and Mieth, D., (Eds.) *In Vitro Fertilisation in the 1990s: Towards a Medical, Social and Ethical Evaluation*, Ashgate: Aldershot. pp. 247-260.

Beyleveld, D. 1998b. Some Observations on Human Dignity and Human Rights. In: Hildt, E. and Mieth, D., (Eds.) *In Vitro Fertilisation in the 1990s: Towards a Medical, Social and Ethical Evaluation*, Aldershot: Ashgate. pp. 335-337.

Beyleveld, D. 2000a. Is Embryo Research and Preimplantation Genetic Diagnosis Ethical? *Forensic Science International* 113: 461-475.

Beyleveld, D. 2000b. The Moral Status of the Human Embryo and Foetus. In: Haker, H. and Beyleveld, D., (Eds.) *The Ethics of Human Procreation*, Aldershot: Ashgate. pp. 59-85.

Beyleveld, D. 2002. A Reply to Marcus G. Singer on Gewirth, Beyleveld and Dialectical Necessity. *Ratio Juris* 15: 458-473.

Beyleveld, D. and Brownsword, R. 1994. *Law as a Moral Judgement*, Sheffield, England: Sheffield Academic Press.

Beyleveld, D. and Brownsword, R. 2000. Legal Argumentation in Biolaw. In: Kemp, P., Rendtorff, J. and Johansen, N.M., (Eds.) *Bioethics and Biolaw: Volume I: Judgement of Life*, Copenhagen: Rhodos International Science and Art Publishers and Centre for Ethics in Law. pp. 179-217.

Beyleveld, D. and Brownsword, R. 2001. *Human Dignity in Bioethics and Biolaw.* Oxford: Oxford University Press.

Beyleveld, D. and Pattinson, S. 2000. Precautionary Reason as a Link to Moral Action. In: Boylan, M., (Ed.) *Medical Ethics*, Upper Saddle River, New Jersey: Prentice-Hall. pp. 39-53.

Beyleveld, D. and Pattinson, S.D. 2001. Embryo Research in the UK: Is Harmonisation in the EU Needed or Possible. In: Friele, M. B. (ed.); *Embryo Experimentationin Europe: Bio-medical, Legal, and Philosophical Aspects. Bad Neuenahr- Ahrweiler GmbH: Europäische Akademia zur Erforschung von Folgen wissenschaftlich-technischer Entwicklugen:* Gray Series. pp. 58-74.

Beyrer, C. and Kass, N.E. 2002. Human Rights, Politics, and Reviews of Research Ethics. *Lancet* 360: 246-251.

Bhattacharya, N., Bandopadhyay, T., Bhattacharya, M. and Bhattacharya, S. 2001. Do not Discard 99.99% of Human Placental Umbilical Cord Blood for the Sake of Stem Cells Only. *BMJ Electronic Responses,* 6 October.

Bhattacharya, S. 2003a. World's First Cloned Horse is Born. *NewScientist.com:* 6 August.

Bhattacharya, S. 2003b. Stem Cell 'Immortality' Gene Found. *Cell* 113: 643.

Bianco, P. and Robey, P.G. 2001. Stem Cells in Tissue Engineering. *Nature* 414: 118-121.

Bionews 2003. Restrictive Laws in Europe are Harming Patients. *Bionews:* 215, at: http://www.BioNews.org.uk. 30 July.

Bishop, A.E., Buttery, L.D. and Polak, J.M. 2002. Embryonic Stem Cells. *Journal of Pathology* 197: 424-429.

Björklund, A. and Lindvall, O. 2000. Cell Replacement Therapies for Central Nervous System Disorders. *Nature Neuroscience* 3: 537-544.

Björklund, L.M., Sanchez-Pernaute, R., Chung, S., Andersson, T., Chen, I.Y., McNaught, K.S., Brownell, A.L., Jenkins, B.G., Wahlestedt, C., Kim, K.S. and Isacson, O. 2002. Embryonic Stem Cells Develop into Functional Dopaminergic Neurones after Transplantation in a Parkinson Rat Model. *Proceedings of the National Academy of Sciences* 99: 2344-2349.

Bjornson, C.R.R., Rietze, R.L., Reynolds, B.A., Magli, M.C. and Vescovi, A.L. 1999. Turning Brain into Blood: A Hematopoietic Fate Adopted by Adult Neural Stem Cells *In Vivo*. *Science* 283: 534-537.

Blau, H.M., Brazelton, T.R. and Weimann, J.M. 2001. The Evolving Concept of a Stem Cell: Entity or Function. *Cell* 105: 829-841.

Boden, M.A. 1990. Escaping from the Chinese Room. In: Boden, M.A., (Ed.) *The Philosophy of Artificial Intelligence*, Oxford: Oxford University Press. pp. 89-104.

Bond, E.J. 1980. Gewirth on Reason and Morality. *Metaphilosophy* 11: 36-53.

Bonner-Weir, S. and Sharma, A. 2002. Pancreatic Stem Cells. *Journal of Pathology* 197: 519-526.

Bonnet, D. 2002. Haematopoietic Stem Cells. *Journal of Pathology* 197: 430-440.

Bosch, X. 2002a. European Bodies Reach an Uneasy Truce on Embryonic Stem Cell Research. *Lancet* 360: 1080.

Bosch, X. 2002b. European Parliament Debate on Human Cloning Collapses. *Lancet* 358: 1974.

Bosch, X. 2003a. Spain to Allow Human Embryo Research. *The Scientist* July 31, at: www.the-scientist.com.

Bosch, X. 2003b. Brain Drain Robbing Europe of its Brightest Young Scientists: Money and Independence Lure Young Researchers to the USA, Scientists Say. *Lancet* 361: 2210-2211.

Bosch, X. 2003c. Spanish Government Approves Frozen Embryo Research. *Lancet* 362: 1385.

Bousingen, D.D.d. 2001. France Cautiously Proposes Research on Embryos. *Lancet* 357: 2114

Boylan, M. 1999a. Introduction. In: Boylan, M., (Ed.) *Gewirth: Critical Essays on Action, Rationality, and Community*, Lanham, Maryland: Rowman & Littlefield Publishers, Inc. pp. 1-11.

Boylan, M. 1999b. Choosing as Ethical Theory. In: Boylan, M., (Ed.) *Gewirth: Critical Essays on Action, Rationality, and Community*, Lanham, Maryland: Rowman & Littlefields Publishers, Inc. pp. 75-90.

Brazelton, T.R., Rossi, F.M.V., Keshet, G.I. and Blue, H.M. 2000. From Marrow to Brain: Expression of Neuronal Phenotypes in Adult Mice. *Science* 290: 1775-1779.

Brazier, M. 2003. *Medicine, Patients and the Law*, 3rd edn. London: Penguin Books.

Brittan, M. and Wright, N.A. 2002. Gastrointestinal Stem Cells. *Journal of Pathology* 197: 492-509.

Britten, R.J. 2002. Divergence Between Samples of Chimpanzee and Human DNA Sequences is 5%, Counting Indels. *Proceedings of the National Academy of Sciences* 99:13633-13635.

Brivanlou, A.H., Gage, F.H., Jaenisch, R., Jessell, T., Melton, D. and Rossant, J. 2003. Setting Standards for Human Embryonic Stem Cells. *Science* 300: 913-916.

Brown, M. 2002. Abortion and the Value of the Future - A Reply to: a Defence of the Potential Future of Value Theory. *Journal of Medical Ethics* 28: 202

Brown, M.T. 2000. The Morality of Abortion and the Deprivation of Futures. *Journal of Medical Ethics* 26: 103-107.

Brownsword, R. 2002. Stem Cells, Superman, and the Report of the Select Committee. *Modern Law Review* 65: 568-587.

Brownsword, R. 2003. Bioethics Today, Bioethics Tomorrow: Stem Cell Research and the 'Dignitarian Alliance'. *Notre Dame Journal of Law, Ethics and Public Policy* 17: 15-51.

Bruce, Donald M. 2002. Stem Cells, Embryos and Cloning: Unravelling the Ethics of a Knotty Debate. *Journal of Molecular Biology* 319: 917-925.

Brustle, O., Spiro, A.C., Karram, K., Choudhary, K., Okabe, S. and McKay, R.D. 1997. *In Vitro*-Generated Neural Precursors Participate in Mammalian Brain Development. *Proceedings of the National Academy of Sciences* 94: 14809-14814.

Brustle, O., Jones, K.N., Learish, R.D., Karram, K., Choudhary, K., Wiestler, O.D., Duncan, I.D. and McKay, R.D. 1999. Embryonic Stem Cell-Derived Glial Precursors: A Source of Myelinating Transplants. *Science* 285: 754-756.

Buckingham, M. 2000. A Cellular Cornucopia. *Nature* 408: 773.

Buckle, S. 1988. Arguing from Potential. *Bioethics* 2: 227-253.

Buckle, S. 1990. Biological Processes and Moral Events. In: Singer, P., Kuhse, H., Buckle, S., Dawson, K. and Kasimba, P., (Eds.) *Embryo Experimentation*, Cambridge: Cambridge University Press. pp. 90-108.

Burgermeister, J. 2003. Stem Cell Stand-off in Germany. *The Scientist* September 26, at: www.the-scientist.com.

Burley, J. 1999. The Ethics of Therapeutic and Reproductive Human Cloning. *Cell and Developmental Biology* 10: 287-294.

Burton, B. 2003. Australia Opts to Label Drugs Developed through Stem Cell Research. *BMJ* 327: 700-701.

Busquin, P. 2000. Joint Answer to Written Question P-2852/00 and P-2931/00. *Official Journal of the European Communities* C 136E/ 111-112.

Butler, D. 2000. France Opens Door to use of Embryos in Stem-Cell Research. *Nature* 408: 629.

Butterfill, S. 2001. Two Kinds of Purposive Action. *European Journal of Philosophy* 9: 141-165.

Byrne, E. and Howells, D.W. 2003. Stem Cell Therapies: a Tale of Caution. *Medical Journal of Australia* 179:164-166.

Byrne, J.A., Simonsson, S. and Gurdon, J.B. 2002. From Intestine to Muscle: Nuclear Reprogramming through Defective Cloned Embryos. *Proceedings of the National Academy of Sciences* 99:6059-6063.

Callahan, D. 1995. The Puzzle of Profound Respect. *Hastings Centre Report* 25: 39-41.

Campbell, A.V. 2000. Dignity of the Human Person in Relation to Biomedical Problems. In: Kemp, P., Rendtorff, J. and Johansen, N.M., (Eds.) *Bioethics and Biolaw: Volume Two: Four Ethical Principles*, Copenhagen: Rhodos International Science and Art Publishers & Centre for Ethics and Law. pp. 103-111.

Campbell, C.S. 2001. Source or Resource? Human Embryo Research as an Ethical Issue. In: Lauritzen, P., (Ed.) Cloning *and the Future of Human Embryo Research*, Oxford: Oxford University Press. pp. 34-49.

Campbell, T., Ewing, K.D. and Tomlins, A. 2001. *Sceptical Essays on Human Rights*. Oxford: Oxford University Press.

Cantalupo, C. and Hopkins, W.D. 2001. Asymmetric Broca's Area in Great Apes. *Nature* 414: 505.

Caplan, A.L. 1992. *When Medicine Went Mad: Bioethics and the Holocaust*, Totowa, New Jersey: Humana Press.

Capps, B. 2003. The European Union and Stem Cell Research: A Turnaround on Policy Regarding Human Embryo Research? *Legal Ethics* 5: 18-26.

Capps, P. 2001. The Kantian Project in Modern International Legal Theory. *European Journal of International Law* 15: 1003-1025.

Carruthers, P. 1989. Brute Experience. *Journal of Philosophy*. 86: 258-269.

Carter, W.R. 1982. Do Zygotes become People. *Mind* 91: 77-95.

Cassese, A. 2001. *International Law*, Oxford: Oxford University Press.

Cassidy, R. and Frisén, J. 2002. Embryonic Stem Cells: Taming the Fountain of Youth. *Current Biology* 12: R705-R706.

Castro, R.F., Jackson, K.A., Goodell, M.A., Robertson, C.S., Liu, H. and Shine, H.D. 2002. Failure of Bone Marrow Cells to Transdifferentiate into Neural Cells *In Vivo*. *Science* 297: 1299-1299.

Castro, R.F., Jackson, K.A., Goodell, M.A., Robertson, C.S., Liu, H. and Shine, H.D. 2003. Response to Comment on 'Failure of Bone Marrow Cells to Transdifferentiate into Neural Cells *In Vivo*'. *Science* 299: 1184-1184.

Cavalieri, P. 1998. Human Rights and the Nonhuman Great Apes. *Etica & Animali* 9: 1-10.

Cervantes, R.B., Stringer, J.R., Shao, C., Tischfield, J.A. and Stambrook, P.J. 2002. Embryonic Stem Cells and Somatic Cells Differ in Mutation Frequency and Type. *Proceedings of the National Academy of Sciences* 99: 3586-3590.

Chambers, I., Colby, D., Robertson, M., Nichols, J., Lee, S., Tweedie, S. and Smith, A. 2003. Functional Expression Cloning of Nanog: a Pluripotency Sustaining Factor in Embryonic Stem Cells. *Cell* 113: 643-655.

Charo, R.A. 2001. Every Cell is Sacred: Logical Consequences of the Argument from Potential in the Age of Cloning. In: Lauritzen, P., (Ed.) *Cloning and the Future of Human Embryo Research*, Oxford: Oxford University Press. pp. 82-89.

Check, E. 2002. Cloning agenda 'skewed' by media frenzy. *Nature* 415: 722

Chen, Y., He, Z.X., Liu, A., Wang, K., Mao, W.W., Chu, J.X., Lu, Y., Fang, Z.F., Shi, Y.T., Yang, Q.Z., Chen, D.Y., Wang, M.K., Li, J.S., Huang, S.L., Kong, X.Y., Shi, Y.Z., Wang, Z.Q., Xia, J.H., Long, Z.G., Xue, Z.G., Ding, W.X. and Sheng, H.Z. 2003. Embryonic Stem Cells Generated by Nuclear Transfusion of Human Somatic Nuclei into Rabbit Oocytes. *Cell Research* 13: 251-263.

Chu, V.T. and Gage, F.H. 2001. Chipping Away at Stem Cells. *Proceedings of the National Academy of Sciences* 98: 7652-7653.

Ciba Foundation. 1986. *Human Embryo Research: Yes or No?* London, New York: Tavistock Publications.

Cibelli, J.B., Grant, K.A., Chapman, K.B., Cunniff, K., Worst, T., Green, H.L., Walker, S.J., Gutin, P.H., Vilner, L., Tabar, V., Dominko, T., Kane, J., Wettstein, P.J., Lanza, R.P., Studer, L., Vrana, K.E. and West, M.D. 2002. Parthenogenetic Stem Cells in Nonhuman Primates. *Science* 295: 819.

Cibelli, J.B., Kiessling, A.A., Cunniff, K., Richards, C., Lanza, R.P. and West, M.D. 2001. Somatic Cell Nuclear Transfer in Humans: Pronuclear and Early Embryonic Development. *e-Biomed: The Journal of Regenerative Medicine* 2: 25-31.

Clarke, D. and Frisen, J. 2001. Differentiation Potential of Adult Stem Cells. *Current Opinion in Genetics and Development* 11: 575-580.

Clarke, D.L., Johansson, C.B., Wilbertz, J., Veress, B., Nilsson, E., Karlstøm, H., Lendahl, U., Frisén, J. 2000. Generalized Potential of Adult Neural Stem Cells. *Science* 288:1660-1663.

Clarke, H. 2003. Italy Approves Controvercial Legislation on fertility Treatment. *Lancet* 362: 2076.

Clarke, T. 2003. Eggs Made from Embryos. *Nature Science Update,* 2nd May.

Coalition of Americans for Research Ethics (CARE). 2001. *Stem Cell Report: Advances in Alternatives to Embryonic Stem Cell Research*. At: www.stemcellresearch.org (accessed: February 2002).

Coghlan, A. and Young, E. 2001. Quick Change: Adult Skin Cells are Turned into Heart Cells without Creating Embryos, Claim Scientists. *New Scientist Online News* 23 February.

Coghlan, A. 2003. Adult Stem Cells Tackle Multiple Sclerosis. *NewScientist.com* 16 April.

Cohen, C.B. 2000. Use of 'Excess' Human Embryos for Stem Cell Research: Protecting Women's Rights and Health. *Women's Health Issues* 10: 121-126.

Cohen, C.B. 2001. Leaps and Boundaries: Expanding Oversight of Human Stem Cell Research. In: Holland, S., Lebacqz, K. and Zoloth, L., (Eds.) *The Human Embryonic Stem Cell Debate: Science, Ethics, and Public Policy*, Cambridge, Massachusetts: Massachusetts Institute of Technology. pp. 209-222.

Cohen, C.B. 2003. Creating Human-Nonhuman Chimeras: Of Mice and Men. *American Journal of Bioethics* 3: 3-5.

Cohen, P. 2002. Cloners Create World's First Copy-Cat. *NewScientist.com* 15 February.

Cohen, P. 2003. Human Reproductive Cloning 'Currently Impossible'. *NewScientist.com* 10 April.

Cohen, P. and Carrington, D. 2003. Baby Doctor Reveals Cloned Human Embryo. *NewScientist.com* 9 April.

Colman, A. and Kind, A. 2000. Therapeutic Cloning: Concepts and Practicalities. *Trends in Biotechnology* 18: 192-153.

Committee on Gene Technology (ad hoc.) (CGT). 2002. *Fremtidens bioteknologier – muligheder og risici.* Ministry of the Interior and Health. Copenhagen, 24 October.

Committee on Genetic Integrity (SCGI). 2003. *Summary of the Committee on Genetic Integrity Report Concerning Embryonic Stem Cell Research.* Ministry of Health and Social Affairs SOU 2002: 119. Stockholm, 29 January.

Connor, S. 2003. British Association Conference: Winston Warns of Risk to Test-Tube Babies in Later Life; Expert Calls for More IVF Studies, While Doctors will Investigate. *The Independent* September 11.

Coors, M.E. 2002. Therapeutic Cloning: From Consequences to Contradiction. *Journal of Medicine and Philosophy* 27: 297-317.

Council of Europe (CE). 1998. *Medically Assisted Procreation and the Protection of the Human Embryo: Comparative Study of the Situation in 39 States/ Cloning: Comparative Study on the Situation in 44 States.* CDBI/INF (98) 8; Strasbourg, 4 June.

Council of the European Union (CEU). 2003. *Proposal for a Council Decision Amending Decision 2002/834/EC on the Specific Programme for Research, Technological Development and Demonstration: 'Integrating and Strengthening the European Research Area' (2002-2006) ('Bioethics / Stem Cell research').* RECH 138 (2003/0151 (CNS); Brussels, 15 September.

Crosby, J.F. 1993. The Personhood of the Human Embryo. *Journal of Medicine and Philosophy* 18: 399-417.

D'Amato, A. and Chopra, S.K. 1991. Whales: Their Emerging Right to Life. *American Journal of International Law* 85: 21-62.

D'Amour, K.A. and Gage, F.H. 2002. Are Somatic Stem Cells Pluripotent or Lineage-Restricted? *Nature Medicine* 8: 213-214.

D'Angelo A. and Amso N. N. 2002. Embryo Freezing for Preventing Ovarian Hyperstimulation Syndrome: a Cochrane Review. *Human Reproduction* 17: 2787-2794.

D'Oronzio, J. 2001. Keeping Human Rights on the Bioethics Agenda. *Cambridge Quarterly of Healthcare Ethics* 10: 223-226.

DaCosta, V., Wynter, S., Frederick, J., Wynter, H. and Fletcher, H. 2002. Cervical Pregnancy - Case Report and Literature Review. *West Indian Medical Journal* 51: 257-259.

Daley, G.Q. 2002. Prospects for Stem Cell Therapeutics: Myths and Medicines. *Current Opinion in Genetics and Development* 12: 607-613.

Danish Council of Ethics (DCE). 2002. *Cloning: Statements of the Danish Council of Ethics*. Copenhagen.

Dashwood, A. 1996. The Limits of European Community Powers. *European Law Review* 21: 113-128.

Dawkins, R. 1998. What's Wrong with Cloning. In: Nussbaum, M.C. and Sunstein, C.R., (Eds.) *Clones and Clones: Facts and Fantasies About Human Cloning*, New York; London: W. W. Norton and Company. pp. 54-66.

Dawson, K. 1990. Fertilisation and Moral Status: A Scientific Perspective. In: Singer, P., Kuhse, H., Buckle, S., Dawson, K. and Kasimba, P., (Eds.) *Embryo Experimentation*, Cambridge: Cambridge University Press. pp. 43-52.

Dean, W., Bowden, L., Aitchison, A., Klose, J., Moore, T., Meneses, J.J., Reik, W. and Feil, R. 1998. Altered Imprinted Gene Methylation and Expression in Completely ES Cell-Derived Mouse Fetuses: Association with Aberrant Phenotypes. *Development* 125: 2273-2282.

Dean, W., Santos, F., Stojkovic, M., Zakhartchenko, V., Walter, J., Wolf, E. and Reik, W. 2001. Conservation of Methylation Reprogramming in Mammalian Development: Aberrant Reprogramming in Cloning Embryos. *Proceedings of the National Academy of Sciences* 98: 13734-13738.

Deasy, B.M., Jankowski, R.J. and Huard, J. 2001. Muscle-Derived Stem Cells: Characterisation and Potential for Cell-Mediated Therapy. *Blood Cells, Molecules and Diseases* 27: 924-933.

Dennis, C. 2002. Stem Cells Rise in the East. *Nature* 419: 334-336.

Dennis, C. 2003. Chinese Fusion Method Promises Fresh Route to Human Stem Cells. *Nature* 424: 711.

Department of Health (DoH). 2000. *Stem Cell Research: Medical Progress with responsibility - A Report from the Chief Medical Officer's Expert Group Reviewing*

the Potential of Developments in Stem Cell research and Cell Nuclear Replacement to Benefit Human Health. London, June.

Descartes, R. 1970. *Philosophical Letters*. Translated and edited by Kenny, A. Oxford: Clarendon Press.

Descartes, R. 1993. *Meditations on First Philosophy*. Translated by Cress, D. A. Third edn. Indianapolis/Cambridge: Hackett Publishing Company.

Dettweiler, U. and Thiem, A. 2000. Discussion of the Moral Status of the Human Embryo and Foetus. In: Haker, H. and Beyleveld, D., (Eds.) *The Ethics of Genetics in Human Procreation*, Aldershot: Ashgate. pp. 309-312.

Deutsche Forschungsgemeinschaft (DFG). 2000. *Recommendation of the Deutsche Forschungsgemeinschaft Concerning Research with Human Embryonic Stem Cells*. 3 May.

DeWitt, N. 2002. Biologists Divided Over Proposal to Create Human - Mouse Embryos. *Nature* 420: 255.

Dominguez-Bendala, J., Ricordi, C. and Inverardi, L. 2002. Stem Cells and Their Clinical Application. *Transplantation Proceedings* 34: 1372-1375.

Donagan, A. 1977. *The Theory of Morality*, Chicago & London: University of Chicago Press.

Donagan, A. 1982. Comments on Aaron Ben-Zeev, 'Who is a Rational Agent?'. *Canadian Journal of Philosophy* 12: 663-666.

Donaldson, C., Armitage, W.J., Laundy, V., Barron, C., Buchanan, R., Webster, J., Bradly, B. and Hows, J. 1999. Impact of Obstetric Factors on Cord Blood Donation for Transplantation. *British Journal of Haematology* 106: 128-132.

Dondorp, W. 2002. *Stem Cell Research in the Netherlands: Perspectives and Legislation*. Paper presented at: 4th Summit of National Bioethics Committees, Brasilia, Brazil, November.

Donovan P. J. 2001. High Oct-ane Fuel Powers the Stem Cell. *Nature Genetics* 29: 246-247.

Drukker, M., Katz, G., Urbach, A., Schuldiner, M., Markel, G., Itskovitz-Eldor, J., Reubinoff, B., Mandelboim, O. and Benvenisty, N. 2002. Characterization of the

Expression of MHC Proteins in Human Embryonic Stem Cells. *Proceedings of the National Academy of Sciences* 99: 9864-9869.

Duhrssen, A. 1960. Philosophic Alienation and the Problem of Other Minds. *Philosophical Review* 69: 211-220.

Durcova-Hills, G., Ainscough, J.F.X. and McLaren, A. 2001. Pluripotential Stem Cells Derived from Migrating Primordial Germ Cells. *Differentiation* 68: 220-226.

Dworkin, R. 1978. *Taking Rights Seriously*, Cambridge, Massachusetts: Harvard University Press.

Dworkin, R. 1984. Rights as Trumps. In: Waldron, J., (Ed.) *Theories of Rights*, Oxford: Oxford University Press. pp. 153-167.

Dworkin, R. 1995. *Life's Dominion: An Argument About Abortion and Euthanasia*, London: HarperCollins Publishers.

Dwyer, D. 2003. Beyond Autonomy: The Role of Dignity in 'Biolaw'. *Oxford Journal of Legal Studies* 23: 319-331.

Dyer, O. 2003. Scientists Harvest Stem Cells from Blastocysts Created by Parthenogenesis. *BMJ* 326: 952.

Ebrahim, G.J. 2002. Umbilical Cord Blood - A Rich Source if Haematopoietic Stem Cells. *Journal of Tropical Paediatrics* 48: 64-66.

Edwards, B.E., Gearhart, J.D. and Wallach, E.E. 2000. The Human Pluripotent Stem Cell: Impact on Medicine and Society. *Fertility and Sterility* 74: 1-7.

Edwards, R.G. 2001. IVF and the History of Stem Cells. *Nature* 413: 349-351.

Engelhardt, Jr. H.T. 1986. *The Foundations of Bioethics*, New York: Oxford University Press.

Engelhardt, Jr. H.T. 1974. The Ontology of Abortion. *Ethics* 84: 217-234.

Ehtesham, M., Kabos, P., Kabosova, A., Neuman, T., Black, K.L. and Yu, J.S. 2002. The Use of Interleukin 12-secreting Neural Stem Cells for the Treatment of Intracranial Glioma. *Cancer Research* 62: 5657-5663.

Enquete-Kommission (EK). 2001. *Stem Cell Research*. Second Interim Report of the Study Commission on the Law and Ethics of Modern Medicine 14/7546, German Bundestag, Berlin.

Erices, A., Conget, P. and Minguell, J.J. 2000. Mesenchymal Progenitor Cells in Human Umbilical Cord Blood. *British Journal of Haematology* 109: 235-242.

Eridani, S. 2002. Stem Cells for all Seasons? Experimental and Clinical Issues. *Journal of the Royal Society of Medicine* 95: 5-8.

European Commission. 2003a. *Report on Hman Embryonic Stem Cell Research.* Commission Staff Working Paper SEC(2003) 441; Brussels, 4 April.

European Commission. 2003b. *European Commission Proposes Strict Ethical Guidlines on EU Funding of Embryonic Stem Cell Research.* EU Press Release IP/03/9699; Brussels, 9 July.

European Commission. 2003c. *Proposal for a Council Decision Amending Deciiosn 2002/834/EC on the Specific Programme for Research, Technological Development and Demonstration: 'Intergrating and Strenghthening the European Research Area' (2002-2006).* COM(2003) 390 Final; 2003/0151 (CNS); Brussels, 9 July.

European Commission. 2003d. *Background information note on: FP6 Work Programme for the specific programme for research, technological development and demonstration: 'Integrating and strengthening the European research area' (2002-2006); Thematic Priority 1: "Life sciences, genomics and biotechnology for health" Update July 2003 - Topic for second call: LSH-2003-1.2.4-3, "Design of rational protocols for safety, quality and standardisation of stem cells and establishment of a European registry of stem cells", Integrated Project.* F.1 GJB/hs D(2003) 56075, Brussels, 8 October.

European Federation of Biotechnology Task Group on Public Perceptions of Biotechnology (EFBTG). 2001. *Advanced Workshop on Embryo Research.* Report of an Advanced Workshop held at the Club de la Fondation Universitaire, Bruxelles, 14-16 September.

European Group on Ethics in Science and New Technologies (EGE). 1998. *Ethical Aspects of Research Involving the Use of Human Embryo in the Context of the Fifth Framework Programme.* European Commission, Opinion No. 12, 23 November. Brussels.

European Group on Ethics in Science and New Technologies (EGE). 2000. *Ethical Aspects of Human Stem Cell Research and Use*. European Commission, Opinion No. 15, 14 November. Brussels.

European Science Foundation (ESF). 2002. *Human Stem Cell Research: Scientific Uncertainties and Ethical Dilemmas*. European Science Foundation Policy Briefing 18; Strasbourg, August.

European Society of Human Reproduction and Embryology (ESHRE). 2001. The Moral Status of the Pre-Implantation Embryo (Guidelines I). *Human Reproduction* 16: 1046-1048.

European Society of Human Reproduction and Embryology (ESHRE). 2002. Stem Cells (Guidelines IV). *Human Reproduction* 17: 1409-1410.

Evans, D. 1996. Pro-Attitudes to Pre-Embryos. In: Evans, D., (Ed.) *Conceiving the Embryo: Ethics, Law and Practice in Human Embryology*, The Hague, The Netherlands: Kluwer Law International. pp. 27-46.

Evans, D. and Evans, M. 1996. Fertility, Infertility and the Human Embryo: Ethics, Law and Practice of Human Artificial Procreation (Final Report to the European Commission, March 1996). *Human Reproduction Update* 2: 208-224.

Evans, M. and Hunter, S. 2002. Source and Nature of Embryonic Stem Cells. *C. R. Biologies* 325: 1-5.

Evans, M.J., Gurer, C., Loike, J.D., Wilmut, I., Schnieke, A.E. and Schon, E.A. 1999. Mitochondrial DNA Genotypes in Nuclear Transfer-Derived Cloned Sheep. *Nature Genetics* 23: 90-93.

Evans, R.W. 2001. The Moral Status of Embryos. In: Kilner, J.F., Cunningham, P.C. and Hager, W.D., (Eds.) *The Reproductive Revolution: A Christian Appraisal of Sexuality, Reproductive Technologies, and the Family*, Cambridge: William B. Eerdmans Publishing Company. pp. 60-76.

Falk, R.A. 1999. Kosovo, World Order, and the Future of International Law. *American Journal of International Law* 93: 847-857.

Farley, P. 2003. Inserted Gene Helps Stem Cell Heal Heart. *Nature Medicine Online* DOI:10.1038/nm912, 11 August.

Feinberg, J. 1964. Wasserstrom on Human Rights: Comments. *Journal of Philosophy* 61: 641-645.

Feinberg, J. 1980. The Nature and Value of Rights. In: Feinberg, J., (Ed.) *Rights, Justice, and the Bounds of Liberty: Essays in Social Philosophy*, Princeton, New Jersey: Princeton University Press. pp. 143-158.

Feinberg, J. 1986. Abortion. In: Regan, T., (Ed.) *Matters of Life and Death: New Introductory Essays in Moral Philosophy*, Second edn. New York: Random House. pp. 256-293.

Findlay, A.L.R. 1984. *Reproduction and the Fetus*, London: Edward Arnold.

Finnis, J. 1997. The Fragile Case for Euthanasia: A Reply to John Harris. In: John Keown, (Ed.) Euthanasia *Examined: Ethical, Clinical and Legal Perspectives*, Cambridge: Cambridge University Press. pp. 46-55.

Fiori, F. 2001a. *Report on the Ethical, Legal, Economic and Social Implications of Human Genetics*. Temporary Committee on Human Genetics and Other New Technologies in Modern Medicine: European Parliament FINAL A5-0391/2001, November. Brussels.

Fiori, F. 2001b. *Report on the Ethical, Legal, Economic and Social Implications of Human Genetics: Genetics - Resolution Rejected*. European Parliament, Own-Initiative Report A5-*0391/2001*. Brussels.

Fiori, F. 2001c. Cautious Approach Needed to Embryo Research: Report on the Ethical, Legal, Economic and Social Implications of Human Genetics. *European Parliament: Daily Notebook* 29: November. Brussels.

Fisher, J.A. 1994. Why Potentiality Does Not Matter: A Reply to Stone. *Canadian Journal of Philosophy* 24: 261-280.

Flathman, R.E. 1976. *The Practice of Rights*, Cambridge: Cambridge University Press.

Fletcher, J.C. 2001. NBAC's Arguments on Embryo Research: Strengths and Weaknesses. In: Holland, S., Labacqz, K. and Zoloth, L., (Eds.) *The Human Embryonic Stem Cell Debate: Science, Ethics and Public Policy*, Cambridge, Massachusetts: Massachusetts Institute of Technology. pp. 61-72.

Forbes, S., Vig, P., Poulsom, R., Thomas, H. and Alison, M. 2002. Hepatic Stem Cells. *Journal of Pathology* 197: 510-518.

Ford, N.M. 1988. *When did I begin? Conception of the Human Individual in History, Philosophy and Science*, Cambridge: Cambridge University Press.

Frankish, H. 2001. Researchers Turn Human Stem Cells into Heart Tissue. *Lancet* 358: 475.

Freed, C.R. 2002. Will Embryonic Stem Cells be a Useful Source of Dopamine Neurones for Transplant into Patients with Parkinson's Disease? *Proceedings of the National Academy of Sciences* 99: 1755-1757.

Freed, C.R., Greene, P.E., Breeze, R.E., Tsai, W.-Y., DuMouchel, W., Kao, R., Dillon, S., Winfield, H., Culver, S., Trojanowski, J.Q., Eidelberg, D. and Fahn, S. 2001. Transplantation of Embryonic Dopamine Neurones for Severe Parkinson's Disease. *New England Journal of Medicine* 344: 710-719.

Freeman, B. 1992. Moral Analysis and the Use of Nazi Experimental Data. In: Caplan, A., (Ed.) *When Science Went Mad: Bioethics and the Holocaust*, Totowa, New Jersey: Humana Press. pp. 141-154.

Freidman, R. 1981. The Basis of Human Rights: A Criticism of Gewirth's Theory. In: Pennock, J. and Chapman, J., (Eds.) *Nomos XXIII: Human Rights*, New York: New York University Press. pp. 148-157.

Friedli, D. 2003. Stem Cell Firm to Shift Base from Australia to Scotland. *Scotland on Sunday* September 7.

Friele, M.B. 2003. Do Committees Ru(i)n the Bio-Political Culture? On the Democratic Legitimacy of Bioethics Committees. *Bioethics* 17: 301-318.

Fuchs, E. and Segre, J.A. 2000. Stem Cells: A New Lease on Life. *Cell* 100: 143-155.

Gage, F.H. 2000. Mammalian Neural Stem Cells. *Science* 287: 1433-1438.

Galli, R., Borello, U., Gritti, A., Minasi, M.G., Bjornson, C., Coletta, M., Mora, M., Gabriella, M., De Angelis, C., Fiocco, R., Cossu, G. and Vescovi, A.L. 2000. Skeletal Myogenic Potential of Human and Mouse Neural Stem Cells. *Nature.com* 3: 986-991.

Garcia, R.A. 2002. The General Provisions of the Charter of Fundamental Rights of the European Union. *European Law Journal* 8: 492-514.

Gardner, R.L. 2002. Stem Cells: Potency, Plasticity and Public Perception. *Journal of Anatomy* 200: 277-282.

Gavaghan, H. 2001. The Promise of Stem Cells. *Bulletin of the World Health Organization* 79: 800-801.

Gepstein, L. 2002. Derivation and Potential Applications of Human Embryonic Stem Cells. *Circulation Research* 91: 866-876.

Gethmann, C.F. 2002. The Moral Status of the Embryo and the Protection of its Life. *Europäische Akademie: Newsletter Akademie-Brief* 34: 1-2.

Gewirth, A. 1969. The Non-Trivializability of Universalizability. *Australasian Journal of Philosophy* 47: 123- 131.

Gewirth, A. 1978. *Reason and Morality,* Chicago; London: University of Chicago Press.

Gewirth, A. 1980. Comments on Bond's Article. *Metaphilosophy* 11: 54-69.

Gewirth, A. 1981. The Basis and Content of Human Rights. In: Pennock, J.R. and Chapman, J.W., (Eds.) *Human Rights: NOMOS XXIII*, New York: New York University Press. pp. 119-147.

Gewirth, A. 1982a. *Human Rights: Essays on Justification and Applications*, Chicago: University of Chicago Press.

Gewirth, A. 1982b. On Rational Agency as the Basis of Moral Equality: Reply to Ben Zeev. *Canadian Journal of Philosophy* 12: 667-671.

Gewirth, A. 1995. Rights. In: Honderich, T., (Ed.) *The Oxford Companion to Philosophy*, Oxford: Oxford University Press. pp. 776.

Gewirth, A. 1996. *The Community of Rights*, Chicago: University of Chicago Press.

Gewirth, A. 1998. *Self-Fulfillment,* Princeton, New Jersey: Princeton University Press.

Gewirth, A. 1999. Replies to My Colleagues. In: Boylan, M., (Ed.) *Gewirth: Critical Essays on Action, Rationality, and Community*, Lanham, Maryland: Rowman & Littlefield Publishers, Inc. pp. 191-213.

Giacino, J.T., Ashwal, S., Childs, N., Cranford, R., Jennett, B., Katz, D.I., Kelly, J.P., Rosenberg, J.H., Whyte, J., Zafonte, R.D. and Zasler, N.D. 2002. The Minimally Conscious State: Definitions and Diagnostic Criteria. *Neurology* 58: 349-353.

Gillespie, N.C. 1977. Abortion and Human Rights. *Ethics* 87: 237-243.

Gillis, J. 2002. Questions Raised on Stem Cells: Adult Cells Found Less Useful Than Embryonic Ones. *Washingtonpost.com* 14 March, A03.

Gillon, R. 1991. Human Embryos and the Argument from Potential. *Journal of Medical Ethics* 17: 59-61.

Glannon, W. 2002. Extending the Human Life Span. *Journal of Medicine and Philosophy* 27: 339-354.

Glennon, M.J. 1990. Has International Law Failed the Elephant? *American Journal of International Law* 84: 1-43.

Glover, J. 1999. Eugenics and Human Rights. In: Burley, J., (Ed.) *The Genetic Revolution and Human Rights: The Oxford Amnesty Lectures 1998*, Oxford: Oxford University Press. pp. 101-124.

Gluckman, E. 2000. Current Status of Umbilical Cord Blood Hematopoietic Stem Cell Transplantation. *Experimental Hematology* 28: 1197-1205.

Goldring, K., Partridge, T. and Watt, D. 2002. Muscle Stem Cells. *Journal of Pathology* 197: 457-467.

Gordijn, B. 1999. The Troublesome Concept of the Person. *Theoretical Medicine and Bioethics* 20: 347-359.

Gorman, C. 2000. Brave New Cells. TIME Europe 155: 28-30.

Gottlieb, S. 2001. Scientists 'Grow' Monkey Stem Cell Lines from Cloned Embryos. *BMJ* 323: 1386.

Gratton, B. 2002. *Survey on the National Regulations in the European Union regarding Research on Embryos*. Secretariat of the European Group on Ethics in Science and New technologies European Commission. Brussels: Belgium.

Green, R.M. 2002. Benefiting from 'Evil'; An Incipient Moral Problem in Human Stem Cell Research. *Bioethics* 16: 544-556.

Greene V.W. 1992. Can Scientists Use Information Derived from the Concentration Camps? In: Caplan A, (Ed.) *When Science Went Mad: Bioethics and the Holocaust*, Totowa, New Jersey: Humana Press. pp. 155-170.

Greenwood, J. 2001. The New Ethics of Abortion. *Journal of Medical Ethics* 27: (suppl II) ii2-ii4.

Gross, O. and Aoláin, F.N. 2001. From Discretion to Scrutiny: Revisiting the Application of the Margin of Appreciation Doctrine in the Context of Article 15 of the European Convention on Human Rights. *Human Rights Quarterly* 23: 625-649.

Grosschedl, R. and Watt, F.M. 2001. Differentiation and Gene Regulation: 'From Stem Cells to Specialized Cells: Signalling and Gene Regulation in Cell Differentiation'. *Current Opinion in Genetics and Development* 11: 493-496.

Gruss, P. 2003. Human ES Cells in Europe. *Science* 301: 1017.

Gunsilius, E., Gastl, G. and Petzer, A.L. 2001. Hematopoietic Stem Cells. *Biomedical Pharmacotherapy* 55: 186-194.

Gurdon, J.B. and Byrne, J.A. 2003. The First Half-Century of Nuclear Transplantation. *Proceedings of the National Academy of Sciences* 100: 8048-8052.

Gussoni, E., Soneoka, Y., Strickland, C.D., Buzney, E.A., Khan, M.K., Flint, A.F., Kunkel, L.M. and Mulligan, R.C. 1999. Dystrophin Expression in the *mdx* Mouse Restored by Stem Cell Transplantation. *Nature* 401: 390-394.

Hadjantonakis, A.K. and Papaioannou, V.E. 2001. The Stem Cells of Early Embryos. *Differentiation* 68: 159-166.

Hagen, P. 2003. Stem Cell Forum Launched. *The Scientist* July 17, at: www.the-scientist.com.

Haksar, V. 1979. *Equality, Liberty and Perfectionism,* Oxford: Oxford University Press.

Hansen, J.E.S. 2002. Embryonic Stem Cell Production through Therapeutic Cloning has Fewer Ethical Problems than Stem Cell Harvest from Surplus IVF Embryos. *Journal of Medical Ethics* 28: 86-88.

Hardy, K., Wright, C., Rice, S., Tachataki, M., Roberts, R., Morgan, D., Spanos, S. and Taylor, D. 2002. Future Developments in Assisted Reproduction in Humans. *Reproduction* 123:171-183.

Hare, R.M. 1997. When Does Potentiality Count? A Comment on Lockwood. In: Fotion, N. and Heller Jan C., (Eds.) *Contingent Future Persons*, Dordrecht, The Netherlands: Kluwer Academic Publishers. pp. 9-18.

Harnad, S. 2000. Minds, Machines and Turing: The Indistinguishability of Indistinguishables. *Journal of Logic, Language, and Information* 9: 425-445.

Harris, J. 1985. *The Value of Life*, London: Routledge and Kegan Paul Plc.

Harris, J. 1992. *Wonderwoman and Superman: The Ethics of Human Biotechnology*, Oxford: Oxford University Press.

Harris, J. 1997. Final Thoughts on Final Acts. In: Keown, J., (Ed.) *Euthanasia Examined: Ethical, Clinical and Legal Perspectives*, Cambridge: Cambridge University Press. pp. 56-61.

Harris, J. 1999. Clones, Genes, and Human Rights. In: Burly, J., (Ed.) *The Genetic Revolution and Human Rights: The Oxford Amnesty Lectures 1998*, Oxford: Clarendon Press. pp. 61-94.

Harris, J. and Holm, S. 2002. Extending Human Lifespan and the Precautionary Paradox. *Journal of Medicine and Philosophy* 27: 355-368.

Hauser, L. 1993. Reaping the Whirlwind: Reply to Harnad's 'Other Bodies, Other Minds'. *Minds and Machines* 3: 219-238.

Hauser, M.D., Chomsky, N. and Fitch, W.T. 2002. The Faculty of Language: What is it, Who has it, and How did it Evolve. *Science* 298: 1569-1579.

He, J.-Q., Ma, Y., Lee, Y., Thomson, J.A. and Kamp, T.J. 2003. Human Embryonic Stem Cells Develop into Multiple Types of Cardiac Myocytes: Action Potential Characterization. *Circulation Research* 93: 32-39.

Health Council of the Netherlands: Committee on *In Vitro* Fertilisation (HCN). 1998. *IVF-Related Research*. Health Council of the Netherlands 1998/08E, 19 March, Rijswijk.

Health Council of the Netherlands (HNC). 2002. *Stem Cells for Tissue Repair: Research on Therapy Using Somatic and Embryonic Stem Cells*. Ministry of Health, Welfare and Sport 2002/09E, 27 June, The Hague.

Heinemann, T. and Honnefelder, L. 2002. Principles of Ethical Decision Making Regarding Embryonic Stem Cell Research in Germany. *Bioethics* 16: 530-543.

Held, V. 1999. The Normative Import of Action. In: Boylan, M., (Ed.) *Gewirth: Critical Essays on Action, Rationality, and Community*, Lanham, Maryland: Rowman & Littlefields Publishers Inc. pp. 13-27.

Hellemans, A. 2001. Beating the European Brain Drain. *Nature* 414: 4-5.

Hellenic National Bioethics Commission (HNBC). 2002. *Comments on the Draft Bill Concerning Medically Assisted Human Reproduction*.

Henderson, M. 2003. Lord Winston Warns of IVF Danger. *The Times* September 11.

Henkin, L. 1981. International Human Rights As 'Rights'. In: Pennock, J.R. and Chapman, J.W., (Eds.) *Human Rights: NOMOS XXIII,* New York: New York University Press. pp. 257-280.

Herder, J.G. 1966. *Essay on the Origin of Language*, Chicago and London: University of Chicago Press.

Hescheler, J. and Fleischmann, B.K. 2001. Indispensable Tools: Embryonic Stem Cells Yield Insights into the Human Heart. *Journal of Clinical Investigation* 108: 363-364.

Hescheler, J., Fleischmann, B.K., Lentini, S., Maltsev, V.A., Rohwedel, J., Wobus, A.M. and Addicks, K. 1997. Embryonic Stem Cells: a Model to Study Structural and Functional Properties in Cardiomyogenesis. *Cardiovascular Research* 36: 149-162.

Hewson, B. 2001. Reproductive Autonomy and the Ethics of Abortion. *Journal of Medical Ethics* 27: ii10-ii14

Heyes, C.M. 1998. Theory of Mind in Nonhuman Primates. *Behavioural and Brain Sciences* 21: 101-114.

Heyns, C. and Viljoen, F. 2002. *The Impact of the United Nations Human Rights Treaties on the Domestic Level*, The Hague: Kluwer.

Highfield, R. 2002. Pro-Life Groups Suffer Setback over Results of Stem Cell Studies. *The Telegraph* 19 March.

Highfield, R. 2003. Boost to Transplant Surgery by Cloning Miniature Pig. *The Telegraph* January 13.

Hill, J.F. 1984. Are Marginal Agents 'Our Recipients'? In: Regis, E.Jr., (Ed.) *Gewirth's Ethical Rationalism: Critical Essays with a Reply by Alan Gewirth*, Chicago & London: The University of Chicago Press. pp. 180-191.

Hill, J.R. 2002. Abnormal *In Utero* Development of Cloned Animals: Implications for Human Cloning. *Differentiation* 69: 174-178.

Hobbes, T. 1985. *Leviathan*, edited, with an introduction by MacPherson, C.B. London: Penguin Books.

Hohfeld, W.N. 1966. *Fundamental Legal Conceptions as Applied in Judicial Reasoning.* Edited by Cook, W.W. With a New Foreword by Corbin, A.L. (*Fourth Printing)*, New Haven & London: Yale University Press.

Holden, C. and Vogel, G. 2002a. Plasticity: Time for A Reappraisal? *Science* 296: 2126-2129.

Holden, C. and Vogel, G. 2002b. 'Show Us the Cells,' U.S. Researchers Say. *Science* 297: 923.

Holden, C. 2002. Primate Parthenotes Yield Stem Cells. *Science* 295: 779-980.

Holden, C. 2003. Spaniards Go for Stem Cells. *Science* 299: 1009.

Holland, A. 1991. A Fortnight of My Life is Missing: A Discussion of the Status of the Human 'Pre-embryo'. In: Almond, B. and Hill, D., (Eds.) *Applied Philosophy: Morals and Metaphysics in Contemporary Debate*, New York: Routledge. pp. 299-311.

Hollis, M. 1977. *Models of Man: Philosophical Thoughts on Social Action,* Cambridge: Cambridge University Press.

Holm, S. 2001. *European and American Ethical Debates About Stem Cells - Common Underlying Themes and Some Significant Differences*. The Ethical Issues in Human Stem Cell Research: Report from a Workshop Organised by The Nordic Committee on Bioethics, 10-11 October.

Holm, S. 2002. Going to the Roots of the Stem Cell Controversy. *Bioethics* 16: 493-507.

Holm, S. 2003. Regulating Stem Cell Research in Europe by the Back Door. *Journal of Medical Ethics* 29: 203-204.

Honnefelder, L. 2002. *The Status of Stem Cell Research in Germany*. Human Genetics Commission: Information Gathering Session on Stem Cell Research - Joint Meeting between Eurostem and the Human Genetics Commission, 13 May.

House of Lords Select Committee (Sel Com.). 2002. *Stem Cell Research*. HL Paper 83(i) London: HMSO, February.

Hovatta, O. 2002. A North European Perspective in Assisted Reproduction - New Legislation is Coming in Finland and in Sweden. *RBM Online* 4(2).

Hows, J.M. 2001. Status of Umbilical Cord Blood Transplantation in the Year 2001. *Journal of Clinical Pathology* 54: 428-483.

Howsepian, A.A. 1997. Lockwood on Human Identity and the Primitive Streak. *Journal of Medical Ethics* 23: 38-41.

Hubner, K., Fuhrmann, G., Christenson, L.K., Kehler, J., Reinbold, R., De La Fuente, R., Wood, J., Strauss III, J.F., Boiani, M. and Scholer, H.R. 2003. Derivation of Oocytes from Mouse Embryonic Stem Cells. *Science* 300: 1251-1256.

Huestis, M.A. and Choo, R.E. 2002. Drug Abuse's Smallest Victims: *In Utero* Drug Exposure. *Forensic Science International* 128: 20-30.

Hughes E. G. 2003. 'Effective Treatment' or 'Not a Natural Choice'? *Human Reproduction* 18: 912-914.

Hughes, S. 2002. Cardiac Stem Cells. *Journal of Pathology* 197: 468-478.

Human Genetics Advisory Commission and Human Fertilisation and Embryology Authority (HGAC/HFEA). 1998. *Cloning Issues in Reproduction, Science and Medicine*. London: Department of Trade and Industry.

Hume, D. 1975. *Enquiries Concerning Human Understanding and Concerning the Principles of Morals*. Edited by Selby-Bigge, L A (revised by Nidditch, P.H.), Third edn. Oxford: Clarendon Press.

Hume, D. 1978. *A Treatise of Human Nature*. Edited by Selby-Bigge L.A. with text and notes by Nidditch. P. H. Second edn. Oxford: Oxford University Press.

Humphreys, D., Eggan, K., Akutsu, H., Hochedlinger, K., Rideout, W.M., Biniszkiewicz, D., Yanagimachi, R. and Jaenisch, R. 2001. Epigenetic Instability in ES Cells and Cloning Mice. *Science* 293: 95-97.

Hutchinson, M. 2003. Mixed-Sex Human Embryo Created. *BBC News* July 2003.

Igelsias, T. 1984. *In Vitro* Fertilisation: the Major Issues. *Bioethics* 1: 32-37.

In 't Anker, P.S., Scherjon, S.A., Kleijburg-Van Der Keur, C., Noort, W.A., Claas, F.H.J., Willemze, R., Fibbe, W.E. and Kanhai, H.H.H. 2003. Amniotic Fluid as a Novel Source of Mesenchymal Stem Cells for Therapeutic Transplantation. *Blood* 102: 1548-1549.

Interacademy Panel on International Issues (IAP) 2003. *Statement on Human Cloning*. Global Network of Science Academies. Trieste, Italy.

International Federation of Gynaecology and Obstetrics (FIGO). 1990. FIGO News: Committee Statements - Research on Pre-embryos. *International Journal of Gynaecology and Obstetrics* 33: 79-80.

International Federation of Gynaecology and Obstetrics (FIGO). 1997. *Recommendations on Ethical Issues in Obstetrics and Gynaecology*. The FIGO Committee for the Study of Ethical Aspects of Human Reproduction, June, London: FIGO.

Isaacs, D. 2003. Moral Status of the Fetus: Fetal Rights or Maternal Autonomy? *Journal of Paediatrics and Child Health* 39: 58-59.

Jackson, K.A., Mi, T. and Goodell, M.A. 1999. Hematopoietic Potential of Stem Cells Isolated from Murine Skeletal Muscle. *Proceedings of the National Academy of Sciences* 96: 14482-14486.

Jacquette, D. 2001. Two Kinds of Potentiality: A Critique of McGinn on the Ethics of Abortion. *Journal of Applied Philosophy* 18: 79-86.

Jamieson, D. 1998. Science, Knowledge, and Animal Minds. *Proceedings of the Aristotelian Society* 98: 79-102.

Janes, S.M., Lowell, S. and Hutter, C. 2002. Epidermal Stem Cells. *Journal of Pathology* 197: 479-491.

Jaswal, T.S., Singh, S., Nanda, S., Sangwan, K., Chauhan, M. and Marwah, N. 2002. Cervical Ectopic Pregnancy with Placenta Percreta and Bladder Wall Invasion. *Acta Obstetricia et Gynecologica Scandinavica* 81: 991-992.

Jennett, B. 2002. The Vegetative State. *Journal of Neurology, Neurosurgary and Psychiatry* 73: 355-356.

Jensen-Seaman, M.I., Deinard, A.S. and Kidd, K.K. 2001. Modern African Ape Populations as Genetic and Demographic Models of the Last Common Ancestor of Humans, Chimpanzees, and Gorillas. *Journal of Heredity* 92: 475-480.

Jiang, Y., Jahagirdar, B.N., Reinhardt, R.L., Schwartz, R.E., Keene, D., Ortiz-Gonzalez, X.R., Reyes, D.A., Lenvik, T., Blackstad, M., Du, J., Aldrich, S., Low, W.C., Largaespada, D.A. and Verfaillie, C.M. 2002. Pluripotency of Mesenchymal Stem Cells Derived from Adult Marrow. *Nature* 418: 41-49.

Johnson, M.H. 1998. Should the Use of Assisted Reproduction Techniques be Deregulated? The UK Experience: Option for Change. *Human Reproduction* 13: 1769-1776.

Johnstone, J. 2003. Chimeras and 'Human Dignity'. *American Journal of Bioethics* 3: 6-8.

Jokic, A. 2001. More on Potentiality and Possibilia: A Response to Stone. *Journal of Social Philosophy* 32: 224-231.

Jones, H.W.Jr. and Veeck, L. 2002. What is an Embryo? *Fertility and Sterility* 77: 658-659.

Jones, L. 2001. Stem Cells: So what's in a Niche? *Current Biology* 11: R484-R486.

Josefson, D. 2001. Embryos Created for Stem Cell Research. *BMJ* 323: 127.

Josefson, D. 2003. Stem Cells in Tooth Pulp Could be Used in Research. *BMJ* 326: 950b.

Joseph, R. 2000. Fetal Brain Behaviour and Cognitative Development. *Development Review* 20: 81-98.

Kaessmann, H. and Pääbo, S. 2002. The Genetical History of Humans and the Great Apes. *Journal of Internal Medicine* 251: 1-18.

Kahn, A. 1997. Clone Mammals... Clone Man. *Nature* 386: 119.

Kahn, J.P. 2002. It if Looks Like a Clone and Acts Like a Clone, Is it Not a Clone? *Journal of Andrology* 23: 316.

Kampfl, A., Schmutzhard, E., Franz, G., Pfausler, B., Haring, H.-P., Ulmer, H., Felber, S., Golaszeewski, S. and Aichner, F. 1998. Prediction of Recovery from Post-Traumatic Vegetative State with Cerebral Magnetic-Resonance Imaging. *Lancet* 351: 1763-1767.

Kamenka, E. 1978. The Anatomy of an Idea. In: Kamenka, E. and Erh-Soon Tey, A., (Eds.) *Human Rights*, London: Edward Arnold. pp. 1-12.

Kant, I. 1948. *Groundwork of the Metaphysics of Morals.* Translated with an introduction by Paton, H. J. as: *The Moral Law* (2003 edition). Cambridge: Cambridge University Press.

Kant, I. 1991. *The Metaphysics of Morals*, Translated, edited and notes by Gregor, M. Cambridge: Cambridge University Press.

Kant, I. 1997. *Lectures on Ethics.* Translated by Heath, P., edited by Heath, P and Schneewind, L.B. Cambridge: Cambridge University Press.

Kant, I. 1998. *The Metaphysics of Morals*. Translated and edited by Gregor, M. (with an introduction by Sullivan, R. J.). Cambridge: Cambridge University Press.

Karpowicz, P. 2003. In Defence of Stem Cell Chimeras: A Response to 'Crossing Species Boundaries'. *American Journal of Bioethics* 3: 17-19.

Katz, J. 1992. Abuses of Human Beings for the Sake of Science. In: Caplan, A.L., (Ed.) *When Science Went Mad: Bioethics and the Holocaust*, Totowa, New Jersey: Humana Press. pp. 233-270.

Kaufman, D.S., Hanson, E.T., Lewis, R.L., Auerbach, R. and Thomson, J.A. 2001. Hematopoietic Colony-Forming Cells Derived from Human Embryonic Stem Cells. *Proceedings of the National Academy of Sciences* 98: 10716-10721.

Kaufman, D.S., Odorico, J.S. and Thomson, J.A. 2000. Transplantation Therapies from Human Embryonic Stem Cells: Circumventing Immune Rejection. *e-Biomed: The Journal of Regenerative Medicine* 1: 11-14.

Kehat, I., Kenyagin-Karsenti, D., Snir, M., Segev, H., Amit, M., Gepstein, A., Livne, E., Binah, O., Itskovitz-Eldor, J. and Gepstein, L. 2001. Human Embryonic Stem Cells can Differentiate into Myocytes with Structural and Functional Properties of Cardiomyocytes. *Journal of Clinical Investigation* 108: 407-414.

Kennea, N.L. and Mehmet, H. 2002. Neural Stem Cells. *Journal of Pathology* 197: 536-550.

Kennedy, D. 2003. Stem Cells: Still Here, Still Waiting. *Science* 300: 865.

Kennedy, J.S. 1992. *The New Anthropomorphism*, Cambridge: Cambridge University Press.

Kereiakes, D.J. 2003. Stem Cells: The Chameleon Fountain of Youth. *Circulation* 107: 939-940.

Kim, J.H., Auerbach, J.M., Rodriguez-Gomez, J.A., Velasco, I., Gavin, D., Lumelsky, N., Lee, S.H., Nguyen, J., Sanchez-Pernaute, R., Bankiewicz, K. and McKay, R. 2002. Dopamine Neurones Derived from Embryonic Stem Cells Function in an Animal Model of Parkinson's Disease. *Nature* 418: 50-56.

Kind, A. and Colman, A. 1999. Therapeutic Cloning: Needs and Prospects. *Cell and Developmental Biology* 10: 279-286.

Kim, T.F. 2001. Cord Stem Cell: Results, Not Hype. *Obstetrics and Gynaecological News* 36: 1-2.

Klug, M.G., Soonpaa, M.H., Koh, G.Y. and Field, L.J. 1996. Genetically Selected Cardiomyocytes from Differentiating Embryonic Stem Cells form Stable Intracardiac Grafts. *Journal of Clinical Investigation* 98: 216-24.

Kmietowicz, Z. 2001. Doctors Object to Companies Offering to Store Cord Blood. *BMJ* 323: 1203.

Kobayashi, N.R. 2003. A Scientist Crossing a Boundary: A Step into the Bioethical Issues Surrounding Stem Cell Research. *American Journal of Bioethics* 3: 15-16.

Koch, H.-G. 1998. The Legal Status of the Human Embryo. In: Hildt, E. and Mieth, D., (Eds.) *IVF in the 1990s: Towards a Medical, Social and Ethical Evaluation*, Aldershot: Ashgate. pp. 261-263.

Kooy, D.v.d. and Weiss, S. 2000. Why Stem Cells? *Science* 287: 1439-1441.

Körbling, M., Estrov, Z. and Champlin, R. 2003. Adult Stem Cells and Tissue Repair. *Bone Marrow Transplantation* 32: S23-S24.

Kovács, J. 1996. The Idea of Brain-Birth in Connection with the Moral Status of the Embryo and Foetus. In: Evans, D., (Ed.) *Conceiving the Embryo: Ethics, Law and Practice in Human Embryology*, The Hague, The Netherlands: Kluwer Law International. pp. 221-245.

Kramer, M.H. 1998. Rights without Trimmings. In: Kramer, M.H., Simmonds, N.E. and Steiner, H., (Eds.) *A Debate Over Rights*, Oxford: Clarendon Press. pp. 7-111.

Krause, D.S., Theise, N.D., Collector, M.I., Henegariu, O., Hwang, S., Gardner, R., Neutzel, S. and Sharkis, S.J. 2001. Multi-Organ, Multi-Lineage Engraftment of a Single Bone Marrow-Derived Stem Cell. *Cell* 105: 369-377.

Kuehnle, I. and Goodell, M.A. 2002. The Therapeutic Potential of Stem Cells from Adults. *BMJ* 325: 372-376.

Kuhse, H. 2000. Is There a Tension Between Autonomy and Dignity. In: Kemp, P., Rendtorff, J. and Johansen, N.M., (Eds.) *Bioethics and Biolaw: Volume Two: Four Ethical Principles*, Copenhagen: Rhodos International Science and Arts Publishers & Centre for Ethics and Law. pp. 61-74.

Kuhse, H. and Singer, P. 1990. Introduction: The Nature of Ethical Argument. In: Singer, P., Kuhse, H., Buckle, S., Dawson, K. and Kasimba, P., (Eds.) *Embryo Experimentation*, Cambridge: Cambridge University Press. pp. 37-42.

Kyba, M., Perlingeiro, R.C. and Daley, G.Q. 2002. HoxB4 Confers Definitive Lymphoid-Myeloid Engraftment Potential on Embryonic Stem Cell and Yolk Sac Hematopoietic Progenitors. *Cell* 109: 29-37.

Labat, M.L. 2001. Stem Cells and the Promise of Eternal Youth: Embryonic Versus Adult Stem Cells. *Biomedical Pharmacotherapy* 55: 179-185.

Lagasse, E., Connors, H., Al-Dhalimy, M., Reitsma, M., Dohse, M., Osborne, L., Wang, X., Finegold, M., Weissman, I.L. and Grompe, M. 2000. Purified Hematopoietic Stem Cells can Differentiate into Hepatocytes *In Vivo*. *Nature Medicine* 6: 1229-1234.

Lane, N., Dean, W., Erhardt, S., Hajkova, P., Surani, A., Walter, J. and Reik, W. 2003. Resistance of IAPs to Methylation Reprogramming May Provide a Mechanism for Epigenetic Inheritance in the Mouse. *Genesis* 35: 88-93.

Lanza, R.P., Caplan, A.L., Silver, L.M., Cibelli, J.B., West, M.D. and Green, R.M. 2000. The Ethical Validity of Using Nuclear Transfer in Human Transplantation. *Journal of the American Medical Association* 284: 3175-3179.

Lanza, R., Chung, Y., West, M.D. and Campbell, K.H.S. 2003. Comment on 'Molecular Correlates of Primate Nuclear Transfer Failures'. *Science* 301: 1482b.

Lanza, R.P., Arrow, K.J., Axelrod, J., Baltimore, D., Benacerraf, B., Bloch, K.E., Bloembergen, N., Brown, H.C., Brown, M.S., Cibelli, J.B., Cohen, S., Cooper, L.N., Corey, E.J., Dulbecco, R., Fischer, E.H., Fitch, V.L., Friedman, J.I., Friedman, M., Furchgott, R.F., Gell-Mann, M., Glaser, D.A., Glashow, S.L., Gilbert, W., Goldstein, J.L., Gould, S.J., Guillemin, R., Hauptman, H.A., Herschbach, D., Hoffman, R., Hood, L., Hubel, D.H., Karle, J., Klein, L.R., Kohn, W., Kornberg, A., Krebs, E.G., Lederman, L.M., Lederberg, J., Lee, D.M., Lucas Jr., R.E., Marcus, R.A., Merrifield, R.B., Miller, M.H., Modigliani, F., Molina, M.J., Mullis, K., Murad, F., Murray, J.E., Nathans, D., Nirenberg, M.W., North, D.C., Olah, G.A., Palade, G.E., Perl, M.J., Ramsey, N.F., Richter, B., Roberts, R.J., Robl, J.M., Samuelson, P.A., Schwartz, M., Sharp, P.A., Smalley, R.E., Smith, H.O., Solow, R.M., Taube, H., Tonegawa, S., Watson, J.D., Weinberg, S., Weller, T.H., West, M.D., Wieschaus, E.F., Wiesel, T.N. and Wilson, R.W. 1999. Science Over Politics. *Science* 283: 1849b.

Lanza, R.P., Cibelli, J.B., West, M.D., Dorff, E., Tauer, C. and Green, R.M. 2001. The Ethical Reasons for Stem Cell Research. *Science* 292: 1299.

Lanzendorf, S.E., Boyd, C.A., Wright, D.L., Muasher, S., Oehninger, S. and Hodgen, G.D. 2001. Use of Human Gametes Obtained from Anonymous Donors for the Production of Human Embryonic Stem Cell Lines. *Fertility and Sterility* 76: 132-137.

Larsen, W.J. 2001. *Human Embryology,* New York; Edinburgh: Churchill Livingstone.

Lasker, J.N. and Toedter, L.J. 2003. The Impact of Ectopic Pregnancy: A 16-Year Follow-up Study. *Health Care for Women International* 24: 209-220.

Leake, J. 2003. Cloning Expert Claims to have Created 'Human-Cow' Embryo. *Sunday Times* September 14.

Leaston, L. 1998. Research on Human Embryos. In: Hildt, E. and Mieth, D., (Eds.) *In Vitro Fertilisation in the 1990s: Towards a Medical, Social and Ethical Evaluation*, Aldershot: Ashgate. pp. 275-277.

Lebacqz, K. 2001. On the Elusive Nature of Respect. In: Holland, S., Lebacqz, K. and Zoloth, L., (Eds.) *The Human Embryonic Stem Cell Debate: Science, Ethics, and Public Policy*, Cambridge, Massachusetts: Massachusetts Institute of Technology. pp. 149-162.

Lebech, A.M.M. 1997. Principles, Compromise and Human Embryos in Europe. *Bulletin of Medical Ethics* August: 18-21.

Lee, S.H., Lumelsky, N., Studer, L., Auerbach, J.M. and McKay, R.D. 2000. Efficient Generation of Midbrain and Hindbrain Neurones from Mouse Embryonic Stem Cells. *Nature Biotechnology* 18: 675-679.

Lee, R.G. and Morgan, D. 2001. *Human Fertilisation and Embryology: Regulating the Reproductive Revolution*, London: Blackstone Press Limited.

Lemischka, I. 1999. The Power of Stem Cells Reconsidered? *Proceedings of the National Academy of Sciences* 96: 14193-14195.

Lemischka, I. 2001. Stem Cell Dogmas in the Genomics Era. *Review of Clinical and Experimental Hematology* 5: 15-25.

Lichtarowicz, A. 2002. Stem Cell Research Doubts. *BBS News Online* 13 March.

Liese, P. 2003a. *Report on the Proposal for a European Parliament and Council Directive on Setting Standards of Quality and Safety for the Donation, Procurement, Testing, Processing, Storage, and Distribution of Human Tissues and Cells* (COM(2002) 319

- C5-0302/2002 - 2002/0128(COD)). European Parliament FINAL A5-0103/2003, Brussels, 25 March.

Liese, P. 2003b. *No Cloning and Restrictions on Stem Cell Research*. Report on Medicine: Standards of Quality and Safety of Human Tissues and Cells A5-0103/2003, Brussels: 09-10/04/2003; Brussels.

Lin, H., Lei, J., Wininger, D., Nguyen, M.-T., Khanna, R., Hartmann, C., Yan, W.-L. and Huang, S.C. 2003. Multilineage Potential of Homozygous Stem Cells Derived from Metaphase II Oocytes. *Stem Cells* 21: 152-161.

Little, M.-T. and Storb, R. 2002. History of Haematopoietic Stem-Cell Transplantation. *Nature Reviews* 2: 231-238.

Liu, S., Qu, Y., Stewart, T.J., Howard, M.J., Chakrabortty, S., Holekamp, T.F. and McDonald, J.W. 2000. Embryonic Stem Cells Differentiate into Oligodendrocytes and Myelinate in Culture and After Spinal Cord Transplantation. *Proceedings of the National Academy of Sciences* 97: 6126-6131.

Lo, B., Chou, V., Cedars, M.I., Gates, E., Taylor, R.N., Wagner, R.M., Wolf, L. and Yamamoto, K.R. 2003. Consent from Donors for Embryo and Stem Cell Research. *Science* 301: 921.

Locke, J. 1975. *An Essay Concerning Human Understanding*, Edited with a Forward by Nidditch, P.H. Oxford: Clarendon Press.

Locke, J. 1988. *Two Treatises of Government*, Edited with an Introduction and Notes by Laslett, P, Student Edn. Cambridge: Cambridge University Press.

Lockwood, M. 1995. Human Identity and the Primitive Streak. *Hastings Center Report* 25: 45-49.

Lockwood, M. 1997. Hare on Potentiality: Rejoinder. In: Foltion, N. and Heller, J.C., (Eds.) *Contingent Future Persons*, Dordrecht, Netherlands: Kluwer Academic Publishers. pp. 19-26.

Lodie, T.A., Blickarz, C.E., Devarakonda, T.J., He, C., Dash, A.B., Clarke, J., Gleneck, K., Shihabuddin, L. and Tubo, R. 2002. Systematic Analysis of Reportedly Distinct Populations of Multipotent Bone Marrow-Derived Stem Cells Reveals a Lack of Distinction. *Tissue Engineering* 8: 739-751.

Lorenzi, R. 2002. Italy Assisted Reproduction Bill Called 'Medieval'. *Reuters.com* June 11 at: http://www.reuters.com.

Lovell-Badge, R. 2001a. The Future for Stem Cell Research. *Nature* 414: 88-91.

Lovell-Badge, R. 2001b. Stem Cell Therapy: The Potential Importance of Research into 'Therapeutic Cloning', Embryonic Stem Cells and Adult Stem Cells. *Academie-Brief: Newsletter* 25, Europäische Akademie.

Lyall, H., Murray, E., Glasier, A. and Baird, D.T. 1995. Donated Ovarian Tissue in Embryo Research and Assisted Conception - The View of Women of Reproductive Age. *Human Reproduction* 10: 1242-1245.

Lyons, D. 1984. Utility and Rights. In: Waldron, J., (Ed.) *Theories of Rights*, Oxford: Oxford University Press. pp. 110-136.

MacKellar, C. 1997. *Reproductive Medicine and Embryological Research: A European Handbook of Bioethical Legislation 1997-1998*, Edinburgh: European Bioethical Research.

MacKellar, C. 1998. Legal Regulations in Europe. In: Hildt, E. and Mieth, D., (Eds.) *In Vitro Fertilisation in the 1990s: Towards a Medical, Social and Ethical Solution*, Aldershot: Ashgate. pp. 265-269.

Madden, D. 1998. The Status of Human Embryos in Irish Medical Practice. In: Hildt, E. and Mieth, D., (Eds.) *In Vitro Fertilisation in the 1990s: Towards a Medical, Social and Ethical Evaluation*, Aldershot: Ashgate. pp. 223-225.

Maienschein, J. 2003. The Language Really Matters. In: Ruse, M. and Pynes, C.A., (Eds.) *The Stem Cell Controversy: Debating the Issues*, Amherst, New York: Prometheus Books. pp. 35-51.

Malhotra, N., Deka, D., Takkar, D., Kochar, S., Goel, S. and Sharma, M.C. 2001. Hydatiform Mole with Coexisting Live Fetus in Dichorionic Twin Gestation. *European Journal Of Obstetrics, Gynaecology, and Reproductive Biology* 94: 301-303.

Mann, J.R. 2001. Imprinting the Germ Line. *Stem Cells* 19: 287-294.

Marcus, R. 1993. *Violence Against Women in Bangladesh, Pakistan, Egypt, Sudan, Senegal and Yemen*. Bridge: Development - Gender: Report Prepared for the Special

Programme WID, Netherlands Ministry for Foreign Affairs Report No. 10, March. Institute of Development Studies, Brighton: United Kingdom.

Markl, H. 2001. Research Doesn't Denigrate Humanity. *Nature* 412: 479-480.

Marquis, D. 1989. Why Abortion is Immoral. *Journal of Philosophy* 86: 183-202.

Marquis, D. 2001. Deprivations, Futures and the Wrongness of Killing. *Journal of Medical Ethics* 27: 363-369.

Marshak, D.R., Gottlieb, D. and Gardner, R.L. 2001. Introduction: Stem Cell Biology. In: Marshak, D.R., Gardner, R.L. and Gottlieb, D., (Eds.) *Stem Cell Biology*, Cold Spring Harbor; New York: Cold Spring Harbor Laboratory Press. pp. 1-16.

Marshall, E. and Vogel, G. 2001. Cloning Announcement Sparks Debate and Scientific Skepticism. *Science* 294: 1802-1803.

Martinez, J.V. 1996. Spanish Legislation on Uses of Gametes and Zygotes (Pre-Embryos). In: Evans, D., (Ed.) *Conceiving the Embryo*, Netherlands: Kluwer Law International. pp. 347-349.

Matthiessen-Guyader, L. (ed.). 2003. *Survey on Opinions from National Ethics Commitees or Similar Bodies, Public Debate and National Legislation in Relation to Human Embryonic Stem Cell Research and Use: Volume One – In Member States.* Directorate E; Biotechnology, Agriculture and Food. European Commission: Brussels.

Mayor, S. 2002. Adult Stem Cells may not be able to Differentiate into Other Cell Types. *BMJ* 324: 696.

McCall Smith, A. and Revel, M. 2001. *The Use of Embryonic Stem Cells in Therapeutic Research: Report of the IBC on the Ethical Aspects of Human Embryonic Stem Cell Research. International Bioethics Committee (IBC): United Nations Educational, Scientific and Cultural Organization (UNESCO).* BIO-7/00/GT-1/2 (Rev. 3); UNESCO: Paris.

McCloskey, H.J. 1965. Rights. *Philosophical Quarterly* 15: 115-127.

McCullough, L.B. and Chervenak, F.A. 1994. *Ethics in Obstetrics and Gynaecology*, New York; Oxford: Oxford University Press.

McDonald, J.W., Liu, X.Z., Qu, Y., Liu, S., Mickey, S.K., Turetsky, D., Gottlieb, D.I. and Choi, D.W. 1999. Transplanted Embryonic Stem Cells Survive, Differentiate and Promote Recovery in Injured Rat Spinal Cord. *Nature Medicine* 5: 1410-11412.

McDowell, N. 2003a. Dutch Clone Claimed - But No Proof. *New Scientist Online* 6 January.

McDowell, N. 2003b. Second Cloned Baby Claim. *New Scientist Online* 3 January.

McGee, G. and Caplan, A. 2003. The Ethics of Small Sacrifices in Stem Cell Research. In: Ruse, M. and Pynes, C.A., (Eds.) *The Stem Cell Controversy: Debating the Issues*, Amherst, New York: Prometheus Books. pp. 151-158.

McGinn, C. 1992. *Moral Literacy, or How to do the Right Thing*, London: Gerald Duckworth & Co. Limited.

McGleenan, T. 2000. The Ethical Implications of Research Involving Human Embryos. *Scientific and Technological Options Assessment Panel (STOA)* Directorate General for Research: Directorate A: Division Industry, Research and Energy (DGRA), PE 289.665/Fin.St; Luxembourg.

McKie, R. 2002. Scientists' Fear Over Embryo Cell Implants. *The Observer* July 7.

McKinnel, R.G. 2002. Cloning of *Homo sapiens*? No! *Differentiation* 69: 150-153.

McKinney-Freeman, S.L., Jackson, K.A., Camargo, F.D., Ferrari, G., Mavilio, F. and Goodell, M.A. 2002. Muscle-Derived Hematopoietic Stem Cells are Hematopoietic in Origin. *Proceedings of the National Academy of Sciences* 99: 1341-1346.

McLaren, A. 1986. Prelude to Embryogenesis. In: Ciba Foundation: *Human Embryo Research: Yes or No?*, London and New York: Tavistock Publications. pp. 5-17.

McLean, M.R. 2001. Stem Cells: Shaping the Future in Public Policy. In: Holland, S., Lebacqz, K. and Zoloth, L., (Eds.) *The Human Embryonic Stem Cell Debate: Science, Ethics and Public Policy*, Cambridge, Massachusetts: Massachusetts Institute of Technology. pp. 197-207.

Melden, A.I. 1977. *Rights and Persons*, Oxford: Basil Blackwell.

Meng, L., Ely, J.J., Stouffer, R.L. and Wolf, D.P. 1997. Rhesus Monkeys Produced by Nuclear Transfer. *Biological Reproduction* 57: 454-459.

Merchant, J. 1996. Biogenetics, Artificial Procreation, and Public Policy in the United States and France. *Technology in Society* 18: 1-15.

Metsuzawa, T. 2003. From Chimpanzees to the Human Mind. *Science* 300: 2034-2035.

Meyer, J.R. 2000. Human Embryonic Stem Cells and Respect for Life. *Journal of Medical Ethics* 26: 166-170.

Mezey, E., Key, S., Vogelsang, G., Szalayova, I., Lange, G.D. and Crain, B. 2003. Transplanted Bone Marrow Generates New Neurones in Human Brains. *Proceedings of the National Academy of Sciences* 100: 1364-1369.

Mezey, E., Nagy, A., Szalayova, I., Key, S., Bratincsak, A., Baffi, J. and Shahar, T. 2003. Comment on 'Failure of Bone Marrow Cells to Transdifferentiate into Neural Cells *In Vivo*'. *Science* 299: 1184b.

Mieth, D. 2000. Going to the Roots of the Stem Cell Debate: The Ethical Problems of Using Embryos for Research. *EMBO Reports* 1: 4-6.

Millard, P. 2001. Terminology Used in Article on Cloning was Incorrect. *BMJ* 323: 804a.

Minguell, J.J., Erices, A. and Conget, P. 2001. Mesenchymal Stem Cells. *Experimental Biology and Medicine* 226: 507-520.

Mitalipov, S.M., Yeoman, R.R., Kuo, H.-C. and Wolf, D.P. 2002. Monozygotic Twinning in Rhesus Monkeys by Manipulation of *In Vitro*-Derived Embryos. *Biology and Reproduction* 66: 1449-1455.

Miura, M., Gronthos, S., Zhao, M., Lu, B., Fisher, L.W., Robey, P.G. and Shi, S. 2003. SHED: Stem Cells from Human Exfoliated Deciduous Teeth. *Proceedings of the National Academy of Sciences* 100: 5807-5812.

Mongoven, A.M. 2003. Duties to Stake Holders Amidst Pressure from Shareholders: Lessons from an Advisory Panel on Transplant Policy. *Bioethics* 17: 319-340.

Monshipouri, M. and Welch, C.E. 2001. The Search for International Human Rights and Justice: Coming to Terms with the New Global Realities. *Human Rights Quarterly* 23: 370-401.

Mooney, D.J. and Mikos, A.G. 1999. Growing New Organs. *Scientific American* April 17.

Moore, A. 2001. Body, Heal Thyself: Research on Stem Cells and Therapeutic Cloning: Great Hope Tinged with Caution. *EMBO Reports* 2: 658-660.

Morgan, D. and Lee, R.G. 1991. *Blackstone's Guide to the Human Fertilisation and Embryology Act 1990: Abortion and Embryo Research, the New Law*, London: Blackstone press limited.

Mori, M. 1998. On the Concept of the Pre-Embryo: The Basis for a New 'Copernican Revolution' in the Current View About Human Reproduction. In: Harris, J. and Holm, S., (Eds.) *The Future of Human Reproduction: Ethics, Choice, and Regulation*, Oxford: Oxford University Press. pp. 38-54.

Morris, K. 2002. Stem-Cell Therapies Here to Stay - But from Where? *Lancet* 1: 204.

Morrison, S.J. 2001. Stem Cell Potentials: Can Anything Make Anything? *Current Biology* 11: R7-R9.

Morshed, C.M., Benveniste, P., Iscove, N.N. and Van der Koov, D. 2002. Hematopoietic Competence is a Rare Property of Neural Stem Cells that may Depend on Genetic and Epigenetic Alterations. *Nature Medicine* 8: 268-273.

Moser, C.A. and Kalton, G. 1993. *Survey Methods in Social Investigation*, Second Edition. Aldershot: Dartmouth.

Munsie, M.J., Michalska, A.E., O'Brien, C.M., Trounson, A.O., Pera, M.F. and Mountford, P.S. 2000. Isolation of Pluripotent Embryonic Stem Cells from Reprogrammed Adult Mouse Somatic Cell Nuclei. *Current Biology* 10: 989-992.

Munthe, C. 2001. Divisibility and the Moral Status of Embryos. *Bioethics* 15: 382-397.

Murphy, F. 1994. Maastricht: Implementation in Ireland. *European Law Review* 19: 94-104.

Nagel, T. 1974. What is it Like to be a Bat? *Philosophical Review* 4: 435-450.

Nagel, T. 1986. *The View from Nowhere*, New York; Oxford: Oxford University Press.

Nagy, A., Rossant, J., Nagy, R., Abramow-Newerly, W. and Roder, J.C. 1993. Derivation of Completely Cell Culture-Derived Mice from Early-Passage Embryonic Stem Cells. *Proceedings of the National Academy of Sciences* 90: 8424-8428.

National Commission of Human Assisted Reproduction (NCHAR). 1998. *Reproducción Humana Asistida: Informe Annual* 1998. Ministerio de Sanidad Y Consumo. Madrid: Spain.

National Bioethics Committee (CNB). 2000. *Opinion of the National Bioethics Committee on the Therapeutic use of Stem Cells*. Rome: Italy, 27 October.

National Consultative Ethics Committee for Health and Life Sciences (CCNE). 2001. *Opinion on the Preliminary Draft Revision of the Laws on Bioethics*. No. 67, Paris: France, January 18.

Nationaler Ethikrat (National Ethics Council) (NEC). 2001. *The Import of Human Embryonic Stem Cells*. Berlin: Germany.

Nature Editorial. 2001. The Meaning of Life. *Nature* 412: 255.

Nature Neuroscience Editorial 1999. A Hard Sell for Stem Cells. *Nature Neuroscience* 2: 683-684.

Nelson, W. 1976. On the Alleged Importance of Moral Rights. *Ratio* 18: 145-155.

Nielsen, K. 1984. Against Ethical Rationalism. In: Regis, E. Jr. (Ed.). *Gewirth's Ethical Rationalism: Critical Essays with a Reply by Alan Gewirth,* Chicago: University of Chicago Press. pp. 59-83.

Nielsen, K. 1968. Scepticism and Human Rights. *Monist* 52: 573-594.

Nielsen, L. 1996. Legal Consensus and Divergence in Europe in the Area of Human Embryology - Room for Harmonisation. In: Evans, D., (ed.). *Conceiving the Embryo.* Netherlands: Kluwer Law International. pp. 325-338.

Nilsson, A. and Rose, J. 1999. Sweden Takes Steps to Protect Tissue Banks. *Science* 286: 894.

Noonan, J.T.Jr. 1968. Deciding Who is Human. *Natural Law Forum* 13: 134.

Nordic Committee on Bioethics (NorCB). 2000. *Opinion from the Nordic Committee on Bioethics based on the Workshop 'Ethical Issues in Human Stem Cell Research.* Helsingfors: Finland, October 10.

Norwitz, E.R., Schust, D.J. and Fisher, S.J. 2001. Implantation and the Survival of Early Pregnancy. *New England Journal of Medicine* 345: 1400-1408.

Novak, M. 2003. The Stem Cell Slide: Be Alert to the Beginnings of Evil. In: Ruse, M. and Paynes, C.A., (eds.), *The Stem Cell Controversy: Debating the Issues*. Amherst, New York: Prometheus Books. pp. 101-105.

Nozick, R. 1997. Do Animals Have Rights? In: *Socratic Puzzles*; Chapter 18. Harvard University Press; Cambridge, Massachusetts. pp. 305-310. Origanlly appeared as: About Mammals and People; *New York Times Book Review*, November 27, 1983, 11.

Nozick, R. 1981. *Philosophical Explanations,* Cambridge, Mass.: Harvard University Press.

Nuffield Council on Bioethics (NCB). 2000. *Stem Cell Therapy: The Ethical Issues - A Discussion Paper.* Nuffield Council on Bioethics: London.

O'Mathúna, D.P.O. 2002. What to Call Human Cloning. *EMBO Reports* 3: 502-505.

O'Neill, O. 2002. *BBC Reith Lectures 2002: A Question of Trust*. BBC Radio Four, at http://www.bbc.ukradio4 (accessed September 2003). Published in 2002 as: *A Question of Trust: The BBC Reith Lectures 2002*. Cambridge: Cambridge University Press.

Onyango, P., Jiang, S., Uejima, H., Shamblott, M.J., Gearhart, J.D., Cui, H. and Feinberg, A.P. 2002. Monoallelic Expression and Methylation of Imprinted Genes in Human and Mouse Embryonic Germ Cell Lineages. *Proceedings of the National Academy of Sciences* 99: 10599-10604.

O'Shea, K.S. 2001. Directed Differentiation of Embryonic Stem Cells: Genetic and Epigenetic Methods. *Wound Repair and Regeneration* 9: 443-459.

Odorico, J.S., Kaufman, D.S. and Thomson, J.A. 2001. Multilineage Differentiation from Human Embryonic Stem Cell Lines. *Stem Cells* 19: 193-204.

Oduncu, F.S. 2003. Stem Cell Research in Germany: Ethics of Healing vs. Human Dignity. *Medicine, Health Care and Philosophy* 6: 5-16.

Okarma, T.B. 2001. Human Embryonic Stem Cells: A Primer on the Technology and its Medical Applications. In: Holland, S., Lebacqz, K. and Zoloth, L., (Eds.) *The Human Embryonic Stem Cell Debate: Science, Ethics, and Public Policy*, Cambridge, Massachusetts: Massachusetts Institute of Technology. pp. 3-13.

Olson, E.T. 1997. Was I Ever a Fetus? *Philosophy and Phenomenological Research* 57: 95-110.

Oppenheim, A.N. 1993. *Questionnaire Design, Interviewing and Attitude Measurement*, New Edition. London and New York: Pinter Publishers.

Orkin, S.H. 2000. Stem Cell Alchemy. *Nature Medicine* 6: 1212-1213.

Orkin, S.H. 2001. Hematopoietic Stem Cells: Molecular Diversification and Developmental Interrelationships. In: Marshak, D.R., Gardner, R.L. and Gottlieb, D., (Eds.) *Stem Cell Biology*, New York: Cold Spring Harbour Laboratory Press. pp. 289-306.

Orkin, S.H. and Morrison, S.J. 2002. Stem Cell Competition. *Nature* 418: 25-27.

Otani, A., Kinder, K., Ewalt, K., Otero, F.J., Schimmel, P. and Friedlander, M. 2002. Bone Marrow-Derived Stem Cells Target Retinal Astrocytes and can Promote or Inhibit Retinal Angiogenesis. *Nature Medicine Online* DOI.10.1038/nm744, 20 July.

Otto, W.R. 2002. Lung Epithelial Stem Cells. *Journal of Pathology* 197: 527-535.

Ovey, C. and White, R. 2002. *Jacobs and White, The European Convention on Human Rights*, Third edn. Oxford: Oxford University Press.

Pagani, F.D., DerSimonian, H., Zawadzka, A., Wetzel, K., Edge, A.S.B., Jacoby, D.B., Dinsmore, J.H., Wright, S., Aretz, T.H., Eisen, H.J. and Aaronson, K.D. 2003. Autologous Skeletal Myoblasts Transplanted to Ischemia-Damaged Myocardium in Humans. *Journal of the American College of Cardiology* 41: 879-888.

Palmer, T.D., Schwartz, P.H., Taupin, P., Kaspar, B., Stein, S.A. and Gage, F.H. 2001. Progenitor Cells from Human Brain After Death. *Nature* 411: 42-43.

Papaioannou, V.E. 2001. Stem Cells and Differentiation. *Differentiation* 68: S1-S2.

Parens, E. 2001. On the Ethics and Politics of Embryo Stem Cell Research. In: Holland, S., Labacqz, K. and Zoloth, L., (Eds.) *The Human Embryonic Stem Cell Debate: Science, Ethics, and Public Policy*, Cambridge, Massachusetts: Massachusetts Institute of Technology Press. pp. 37-50.

Parfit, D. 1987. *Reasons and Persons*, Oxford: Clarendon Press.

Paton, H.J. 1948. Analysis of the Argument. In: Kant, I., (Ed.) *Groundwork for the Metaphysics of Morals (1785)* (Translated as The Moral Law by Paton, H.J), London: Hutchinson University Library. pp. 13-49.

Paul, G., Li, J.-Y. and Brundin, P. 2002. Stem Cells: Hype or Hope? *Drug Discovery Today* 7: 295-302.

Pennock, J.R. 1981. Rights, Natural Rights, and Human Rights - A General View. In: in, (Ed.) *Human Rights: NOMOS XXIII*, New York & London: New York University Press. pp. 1-28.

Pera, M.F. 2002. Overview of the Current Status of Research on Human Pluripotent Stem Cells. *Bundesgesundheitsbl-Gesundheitsforsch-Gesundheitsschutz* 45, 123-129.

Pera, M.F. 2001. Human Pluripotent Stem Cells: A Progress Report. *Current Opinion in Genetics and Development* 11: 595-599.

Perin, E.C., Geng, Y.-J. and Willerson, J.T. 2003a. Adult Stem Cell Therapy in Perspective. *Circulation* 107: 935-938.

Perin, E.C., Dohmann, H.F.R., Borojevic, R., Silva, S.A., Sousa, A.L.S., Mesquita, C.T., Rossi, M.I.D., Carvalho, A.C., Dutra, H.S., Dohmann, H.J.F., Silva, G.V., Belem, L., Vivacqua, R., Rangel, F.O.D., Esporcatte, R., Geng, Y.J., Vaughn, W.K., Assad, J.A.R., Mesquita, E.T. and Willerson, J.T. 2003b. Transendocardial, Autologous Bone Marrow Cell Transplantation for Severe, Chronic Ischemic Heart Failure. *Circulation* 107: 2294 -2302.

Perret, R.W. 2000. Taking Life and the Argument from Potentiality. *Midwest Studies in Philosophy* 24: 186-197.

Pertersen, B.E. and Terada, N. 2001. Stem Cells: A Journey into a New Frontier. *Journal of the American Society of Nephrology* 12: 1773-1780.

Pickering, S., Braude, P., Patel, M., Burn, C.J., Bolton, V. and Minger, S. 2003. Preimplantation Genetic Diagnosis as a Novel Source of Embryos for Stem Cell Research *RBM Online* 7(3).

Pilcher, H.R. 2003a. Stem Cells Help Paralysed Mice Walk. *Nature Online* 17 April.

Pilcher, H.R. 2003b. Excess DNA Prompts Stem-cell Rethink. *Nature Online* 13 March.

Pittenger, M.F., Mackay, A.M., Beck, S.C., Jaiswal, R.K., Douglas, R., Mosca, J.D., Moorman, M.A., Simonetti, D.W., Craig, S. and Marshak, D.R. 1999. Multilineage Potential of Adult Human Mesenchymal Stem Cells. *Science* 284: 143-147.

Pittenger, M.F. and Marshak, D.R. 2001. Mesenchymal Stem Cells of Human Adult Bone Marrow. In: Marshak, D.R., Gardner, R.L. and Gottlieb, D., (Eds.) *Stem Cell Biology*, Cold Spring Harbor, New York: Cold Spring Harbor Laboratory Press. pp. 349-373.

Pluchino, S., Quattrini, A., Brambilla, E., Gritti, A., Salani, G., Dina, G., Galli, R., Del Carro, U., Amadio, S., Bergami, A., Furlan, R., Comi, G., Vescovi, A.L. and Martino, G. 2003. Injection of Adult Neurospheres Induces Recovery in a Chronic Model of Multiple Sclerosis. *Nature* 422: 688-694.

Pluhar, E.B. 1995. *Beyond Prejudice: The Moral Significance of Human and Nonhuman Animals*, Durham and London: Duke University Press.

Pluhar, W.S. 1977. Abortion and Simple Consciousness. *The Journal of Philosophy* 74: 159-172.

Postema, G.J. 1986. *Bentham and the Common Law Tradition*. Oxford: Clarendon Press.

Poulsom, R., Alison, M.R., Forbes, S.J. and Wright, N.A. 2002. Adult Stem Cell Plasticity. *Journal of Pathology* 197: 441-456.

Powell, K. 2002. Stem Cells Rescue Retina. *Nature Medicine Online* DOI:10.1038/nm744, 29 July.

Prelle, K., Zink, N. and Wolf, E. 2002. Pluripotent Stem Cells - Model of Embryonic Development, Tool for Gene Targeting, and Basis of Cell Therapy. *Anatomia, Histologia, Embryologia: Journal of Veterinary Medicine Series C* 31: 169-186.

Presnell, S.C., Petersen, B. and Heidaran, M. 2002. Stem Cells in Adult Tissues. *Cell and Developmental Biology* 13: 369-376.

Preston, S.L., Alison, M.R., Forbes, S.J., Direkze, N.C., Poulsom, R. and Wright, N.A. 2003. The New Stem Cell Biology: Something for Everyone. *Journal of Clinical Molecular Pathology* 56: 86-96.

Prockop, D.J. 2001. Stem Cell Research has Only Just Begun. *Science* 293: 211-212.

Prockop, D.J. 2003. Further Proof of the Plasticity of Adult Stem Cells and their Role in Tissue Repair. *Journal of Cell Biology* 160: 807-809.

Proctor, R.N. 1992. Nazi Biomedical Policies. In: Caplan, A.L., (Ed.) *When Science Went Mad: Bioethics and the Holocaust*, Totowa: NJ: Humana Press. pp. 23-42.

Proctor, S.J., Dickinson, A.M., Parekh, T. and Chapman, C. 2001. Umbilical Cord Banks in the UK. *BMJ* 323: 60-61.

Prusa, A.-M., Marton, E., Rosner, M., Bernaschek, G. and Hengstschlager, M. 2003. Oct-4-Expressing Cells in Human Amniotic Fluid: A New Source for Stem Cell Research? *Human Reproduction* 18: 1489-1493.

Puccetti, R. 1983. The Life of a Person. In: Bondeson, W.B., Engelhardt, H.T., Spicker, S.F. and Winship, D.H., (Eds.) *Abortion and the Status of the Fetus*. Dordrecht, Holland: D. Reidel Publishing Company. pp. 169-182.

Putman, H. 1964. Robots: Machines or Artificially Created Life? *Journal of Philosophy* 61: 668-691.

Rachels, J. 1990. *Created from Animals: The Moral Implications of Darwinism*, Oxford: Oxford University Press.

Ramus, F., Hauser, M.D., Miller, C., Morris, D. and Mehler, J. 2000. Language Discrimination by Human Newborns and by Cotton-Top Tamarin Monkeys. *Science* 288: 349.

Rawls, J. 1973. *A Theory of Justice*. (Originally published in 1972). London: Oxford University Press.

Regis, E. Jr. 1984. *Gewirth's Ethical Rationalism: Critical Essays with a Reply by Alan Gewirth*, Chicago: The University of Chicago Press.

Rehmann-Sutter, C. 2002. Why Care About the Ethics of Therapeutic Cloning? *Differentiation* 69: 179-181.

Reichlin, M. 1997. The Argument from Potential: A Reappraisal. *Bioethics* 11: 1-23.

Reik, W. and Dean, W. 2002. Back to the beginning. *Nature* 420: 127.

Reik, W., Dean, W. and Walter, J. 2001. Epigenic Reprogramming in Mammalian Development. *Science* 293: 1089-1093.

Reisman, W.M. 1990. Sovereignty and Human Rights in Contemporary International Law. *American Journal of International Law* 84: 866-876.

Rendtorff, J.D. and Kemp, P. 2000a. *Basic Ethical Principles in European Bioethics and Biolaw: Volume One: Autonomy, Dignity, Integrity and Vulnerability*, Centre for Ethics and Law, Copenhagen, Denmark and Institut Borja de Bioetica, Bacelona, Spain: Report to the European Commission of the BIOMED-II Project in Basic Bioethical Principles 1995-1998.

Rendtorff, J.D. and Kemp, P. 2000b. *Basic Ethical Principles in European Bioethics and Biolaw: Volume Two: Partners' Research: Report to the European Commission of the BIOMED-II Project: Basic Ethical Principles in Bioethics and Biolaw 1995-1998*, Centre for Ethics and Law, Copenhagen, Denmark and Institut Borja de Bioètica, Bacelona, Spain: Centre for Ethics and Law and Institut Borja de Bioètica.

Resnik, D.B. 2002. The Commercialization of Human Stem Cells: Ethical and Policy Issues. *Health Care Analysis* 10: 127-154.

Reubinoff, B.E., Pera, M.F., Fong, C.Y., Trounson, A. and Bongso, A. 2000. Embryonic Stem Cell Lines from Human Blastocysts: Somatic Differentiation *In Vitro*. *Nature Biotechnology* 18: 399-404.

Reuter, L. 2000. Human is What is Born of a Human: Personhood, Rationality, and the European Convention. *Journal of Medicine and Philosophy 25*: 181-194.

Reverby, S.M. 2000. *Tuskegee's Truths: Rethinking the Tuskegee Syphilis Study*, Chapel Hill, North Carolina: University of North Carolina Press.

Reya, T., Morrison, S.J., Clarke, M.F. and Weissman, I.L. 2001. Stem Cells, Cancer, and Cancer Stem Cells. *Nature* 414: 105-111.

Richardson, H.S. 1994. *Practical Reasoning about Final Ends*, Cambridge: Cambridge University Press.

Rideout, W.M. 3rd, Hochedlinger, K., Kyba, M., Daley, G.Q. and Jaenisch, R. 2002. Correction of a Genetic Defect by Nuclear Transplantation and Combined Cell and Gene Therapy. *Cell* 109: 17-27.

Ridge, M. 2001. Taking Solipsism Seriously: Nonhuman Animals and Meta-Cognitive Theories of Consciousness. *Philosophical Studies* 103: 315-340.

Ritter, K. 2001. Swedish Council Wants Cloning. *Yahoo News* 4 December, At: http://uk.news.yahoo.com/.

Roberts, R.M. 1999. Prevention of Human Mitochondrial (mtDNA) Disease by Nucleus Transplantation into an Enuleated Donor Oocyte. *American Journal of Medical Genetics* 87: 265-266.

Robertson, J.A. 2003. Ethics and Policy in Embryonic Stem Cell Research. In: Ruse, M. and Pynes, C.A., (Eds.) *The Stem Cell Controversy: Debating the Issues*, Amherst, New York: Prometheus Books. pp. 121-150.

Robey, P.G. 2000. Stem Cells Near the Century Mark. *Journal of Clinical Investigation* 105: 1489-1491.

Roche, P.A. and Grodin, M.A. 2000. The Ethical Challenge of Stem Cell Research. *Women's Health Issues* 10: 136-139.

Rogers, A. and Bousingen, D.D.d. 1995. *Bioethics in Europe*, Strasbourg: Council of Europe Press.

Rogers, I. and Casper, R.F. 2003. Stem Cells: You Can't Tell a Cell by its Cover. *Human Reproduction Update* 9: 25-33.

Romeo-Casabona, C.M. 2002. Embryonic Stem Cell Research and Therapy: The Need for a Common European Legal Framework. *Bioethics* 16: 557-567.

Rosenthal, N. 2003. Medical Progress: Prometheus's Vulture and the Stem Cell Promise. *New English Journal of Medicine* 349: 267-274.

Rossant, J. 2001. Stem Cells from the Mammalian Blastocyst. *Stem Cells* 19: 477-482.

Royal Society (RS) 2000. *Stem Cell Research and Therapeutic Cloning: An Update.* Statement 12/00; London, November.

Rubenstein, L.S. 2003. The Medical Community's Response to Torture. *Lancet* 361: 1556.

Ruyter, K.W. 1996. Embryos as Moral Subjects and Limits of Responsibility. In: Evans, D., (Ed.) *Conceiving the Embryo*, The Netherlands: Kluwer Law International. pp. 173-192.

Rygaard, K. and Lindenberg, S. 2002. Stem Cells for Obstetricians and Gynaecologists. *Acta Obstetricia et Gynecologica Scandinavica* 81: 383-388.

Rynin, D. 1957. The Autonomy of Morals. *Mind, New Series* 66: 308-317.

Saha, S. and Saha, P.S. 2000. Biomedical Research: Some Ethical Challenges. *Critical Reviews in Biomedical Engineering* 28: 537-540.

Sample, I. 2003. Prospect of Babies from Unborn Mothers. *Guardian* July 1.

Sanchez-Ramos, J., Song, S., Cardozo-Pelaez, F., Hazzi, C., Stedeford, T., Willing, A., Freeman, T.B., Saporta, S., Janssen, W., Patel, N., Cooper, D.R. and Sanberg, P.R. 2000. Adult Bone Marrow Stromal Cells Differentiate into Neural Cells *In Vitro*. *Experimental Neurology* 164: 247-256.

Sapontzis, S.F. 1981. A Critique of Personhood. *Ethics* 91: 607-618.

Savulescu, J. 1999. Should We Clone Human Beings? Cloning as a Source of Tissue for Transplantation. *Journal of Medical Ethics* 25: 87-95.

Savulescu, J. 2002. Editorial: Abortion, Embryo Destruction and the Future of Value Argument. *Journal of Medical Ethics* 28: 133-135.

Schenker, J.G. 1997. Assisted Reproduction in Europe: Legal and Ethical Aspects. *Human Reproduction Update* 3/2: 173-184.

Schiermeier, Q. 2001. European Parliament Rejects Move to Restrict Genetics. *Nature* 414: 572.

Schmidt, H. 2000. *Harmonisation of the EU Member States Legislation Concerning Embryo Research.* European Parliament: Directorate General for Research-Directorate A (Scientific and Technological Options Assessment) 12/2000. Brussels.

Schofield, P., Pease-Watkin, C. and Blamires, C. 2002. *Rights, Representation, and Reform: Nonsense Upon Stilts and Other Writings on the French Revolution*, Oxford: Clarendon Press.

Schroten, E. 1998. A Distinct Category? About the Moral Status of Human Surplus Embryos. In: Hildt, E. and Mieth, D., (Eds.) *In Vitro Fertilisation in the 1990s: Towards a Medical, Social and Ethical Evaluation*, Aldershot: Ashgate. pp. 271-273.

Schüklenk, U. and Ashcroft, R. 2000. The Ethics of Reproductive and Therapeutic Cloning (Research). *Monash Bioethics Review* 19: 33-44.

Schuldiner, M., Yanuka, O., Itskovitz-Eldor, J., Melton, D.A. and Benvenisty, N. 2000. Effects of Eight Growth Factors on the Differentiation of Cells Derived from Human Embryonic Stem Cells. *Proceedings of the National Academy of Sciences* 97: 11307-11312.

Schuldiner, M., Itskovitz-Eldor, J. and Benvenisty, N. 2003. Selective Ablation of Human Embryonic Stem Cells Expressing a 'Suicide' Gene. *Stem Cells* 21: 257-265.

Schwartz, R.E., Reyes, M., Koodie, L., Jiang, Y., Blackstad, M., Lund, T., Lenvik, T., Johnson, S., Hu, W.S. and Verfaillie, C. 2002. Multipotent Adult Progenitor Cells from Bone Marrow Differentiate into Functional Hepatocyte-Like Cells. *Journal of Clinical Investigation* 109: 1291-1302.

Scruton, R. 2000. *Animal Rights and Wrongs*, Third edn. London: Metro Books.

Searle, J. 1984. *Minds, Brains & Science: The 1984 Reith Lectures*, London: Penguin Books.

Searle, J.R. 2002. Consciousness and Language. Cambridge: Cambridge University Press.

Senior, K. 2002. Potential Stem-Cell Treatment for Ocular Diseases. *Lancet* 360: 392-392.

Senior, K. 2001. Cord Blood: From Waste Product to Valuable Resource. *Trends in Molecular Medicine* 7: 3-4.

Shamblott, M.J., Axelman, J., Wang, S., Bugg, E.M., Littlefield, J.W., Donovan, P.J., Blumenthal, P.D., Huggins, G.R. and Gearhart, J.D. 1998. Derivation of Pluripotent Stem Cells from Cultured Human Primordial Germ Cells. *Proceedings of the National Academy of Sciences* 95: 13726-13731.

Shannon, T.A. 2001. From the Macro to the Macro. In: Holland, S., Lebacqz, K. and Zoloth, L., (Eds.) *The Human Embryonic Stem Cell Debate: Science, Ethics and Public Policy*, Cambridge, Massachusetts: Massachusetts Institute of Technology. pp. 176-184.

Sherwin, S. 1991. Abortion through a Feminist Ethics Lens. *Dialogue* 30: 327-342.

Siang, S. 2001. Berlin-Based Bioethics: Germany's National Ethics Council. *BioMedNet* http://news.bmn.com/hmsbeagle/117, 117: December 21.

Siddle, J. 2001. Germany and France Seek Cloning Ban. *BBC Online News* 8 August, at: http://www.bbc.co.uk/.

Siegel, A.W. 2001. Neutrality and Consensus: Towards a Viable Policy on Human Stem Cell Research. *Molecular Aspects of Medicine* 22: 171-181.

Silove, D. 2003. Overcoming Obstacles in Confronting Torture. *Lancet* 361: 1555.

Simerly, C., Dominko, T., Navara, C., Payne, C., Capuano, S., Gosman, G., Chong, K.-Y., Takahashi, D., Chace, C., Compton, D., Hewitson, L. and Schatten, G. 2003. Molecular Correlates of Primate Nuclear Transfer Failures. *Science* 300: 297-297.

Simini, B. 1999. Italy Moves on with in-vitro Fertilisation Legislation. *Lancet* 353: 1950.

Singer, B.J. 1999. Community, Mutuality, and Rights. In: Boylan, M., (Ed.) *Gewirth: Critical Essays on Action, Rationality, and Community*, Lanham, Maryland: Rowman & Littlefield Publishers, Inc. pp. 145-154.

Singer, M.G. 1988. Morality and Universal Law. In: Parkinson, G.H.R., (Ed.) *An Encylopaedia of Philosophy*, London: Routledge. pp. 568-589.

Singer, M.G. 2000. Gewirth, Beyleveld, and Dialectical Necessity. *Ratio Juris* 13: 177-195.

Singer, P. 1995. *Rethinking Life & Death: The Collapse of Our Traditional Ethics*, Oxford: Oxford University Press.

Singer, P. and Dawson, K. 1990. IVF Technology and the Argument from Potential. In: Singer, P., Kuhse, H., Buckle, S., Dawson, K. and Kasimba, P., (Eds.) *Embryo Experimentation*, Cambridge: Cambridge University Press. pp. 76-89.

Smith, A.G. 2001. Embryo-Derived Stem Cells: Of Mice and Men. *Annual Review of Developmental Biology* 17: 435-462.

Smith, M.J. 1998. Humanitarian Intervention: An Overview of the Ethical Issues. *Ethics and International Affairs* 12: 63-80.

Smith, F.O. and Thomson, B.G. 2000. Umbilical Cord Blood Collection, Banking, and Transplantation: Current Status and Issues Relevant to Perinatal Caregivers. *Birth* 27: 127-135.

Soane, B. 1988. Roman Catholic Casuistry and the Moral Status of the Human Embryo. In: Dunstan, G.R. and Seller, M.J., (Eds.) *The Status of the Human Embryo: Perspectives from Moral Tradition*, Oxford: King Edward's Hospital Fund for London. pp. 74-85.

Solbakk, J.H. 2002. *The Status of Stem Cell Research in Scandinavia*. Information Gathering Session on Stem Cell Research - Joint Meeting between Eurostem and the Human Genetics Commission, 13 May. Human Genetics Commission; Manchester: United Kingdom.

Solter, D. 2001. Embryonic Stem Cells and Cloning: A New Era in Human Biology and Medicine. *Europäische Akademia zur Erforschung von Folgen wissenschaftlich-technischer Entwicklugen Bad Neuenahr- Ahrweiler GmbH. Embryo Experimentation in Europe: Bio-medical, Legal, and Philosophical Aspects* 24 (grey series): 13-31.

Solter, D. and Gearhart, J. 1999. Putting Stem Cells to Work. *Science* 283: 1468-1470.

Soria, B., Roche, E., Berná, G., León-Quinto, T., Reig, J.A. and Martín, F. 2000. Insulin-Secreting Cells Derived from Embryonic Stem Cells Normalize Glycemia in Streptozotocin-Induced Diabetic Mice. *Diabetes* 49: 1-6.

Spielman, B. 2003. Should Consensus be 'The Commission Method' in the US? The Perspective of the Federal Advisory Committee Act, Regulations, and Case Law. *Bioethics* 17: 341-356.

Ssemakula, J.K. 2002. Brain Drain and Health Professionals. Relocation is Better Term than Brain Drain. *BMJ* 325: 219.

Stalnaker, R.C. 1975. A Theory of Conditionals. In: Sosa, E., (Ed.) *Causation and Conditionals*, London: Oxford University Press. pp. 165-179.

Steigleder, K. 1998. The Moral Status of Potential Persons. In: Hildt, E. and Mieth, D., (Eds.) *In Vitro Fertilisation in the 1990s: Towards a Medical, Social and Ethical Evaluation*, Aldershot: Ashgate. pp. 239-246.

Steinbock, B. 2001. Respect for Human Embryos. In: Lauritzen, P., (Ed.) *Cloning and the Future of Human Embryo Research*, Oxford, New York: Oxford University Press. pp. 21-33.

Steindler, D.A. and Pincus, D.W. 2002. Stem cells and Neuropoiesis in the Adult Human Brain. *Lancet* 359: 1047-1054.

Stenson, J. 2002. Change Name of Therapeutic Cloning. *Yahoo! News* 14 February. At: http://uk.news.yahoo.com/.

Steering Committee on Bioethics (CDBI). 2001. *Developments in the Field of Bioethics in Member States, Other States and International Organisations*. Coucil of Europe. CDBI/INF(2001) 6; Strasbourg, 17 October.

Steghaus-Kovac, S. 1999. Ethical Loophole Closing up for Stem Cell Researchers. *Science* 286: 31.

Stewart, C.L., Gadi, I. and Bhatt, H. 1994. Stem Cells from Primordial Germ Cells can Re-enter the Germ Line. *Developmental Biology* 161: 626-628.

Stix, G. 2001. Stem cells. What Clones? Widespread Scientific Doubts Greet Word of the First Human Embryo Clones. *Scientific American* 286: 18-19.

Stocum, D.L. 2001. Stem Cells in Regenerative Biology and Medicine. *Wound Repair and Regeneration* 9: 429-442.

Stone, J. 1987. Why Potentiality Matters. *Canadian Journal of Philosophy* 24: 281-294.

Stone, J. 1994. Why Potentiality Still Matters. *Canadian Journal of Philosophy* 17: 815-830.

Stone, J. 1995. Potentiality and Possibilia: A Reply to Jokic. *Journal of Social Philosophy* 26: 139-142.

Strauer, B.E. and Kornowski, R. 2003. Stem Cell Therapy in Perspective. *Circulation* 107: 929-934.

Sugarman, J., Kaalund, V., Kodish, E., Marshall, M.F., Reisner, E.G., Wilfond, B.S., Wolpe, P.R. and Working Group on Ethical Issues in Umbilical Cord Banking 1997. Ethical Issues in Umbilical Cord Blood Banking. *Journal of the American Medical Association* 278: 938-943.

Summerfield, D. 2003. Fighting 'Terrorism' with Torture. *BMJ* 326: 773-774.

Surani, M.A. 2001. Reprogramming of Genome Function through Epigenetic Inheritance. *Nature* 414: 122-128.

Svendsen, C.N. and Smith, A.G. 1999. New Prospects for Human Stem-Cell Therapy in the Nervous System. *Trends in Neuroscience* 22: 357-364.

Swedish National Council on Medical Ethics (SMER). 2002. *Statement of Opinion on Embryonic Stem Cell Research.* Ministry of Health and Social Affairs, Stockholm, Dnr 03/2002.

Swedish Research Council (SRC). 2001. *The Swedish Research Council's Guidelines for Research: Ethical Review of Human Stem Cell Research.* 2001-12-04.

Szawarski, Z. 1996. Talking About Embryos. In: Evans, D., (Ed.) *Conceiving the Embryo: Ethics, Law and Practice in Human Embryology*, The Hague, The Netherlands: Kluwer Law International. pp. 119-133.

Tacheva, D.M. and Vladimirov, I.K. 2002. Embryos, Preembryos, and Stem Cells. *Fertility and Sterility* 78: 1354-1355.

Tada, M., Tada, T., Lefebvre, L., Barton, S.C. and Surani, M.A. 1997. Embryonic Germ Cells Induce Epigenetic Reprogramming of Somatic Nucleus in Hybrid Cells. *EMBO Journal* 16: 6510-6520.

Tajani, A. 2001. Go-Ahead for Human Cloning given by UK Government: Written Question P-2852/00. *Official Journal of the European Communities* C 136E, 111.

Talan, J. 2001. Expert Quits in Cloning Flap: Resigns as Adviser, Derides Study. *Newsday.com* 5 December, at: http://www.newsday.com/.

Tasioulas, J. 2002. Human Rights, Universality and the Values of Personhood: Retracing Griffin's Steps. *European Journal of Philosophy* 10: 79-100.

Tauer, C.A. 1985. Personhood and Human Embryos and Fetuses. *Journal of Medicine and Philosophy* 10, 253-266.

Tauer, C.A. 1997. Bringing Embryos into Existence for Research Purposes. In: Fotion, N. and Heller, J.C., (Eds.) *Contingent Future Persons*, Dordrecht, Netherlands: Kluwer Academic Publishers. pp. 171-189.

Tauer, C.A. 2001. Responsibility and Regulation: Reproductive Technologies, Cloning, and Embryo Research. In: Lauritzen, P. (Ed.) *Cloning and the Future of Human Embryo Research*, Oxford: Oxford University Press. pp. 145-161.

Terada, N., Hamazaki, T., Oka, M., Hoki, M., Mastalerz, D.M., Nakano, Y., Meyer, E.M., Morel, L., Petersen, B.E. and Scott, E.W. 2002. Bone Marrow Cells Adopt the Phenotype of Other Cells by Spontaneous Cell Fusion. *Nature Advance Online Publication* DOI 10.1038/nature730, 1-3, 13 March: 1-3.

Terry, P.F., Terry, S.F., Marais, A.S., Pasquali-Roncheti, I., Boyd, C., Johnson, E., Le Roux, T. and Bercovitch, L. 2001. Effective International Collaboration in Rare Disease Research. *American Journal of Human Genetics* 69: 1167.

Theise, N.D., Krause, D.S. and Sharkis, S. 2003. Comment on 'Little Evidence for Developmental Plasticity of Adult Hematopoietic Stem Cells'. *Science* 299: 1317a.

Thomson, J.A. 2001. Human Embryonic Stem Cells. In: Holland, S., Lebacqz, K. and Zoloth, L., (Eds.) *The Human Embryonic Stem Cell Debate: Science, Ethics, and Public Policy*, Cambridge, Massachusetts: Massachusetts Institute of Technology. pp. 15-26.

Thomson, J.A., Itskovitz-Eldor, J., Shapiro, S.S., Waknitz, M.A., Swiergiel, J.J., Marshall, V.S. and Jones, J.M. 1998. Embryonic Stem Cell Lines Derived from Human Blastocyts. *Science* 282: 1145-1147.

Thomson, J.A. and Odorico, J.S. 2000. Human Embryonic Stem Cell and Embryonic Germ Cell Lines. *Trends in Biotechnology* 18: 53-57.

Thomson, J.J. 1971. A Defence of Abortion. *Philosophy and Public Affairs* 1: 47-66.

Thorne, R. and Kischer, C.W. 2002. Embryos, Preembryos, and Stem Cells. *Fertility and Sterility* 78: 1355.

Tollefsen, C. 2001. Embryos, Individuals and Persons: An Argument against Embryo Creation and Research. *Journal of Applied Philosophy* 18: 65-77.

Toma, J. 2001. Isolation of Multipotent Adult Stem Cells from the Dermis of Mammalian Skin. *Nature Cell Biology* 3: 778-784.

Tooley, M. 1998. Speciesism and Basic Moral Principles. *Etica & Animali* 8: 5-36.

Tooley, M. 1999. The Moral Status of the Cloning of Humans. *Monash Bioethics Review* 18: 27-49.

Tosh, D. and Slack, J.M.W. 2002. How Cells Change their Phenotype. *Nature Reviews* 3: 187-194.

Tran, S.D., Pillemer, S.R., Dutra, A., Barrett, A.J., Brownstein, M.J., Key, S., Pak, E., Leakan, R.A., Kingman, A., Yamada, K.M., Baum, B.J. and Mezey, E. 2003. Differentiation of Human Bone Marrow-Derived Cells into Buccal Epithelial Cells *In Vivo*: a Molecular Analytical Study. *Lancet* 361: 1084-1088.

Tranøy, K.E. 1972. 'Ought' Implies 'Can': A Bridge from Fact to Norm. *Ratio* 14: 116-130.

Tsunoda, Y. and Kato. Y 2002. Recent Progress and Problems in Animal Cloning. *Differentiation* 69: 158-161.

Tucker K. E. 1996. Reproductive Toxicity of Ovulation Induction. *Seminars in Reproductive Endocrinology* 14: 345-353.

Turing, A.M. 1950. Computing Machinery and Intelligence. *Mind* LIX: 433-460.

Turone, F. 2004. Italy to Pass New Law on Assisted Reproduction. *BMJ* 328: 9.

Van de Meerssche, M., Verdonk, P., Jacquemyn, Y., Serreyn, R. and Gerris, J. 1995. Cervical Pregnancy: Three Case Reports and a Review of the Literature. *Human Reproduction* 10: 1850-1855.

Vanderlaan, R.D., Oudit, G.Y. and Backx, P.H. 2003. Electrophysiological Profiling of Cardiomyocytes in Embryonic Bodies Derived From Human Embryonic Stem Cells: Therapeutic Implications. *Circulation Research* 93: 1-3.

Vass, A. 2001. US scientists clone first human embryo. *BMJ* 323: 1267.

Vassilopoulos, G., Wang, P.-R. and Russell, D.W. 2003. Transplanted Bone Marrow Regenerates Liver by Cell Fusion. *Nature Online* doi:10.1038/nature01539, 30 March.

Vastag, B. 2001. Many Say Adult Stem Cells Reports Overplayed. *Journal of the American Medical Association* 286: 293.

Vats, A., Tolley, N.S., Polak, J.M. and Buttery, L.D.K. 2002. Stem Cells: Sources and Applications. *Clinical Otolaryngology* 27: 227-232.

Velleman, J.D. 1992. What Happens when Someone Acts? *Mind, New Series* 101: 461-481.

Verfaillie, C.M., Pera, M.F. and Lansdorp, P.M. 2002. Stem Cells: Hype and Reality. *Hematology* 2002: 369-391.

Verma, I.M. 2001a. Are the Benefits of Stem Cells Being Oversold? *Molecular Therapy* 4: 161.

Verma, I.M. 2001b. Stem Cell Research: Win, Win, Win by Keeping Politics Out. *Molecular Therapy* 3: 641.

Vescovi, A.L., Galli, R. and Gritti, A. 2001. The Neural Stem Cells and their Transdifferentiation Capacity. *Biomedical Pharmacotherapy* 55: 201-205.

Viville, S. and Nisand, I. 1997. International Regulation of Human Embryo Research: Legal Aspects of Human Embryo Research and Preimplantation Genetic Diagnosis in France. *Human Reproduction* 12: 2341-2342.

Vlastos, G. 1962. Justice and Equality. In: Brandt, R., (Ed.) *Social Justice*, New Jersey: Englewood Cliffs. pp. 31-72.

Vlastos, G. 1984. Justice and Equality. In: Waldron, J., (Ed.) *Theories of Rights*,. Oxford: Oxford University Press. pp. 41-76.

Vogel, G. 2001a. Can Adult Stem Cells Suffice? *Science* 292: 1820-1822.

Vogel, G. 2001b. Developmental biology. Stem cells are coaxed to produce insulin. *Science* 292: 615-761.

Vogel, G. 2001c. An Embryonic Alternative. *Science* 292: 1822.

Vogel, G. 2002a. Rat Brains Respond to Embryonic Stem Cells. *Science* 295: 254-255.

Vogel, G. 2002b. Stem Cells not so Stealthy After All. *Science* 297: 175-177.

Vogel, G. 2002c. Studies Cast Doubt on Plasticity of Adult Cells. *Science* 295: 1989-1991.

Vogel, G. 2003. Visiting German Profs Could Face Jail. *Science* 301: 577.

Vogelstein, B., Alberts, B. and Shine, K. 2002. Please Don't Call it Cloning. *Science* 295: 1237.

Vrana, K.E., Hipp, J.D., Goss, A.M., McCool, B.A., Riddle, D.R., Walker, S.J., Wettstein, P.J., Studer, L.P., Tabar, V., Cunniff, K., Chapman, K., Vilner, L., West, M.D.,

Grant, K.A. and Cibelli, J.B. 2003. Nonhuman Primate Parthenogenetic Stem Cells. *Proceedings of the National Academy of Sciences* 100: 11911-11916.

Wade, F.C. 1975. Potentiality and the Abortion Discussion. *Review of Metaphysics* 29, 239-255.

Wagers, A.J., Sherwood, R.I., Christensen, J.L. and Weissman, I.L. 2002. Little Evidence for Developmental Plasticity of Adult Hematopoietic Stem Cells. *Science* 297: 256-259.

Wagers, A.J., Sherwood, R.I., Christensen, J.L. and Weissman, I.L. 2003. Response to Comment on 'Little Evidence for Developmental Plasticity of Adult Hematopoietic Stem Cells'. *Science* 299: 1317b.

Wagers, A.J., Sherwood, R.I., Christensen, J.L. and Weissmen, I.L. 2002. Little Evidence for Developmental Plasticity of Adult Hematopoietic Stem Cells. *Science* 297: 2256-2259.

Wakayama, T., Tabar, V., Rodriguez, I., Perry, A.C., Studer, L. and Mombaerts, P. 2001. Differentiation of Embryonic Stem Cell Lines Generated from Adult Somatic Cells by Nuclear Transfer. *Science* 292: 740-743.

Wakayama, T. and Yanagimachi, R. 2001. Mouse Cloning With Nuclear Donor Cells of Different Age and Type. *Molecular Reproduction and Development* 58: 376-383.

Waldron, J. 1984. *Theories of Rights: Introduction*, Oxford: Oxford University Press.

Waldron, J. 1988. The Philosophy of Rights. In: Parkinson, G.H.R., (Ed.) *An Encyclopaedia of Philosophy*, London: Routledge. pp. 713-737.

Waltz, S. 2001. Universalizing Human Rights: The Role of Small States in the Construction of the Universal Declaration of Human Rights. *Human Rights Quarterly* 23: 44-72.

Wang, X., Willenbring, H., Akkari, Y., Torimaru, Y., Foster, M., Al-Dhalimy, M., Lagasse, E., Finegold, M., Olson, S. and Grompe, M. 2003. Cell Fusion is the Principle Source of Bone-Marrow-Derived Hepatocytes. *Nature Online* doi:10.1038/nature01531, 30 March.

Warnock, M. 1985. *A Question of Life: The Warnock Report on Human Fertilisation and Embryology*, Oxford: Basil Blackwell Limited.

Warren, M.A. 2000. *Moral Status: Obligations to Persons and Other Living Things*, Oxford: Oxford University Press.

Warren, M.A. 1973. On the Moral and Legal Status of Abortion. *Monist* 57: 43-61.

Wasserman, D. 2003. Species and Races, Chimeras, and Multiracial People. *American Journal of Bioethics* 3: 13-14.

Wasserstrom, R. 1964. Rights, Human Rights, and Rights Discrimination. *Journal of Philosophy* 61: 628-641.

Watt, F.M. and Hogan, B.L.M. 2000. Out of Eden: Stem Cells and Their Niches. *Science* 287: 1427-1430.

Watt, H. 2000. *Life and Death in Healthcare Ethics: A Short Introduction*, London: Routledge.

Weale, A. 2001. *Science and the Swastika*, Oxford: Channel 4 Books.

Weimann, J.M., Johansson, C.B., Trejo, A. and Blau, H.M. 2003. Stable Reprogrammed Heterokaryons Form Spontaneously in Purkinje Neurons After Bone Marrow Transplant. *Nature Cell Biology* advance online publication article, 18 October.

Weiss, R. 2003. 'Parthenote' Expand the Debate on Stem Cells. In: Ruse, M. and Pynes, C.A., (Eds.) *The Stem Cell Controversy: Debating the Issues*, Amherst, New York: Prometheus Books. pp. 63-66.

Weissman, I.L. 2000a. Stem Cells: Units of Development, Units of Regeneration, and Units of Evolution. *Cell* 100: 157-168.

Weissman, I.L. 2000b. Translating Stem and Progenitor Cell Biology to the Clinic: Barriers and Opportunities. *Science* 287: 1442-1446.

Weissman, I.L. 2002. Sounding Board: Stem Cells - Scientific, Medical, and Political Issues. *New England Journal of Medicine* 346: 1576-1579.

Weissman, I.L., Anderson, D.J. and Gage, F. 2001. Stem and Progenitor Cells: Origins, Phenoypes, Lineage Commitments, and Transdifferentiations. *Annual Reviews of Cell and Developmental Biology* 17: 387-403.

Wellcome Trust (WT). 2000. *Wellcome Trust Interim Position Statement on Stem Cell Research*, October, at: http://www.wellcome.ac.uk/en/1/awtvispolstm.html.

Wells, W.A. 2002. Is Transdifferentiation in Trouble? *Journal of Cell Biology* 157: 15-18.

Wendler, D. 1999. Understanding the 'Conservative' View on Abortion. *Bioethics* 13: 32-56.

Wert, G.d., Berghmans, R.L.P., Boar, G.J., Andersen, S., Brambati, B., Carvalho, A.S., Dierickx, K., Elliston, S., Nunez, P., Osswald, W. and Vicari, M. 2002. Ethical Guidance on Human Embryonic and Fetal Tissue Transplantation: A European Overview. *Medicine, Health Care and Philosophy* 5: 79-90.

Westphal, S.P. 2002. Re-Implanted Stem Cells Tackle Parkinson's. *NewScientist.com* 8 April.

Westphal, S.P. 2003. Greater Potential of Adult Stem Cells Revealed . *NewScientist.com* 17 May.

White, A.R. 1984. *Rights*. Oxford: Clarendon Press.

Whiten, A., Goodall, J., McGrew, W.C., Nishidas, T., Reynolds, V., Sugiyama, Y., Tutin, C.E.G., Wrangham, R.W. and Boesch, C. 1999. Cultures in Chimpanzees. *Nature* 399: 682-684.

Wildman, D.E., Uddin, M., Liu, G., Grossman, L.I. and Goodman, M. 2003. Implications of Natural Selection in Shaping 99.4% Nonsynonymous DNA Identity Between Humans and Chimpanzees: Enlarging Genus Homo. *Proceedings of the National Academy of Sciences* 100: 7181-7188.

Williams, B. 1978. *Descartes: The Project of Pure Enquiry*, London: Penguin Books.

Williams, B. 1986. Types of Moral Argument Against Embryo Research. In: The Ciba Foundation, (Ed.) *Human Embryo Research: Yes or No?*, London: Traistock Publications. pp. 185-194.

Wilmut, I., Schnieke, A.E., McWhir, J., Kind, A.J. and Campbell, K.H.S. 1997. Viable Offspring Derived from Fetal and Adult Mammalian Cells. *Nature* 385: 810-813.

Wilmut, I. 2001. Pluripotent Stem Cells: Biology and Applications. *Trends in Molecular Medicine* 7: 240-241.

Wilmut, I. 2002. Are there any Normal Cloned Mammals? *Nature Medicine* 8: 215-216.

Wilson, M.D. 1969. *The Essential Descartes*, New York and Scarborough, Ontario: Meridian.

Wittgenstein, L. 1969. *Preliminary Studies for the 'Philosophical Investigations'* (Generally Known as The Blue and Brown Books), Second edn. Oxford: Basil Blackwell.

Wittgenstein, L. 1980. *Remarks on the Philosophy of Psychology: Volume II*, Oxford: Basil Blackwell.

Wobus, A.M., Wallakut, G. and Hescheler, J. 1991. Pluripotent Mouse Embryonic Stem Cells are Able to Differentiate into Cardiomycocytes Expressing Chronotropic Responses to Adrenergic and Cholinergic Agents and Ca2+ Channel Blockers. *Differentiation* 48: 173-182.

Wobus, A.M. 2001. Potential of Embryonic Stem Cells. *Molecular Aspects Medicine* 22: 149-164.

Wolpert, L. 2001. Ethical Link Between IVF and Stem-Cell Research. *Nature* 413: 107-108.

Wood, P.G. 1999. To What Extent can the Law Control Human Cloning. *Medicine, Science and the Law* 39: 3-10.

Woodbury, D., Schwarz, E.J., Prockop, D.J. and Black, I.B. 2000. Adult Rat and Human Bone Marrow Stromal Cells Differentiate into Neurones. *Journal of Neuroscience Research* 61: 364-370.

Wreen, M.J. 1986. The Power of Potentiality. *Theoria* 52: 16-40.

Wu, P., Tarasenko, Y.I., Gu, Y., Huang, L.Y., Coggeshall, R.E. and Yu, Y. 2002. Region-Specific Generation of Cholinergic Neurons from Fetal Human Neural Stem Cells Grafted in Adult Rat. *Nature Neurosciece* 5: 1271-1278.

Wulf, G.G., Jackson, K.A. and Goodell, M.A. 2001. Somatic Stem Cell Plasticity: Current Evidence and Emerging Concepts. *Experimental Hematology* 29: 1361-1370.

Wurmser, A.E. and Gage, F.H. 2002. Stem Cells: Cell Fusion Causes Confusion. *Nature* 416: 485-487.

Wynter, E.A.d. and Testa, N.G. 2001. Interest of Cord Blood Stem Cells. *Biomedical Pharmacotherapy* 55: 195-200.

Ying, Q.-L., Nichols, J., Evans, E.P. and Smith, A.G. 2002. Changing Potency by Spontaneous Fusion. *Nature Advance Online Publication* DOI 10.1038/nature729, 13 March: 1-3.

Young, E. 2001a. Blood Breakthrough for Embryonic Stem Cells. *NewScientist.com* September 4.

Young, E. 2001b. Life Line: Umbilical Cords Appear to be an Excellent Source of Stem Cells to Treat Stroke Damage, Says a US Team. *NewScientist.com* February 1.

Young, E. 2002. Human Embryonic Stem Cell Research Begins in UK. *NewScientist.com* 1 March.

Young, F.E. 2000. A Time for Restraint. *Science* 287: 1424.

Young, R. 1978. Dispensing with Moral Rights. *Political Theory* 6: 63-65.

Zandonella, C. 2003. Baby Teeth Revealed as Source of Stem Cells. *NewScientist.com* 21 April.

Zeman, A. 1997. Persistent Vegetative State. *Lancet* 350: 795-799.

Zeman, A. 2001. Consciousness. *Brain* 124: 1263-1289.

Zerhouni, E. 2003. Stem Cell Programs. *Science* 300: 911-912.

Zhen, H. 2002. On the Historical and Legal Nature of Human Rights: Reading *Human Rights and Human Diversity* by A. J. M. Milne. *Educational Philosophy and Theory* 34: 239-246.

Zoloth, L. 2001. Jordan's Banks: A View from the First Years of Human Embryonic Stem Cell Research. In: Holland, S., Lebacqz, K. and Zoloth, L., (Eds.) *The Human Embryonic Stem Cell Debate: Science, Ethics, and Public Policy*, Cambridge, Massachusetts: Massachusetts Institute of Technology. pp. 223-241.

Zuk, P.A., Zhu, M., Mizuno, H., Huang, J., Futrell, W., Katz, A.J., Benhaim, P., Lorenz, H.P. and Hedrick, M.H. 2001. Multilineage Cells from Human Adipose Tissue: Implications for Cell-Based Therapies. *Tissue Engineering* 7: 211-228.

Zwanziger, L.L. 2003. Crossing Perspecitival Chasms about Species. *American Journal of Bioethics* 3: 9-10.

List of Abbreviations

Scientific

AS Cell	Adult Stem Cell
BM	Bone Marrow
BMSC	Bone Marrow Stem Cell
CB	Cord Blood
CBS Cell	Cord Blood Stem Cell
CNR	Cell Nuclear Replacement
ECNT	Embryonic Cell Nuclear Transfer
EG Cell	Embryonic Germ Cell
ES Cell	Embryonic Stem Cell
HSC	Haematopoietic Stem Cell
ICM	Inner Cell Mass
IVF	In Vitro Fertilisation
MHC	Major Histocompatibility Complex
MSC	Multipotent Stem Cell
MS Cell	Mesenchymal Stem Cell
NT	Nuclear Transfer
NSC	Neural Stem Cell
TSC	Totipotent Stem Cell
PG Cell	Primordial Germ Cell
PSC	Pluripotent Stem Cell
SC	Stem Cell
SCNT	Somatic Cell Nuclear Transfer

Other

ASA	Argument from the Sufficiency of Agency
CFREU	Charter of Fundamental Rights of the European Union
CE	Council of Europe

CEU	Council of European Union
ECJ	European Court of Justice
ECHR	European Convention of Human Rights 1950
ECHRB	European Convention of Human Rights and Biomedicine 1997
EP	European Parliament
EU	European Union
FP6	Framework Six Programme
PGC	Principle of Generic Consistency
SPC	Strict Potentiality Criterion
UDGR	Universal Declaration of Human Rights 1948

Abbreviations of Advisory Bodies

ABC	Austrian Bioethics Committee (Austria)
ACE	Advisory Committee on Ethics of Scientific and technical Research (Spain)
CCB	Belgian National Consultative Bioethics Committee (Belgium)
CCNE	National Consultative Ethics Committee for Health and Life Sciences (France)
CDBI	Steering Committee on Bioethics (Council of Europe)
CGT	ad hoc Committee on Genetic Technology (Denmark)
CNB	National Bioethics Committee (Italy)
CNEVC	National Council on Ethics for the Life Sciences (Portugal)
CNRS	Centre for Scientific Research (France)
COMETS	Committee on Ethics for the Sciences (France)
CVK	Central-Scientific-Ethical Committee of Denmark (Denmark)
DCE	Danish Council on Ethics (Denmark)
DFG	German Research Council (Germany)
DoH	Department of Health (UK)
DRA	Danish Research Agency (Denmark)
EGE	European Group on Ethics in Science and New Technologies (European Commission)
EK	Enquete-Kommission (Germany)

ESHRE	European Society of Human Reproduction and Embryology (Task Force on Ethics and Law)
ESF	European Science Foundation
ETENE	National Advisory Board on Health Care Ethics (Finland)
FIGO	International Federation of Gynaecology and Obstetrics
FWO	National Fund for Scientific Research (Belgium)
HCN	Health Council of the Netherlands (Netherlands)
HFEA	Human Fertilisation and Embryology Authority (UK)
HGAC	Human Genetic Advisory Commission
HNBC	Hellenic National Bioethics Commission (Greece)
IAP	Interdisciplinary Panel (International)
IBC	International Bioethics Committee (UNESCO)
MRC	Medical Research Council (UK)
NABHCE	National Advisory Board on Research Ethics (Finland)
NCB	Nuffield Council on Bioethics
NCEC	National Consultative Committee for Life and Health Sciences (Luxembourg)
NCHAR	National Commission of Human Assisted Reproduction (Spain)
NEC	National Ethics Council (Germany)
NorCB	Nordic Committee on Bioethics
OBL	Observatory on Ethics and Biolaw, Barcelona (Spain)
RS	The Royal Society (UK)
SCGI	Committee on Genetic Integrity (Sweden)
Sel. Com.	House of Lords Select Committee on Stem Cell Research (UK)
SMER	Swedish National Council on Medical Ethics (Sweden)
SRC	Swedish Research Council (Sweden)
WT	Wellcome Trust (UK)
ZonMw	Netherlands Organisation for Health Research and Development (Netherlands)

Glossary

Abortion	Spontaneous or induced termination of pregnancy.
Blastocyst	An early stage in the development of embryos, when (in mammals) the embryo is a spherical body comprising an inner cell mass that will become the foetus surrounded by an outer ring of cells (trophoblast) that will become part of the placenta.
Blastomere	One of the (totipotent) cells formed by division of the fertilised egg making up the blastula.
Carcinoma	Any of the various types of cancerous tumours that form in the epithelial tissue, the tissue forming the outer layer of the body surface and lining the digestive tract and other hollow structures.
Chimera	A chimera; a tissue containing two or more genetically distinct cell types, or an individual composed of such tissues. Individual made up of two or more genetically distinct cell lines.
Chromosome	One of the threadlike "packages" of genes and other DNA in the nucleus of a cell. Different kinds of organisms have different numbers of chromosomes. Humans have 23 pairs of chromosomes, 46 in all: 44 autosomes and two sex chromosomes. Each parent contributes one chromosome to each pair, so children get half of their chromosomes from their mothers and half from their fathers. Heritable determinant of the phenotype. The fundamental physical and functional unit of heredity, which carries information from one generation to the next.
Cloning	(1) the isolation and characterisation of DNA segments coding for proteins (genes) using carrier pieces of DNA called vectors; or (2) the asexual reproduction of a new human organism that is, at all stages of development, genetically virtually identical to a currently existing, or previously existing, human being.
Conceptus	The product of conception, including the embryo proper and extra embryonic tissues.
Cryopreservation	Storage by Freezing. Usually to store embryos created by IVF.
Culture	Tissue or cells multiplying by asexual division, grown for experimentation.
Cytoplasm	The material between the nuclear and cell membranes.
Differentiation	The changes in cell shape and physiology associated with the production of the final cell types of a particular organ or tissue.
Diploid	The state of having each chromosome in two copies per nucleus or cell. A cell having two chromosome sets, or an individual having two chromosome sets in each of its cells.
DNA	The chemical inside the nucleus of a cell that carries the genetic instructions for making living organisms.

Ectoderm	The outer of the three germ layers of the embryo. Gives rise of the nervous system and sense organs, teeth and lining of the mouth and to the epidermis and its associated structures.
Ectopic Pregnancy	The development of the foetus at any other site other than the uterus.
Embryo	An organism in the early stages of development.
Embryo Proper	Sometimes used to define the part of the conceptus that will develop into the foetus from those cells which will support its growth.
Embryo Splitting	(Artificial) dividing of an early (pre-) embryo into one or more embryos by the separation of the blastomeres.
Embryonic Germ Cell	Cells that are derived from the primordial germ cells of the embryo/foetus.
Embryonic Stem Cell	Pluripotent cells derived from the ICM of a blastocytst embryo
Endoderm	The inner most of the three germ layers. Gives rise to the lining of most of the alimentary canal and its associated glands, the liver, gall bladder, and pancreas. It forms the lining of the bronchi and alveoli of the lung and most of the unary tract.
Enucleate	To remove the nucleus of a cell leaving it intact and competent to accommodate a foreign nucleus.
Epigenetic/ Epigenesis	The process of turning genes on and off during cell differentiation. It may be accomplished by changes in (a) DNA methylation, (b) the assembly of histone proteins into nucleosomes, and (c) remodelling of chromosome-associated proteins such as linker histones.
Extra-embryonic tissue	The membranous structures that surround the embryo which contributes to the placenta and umbilical cord.
Fertilisation	The process beginning with penetration of the secondary oocyte by the spermatozoon and completed by fusion of the male and female pro-nuclei.
Foetus	Mammalian embryo during that later stages of development with in the uterus.
Gamete	A reproductive cell (egg or sperm). A germ cell having a haploid chromosome complement. Gametes from parents of opposite sexes fuse to form diploid zygotes.
Gene	The functional and physical unit of heredity passed from parent to offspring. Genes are pieces of DNA, and most genes contain the information for making a specific protein.
Genome	The entire complement of genetic material in a chromosome set.

Genotype	The specific genetic composition of a cell, either of the entire cell or more commonly for a certain gene or a set of genes. The genes that an organism possesses.
Germ Layer	Any one of the three distinct types of tissue found in the early states of embryonic development (see ectoderm, endoderm and mesoderm).
Graft-versus-Host Disease	Immune reaction of the body to bone marrow transplantation and blood transfusions.
Haploid	The state of having one copy of each chromosome per nucleus or cell. A cell having one chromosome set, or an organism composed of such cells.
Hybrid	A progeny individual from any cross involving parents of differing genotypes. Offspring of unlike parents
Hydatidiform Mole	A collection of fluid filled sacs that develops when the extra-embryonic membranes degenerates in pregnancy. The embryo dies and a malignant condition may subsequently develop.
Implantation	(or nidation) the attachment of the early embryo to the lining of the uterus, which occurs at the blastocyst stage.
Immune Reaction (response)	Response of the immune system to antigens (a foreign substance/organ/tissue/infection) to provide an ability to resist infection.
In utero	Occurring in the uterus.
In vitro	The union of an egg and sperm, where the event takes place outside the body and in an artificial environment (the literal meaning of "in vitro" is "in glass"; for example, in a test tube). In an experimental situation outside the organism. Biological or chemical work done in the test tube (literally in glass) rather than in living systems.
In vivo	In a living cell or organism
Inner Cell Mass (ICM)	Centrally located cells within the blasocyts which give rise to the embryo proper.
***In vitro* fertilisation (IVF)**	An artificial process where an egg is fertilised (in vitro) with a sperm outside the uterus.
Karyotype	The chromosome complement of a cell.
Mesoderm	Middle of the three germ layers of the embryo; origin of all connective tissue, all body musculature, blood, cardiovascular and lymphatic systems, most of the urogenital system, and lining of the pericardial, plural, and peritoneal cavities.
Meiosis	The division of a haploid genome into a diploid state. The diploid number of chromosomes is restored in fertilisation.
Mitosis	Cell division where a single cell produces two genetically identical daughter cells.

Multipotent	Capacity to divide into one or more phenotypically distinct cells.
Neurone	Nerve cell and one of the basic functional units of the nervous system.
Nucleus	The membrane bound organelle containing the genome of a cell organised into chromosomes.
Oocyte	Cell in the ovary that undergoes meiosis to form the ovum. Oocyte is often used to denote the ovum as well, because the final stage of meiosis only occurs when the oocyte has been activated by fertilisation.
Ovum	The mature female egg cell.
Parthenogenesis	The development of an ovum without sperm.
Phenotype	(1) The form taken by some character (or group of characters) in a specific individual. (2) The detectable outward manifestations of a specific genotype. (3) The observable attributes of an organism.
Placenta	An organ within the uterus by means of which the embryo is attached to the wall of the uterus and to provide nourishment, eliminate wastes and exchange respiratory gasses.
Pluripotent	Cells that can generate all the cell types in a foetus and are able to self renew.
Pre-embryo	(Sometimes used to) refer to the embryo before cellular commitment occurs (normally cited at around the 14th day or the development of the primitive streak).
Primitive Streak	The region of the embryo that proliferates to produce the mesoderm cells that spread outwards between the layers of the ectoderm and the endoderm.
Potency	An ability of a cell to differentiate and divide by cloning itself.
Reproductive Cloning	Production of a cloned human embryo, formed for the (proximate) purpose of initiating a pregnancy, with the (ultimate) goal of producing a child who will be genetically virtually identical to a currently existing or previously existing individual.
Somatic cell	A cell that is not destined to become a gamete; a cell whose genes will cannot be passed on to future generations.
Species	(1) A group of organisms belong to the same biological species if they are capable of interbreeding to produce fertile offspring; (2) Organisms are classified in the same species if they appear identical by morphological (anatomical) criteria.
Sperm	Cells that are capable both of perpetuating themselves and of undergoing differentiation into one or more specialised types of cells.
Syngamy	The final stages of fertilisation in which the chromosomes from the male and female gametes come together to form the zygote.

Teratoma	Tumour containing a number of tissues not normally found at that site.
Therapeutic Cloning	Production of a cloned human embryo, formed for the (proximate) purpose of using it in research or for extracting its stem cells, with the (ultimate) goals of gaining scientific knowledge of normal and abnormal development and of developing cures for human diseases.
Totipotent	Cells that can differentiate into all the cells of the conceptus and therefore generate an entire organism.
Trophoblast	Outer most layer of the blasocytst in mammals and will develop the extra-embryonic tissues.
Tumour	Abnormal growth of tissue which may be benign (does not invade adjacent tissue or spread to distant sites) or malignant (invades and destroys the tissues in which it originates and can spread to other sites).
Umbilical Cord	The strand of tissue connecting the foetus to the placenta.
Uterus	(womb) The part of the female reproductive tract that is specialised to allow the embryo to become implanted.
Viable	Capable of living a separate existence.
Zygote	The diploid cell that results from the fertilisation of an egg cell by a sperm cell. The unique diploid cell formed by the fusion of two haploid cells (often an egg and a sperm) that will divide mitotically to create a differentiated diploid organism.

Appendix One

Foetal and Cord Blood Stem Cells

1. Foetal Stem Cells

This account continues from the end of the second week, and is termed as the *late embryonic stage*. Once implanted in the uterine lining, full development commences with the development of a faint groove along the surface of the embryo (the 'embryo proper' is made up from the cells of the epiblast) called the primitive streak and signals the symmetrical development of the embryo. Between the 10th and 14th day, primordial germ cells can be isolated from the gonadal (genital) ridges. At around this point, these cells are the only remaining pluripotent cells in the embryo and are the progenitors of the female and male germ cells. The primordial germ cells migrate to populate the gonads, and will eventually form the gametes.

Gastrulation begins around the 16th day – the formation of distinct cellular layers from the epiblast via cell migration that establish all three germ layers: the endoderm (forms gut and gut derivatives) and mesoderm (skeleton, voluntary muscle, skin, urinary system and parts of the genital system, inner lining of the body and dermis); the epiblast itself becomes the ectoderm which forms the parts of the epidermis and cells of the central nervous system. The embryo at this point resembles a flat pear-shaped disc.

On the 17th day the notocord begins development, which will become the axial skeleton. On day 20 the somite cells start to form the segmental organisation of the body of the embryo. Organogenesis begins at the end of the third week. The neural plate forms, and at day 27 neurulation is complete, consisting of an enclosed neural tube (this will become the spinal cord; at one end the tube will form the anterior neuropore which will become the head of the embryo). By 28 days, the beginning of eye and ear development can be seen at the neuropore. The cells of the mesoderm differentiate into blood cells and blood vessels; the beginning of the heart's functional development is evident (between the 19th and 26th day).

At the end of the fourth week the embryo begins to look like a 'foetus'; with a head, limbs (and tail, signalling its evolutionary heritage). Internally, the primitive skeleton develops. Embryonic folding, that began around the 22nd day, is complete and

yields a three-dimensional embryo that is enclosed in the amniotic sac. From around the 28th day onwards all other rudimentary organs begin to develop. Some begin to fully function: notably the circulatory system and heart. At around the 42nd day the first signs of the cerebral cortex are discernible and the umbilical cord is fully formed. The embryo has a face and rudimentary arms and legs with digital rays.

There is general agreement that the foetal stage commences at around 56 days[1]. By this point most of the organs and systems of the body are formed. The foetal stage sees the maturation of these organ systems and net growth[2].

The foetal period is devoted mainly to the maturation of the organ systems and to growth, and is divided into three 3-month trimesters (1st: 1-3 months; 2nd 4-6: 3rd 7-9). It has not yet been possible to keep alive a foetus born before 22 weeks, and foetuses born before 28 weeks have a high morbidity. All of the organ systems are present at 8 weeks but only the heart and blood vessels (4th week) are functionally circulating blood. Most have full or rudimentary functionality by birth, with some notable exceptions: this accounts for the prolonged helplessness of human infancy in comparison with other mammals. The most slowly maturing organ of humans, and one that largely sets the pace of infancy and childhood, is the brain.

Human embryonic germ (EG) cells can be isolated from the primordial germ cells (Shamblott et al. 1998; also see Stewart et al. 1994; & Durcova-Hills et al. 2001). It would seem that the time of derivation of the cells alters their developmental potential, which may be a result of genomic imprinting (Durcova-Hills et al. 2001).

In chimeras, EG cells can contribute to a number of tissues as well as the germ line. In animal models they have derived in vitro a number of tissues. These cells *in vitro,* are self-renewing over a number of generations, and evidently pluripotent, and so can be coaxed into forming any cells of the organism (several cell types in animal models, including cardiac muscle, have been differentiated in vitro; Durcova-Hills et al. 2001).

---

[1] Although there is disagreement; See for example Lee and Morgan (2001) pp. 58-64.

[2] It also the case that mere biological 'will' (or simple tendency in the nature of things) is not sufficient for agency by itself: 'The foetus is not thought of nowadays as an inert passenger in pregnancy but, rather, as in command of it. The foetus, in collaboration with the placenta, (a) ensures the endocrine success of pregnancy, (b) induces changes in maternal physiology which make her a suitable host, (c) is responsible for solving immunological problems raised by its intimate contact with its mother, and (d) determines the duration of pregnancy' (Findlay 1984 p. 96). This however only attributes 'biological agency' to the embryo/foetus. It cannot be taken for granted that there is a rational will at work (that it is taking responsibility for its own interest, and is aware of, and capably of acting on them), and not only a state of nature.

At present, EG cells differ in situational, morphology and functionally distinct ways from their ES counterparts, casting doubt on the assumption that they are of the same type as ES cells. The main difference is that when the EG cells are implanted into early mouse embryos, they are apt to develop abnormally (Hadjantonakis & Papaioannou 2001). This is thought to occur because the genes of the EG cells lack certain modifications needed for their normal activity during development (Steghaus-Kovac 1999)[3]. The changing epigenetic state of imprinted gene in EG cells may render them less suitable than other cells for use in cell and tissue therapy (Onyango et al. 2002). On the other hand, as Durcova-Hills et al. (2001) point out, reports of defects in some EG cell derived chimeras do not necessarily mean that all EG-derived differentiated tissue will show the same abnormalities.

Stem cells isolated from the foetus are biologically similar to ES stem cells (Wu et al. 2002). Foetal neural stem cells have been taken from mice and genetically altered (to produce the cancer-killing immune chemical interleukin 12) to attack brain tumours in mice (Ehtesham et al. 2002). These cells do appear to have a limited culture life, but they also do not seem to produce carcinomas (Rosenthal 2003).

Human neural stem cells have also been coaxed to form committed neurones after specific chemical treatment in vitro and then implanted into live animals' brain or spinal cord (Wu et al. 2002). At present it is not known whether these transplanted cells are functional or remain long-term, or have a capacity to form tumours. Human foetal stem cells are extremely difficult to obtain in sufficient quantities and quality for transplant or research (Svedsen & Smith 1999).

Additionally, amniotic fluid may contain stem cells (In't Anker et al. 2003). Researchers have isolated cells that express tell-tell markers of pluripotent stem cells (see Donovan 2001); and differentiated them in vivo (In 't Anker et al. 2003).

---

[3] These reversible modifications are *imprinting*, stable and heritable epigenetic modifications leading to monoallelic expression of some genes (the mechanism is responsible for such essential genomic features as female X chromosome silencing). The process alters the DNA by selectively silencing the DNA without alteration to the actual sequence. Importantly, this process controls the expression of genes in differentiating cells so that diverse appearance and function can be obtained in tissues. A wiped clean genome therefore corresponds to a totipotent cell, and subsequent programming will define the fate of that cell (Lane et al. 2003; Reik & Dean 2002). The problem therefore arises that if cells are isolated from the germ cells then the imprints may be absent or mismatched, so that either both copies of the parental genes are either expressed or both are inactive. This can seemingly cause development problems, and are thought to be the cause of the high incidence of premature fatality and developmental abnormalities in offspring created by somatic cell nuclear transfer (Reik et al. 2001).

There is general agreement in policy with regards to foetal research and cord blood research on stem cells. The following outlines the most salient factors in these types of research.

There is relatively little formal information regarding the policies of research on foetuses *in vitro* available in English. Generally, however, there seems to be a similar paradigm internationally (which can be implicitly gleaned from the Advisory Reports). Two forms of regulation are found in the Netherlands (Embryo Act 2001) and the United Kingdom (Polkinghorne Report 1989); the first is a legislative act, the latter a voluntary *code of practice*. The latter will be used to illustrate this common approach, since it is at present the most detailed account of this type of research (and the former, as with other available codes, regulations or policies, does not substantially differ).

The *Polkinghorne Report*[4] relates to the foetus, whether *in vitro* and *in utero* (2.4). The *live* foetus cannot be used in research unless it carries a minimal risk of harm, or if greater risk than this is involved, the action is, on balance, for the benefit of the foetus (para 3.2). Only the *dead* foetus can be used in research (p. 22, para 1.1(b)). The decision to carry out an abortion or management of the pregnancy cannot be a consideration of the subsequent use (p. 22 paras 3.1 & 3.2) (see Appendix Five on *Abortion in the Member States*). Furthermore, consent to a termination must be reached before consent is sought to use the foetal tissue (p. 23 para 4.2). Written consent should be obtained from the mother before any research takes place (p. 23 para 4.1); and all research must be evaluated by a local ethics committee (p. 24 para 6).

The general pattern of EU regulation (where it is explicit) states that where foetal research is permitted (and this is unanimously permissible only on dead foetuses and with the informed consent or veto of the mother; Wert et al. 2002), it is normally an unequivocal condition that the research and researcher are entirely separated (to a more or less degree) from the context of the abortion. This is normally achieved by allowing no access to the woman by the researcher, and the decision to terminate being made prior to any consent to donate tissue (there is sometimes a 'waiting period' between an elective abortion and giving consent for research). Sometimes a more specific limitation is included, that the woman should not be able to designate the recipient of the cells (Wert et al. 2002). As with embryo research, the commercialisation of foetal

---

[4] Polkinghorne, John. 1989. *Review of the Guidance on Research Use of Foetuses and Foetal Material.* HMSO: London. This replaced the *Peel Report.* 1972. *The Use of Foetuses and Foetal Material for Research.* HMSO: London.

derived cells is generally not endorsed, and approval for experimental use must be reviewed by a relevant ethics committee.

These views are expressed by Advisory Bodies that comment on such matters, and in general, if these general provisions are followed, there are no new or unrecognisable concerns with this type of research (see: ABC 2002a; EK 2001; FIGO 1997; HNBC 2002; HCN 2002; DCE 2002; SRC 2001; & SMER 2002).

2. Cord Blood Stem Cells

UCB contains a number of normal biological constituents. The various phenotypic stem cells are identified as a small percentage of the total volume of UCB, which also contains red cells (erythrocytes), platelets, white cells (leucocytes), and other normal (unrelated) biological elements, as well as any contaminants (such as viruses, bacteria and maternal blood), suspended in the plasma. Cord blood has a higher proliferative capacity than cells obtained from the bone marrow and peripheral blood and is often used successfully in reconstituting a patient's deficient or compromised haemopoietic (blood) system caused by a rare genetic condition or disease or to recover post-cancer therapy[5].

The cells of the haemopoietic system share a common lineage in that they all originate from an ancestral stem cell. The common parental cell is the multipotent *haemopoietic stem cell* (HSC)[6], which is able to differentiate into the cells typical of the lymph/haemopoietic system. All blood cells derive from HSCs via secondary multipotent progenitor cells and tertiary myeloid (common myeloid progenitors) and lymphoid (common lymphoid progenitors) stem cells (two related lineages leading to the cell constituents of the myeloid[7] system and the lymphatic system[8]). The final hierarchically ordered unipotent progenitor cells (differentially limited to a single cell lineage; e.g. Pro-B cells) or progenitors that produce very few different phenotypes

---

[5] Other constituents of the cord blood can be used in therapeutic treatment. For example, foetal haemoglobin, which is particularly oxygen rich, can be used in treating critically ill from intensive care units (Bhattacharya et al. 2001).

[6] Which exists as two classes: long-term-HSC (LT-HSC) (which self-renews for the life of the host) and short-term-HSC (ST-HSC) (which retain self-renewal capacity for approximately 8 weeks) (Weissman 2000b; Reya et al. 2001). The ST-HSC derives from the LT-HSC.

[7] Related to the bone marrow that produces all constituents of the blood.

[8] A network of vessels that forms the fluid connection between the tissues and blood system.

(such as granulocyte macrophage precursors, from which dendritic cells, granulocytes and macrophages are derived), are directly responsible for the derivation of the blood cells. It is also speculated that 'true' pluripotent[9] stem cells[10], similar to mesenchymal stem cells isolated from bone marrow, may exist in the cord blood (for review, see: Pittenger & Marshak 2001; Bianco & Robey 2001).

While the presence of a cord blood pluripotent stem cell remains elusive, therapeutic treatments presently exist using the multipotency of the HSC to reconstitute the host lymph/haemopoietic compartment. However, it is not clear whether reconstitution is achieved by cord blood HSCs (either multi- or pluripotent) or some other stem cell 'contaminant' (i.e. freely circulating mesenchymal stem cells). 'Purified' UCB is always contaminated to an extent, and therefore it remains to be conclusively shown whether a single HSC is capable of regenerating both blood-associated cells and novel cell types, thus be truly pluripotent (Wulf et al. 2001).

There are few ethical concerns with the collection and research using cells from cord blood, and this is reflected in the national advisory bodies almost universally promoting such research[11] (see: ABC 2002a; FIGO 1997; EK. 2001; HNBC 2002; HCN 2002; DCE 2002; SRC 2001; SMER 2002; NCB 2000). The lack of contention in the use of umbilical cord blood cells has been often quoted by anti-ES cell research positions, but like all stem cell research, the results are far from conclusive, and therefore is generally promoted concurrently with other avenues of research.

---

[9] These stem cells can differentiate into all the cells of the organism but not the placental support tissue.
[10] The existence of such cells is yet to be demonstrated and their hypothetical presence is extrapolated from the identification of such cells from related and unrelated somatic environments. There is evidence to suggest that such cells are not present in umbilical cord blood; although it has been reported that it is possible to isolate stem cells in human peripheral blood capable of differentiation into skin, liver and intestinal tissue (Hows, J. *personal communication*).
[11] There are concerns as to the timing of collection, storage and use of cord blood stem cells (Kmietowicz 2001; Hows 2001; Smith & Thomson 2000). In the development of UCB transplantation it has been emphasised that there would be an advantage to setting up minimum standards of storage and agreement on international aspects that protect the infant donor and the mother and the effects this has on their consent. In the context progress has been made in setting up registries for finding immunological matches and programmes with the aim of creating a standardised system of accreditation officially recognised across Europe. These programmes are centralised in order to maintain the same strictness, criteria and standards in different European countries.

Appendix Two

Gewirth Argument for Human Rights from the Content of Agent Action

In *Reason and Morality* (1978) Gewirth argues that:

> ...every agent, by the fact of engaging in action, is logically committed to the acceptance of certain evaluative and deontic judgements and ultimately of a supreme principle of morality, the Principle of Generic Constancy [PGC], which requires that he respect his recipients' necessary conditions of action (Gewirth 1978 p. x; in the following, square bracketed numbers will refer to page numbers in *Reason and Morality* 1978).

The task at hand is to present (and not defend) Gewirth's argument in a manner suitable for the reader to understand the theory behind the contingent argument presented in the text (Chapt Two s. 7.2). Therefore, I will summarise the main structural points of the argument (with few points of clarification where there is need to redress for application).

Gewirth constructs a *dialectically necessary* (*non-contingent*) argument for the PGC. This requires the necessary assumption of a 'correspondence correlate', in this case, rational agency, and an argument to explain what this logically entails from the viewpoint of the agent; so for Gewirth, the argument follows from the internal viewpoint of the agent. The argument is *dialectically necessary* because the method begins from statements that are necessarily attributed to every agent because of the generic features of action (i.e. all agents act according to the same premise), and from this premise, the following statements cannot be denied without self-contradiction [43-44, 80] (on '*The Pain of Self Contradiction*', also see Gewirth 1982a p. 26). Therefore, rational beings, according to Gewirth, are incapable of *maintaining* a pattern of thought that is irrational.

The PGC establishes judgements of moral obligation as 'categorical': '...in that what persons morally ought to do sets requirements from them that they cannot rightly evade by consulting their own self-interested desires or variable opinions, ideals, or institutional practices' [24]. So that the argument progresses from a positive evaluation of the generic features of agency, to the idea of generic rights, to the universalisation of generic rights. Each of these stages, according to Gewirth, logically can be traced back to an agent's acceptance of the statement 'I am an agent'. All moral beings are agents

that act for chosen purposes, Gewirth continues that from this premise it is impossible, without self-contradiction, for an agent to deny that it is an agent, and therefore not accept the precepts of the PGC.

The argument has provoked a great deal of debate, not least because '...it gives every appearance of having developed a watertight case, for its arguments are set out with enormous deductive rigor and frightening dialectical skill' (Regis 1984 p. 2). Regis continues, '...is to experience the sense of being caught in an ever-tightening net from which all conceivable avenues of escape have been blocked in advance' (ibid.). Regis then turns to the work of Nozick[1], in stating that '[t]his is "philosophy as a coercive activity,"' and Gewirth come quite close to the extreme of propounding 'arguments so powerful they set up reverberations in the brain: if the person refuses to accept the conclusion, he *dies*' (ibid.). Neilsen continues this line: 'Remember that Gewirth, like Kant, is trying to get categorically binding moral principles (principles binding on every rational agent) – including categorical right-claims – from the sheer concept of agency ...trying to get so much out of a bare concept of agency is like trying to squeeze blood out of a turnip...' (1984 p. 79).

The objections to the argument to the PGC, up until 1988, have been responded to by Deryck Beyleveld in *The Dialectical Necessity of Morality* (1991). Two books have been dedicated to discussions about the criticisms of the theory to date, and include specific responses by Gewirth (Boylan 1999a; Regis 1984). The argument has also been subject to continuing criticism and defences published in numerous articles, some of which will be referenced in the following.

The dialectically necessary procedure that Gewirth employs does not establish the:

> ...PGC itself as a necessary truth or even that it requires the PGC to be thought of as capable of being either true or false ...Gewirth certainly never claims ...that statements contradicting the PGC is a contradiction; only that those who make statements contradicting the PGC contradict that they are agents! What Gewirth's argument establishes is that, because the PGC is dialectically necessary, agents are as much required to accept that they (rationally) ought to act in accordance with the PGC as they would be required to do if the PGC itself were a necessary truth (Beyleveld 2002 p. 470).

---

[1] Nozick (1981) p. 4. Nozick introduces *Philosophical Explanations* with an account of 'Coercive Philosophy'; arguments that *force* you to a conclusion, regardless of whether you want to believe it or not. He does not, suffice to say, agree with such coercive methods.

Gewirth shows that an agent's claim to a right derived from her rational propensity to act[2]. Her status as an agent is vulnerable and therefore through the actions of others she reasons[3] that she could lose them; she not only *wants* these goods not to be interfered with, but she also (prudentially) requires them because of their instrumental function as means to her acting, and acting successfully, at all.

Gewirth addresses three questions. The authoritative question requires one to consider why should one be moral? Gewirth shows that the requirement of 'morality' is that all agents are categorically obliged to have concern for other persons rights to the necessary goods that allow the very prospect of them being a successful and flourishing agent. These requirements purport to set a guide for conduct, which takes precedence over all other modes of guiding action; the compliance of which is mandatory for every agent whether it wants to accept them or their results, and may only be overridden by another similarly derived moral requirement and not by any non-moral requirement. Thus the obligatoriness of the requirements for any persons conduct are not contingent on accepting the PGC or the rules that flow from it and regardless of the prospective ends. The 'first-order' analysis (of the supreme principle of morality – the PGC) shows that it would be contradictory not to accept and act on the 'second-order' principles (the precepts of the PGC) and rules; and that these 'second-order' judgements must be addressed to the generic rights all agents according to the ends pursued.

The distributive question considers whose interests, other than ones own, should the agent favourably consider in action [3]. The holding of a right is assumed in international law to be a requisite value in all human beings. However, on Gewirth's understanding of rights, some human beings cannot be members of the community of rights, because they are not capable of controlling their actions in a rule-governed way. They do not have the capacities to be bearers of duties, as well as holders of rights.

---

[2] Action as a justificatory argument for morality is itself morally neutral. This as opposed to evaluative concept such as human dignity as identified as the valuable status for a characteristically human existence protected in human rights. This is because action is comprised of the *generic features of action* which are certain invariant features generic of all action – '...it fits all moralities rather than reflecting or deriving from any one normative moral position as against another' [25]. The generic features of action are a feature of all morality. All moral precepts, regardless of their further contents, deal directly or indirectly with how a person ought to act.

[3] Reason, according to Gewirth is used in a 'strict sense as comprising only the cannons of deductive and inductive logic... deduction and induction are the only sure ways of avoiding arbitrariness and obtaining objectivity and hence a correctness or truth that reflects not personal whims or prejudices but the requirements of the subject matter [22]. ...reason itself [must] in turn pass various justificatory test... But the very scrutiny to determine whether these tests are passed must make use of reason... Thus any attack on reason or any claim to supersede it by some other human power or criterion must rely on reason to

Despite much work to clarify the concept of the moral 'right'; which has been in part successful in limiting by way of positive law actions that cannot be acceptable in a social society – little has been agreed upon the substantive question – or what rights there are. The clarification of a substantive justification of human rights would indicate the scope and content of those rights

The argument that follows is an overview of Gewirth's argument to the PGC, primarily taken from Beyleveld's account in *The Dialectical Necessity of Morality* (1991), which is a concise version of the argument in *Reason and Morality*. For clarity, Beyleveld divided the argument to the PGC into three stages[4].

Stage 1: From Agency to Necessary Goods

Gewirth's account of morality is derived from his application of reason to the concept of action. 'Action', viewed as behaviour done voluntarily to achieve a freely chosen purpose, as was previously discussed, is a grounding nature of an agent [22, 27; on the *generic features of action* see especially 26-42]. The following statement can be considered an articulation (by definition) of the purposive nature of such an agent[5] (PPA[6]) from its internal point of view:

(1) 'I do (or intend to do) X voluntarily for (my freely chosen) purpose E.'

What is important here is not only a minimal relationship between means and ends, but also the commitment of a PPA to its freely chosen purposes, E[7]. For Beyleveld, this entails that the PPA must hold[8]:

---

justify its claims' [23]. Reason is therefore shown to be a morally neutral, non-arbitrary and logically coherent starting justification for action [25].

[4] This summary is mainly from Beyleveld 1991 and a general reference should be made to that. The format of the argument is based upon the presentation of the argument by Beyleveld in *Dialectical Necessity of Morality* 1991 chapter 2. Again, numbers in square brackets will refer to Gewirth 1978.

[5] 'Agent' and 'PPA' do not necessarily refer to a human being or 'person'. An agent can be any being that has the sufficient and necessary capacities of agency.

[6] Beyleveld tends to use the term PPA (prospective purposive agent), rather than agent, for the accurate account of the argument.

[7] This can also include such purposes as entering a state of 'desireless nirvana' (Bond 1980 p. 45; & reply by Gewirth 1980 p. 64), 'selling oneself into slavery', or 'committing suicide' (Beyleveld 1991 pp. 77-78); as such purposes would '...require the practical use or availability of certain resources, and hence, potentially at least, certain actions' (Gewirth 1980 p. 64). For example, '...I still need to be free to do the things necessary to bring this state of affairs about' (Beyleveld 1991 p. 78). The selection of X does not need to be instrumentally rational for a PPA. All the PPA has to be able to do is understand that the ends requires means to achieve it, even if they may not be the most effective means to that end. It does not

(2) 'E is good.'

This does not mean that the end must be considered good in a moral sense or is intrinsically good, as an assertoric[9] evaluation may entail[10]. Must the pro-active attitude attached to E be good in a 'definitive' or 'fixed' sense[11]? The answer is no, since Gewirth is attempting to argue more simply that a PPA is making the pro-active evaluation of E on the grounds that if it did not value E in a minimal sense, there would be no motivation to attempt to achieve it over all other potential purposes or to stir it from quiescence [51-52][12]. Beyleveld puts Gewirth's argument another way, which employs less critical terminology:[13]

(2a) 'I attach a positive value to E on some ground, which motivates me to pursue E.'

Gewirth now employs the concept of the *generic features of agency*[14]. As was argued above, the generic features of agency are required for the possibility of a PPA achieving its purposes, or achieving its purposes with any chance of success. Therefore, a PPA, from the dialectical point of view, must acknowledge that[15]:

---

presuppose a distinction between dispositional and occurrent ends or the abandonment of purposes to achieve 'long-term' good.

[8] Beyleveld (1991) p. 21.

[9] Assertoric is *about* E (so that assertorically, E is good), and not about some person's judgement or statement about E, as in the dialectical method (so that E is good from the standpoint of some person, or that some person says or thinks 'E is good') [45].

[10] E could be considered morally good by PPA who adopts 'S' viewpoint on morality which coincides with E. Equally, E could be morally bad on the same viewpoint 'S' [44, 50-51].

[11] Puolimatka argues that a '...PPA could be agnostic about what is good' or '...have purposes it regards as bad and act because it is moved by these bad purposes' (quoted in Beyleveld 1991 p. 76). See Beyleveld for a detailed reply (pp. 76-77).

[12] If the PPA is acting under compulsion, then the PPA may not consider E to be 'good'. However, if the PPA is being coerced in this way, it is not engaging in practical action according to the definition of action in (1). See Beyleveld (1991) pp. 76-77.

[13] Beyleveld 1991 p. 22.

[14] Or *generic features of action*. All agents act, therefore, action is the same as agency, for these purposes [25]. Gewirth states: '...just as action provides the necessary content of all morality, so the generic features provide the necessary content of all action' [ibid.].

[15] Both as being rational to follow the argument and also as being the subject-matter of the argument (Gewirth 1982b p. 669). Importantly the argument proceeds on the claim that it is the agent's purposivness, rather than his rationality as such, that is shown to be crucial to the claiming and allocation of rights (and hence the agents degree of rationality does not affect the argument: '...his claiming of rights is based simply on his having purposes he wants to fulfil, not on his degree of rationality or of

(3) 'The generic features of agency are the necessary conditions of my agency.'

From this point of view, whatever purposes I want to achieve, I must value the generic features of agency [52-58]. If a PPA does not have the generic features of agency, then it is highly unlikely or impossible to achieve its given purpose E[16].

Gewirth is concerned with the *generic instrumental value* the generic features of agency have for a PPA's agency[17]. They are the means to any purpose that PPA wants to achieve, and without the generic features of agency, there is none or little chance of PPA being able to achieve this purpose[18]. Therefore, a PPA must assert that:

(4) 'The generic features of agency are necessary goods';

because having the features of agency is good (and necessary) for my achieving E, whatever E might be.

Thus far, Gewirth has shown that rights and rights-claims are necessarily connected with action, in that every agent, on pain of self-contradiction, must hold or accept that he has rights to the necessary conditions of action. In the next stage, Gewirth shows that from this an agent must, at least prudentially, accept that she has (generic) rights to the necessary goods of freedom and wellbeing.

---

practical effectiveness in achieving his purposes. Rationality is, however, involved in being a prospective purposive agent, in that such agency requires certain practical abilities') (ibid.).

[16] Basic goods and freedom are required for the possibility of action is both an occurrent and dispositional sense. 'Occurant' means in a specific situation and time [253]. For example, if I was lied to concerning an important aspect of a transaction, I would have very little chance of achieving what I set out to achieve in the transaction [58-61]. 'Dispositional' means that a PPA requires a specific generic feature of agency over a long period if it is to achieve its purposes [253]. For example, an access to adequate standards of education is required so that agents have the ability to achieve their given purposes over their life-time as PPAs. Often, a PPA may be able to achieve a few purposes without non-subtractive and additive wellbeing in an occurrent sense, but in a dispositional sense, these goods are required permanently.

[17] Beyleved 1991 pp. 77-78.

[18] How can the generic features of agency be necessary conditions if a PPA's purpose is to commit suicide, wants to live in a 'desireless nirvana' or to sell itself into slavery (see Beyleveld 1991 pp. 77-78)? Given the argument in the text, it is clear that any purpose, such as committing suicide, necessarily require the generic features of agency. The ability to choose suicide employs the freedom component of agency. The ability to act towards such a purpose requires the well-being component (minimally basic wellbeing) in order to achieve it.

Stage 2: From Necessary Goods to Rights

In stage 2 of the argument, Gewirth contends that a PPA must claim that it has a right to the generic features of agency from its internal point of view of agency. More specifically, Gewirth attempts to show why it can be shown to be dialectically necessary that (5) 'I have a right to the generic features of agency' can be derived from (4) 'The generic features of agency are necessary goods'. If the argument is sound, to deny (5) is to deny (1) 'I am a PPA'.

Gewirth argues that (4) 'The generic features of agency are necessary goods' implies (4a) which is 'I strictly-ought to pursue the generic features of agency whatever my purposes'. Because of the correlativity between strict other-referring oughts (duties or obligations) and claim-rights[19], Gewirth argues that:

(5) 'I at least have a *prima facie* claim right to the generic features of agency'.

This means that whatever purpose a PPA chooses, she must consider that she has a right to 'freedom' and 'wellbeing' as *basic and necessary goods* [52-63][20]. She has to adopt a viewpoint from which, *at least prudentially*, she has to claim a right to the generic features of agency because other agents categorically ought not to interfere with her having the generic features of agency *against her will*, and ought to aid her to secure the generic features of agency when she cannot do so by her own unaided efforts *if she so*

---

[19] Since others ought not interfere with my having the necessary goods required for my successful purpose fulfilment, then (because a right correlates to a duty), that duty for others to refrain correlates to my right for those things that they ought not to do (see Beyleveld 1991 pp. 26-42).

[20] 'Freedom' consists in controlling one's behaviour by one's unforced choice, while in possession of knowledge of relevant circumstances [52-53]. Freedom may be dispositional or occurent. The former is necessary to achieve any purpose; the latter can also be interpreted in a dispositional and generic fashion, in that, regardless of my *particular* purpose, I cannot pursue or achieve it without occurrent freedom. 'Wellbeing' consists of the other general abilities and conditions (*goods*) necessary for agency, which are arranged hierarchically. Gewirth divides wellbeing into three categories: *basic* wellbeing comprises essential conditions such as life, physical integrity and mental equilibrium, without which it would be difficult or impossible to achieve, or have a reasonable chance of achieving any purposes [53]. *Non-subtractive* wellbeing comprises of the goods required for maintaining, undiminished, one's level of purpose fulfilment [53-54]. Finally, *additive* wellbeing comprises the goods that an agent requires to increase her existing level of purpose fulfilment [54]. The latter two are conditions only necessary for ensuring general success in one's actions. Occurent wellbeing may vary with individual circumstances but dispositional (in the three senses) is seen as invariable (Beyleveld 1991 pp. 18-21).
Although I will continue to use these terms throughout as a matter of convenience, Beyleveld & Brownsword argue that '[i]t is better to present the argument for the PGC simply in terms of the abstract category of generic needs, and to leave specification of the generic needs (both abstract and concrete) to applications of the PGC' (2001 p. 71 fn).

wished (see Beyleveld & Brownsword 2001 p. 74)[21]. This is in a negative *and* positive sense[22]. Thus a sado-masochist may constantly waive their right to the generic features of agency, or an agent decided on a course of suicide may waive them once and for all. However, at least they must consider that they have a claim right to the generic features of agency, which is based upon their prudential criterion, to pursue these goals.

In stage three, the prudential claim that 'I have rights to the generic features of action', is translated into a moral (other-regarding) claim, that every agent, on pain of self-contradiction, must accept the generalisation that all prospective purposive agents have the generic rights to freedom and wellbeing.

Stage 3: The Universalisation of Prudential Rights

Gewirth argues in stage 3 of the argument to the PGC, that the claim 'I have a claim right to the generic features of agency' can be universalised to the claim 'I am a PPA, therefore I must acknowledge that all PPAs have a right to freedom and wellbeing'. This latter statement is from which Gewirth derives the statement of the PGC. Gewirth's argument progresses as follows:

(6) 'I at least have a *prima facie* claim right, on my prudential criterion, to my freedom and well-being'[23],

to:

---

[21] This shows that the PGC establishes generic rights under the will conception. Thus they are correlative to duties from other agents, in the sense of a positive and negative obligation to not interfere and to assist with the rights to generic needs, should the agent will it, or otherwise contradict that they are agents (the reason for this will become clear in stage 3, below) (Beyleveld 1991 pp. 32-33). The 'benefit' and 'choice' (will) theories of rights are probably best deployed in some form of combination (see Chapter Two section 6.2).

[22] Gewirth argues that generic rights are owed in a positive sense, as he claims that to reject (5a) 'I have a positive right to the generic features of agency' contradicts (4) 'The generic features of agency are necessary goods that I must hold regardless of my purposes'. Therefore, Gewirth's argument to the PGC demonstrates why agents must act morally. The 'must' in this sentence is a categorical 'must', as the action is required regardless of the subjective views of a purposive agent on pain of contradicting that it is such an agent. Of course individual agents are going to act on purposes which are contrary to the PGC, but Gewirth's argument demonstrates that such purposive acts entails the PPA and contradicts that it is such.

[23] Or otherwise accept that: (6a) 'Otherwise accept that other persons may interfere with my having the generic rights, which contradicts (3); I must accept also accept (5) because it entails (6)'. If I contradict 3, then I would contradict that I am an agent. Since the very prospect of being an agent requires that I have the necessary goods to be able to act towards the purposes that I have chosen.

(7) 'From my internal viewpoint as a PPA, I am logically required to treat (I am a PPA → I must consider that I have *prima facie* generic rights) as a valid inference'[24].

From (6), Gewirth universalises the argument by employing the logical *Principle of Universalisability*. This is the move from the *prudential* (self-regarding) to the *moral* (other-regarding). Gewirth attempts to show that, because I value my purposes, I must also take account of the interests of other agents. The logical principle of universalisability can be stated that if there is an S that if S has Q then it has P, then for all S, if S has Q then it has P [105][25]. If we substitute into this formula (6), then we get:

(8) 'From my internal viewpoint as a PPA, I am logically required to treat (Other PPA (PPAO) is a PPA → I must consider that PPAO has *prima facie* generic rights) as a valid inference'.

This follows because, from (6), the PPA has acknowledged that its PPA status (from within the internal viewpoint) is the sufficient condition for the claim right. Therefore, it is dialectically necessary for a PPA to acknowledge:

(9) 'I am a PPA → PPAO[26] has *prima facie* generic rights.'

As PPAO is a PPA, we can universalise again to the statement:

(10) '(I am a PPA → PPAO has *prima facie* generic rights) → (PPAO is a PPA → PPAO has *prima facie* generic rights)'

Which amounts to saying that a PPA must claim that it is dialectically necessary that all PPAs have generic rights or contradict that it is a PPA. As all PPAs must be committed to this argument, then:

---

[24] The arrow means 'entails'.
[25] 'For it to be permissible for an agent to act on a maxim, the agent must be able to will that any other agent at the same time act on the same maxim is a moral test under Gewirth's definition of 'morality' because it requires agents to take favourable (indeed, equal) account of the interests of other (indeed all) agents' (Beyleveld & Brownsword 2001 pp. 89-90).
[26] PPAO means 'Other prospective purposive agent'.

(11) All PPAs must accept that all other PPAs have *prima facie* generic rights,

Or:

(12) All PPAs must act in accord with the generic rights of its recipients[27].

Which is the PGC: *Act in accord with the generic rights of your recipients as well as yourself* [135].

The resulting PGC requires that:

> ...under the assumption that the PGC is categorically binding, there can be no justification under any circumstances whatsoever for violating it. Thus, to risk the possibility of violating the PGC, *when this can be avoided*, is itself to violate the PGC. Therefore, it is categorically necessary to do whatever one can to avoid this consequence (provided, of course, that the actions taken do not conflict with more important requirements to be derived from the PGC) (Beyleveld & Brownsword 2001 p. 121).

The *Argument from the Sufficiency of Agency* (ASA) shows that (specifically in step (5)) to contradict that I, as a PPA, have a claim right, incurs a logical contradiction that I am an agent at all [109-110][28]. So, it is necessary to show (6) 'From my internal viewpoint as a PPA, I am logically required to treat (I am a PPA → I must consider that I have prima facie generic rights)[29] as a valid inference'.

The move from (5) to (6) uses the ASA. Beyleveld systematises Gewirth's presentation of this argument, and will be summarised here (Beyleveld 1991 pp. 43-45)[30]. He presents the argument as follows: If (5) does not entail (6), then PPA must be able to deny 'I am a PPA → I have the generic rights (i.e. a *prima facie* claim right to freedom and wellbeing)' without actually denying that it must have the generic rights. For a PPA to deny 'I am an agent → I have the generic rights' is to assert that a PPA considers that having property D – which is not necessarily possessed by all agents – is necessary for the PPA to have the generic rights. Therefore, for the PPA to deny "I am

---

[27] Since if I deny (11), I deny that any agent has the generic rights, which would contradict (5), that I need the generic rights for my freedom and wellbeing, which it has already been shown would contradict that I am an agent. Furthermore, if I don't accept (12) then other agents could act in violation of my rights, which cannot happen if I accept that I am an agent.

[28] 'The agent's description of himself as a perspective purposive agent is both a necessary and sufficient condition of the justifying reason he must adduce for his claim to have generic rights (Gewirth 1978 p. 109).

[29] Generic rights means 'a claim-right to the generic features of agency'.

an agent → I have the generic rights" is to assert 'I have the generic rights → I have D'. This assertion 'I have the generic rights → I have D' logically requires assent to 'I am an agent without D → I do not have the generic rights'. In other words, to be consistent with 'I have the generic rights → I have D,' a PPA must consider, 'even though I am an agent, I do not have the generic rights if I do not have D'.

On the basis of (5), a PPA must, provided only that PPA is an agent, consider that PPA has the generic right – which his to say that PPA must, by virtue of being an agent, consider that it has the generic rights, whether or not it has D. Therefore, the PPA must consider that 'even though I am an agent, I do not have the generic rights if I do not have D' contradicts 'I must, by virtue of being an agent, consider that I have the generic rights, whether or not I have D'. Since, 'I have the generic rights → I have D' contradicts what 'I am a PPA → I have the generic rights' entails, then 'I have the generic rights → I have D' contradicts (5). Thus, in order not to deny (5), I must affirm 'I am an agent → I have the generic rights.' Therefore, to assert, (5) 'I at least have a *prima facie* claim right, on my prudential criterion to my freedom and wellbeing (i.e. generic rights)' is to affirm (6) 'From my internal viewpoint as a PPA, I am logically required to treat (I am a PPA → I must consider that I have prima facie generic rights) as a valid inference (ibid.)[31].

Agency is a capacity for a minimal level of rationality when acting upon moral precepts. All moralities or moral precepts, either directly or indirectly, deal with actions [25]. They tell agents how they should act, especially between one another, or what kind of person one ought to be (and so how one should act). To prescribe a moral precept to an agent therefore must be to command a rule of conduct or moral instruction that that agent can guide its actions upon. Of course, not all actions that an agent undertakes are guided by that agent, some are forced, others are coerced, strongly suggested or impulsive. Such actions may be the result of external circumstances and in which the agent contributes nothing. Therefore, the agent can only act upon a moral precept if the act is voluntary and freely chosen (so that the agent can control their behaviour by their unforced choice while having knowledge of relevant circumstances); and that the agent acts for a reason, normally to attain some goal. And as already discussed, the agents action is thus also purposeful and intentional. Since agents act for

---

[30] Also see Beyleveld & Brownsword 2001 pp. 74 –76; and Hill 1984, especially pp. 183-184.

purposes they regard as worth pursuing, they must, insofar as they are rational, also regard the necessary conditions of such pursuits as necessary goods (and therefore attach an instrumental proactive value to those goods).

An agent therefore has at least a propensity to act rationally according to moral precepts addressed to it with the view to intentionally attaining its purposeful goals (chosen voluntarily and freely). To do this the agent must also be able to control its behaviour accordingly and have knowledge of its relevant and proximate circumstances.

Both rational beings and non-rational beings feel an impulse to do certain things – fight or flight response is one such example. We could say that it is law of nature that beings either run (when able to) or attack (when cornered)[32]. Non-rational beings can only act in accordance with this impulse; but would not be able to comprehend the necessary action should a 'law' prescribe one action over another.

Rational beings can, on the other hand, conceive of the law, and choose whether to act in accordance with it. We can make choices that will limit these situations or avoid them altogether. We can even establish and follow rules that can best preserve our lives in flight or fight circumstances. An agent can attempt to deliberate on the best course of action in a given circumstance – if a mugger threateningly demands your wallet at gun point, a '…hair-brained response as trying to run' or resisting by force may not be appropriate – giving over to the demands or negotiation may be the best course of action (Richardson 1994 pp. 5-6).

The rational agent therefore is the base (or unit) of our moral framework; and this by definition ignores any species membership or 'existence-based' moral status[33]. From this level of rationality there are implicit claims on how the framework must be established.

---

[31] But see Singer 2000, especially pp. 182-183, for a critique of this step; and the reply by Beyleveld 2002 pp. 459-462.

[32] The *choice*, if it is one, is driven by behaviour responses guided by the environment and instinct. For example, an agent, may *rationally* decide that to run when it is able to would likely result in harm. It would be better to defend oneself, even though the situation demands that running and fighting would result in the same net cost.

[33] See the criticism of this point by Dwyer 2003. This criticism fails on account of the reliance upon speciesistic notions of agency.

Appendix Three

The Principle of Proportionality

The *Principle of Proportionality* it is argued, can at least grant some marginal agents, including young children, viable foetuses and higher animals, primary protected interests, not because of their potential proximity to an agent, but because of their actual proportional properties of being an agent. The concern is that without making this distinction there is no moral limit to limitless embryo research, abortion and infanticide (Wreen 1986 p. 33); because '...if an early abortion is morally permissible, why not a late abortion or even, as one philosopher has suggested [Tooley, most recently in his 1983 book], infanticide' (Gillespie 1977 p. 237). Therefore, without accepting proportional status, we are condemning certain stages of human life to separate moral status[1]. Proportional agents have the generic rights *in proportion* to the degree of their *approach* to their attainment of agency (Gewirth 1978 p. 122).

The *Principle of Proportionality* derives 'quasi-rights' for non- and marginal agents because those beings that at least have some of the capacities for agency, may have rights in proportion to that development[2] – it is argued in proportionality that 'personhood' admits in degrees, and the seriousness of any right that anything possesses depends upon the extent to which it is a person (see Tooley 1998 p. 15). Thus, in the case of the embryo, the argument is that it acquires rights as it develops (perhaps basic rights then those rights that will further its partial agent status). This appears to appeal to certain empirical facts about the embryo's actual and developmental powers (Reichlin 1997 p. 12).

So, protection for the marginal agent is recognise by the degrees of proportion to being what it potentially will become. The basic argument asserts that the closer to actualising agency a being achieves, then the more moral significance we embellish to it. There are two general consequences to this: firstly that we accord some moral weight to proportional status, but not necessarily that inferred by the status of an agent (this is

---

[1] Unlike the embryo, the foetus as it develops, is possibly aware of 'pain' and 'stress'; able to move; and have some cogitative capability (Benatar & Benatar 2001; Joseph 2000).

[2] Therefore, while potentiality may admit in degrees it may be possible to admit rights according to those degrees (Feinberg 1980). This is an argument for a type of *proportionality*, however, here protagonists are still talking about the *potential to become an agent*, not the *proportion of actually having those necessary capacities of agents*.

often a clear indication in abortion regulations); or secondly, we commit ourselves to deriving a full moral status for proportional beings. One reason for this latter project is that because if a marginal agent has some rights (e.g. free from pain), then those rights it arguably does not have (such as a right to life), could be removed, thus making limited rights redundant (e.g. one could kill a marginal agent painlessly) (see Wreen 1986 p. 35).

Normally the protection proceeds according to the capacities the organism develops; so that a human foetus has more moral standing than an embryo on account of having more of the capacities we associate with an agent, while a human infant, nearing full agency, has proportionally more than the foetus. The difficulty is, however, at what point the ontological proportion of *Y* actualises *Y*; and thus the degrees of proportion can be pushed to its subjective limits.

Gewirth points out that:

> ...the justifying [non-moral] properties in question [may] involve an important comparative element... The point is that even when a reason for a right or duty directly applies only to one person, where that reason logically involves a comparative element it applies in a comparative or proportional way to other persons (Gewirth 1969 p. 123).

Accordingly, this principle forces us to admit rights in degrees, so that children are in possession of some *rights*, because they are *sufficiently like* full human agents. We therefore restrict certain rights that would harm themselves or others (because they actually do not possess full agency). Similarly, we sometimes restrict those rights to being who are full agents but lack full maturity to safely exercise them (no agent can have the capacities for everything, so, for example, we may require that not every agent can become a pilot).

The reason for protection of marginal agents is not because they are ostensible agents, but because:

> Animals other than humans lack for the most part the ability to control their behaviour by their unforced choice, to have knowledge of relevant circumstances beyond what is present to immediate awareness, and especially to reflect rationally on their purposes. These abilities are also lacked to some extent by children and by the insane and other such mentally deficient persons. Hence, these groups are in varying degrees and on different grounds excluded from the class of prospective agents (Gewirth 1978 p. 120).

Gewirth continues that degrees to *approaching* a fully-fledged agent relies on the *Principle of Proportionality* and this can grant rights to beings in proportion to their approach to being an agent:

> When some quality Q justifies having certain rights R, and the possession of Q varies in degree in the respect that it is relevant to Q's justifying the having of R, the degrees to which R is had is proportional to or varies with the degree to which Q is had... Thus, if x units of Q justify that one have x units of R, then y units of Q justify that one have y units of R (ibid. p. 121).

Importantly, doctrines of proportionality involve a comparative non-moral element to determine moral status (Gillespie 1977). Such properties are the observable characteristics that any given individual may possess to have rights to full or partial extent that can be graded proportionally. Having the characteristic(s) to the full extent derives full rights, having them to a lesser extent derives proportionally fewer rights. Whatever non-moral property(s) that one selects as a basis for determining the possession or degrees of, or approach to, having full rights, it is likely that those properties will be assessed comparatively in their proportion or extent of possession by any individual candidate.

It is therefore 'irrational' to insist upon 'drawing a line' (Gillespie 1977 p. 238). It is, according to this argument, difficult to specify quite precisely (and this is important, because depending where a being falls, it has *full* or *no* rights) where an individual falls along any spectrum of moral rights – one is forced to draw a line, and this is a comparative, not a certain thing. The comparative basis of rights means that the further away a being is in its development to full agency, it should be implied that '...its rights are less than full – *not that it has no rights at all*' (ibid. p. 239). Importantly, we are comparing the strength of a beings explicit claim to protection on its likeness to actual agents, so that '...children are sufficiently like adults to have some rights, that the same is true of small children, that about-to-be-born babies are comparatively like infants, and that fetuses [sic.] are comparatively similar to about-to-be born babies' (Gillespie 1977 p. 238); '...if a person can develop, why should their rights not do the same? The idea that a child acquires more rights as it develops is not incoherent' (ibid. p. 242).

At the outset, this argument has failings similar to those for potentiality; such as the reliance on solely human proportions of agency over those of non-human beings (so that a human embryo cannot be proportionally closer to agency than a great ape, or otherwise commit 'speciesism'; unless potentiality itself is a significant capacity).

One can also argue that policies may not be committed to actions that some find morally reprehensible. If a theory does not allow for degrees of rights then that does not mean that we should look elsewhere for supporting contrary beliefs (the most notable

being the case if infanticide)? We could look to vicarious protections depending on what the community desires, but then firstly, these protections cannot be as important as claim-rights, and secondly, are also entering problems due to subjectivity or community will vs. individual will.

The main problem of proportional rights, however, is what Feinberg has called the 'logical point about potentiality': 'being almost qualified for rights is not the same as being partially qualified for rights; nor is it the same thing as being qualified for partial rights, quasi-rights, or weak rights' (Feinberg 1986 p. 269). It does matter what properties a being has at that time, regardless of its strong potential to become something very different in the future.

Hill puts it another way:

> ...from the two facts – individual *a* is a member of class Q and his membership in Q justifies his membership in class R – it does not follow that another individual, *b*, who approaches in varying degrees membership in Q [proportionally being an agent, see below], possesses thereby membership in R in varying degrees. All that follows is that *b approaches* in varying degrees membership in R ...to approach being an agent is to approach having moral status, but that to approach having moral status to a degree is not to have moral status to a degree[3] (Hill 1984 pp. 186-187).

These conjectures are again based on the *Argument from the Sufficiency of Agency* (ASA). The capacity for purposeful agency may include factors such as sentience, memories of one's past, interests in one continued existence, and so on, but that these features are not sufficient in themselves, nor are they, as discrete capacities, necessary. Many of these capacities are different ways of stating that the proposed agent has minimal rationality, if such rationality exists, then it is also concurrent that that being is a purposeful agent. For example, a being that recognises its pasts and futures, also is purposeful in its pursuit of meaningful interests in such things. Therefore, such a being would be an agent and have full rights. If a being deviates from such rationality (such as sleeping), it does not mean that those capacities are lost (such as in death), but are temporarily ineffectual; but more often, such deviancies do not sink to a non-agent status. The important factor is that a proportional agent cannot, by definition, be an actual agent.

---

[3] This is termed the *Fallacy of Disparateness*. This fallacy is committed where fields or subject -matters are compared on disparate levels or on disparate respects. Comparisons between individuals must be of the same logical type otherwise one may draw invalid inferences. It is committed if there is a disparity 'logically' between two types of individuals that are being compared; i.e. an ostensible agent and a marginal agent; the logical difference is that a marginal agent is not the same as an agent, for if it were, it would not be a marginal agent, but actually an ostensible agent.

Anything below the level of agency does not qualify a being as an agent, and anything above makes no difference to one's agent moral standing, because the ASA infers the sufficient degree. So that while a human being may develop and grow, her agency is fixed upon the point of reaching the ASA. If, however, proportional reasoning was logically correct, then formally stated, the principle *should* be stated as:

> When having some quality Q justifies having some property R, and the extent of having Q *sufficient* to justify having R is *not necessary* to justify having R to any extent at all, the degree to which R is had is a function of the degree to which Q is had (Beyleveld & Brownsword 2001 p. 118).

The practical importance of the criticism of the *Principle of Proportionality* is in its dealings with so called 'Elitist Theories'. An agent cannot be any more of an 'agent' than any other agent; agents with the generic capacities of agency greater than is needed to be an agent cannot acquire the generic rights to a greater extent. Such an elitist, if it could exist, may argue that since he possesses more of the generic abilities constitutive of purposive action (i.e. agent action), he has greater rights than others in *proportion* to its higher capacities for agency; and thus the inherently egalitarian thrust of human rights is lost (Hill 1984)[4]. Because proportionality does not logically work (at least in the form that Gewirth and Gillespie present it) then there cannot be a foundation for elitist formulations of the generic rights.

The problem of denying proportional reasoning is that it must logically force a line to be drawn that signifies the limit of the ASA. Proportionality requires one to make comparative assessments based on why we think agents have rights (the necessary and sufficient conditions (generic features) of agency). And this is by no means a task that creates certainties in all cases, and furthermore, the boundary may be subjective. However, the phases of human development can be clearly discerned, even if the 'borders' are fuzzy: we can '...recognise a typical example of another human person ...[and that] human embryos are *not* typical examples of human people' (Gillon 1991 pp. 60-61). The difference between a being that is an agent, and a being that is very near being an agent is a moral decision with a great deal of importance, and the means to solving this problem is that, although rights are not a thing that one can have more or less of (but can be task limited), the border cases are too close to call and one must err

[4] This is the logical form of the arguments that strive to set the same value for all morally important beings. Of course, in this form it denies the usual format (because of its explicit reliance on agency) of the *sameness* argument, which attempts to determine that all *human beings* are of the same value.

on the side of caution – there is a cut-off slope rather than a cut-off point (Pluhar 1977 p. 166).

The second problem in classing beings failing the ASA as agents is the normative structure of claim rights. Agents are required to claim rights because they are instrumental to their pursuit or achievement of their purposes, what ever they may be, and provided they do not neglect or violate their duties to other agents. Therefore, if a being cannot have the capacities of agency in full, they cannot claim or waiver their own rights nor respect their duties to others; in order to be able to freely waive the benefits of a right, one must have the capacities needed to be an agent. Therefore, proportional agents cannot have the generic rights of agency[5]. It is only agents that can have reciprocal rights and duties and, therefore, any proportionally marginal agent cannot qualify as a rights-holder. This may be avoided if 'rights' is converted into 'protections' (Beyleveld & Brownsword 2000); a value entirely different from the generic rights.

[5] It may be claimed that marginal agents have 'quasi-generic rights' - unwaivable protections correlative to agents not to harm marginal agents, or to assist them in need in proportion to their approach to being an agent (see Hill 1984 pp. 184-185).

Appendix Four

The Principle of Futureality

Futureality can be best illustrated in two forms. Firstly, it can be a protective value in as yet non-existent future beings. In this sense, moral protection is sought for future generations, for example, to have a reasonably healthy environment; moral protection is ascribed to persons as yet unborn or even conceived; but only on reaching actuality. If these generations never exist, then there are not future beings to be harmed. It is clear on this account that moral 'rights' in this case cannot be a function of the potential victims' present capacities or even being, since they are not presently even in existence.

It is difficult to see how the previous framework of rights could apply to future agents, for the reason that claim rights are claims by agents for something intrinsically important to their freedom and wellbeing. Without existing there seems to be no way of making a claim unless it is made on behalf of future generations by actual agents or claimed retrospectively.

In the first case, one cannot demand a proxy right for something (or someone) that does not exist (or at very least there is a ontological being that has a interest in someone else protecting its existence) – if a case can be made, it must be based on a very weak potential (even less than the potential of gametes, because the *idea* of a future person is surely less than the actuality of male and female gametes potentially coming together [which would be necessary to actualise the previous idea] to became an embryo).

In the second case, futureality is deployed as extension of the principles of *Potentiality* and *Proportionality* – direct protection may be granted to a *potential or proportional agent that exists* so that, for example, deliberate injury is prohibited that would cause the potential agent to mature in the future into a damaged agent. Futureality also holds sway on the implications of proportion, because if something is *becoming* something else (of moral concern), then it has a future that lies in being that something unharmed by previous actions.

This means that actions are interfering with the interests of a potential (in the sense of 'future actual') agent. Such a being will become an agent but will be thwarted in certain aspects of its capacity for agency; perhaps with a diminished ability for

freedom or wellbeing. We are concerned with the consequences of different treatments on the embryo/foetus and the *agents that they might become* (Hare 1997 p. 15). Importantly, the being's agency does not exist yet (as opposed to the being not biologically existing), and indeed, may never exist at all. Hare argues that:

> For *whenever* my life as the Richard Hare began, anything that would have interfered with my developing into the grown person that I am now would have been against my interests, and therefore *pro tanto* wrong... (1997 pp. 15).

Lockwood, however, contends that:

> '*...on the assumption that it will in fact give rise to an individual who stands to benefit or lose out according as this potential is or is not properly realised* ...I am an actual individual, that did in fact, somewhere between conception an birth, come into existence ...it is not ...true that, had any of those things happened [to stop my development] they would have run counter to interests that I, ...would have had ...under those circumstances, *I* would never have existed, and *a fortiori* not have had any interests at all' (1997 p. 20-21).

Thus, acts that harm a being that will develop into an individual can be contrary to her interests, but only as an actual future individual, and only as an individual that itself stands to enjoy the benefits: '...there would have been no such (actual) interests, had the process of development been interfered with, so as to cut short before Richard Hare came into existence' (ibid. pp. 22-23). Or to put it another way, if an embryo is damaged (for example in an experiment) then it is possible that a damaged agent could be born, but this does not rule out destroying embryos (as *potential future* agents) in the same research.

For example, it is arguable that a pregnant mother should not smoke because this will damage, not merely the embryo (as a marginal agent), but the agent that the embryo will become if it develops normally[1]. The special status that this confers upon the embryo does not, by itself, protect the embryo absolutely. Because, if the embryo never becomes an agent, then there is no moral being (unless we take potential or proportion to be morally significant) that is affected by the treatment *at the time of embryonic/foetal development.*

---

[1] And smoking and drug abuse can harm the embryo and foetus' in such a way that it continues to develop to the stage of agency, but with certain harmful conditions (see Bagheri et al. 1998; Huestis & Choo 2002). While the embryo is unborn, however, the rights of the mother must prevail as an actual agent, and it is arguable whether policies could *stop* mothers from such actions (particularly when the mother may personally benefit or that forced abstention may cause greater harms). One should also be aware of the complex issues of coercion and inducements that may undermine the mother's freedom and autonomy (Hewson 2001; Isaacs 2003).

The moral harm only transpires upon attaining agency, and therefore the protection is strictly limited to cases where there is an intention by its mother to nurture the embryo to agent status. It would not protect the embryo from abortion before it reaches its status as an agent, because if the embryo never becomes an agent then, as it stands, there is no locator to direct the moral harm from.

Furthermore, future agency is limited to beings that can, all things being equal, become ostensible agents. This has particular relevance to the human condition – for example, embryos/foetuses, young children, and adult patients who may recover from a non/marginal agent debilitating condition. Beings that do not, in the normal course of events, become ostensible agents, cannot be protected under the wing of future agency, because they have no future that will result in the morally important status of agency. Thus, in the same way, beings that can become future agents cannot benefit from such agent concerns until it becomes an ostensible agent.

Appendix Five

Abortion in the Member States

The acceptance of abortion has often been seen in light of three viewpoints: 'pro-life' (the embryo/foetus possesses the same status as any other moral agent), 'pro-choice' (the mother has an absolute status with regards to her reproductive choices and therefore the embryo/foetus only gains a moral status subsequent to, or near to' birth) and 'gradualist' (that the embryo/foetus gains in proportional status as it develops, only gaining full status sometime near to, or after, birth) (Beyleveld 2000b; & Greenwood 2001; there is often a middle ground between these views; see Wendler 1999).

It is evident that from within the Community, there is a generally a gradualist approach regarding the status of the embryo/foetus, so that it becomes increasingly unacceptable to abort a pregnancy as it progresses. Furthermore, early pregnancies are implicitly encouraged, with relatively few obstacles to such terminations. Although Ireland is predominately pro-life, in very limited circumstances, abortion is still possible, and this suggests that the embryo does not have an absolute status (and in all states, abortion is possible when there is a realistic danger of physical harm to the mother) (see Dworkin 1995). It is explicitly understood that the mother does not have a 'right' to abortion, since at most stages a reasoned judgement is necessary for a termination involving medical practitioners (Greenwood 2001). But implicitly, there is a general acceptance that the mother can have an abortion with respect to little actual consideration of the embryo/foetuses status (citing harm to the mother's wellbeing) (ibid.). The following is a summary from Rendtorff & Kemp 2000a & 2000b, and MacKellar 1997, unless otherwise stated.

Austria

Abortion is forbidden in principle by law (s. 96 of the Penal Code 1975), however provisions are made for a termination on the grounds that:

1) It is carried out by a doctor during the first 3 months of pregnancy and after consultation of a doctor by the woman, or;

2) If it is necessary to avert serious and otherwise inevitable danger to life, or to avert serious damage to the physical or mental health of the pregnant woman, or if there is a serious danger that the child will be seriously handicapped, mentally or physically, or if the mother was a minor at the time she fell pregnant and if, in all these cases, the abortion is carried out by a doctor. The decision to terminate cannot be influenced by the subsequent use of the embryo or foetus.

Belgium

Abortion is permitted by law before the 12th week and after counselling. The doctor involved must assess the determination and distress caused to the woman (and the doctor is responsible for assessing this along with the woman). After 12 weeks, two doctors can authorise the abortion on the grounds of harm to the woman or substantial risk of foetal or embryo handicap (Penal Code 1990).

Denmark

Abortion is permitted by law before the 12th week of pregnancy. Abortion may take place after this date if there are social reasons for the woman (based explicitly on the *rights* of the woman), or if the pregnancy was caused by rape or incest or for reasons of foetal handicap. A termination is possible at any time if there is a risk of 'harm' to the woman. The decision to terminate cannot be influenced by the subsequent use of the embryo or foetus.

Finland

Abortion is permitted by law before the 12th week of pregnancy with the permission of two doctors if the result of the pregnancy would cause considerable strain on the family or woman, was caused by rape, or if there is reason to believe that the child would be born handicap. Termination after 12 weeks can only be granted by the *National Board of Medico-legal Affairs* and generally only if there is a risk of harm to

the foetus, or with a physician's permission at any time if there is a risk of harm to the mother. The decision to terminate cannot be influenced by the subsequent use of the embryo or foetus.

France

Pregnancies may be terminated for reasons linked to the health of the child only if there is a strong probability, certified by two doctors, that the child will be born with a particularly serious ailment recognised as incurable at the time of diagnosis. The decision to terminate cannot be influenced by the subsequent use of the embryo or foetus.

Germany

In principle, terminations of pregnancy attract criminal liability pursuant to the Criminal Code in respect of all participants[1]. There are, however, exceptions to this: the offence of terminating a pregnancy is ruled out under certain conditions if, pursuant to the Pregnancy Conflict Act, the pregnant woman has been counselled and not more than 12 weeks have elapsed since conception. It is also permitted in the case of medical indications, i.e. when termination of pregnancy is necessary taking into account present and future circumstances in the life of the pregnant woman, in order to avert a danger to the life, or the risk of causing serious impairment to the physical or mental health of the pregnant woman, without reference to any time limitation.

In the case of the criminological indications, i.e. when there are strong grounds for supposing that pregnancy is due to a sexual offence (sexual abuse of children, rape, sexual coercion or sexual abuse of persons incapable of offering resistance) abortion is permissible until 12 weeks after conception. Since 1 October 1995 the relevant

---

[1] The German Constitutional Court declared that: '1. The life of the child developing in the mother's womb constitutes an independent legal interest protected by the Constitution (Articles 2 (2) first sentence and 1 (1) of the Basic Law). The State's duty of protection not only forbids direct State interference with the life of the developing child but also requires the State to protect and foster it. 2. The State's duty to protect the life of the developing child applies even as against the mother. 3. The protection of the life of the embryo enjoys in principle priority over the pregnant woman's right of self-determination throughout

provisions of the Criminal Code no longer make provision for a so-called 'embryo-pathic' indication - according to which continuation of a pregnancy cannot reasonably be expected on the ground that serious impairment to the child's health is to be expected. Under the new law, however, a medical indication may exist in such cases if, taking into account present and future circumstances in the life of the pregnant woman, a serious danger is posed to the physical or mental health of the mother. The decision to terminate cannot be influenced by the subsequent use of the embryo or foetus.

Greece

Abortion is permitted provided there is consent from the woman and either the embryo is less than 12 weeks old; there is risk of harm of serious abnormality to the embryo (abortion is therefore permitted up to the 24th week); the life of the woman is endangered or risk of physical or mental harm; or the pregnancy is the result of rape or incest (Abortion Law no. 1606/1986).

Italy

Abortion is permitted under a ruling of the Constitutional Court in 1978 that stated that it must be allowed in order to respect the dignity and self-determination of the woman (Abortion Law no. 194 1975). Abortion is permitted within the first 12 weeks and 6 days of pregnancy. After this time termination can occur when continuation of the pregnancy would endanger the woman's life, if there are serious malformations in the embryo that would endanger the woman's wellbeing, or if the pregnancy is the result of rape.

---

the period of pregnancy and may not be considered as subject to derogation during a certain period' (*Brüggemann and Scheuten* v. *Federal Republic of Germany* (1981) 3 E.H.R.R. 244 pp. 248-249).

Ireland

The Constitution guarantees the rights of the unborn. However, the ability to obtain an abortion elsewhere is not limited, since the EU guarantees the freedom to travel between the state and another state, or information relating to services lawfully available in another state (as a consequence of the judgements by the European Court of Human Rights and European Court of Justice). So while the Constitution secures equal rights to the mother and the child, the Irish Supreme Court has interpreted these provisions as permitting termination of pregnancy if its continuation endangers the mother's life. Specific legislation is under consideration[2].

The Protection of Human Life in Pregnancy Act 2002 (25th Amendment to the Constitution) only protects the embryo from implantation in the womb, was rejected in a referendum on 6 March, 2002. It states that abortion would be only permitted when there is a significant risk to the life of the mother (this does not include physiological harm, even when the mother threatens suicide; or reasons arising from an alleged rape or incest, even if under the age of consent). It allegedly separates medical reasons from 'social' reasons.

Luxembourg

Abortion is permitted up to the 12th week after consultation with a medical practitioner and if the mental of physical health of the woman is at risk or if there is a serious physical or mental risk of health to the embryo or the pregnancy is the result of rape. After this date, two doctors can authorise a termination only if there is a serious risk for the health of the mother or the child to be born. The decision to terminate cannot be influenced by the subsequent use of the embryo or foetus.

---

[2] Regulation of Information (Services Outside the State for the Termination of Pregnancies) Act 1995; and *Green Paper on Abortion* (1999) available at the Department of the Taoiseach (at: www.taoiseach.gov.ie).

Netherlands

Abortion is permitted by law up to 24 weeks if there is a danger to the woman and a doctor is convinced that she has an authentic desire to terminate her pregnancy. However the decision to terminate cannot be influenced by the subsequent use of the embryo or foetus (law on Termination of Pregnancy (WAZ) 1981).

Portugal

Abortion is permitted before 12 weeks if there is a risk to woman's health or caused by rape and 16 weeks if there is an indication of a serious malformation of the foetus or serious incurable disease. In the case of non-viable foetuses, abortion can be made at any time. Terminations are also possible at any time if it is a means to preventing the death of the mother. The decision to terminate cannot be influenced by the subsequent use of the embryo or foetus (1984 Penal Code).

Spain

Abortion is permitted by law up to the 12th week for ethical reasons or if the pregnancy is the result of a criminal act and therapeutic reasons (serious mental or physical abnormalities of the foetus) up to the 22nd week. Terminations are permitted after this date if there is a risk of life to the mother. However the decision to terminate cannot be influenced by the subsequent use of the embryo or foetus.

Sweden

Abortion is permitted up to the 18th week if the woman so desires (and she is under no obligation to tell anyone her reasons). After the 18th week any termination has to be sanctioned by the *National Board of Health and Welfare and* only for 'special reasons' or if there is reason to believe that the foetus is not viable. Up to the 22nd week abortions are possible if there is grave risk to the mother or that the health of the foetus

renders it non-viable. The decision to terminate cannot be influenced by the subsequent use of the embryo or foetus in research.

United Kingdom

The Abortion Act 1967 (grounds for medical termination of pregnancy) amended under the Human Fertilisation and Embryology Act 1990 states: (a) that the pregnancy has not exceeded its twenty-fourth week and that the continuance of the pregnancy would involve risk, greater than if the pregnancy were terminated, of injury to the physical or mental health of the pregnant woman or any existing children of her family; or (b) that the termination is necessary to prevent grave permanent injury to the physical or mental health of the pregnant woman; or (c) that the continuance of the pregnancy would involve risk to the life of the pregnant woman, greater than if the pregnancy were terminated; or (d) that there is a substantial risk that if the child were born it would suffer from such physical or mental abnormalities as to be seriously handicapped.

Appendix Six

The European Directive on Human Tissues and Cells

1. Proposal for a European Parliament and Council Directive *on setting standards of quality and safety for the donation, procurement, testing, processing storage, and distribution of human tissues and cells*

Commission	Council	Parliament	Commission
Proposal for the Directive (COM(2002) 319 final; May 2002)	**Opinion of the European Economic and Social Committee (December 2002)**	**Report of the Committee on the Environment, Public Health and Consumer Policy (Liese 2003; A5-0103/2003; March 2003)**	**Amended Proposal for the Directive (COM(2003) 340 final; May 2003)**
Recital '(7) This Directive does not interfere with decisions made by Member States concerning the use or non-use of …embryonic stem cells. If …any particular use of such cells is authorised …this Directive will require the application of all provisions necessary to protect public health and guarantee respect for fundamental rights. Moreover, this Directive does not interfere with provisions of Member States defining the legal term 'person' or 'individual''.	'(4) in the case of …embryonic cells, the ethical questions are vast and as yet there is no consensus or harmonisation of decisions; if …a particular application of these cells is accepted in a Member State, the relevant provisions of this directive will apply'.	'(7) The Directive explicitly recognises the right of Member States to take decisions concerning the banning of donation, experimentation, processing, storage, distribution and use of any …particular cells or human tissues or of cells of a particular origin. If any Member State takes such a decision the ban may also be extended to imports of cells or tissues of such kinds. For ethical reasons, and for reasons connected with the high risks of a medical nature connected with human cloning, Member States must also explicitly ban the use of tissues and cells from cloned human embryos and of hybrids (Amendment 8)'.	'(7) This Directive does not interfere with decisions made by Member States concerning the right of Member States to take decisions to prohibit the donation of, experimentation with, processing, storage, distribution and use or not-use of any type of specific human cells or tissues, or of cells of a specific origin or type, use or non-use of any specific type of human cells, including …embryonic stem cells. If any Member State takes such a decision, the reason for which must be made publicly available, the ban may also be extended to imports of cells or tissues of such kinds. If, however, any particular use of such cells is authorised in a Member State, this Directive will require the application of all provisions necessary to protect public health and guarantee respect for fundamental rights. Moreover, this Directive does not interfere with provisions of Member States defining the legal term 'person' or 'individual'.

X	X	(Article 4, paragraph 2b new) 2b. Member States shall at least prohibit the following activities: - research on human cloning for reproductive purposes, - research designed to create human embryos solely for research purposes or to supply stem cells, including by means of the transfer of somatic cell nuclei (Amendment 30).	Article 4(3). 'This Directive shall not interfere with Member States' decisions prohibiting or restricting the donation, procurement, testing, processing, preservation, storage, distribution or use of any specific type of human tissues or cells or cells from any specified source, including where those decisions also concern imports of the same type of human tissues or cells. Where a Member State decides on such a prohibition, the reason for the prohibition must be made publicly available. If, however, any particular use of such cells is authorised in a Member State, the provisions of this Directive shall apply'.
(Article 9.1). Member States shall take all necessary measures to ensure that all imports of human tissues or cells from third countries are approved by the competent authority. All tissues and cells that are exported to third countries shall comply with the requirements of this Directive.	X	(Article 9.1) '1. Member States shall take all necessary measures to ensure that all imports of human tissues or cells from third countries are approved by the competent authority *and comply with the requirements of the Directive.* All tissues and cells that are Exported to third countries shall comply with the requirements of this Directive' (Amendment 34).	(Article 9.1) 'Member States shall take all necessary measures to ensure that all imports of tissues and cells from third countries are undertaken by credited, designated, authorised or licensed tissue establishments. Those that receive such imports from third countries shall ensure that they meet the equivalent standards of quality and safety to the ones laid down in this Directive and necessary measures to ensure that all imports of human tissues or cells from third countries are approved by the competent authority. All tissues and cells that are exported to third countries shall comply with the requirements of this Directive'.

X	'(4.4) The procurement of human cells and tissue must be conducted with respect for the Charter of Fundamental Rights and the principles of the Convention on Human Rights and Biomedicine'.	X	'(15) The procurement of human tissues and cells must fully respect the Charter of Fundamental Rights of the European Union, and take fully into account the principles of the Convention on Human Rights and Biomedicine of the Council of Europe, in particular in relation to donor consent, including the protocols thereto. However, both the Charter of Fundamental Rights and the Council of Europe Convention lay down minimum requirements only, beyond which both the European Union as a whole and the individual Member States may go in their legislation. Neither text makes express provision for harmonisation but lays down minimum standards'.
X	'(6.5.2) The EESC proposes restricting the concept of the donor to living or deceased individuals for the time being, as the use of foetal or embryonic elements of human origin is liable to generate ethical debates or controversies in individual EU Member States, which would be difficult to manage in the Union context'.	X	X

2. Procedural Details of the Directive (up to October 2003)

- 'The legal Basis for this proposal is Article 152 of the Treaty, in particular (4)(a)...' (*supra* COM(2002) 319 final; p. 13);

- '4. The Council, acting in accordance with the procedures referred to in Article 251 and after consulting the Economic and Social Committee and the Committee of the Regions, shall contribute to the achievement of the objectives referred to in this article through adopting:

(a) measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; these measure shall not prevent any Member State from maintaining or introducing more stringent protective measures' (Consolidated Versions of the Treaty on European Union and of the Treaty Establishing the European Community 2002. Title XIII: *Public Health*; Article 152);

- '1. Where reference is made in this Treaty to this Article for the adoption of an act, the following procedure shall apply.

2. The Commission shall submit a proposal to the European Parliament and the Council.

The Council, acting by a qualified majority after obtaining the opinion of the European Parliament:

- if it approves all the amendments contained in the European parliament's opinion, may adopt the proposed act thus amended,
- if the European Parliament does not propose any amendments, may adopt the proposed act,
-shall otherwise adopt a common position and communicate it to the European Parliament. The Council shall inform the European Parliament fully of the reasons which led it to adopt its common position. The Commission shall inform the European Parliament fully of its position.

If, within three months of such communication, the European Parliament:

(a) approves the common position or has not taken a decision, the act in question shall be deemed to have been adopted in accordance with that common position;
(b) rejects, by an absolute majority of its component members, the common position, the proposed act shall be deemed not to have been adopted;
(c) proposes amendments to the common position by an absolute majority of its component members, the amended text shall be forwarded to the Council and to the Commission, which shall deliver an opinion on those amendments.

3. If, within three months of the matter being referred to it, the Council, acting by a qualified majority, approves all the amendments of the European Parliament, the act in question shall be deemed to have been adopted in the form of the common position thus amended; however, the Council shall act unanimously on the amendments on which the Commission has delivered a negative opinion...' (ibid. Chapter 2: *Provisions Common to Several Institutions*; Article 251).

Appendix Seven

Letter and Questionnaire Sent to the Advisory Groups in the European Union

UNIVERSITY OF BRISTOL

Centre for Ethics in Medicine
73 St Michael's Hill, Bristol,
S2 8BH
United Kingdom
+44 117 928 9843
Fax: +44 117 927 9814
B.Capps@bristol.ac.uk

Benjamin Capps MA, B.Sc.
Researcher in Medical Law and Ethics
(Chercheur en Législation sur l'Exercice Médical et en Déontologie Médicale)

16th October 2002

Dear Sir or Madam

I am currently undertaking a project entitled 'UK and European Policy in Stem Cell Research: Proposals for the Ethical Grounding of Future Regulation'. It is funded by the *Wellcome Trust* on their *Biomedical Ethics Studentship* Scheme and supervised by Professor Alastair V. Campbell at the Centre for Ethics in Medicine at the University of Bristol in the UK.

A significant part of the project is to obtain and analyse the various moral perspectives in the EU. These views will be assessed to see whether an EU-wide policy is necessary, or indeed practically applicable. The positions that will be expressed will be used to propose a framework for future regulation and harmonised advisory structure in EU stem cell research.

I am aware that similar discussions and legislative measures are being considered throughout the States of the EU. A number of advisory reports have already been published and laws have been passed in light of the developments in stem cell research and its implications for embryo and foetal research. In addition to these expressed views, I would like to achieve a full picture of the current moral attitudes and policies in the EU States.

I am therefore seeking your views and expertise on the moral issues raised by recent stem cell research developments. I would be extremely grateful if you could take time to answer the following questions.

The Questionnaire

The questionnaire is intended to find out the views of selected groups and Government policies in the EU on a number of issues related to stem cell research. This is with a

view to identifying and proposing a *moral groundwork* for policy decisions. The groups are selected because of their influence in national and international discussions of scientific and medical ethics. There are three areas of which I have particular interest:

- The *moral basis* of your opinions. 'Morality' is taken here to be the right and wrong of actions concerned with stem cell research and *not necessarily issues related to law*;
- Your opinions in regard to the national and international implications of policy moves and;
- The future possibilities and applicability of an EU-wide policy.

In all questions it would be extremely helpful if you could summarise any relevant recommendations or reports that you have given or plan to give.

UNIVERSITY OF BRISTOL

Madame, Monsieur,

Je travaille actuellement sur un projet intitulé 'Royaume Uni et Politique européenne en matière de Recherche sur les Cellules Souches : Propositions pour la Fondation Ethique de la Réglementation future'. Ce projet est financé par le *Wellcome Trust* via le *Programme Etudiant de Déontologie Biomédicale* et coordonné par le Professeur Alastair V. Campbell du Centre de Déontologie Médicale de l'Université de Bristol au Royaume Uni.

Ce projet vise essentiellement à collecter et à analyser les différentes perspectives morales au sein de l'Union Européenne. Leur évaluation devrait ainsi permettre de juger de la nécessité d'une politique européenne à grande échelle, voire même de sa mise en œuvre dans la pratique. Les diverses positions représentées devraient servir de cadre à l'élaboration d'une réglementation future et à la mise en place d'une structure consultative homogène dans le domaine de la recherche européenne sur les cellules souches.

Je suis néanmoins conscient de l'existence de discussions similaires et de propositions de lois au sein des Etats de l'Union Européenne. Plusieurs rapports consultatifs ont été publiés et des lois ont été votées pour réglementer les progrès de la recherche sur les cellules souches et ses conséquences dans le domaine de la recherche embryonnaire et fœtale. Je souhaiterais en effet compléter cette analyse par un tableau exhaustif des diverses prises de position actuelles sur le plan éthique et des politiques en vigueur au sein des Etats de l'UE.

C'est la raison pour laquelle j'aimerais connaître votre point de vue et votre savoir-faire concernant les questions éthiques soulevées par les récentes avancées de la recherche sur les cellules souches. Je vous serais donc très reconnaissant de bien vouloir consacrer quelques minutes à répondre à ce questionnaire.

Le questionnaire

L'objectif du présent questionnaire est de mettre en évidence les différentes perspectives des groupes sélectionnés et des politiques gouvernementales au sein de l'UE sur un certain nombre de thèmes liés à la recherche sur les cellules souches de manière à élaborer et proposer un *cadre éthique* pour la prise de décisions politiques. Les groupes sont choisis en fonction de leur influence au sein des congrès de déontologie scientifique et médicale sur un plan national et international. Je m'intéresse plus particulièrement à trois axes de réflexion :

- Le *fondement moral* de vos opinions. Le concept de *'moralité'* recouvre ici la notion du bien fondé ou du caractère néfaste des actions liées à la recherche sur les cellules souches *et pas nécessairement les thèmes liés au droit ;*
- Votre point de vue sur les conséquences des changements politiques à l'échelle nationale et internationale ;
- Les perspectives d'avenir et les probabilités de mise en œuvre d'une politique à grande échelle au sein de l'UE.

Je vous serais également extrêmement reconnaissant de me citer, pour chaque question, des exemples pertinents de recommandations ou de rapports que vous avez élaborés ou envisagé d'élaborer.

1. What is the nature of your group's role:
Quelle est la nature du rôle de votre groupe :

Government Advisory / Rôle consultatif auprès du Gouvernement: national international

Public education/ Awareness / Rôle éducatif / informatif auprès de l'opinion publique

Policy / Rôle politique

Professional Guidance / Rôle d'orientation professionnelle

Other (please specify) / Autres (veuillez préciser)

2. What is the membership your group:
Quelle est l'appartenance de votre groupe :

Professional (please specify) / Professionnelle (veuillez préciser)

Lay members / Laïque

Religious / Religieuse

Political / Politique

Other (please specify) / Autres (veuillez préciser)

3. Has your group published any reports, recommendation or opinions on:
Votre groupe a t-il déjà publié un rapport, une recommandation ou un avis dans l'un des domaines suivants :

Stem cell research / Recherche sur les cellules souches

Embryo research / Recherche embryonnaire

Foetal research / Recherche fœtale

Human cloning / Clonage humain

Could you please send references to or copies of these.

Pourriez-vous m'adresser des copies de ces travaux ou m'indiquer la manière de me les procurer ?

4. If you have not published an opinion or reports on any of these issues:
Si vous n'avez publié aucun avis ou rapport en la matière :

(a) are you planning to make any statements of opinion or publish any report, or have you put any of the issues on the agenda for future discussion?

Envisagez-vous de faire une déclaration ou de publier un rapport sur le sujet, ou encore de mettre l'un de ces thèmes de discussion à l'ordre du jour ?

(b) which are you planning to address?

Quel thème envisagez-vous plus particulièrement de traiter ?

(c) when are you planning to do this?

Quand envisagez-vous de le faire ?

Could you please send me information as to attain copies of when they are available.

Pourriez-vous m'indiquer la manière d'obtenir des copies de ces projets ou quand je pourrai me les procurer ?

If you have not, or will not address the issues specific to stem cell research in the near future, could you please answer the following questions, stating your group's official position.

Si vous n'avez pas traité, ou si vous n'envisagez pas, à court terme, de traiter de thèmes spécifiques à la recherche sur les cellules souches, pourriez-vous répondre aux questions suivantes relatives à la prise de position officielle de votre groupe ?

5. What is your position on the following as regards to their use in research and derivation of human stem cells?

Quelle est votre position sur les thèmes suivants en ce qui concerne l'utilisation des cellules humaines souches dans le cadre de la recherche scientifique et les risques liés à leur utilisation ?

(a) embryo / L'embryon

(b) foetus / Le fœtus

(c) cord blood / Le sang du cordon ombilical

(d) 'adults' / Les cellules 'adultes'

(e) cloning / Le clonage

(d) any other source (please specify) / Autres (veuillez préciser).

For each, please state the *moral and scientific* (therapeutic and basic research) reasons for allowing or prohibiting research using these sources?

Veuillez indiquer, pour chaque source, les raisons sur le plan *moral et scientifique* (recherche de base et recherche thérapeutique) d'autoriser ou d'interdire la recherche avec de telles sources.

6. Please state your group's opinions on any present or planned regulations concerning *stem cell research*. Also comment on the effect of any other non-specific legislation, regulation or professional codes to stem cell research.

Pourriez-vous indiquer les opinions de votre groupe sur les réglementations actuelles ou envisagées dans le domaine de la *recherche sur les cellules souches ?* Pourriez-vous également nous faire part de votre opinion sur les implications de toute autre législation, réglementation ou codes professionnels non-spécifiques en matière de recherche sur les cellules souches ?

7. Do you support or not support the national policy on stem cell research? What policy moves would you recommend that may differ from the national position relating to your overall moral position on stem cell research?

Est-ce que vous soutenez la politique nationale en matière de recherche sur les cellules souches ? Quels changements politiques pouvant différer de la position nationale et liés à votre propre position éthique sur la recherche sur les cellules souches souhaiteriez-vous recommander ?

8. Do you think that there is or can be found an EU-wide moral position on stem cell research?

Pensez-vous qu'il existe ou qu'il puisse exister une position morale à grande échelle au sein de l'UE en matière de recherche sur les cellules souches ?

9. Do you think that a harmonised policy in the EU is warranted or necessary?

Pensez-vous qu'une politique homogène au sein de l'UE soit justifiée ou nécessaire ?

10. How would you advise such a policy being implemented? Please define any international measures that you would propose.

Quelles propositions pourriez-vous faire concernant la mise en œuvre d'une telle politique ? Pourriez-vous détailler les mesures que vous envisagez sur le plan international ?

11. Please make any further comments on any aspect that you wish to or feel have not been covered by this questionnaire that arise from stem cell research.

N'hésitez pas à faire d'autres remarques ou commentaires sur les thèmes que vous jugerez pertinents ou sur les thèmes liés à la recherche sur les cellules souches, qui selon vous n'ont pas été suffisamment abordés par ce questionnaire.

12. Are there any national reports or research papers that you would recommend or draw my attention to? (Please send copies or details of how to obtain them)

Pourriez-vous me recommander ou m'indiquer certains rapports ou comptes-rendus de recherche à l'échelon national ? (Dans ce cas, pourriez-vous m'en faire parvenir des copies ou m'indiquer la manière de me les procurer ?)

13. Are there any other groups that you would recommend me seeking views from?

Connaissez-vous d'autres groupes et, dans ce cas, pourriez-vous me recommander auprès d'eux afin de recueillir leurs opinions sur le sujet ?

14. Could you please indicate the person whom I can contact for further information.

Pourriez-vous me donner les coordonnées d'une personne que je puisse contacter pour avoir des renseignements complémentaires ?

Please send your response either by email or post by December 31st 2002. Both addresses are at the top of this letter. If possible, English translations of all your correspondence would be preferred (French would also be acceptable).

Thank you for your valuable time. Please do not hesitate to contact me if you require further information on this questionnaire, my work, and the work of the Centre or for general correspondence. Further information on me, this research and the Centre for Ethics in Medicine can be found at: http://www.bris.ac.uk/Depts/Ethics/CEM/

Veuillez envoyer votre questionnaire par émail ou par courrier avant le 31 décembre 2002. Vous trouverez les coordonnées émail et postales en haut de la présente lettre. Dans la mesure du possible, pourriez-vous m'adresser les versions traduites en anglais (à défaut, en version française) de vos correspondances ?

Je vous remercie de votre précieuse collaboration. N'hésitez pas à me contacter si vous avez besoin d'autres informations sur le présent questionnaire, sur mes travaux ainsi que sur les travaux du Centre, ou pour tout autre motif. Si vous souhaitez en savoir plus sur ma personne, sur mes recherches et sur le Centre de Déontologie Médicale, vous pouvez consulter le site Internet suivant : http://www.bris.ac.uk/Depts/Ethics/CEM/

Sincerely yours
Je vous prie d'agréer madame, monsieur, l'expression de mes meilleures salutations.

Benjamin Capps

Appendix Eight

Opinions of the Advisory Groups in the European Union

1. National Advisory Group Opinions

Note: No group in this list deviates from general rules concerning consent of the donating couple; ethical review/oversight of a regulatory authority; the 14-day limit; or prohibition of the implantation of embryos subsequent to research.

Advisory Group	Member State	Title of Report(s)	Replied/ Personal Comm.	Embryo Research	Therapeutic Cloning
Die Bioethik-kommission / Austrian Bioethics Commission (ABC)[1]	Austria	'Opinion …on the Issue of Stem Cell Research[2]' (2002) 'Interim Report on so-called reproductive cloning'[3] (2003).	No	A majority (11 of 19) '…considered that research on preexisting human embryonic stem cell lines was permissible …without any alternatives …Until further notice, only those stem cell lines may be used which have already existed before a given date, so that the creation and destruction of supernumerary embryos created in IVF treatment are not encouraged for purposes of stem cell research' (2002 pp. 3-4).	'…research in the field of somatic cell nuclear transfer (therapeutic cloning) should remain excluded from funding by the EU's Sixth Framework Programme' (2002 p. 2). '…if reproductive cloning were to be expressly prohibited by (Austrian) law, this would provide a clear signal for a sense of what is fundamentally right and wrong …at the same time, it would have to be clearly evident from the formulation that this ban involves a deterrent measure from which no assessment can be derived about so-called therapeutic cloning' (2003 p. 3).

[1] By an order issued by the Federal Chancellor on 29 June 2001, a Bioethics Commission was established at the Federal Chancellery. The constituent meeting was held on 2 July 2001. The task of the Bioethics Commission is to advise the Federal Chancellor from an ethical point of view on all social, natural scientific and legal issues arising from the scientific developments in human medicine and human biology. Website: http://www.bka.gv.at/bioethik/.

[2] Full title: '*Opinion of the Bioethics Commission on the Issue of Stem Cell Research in the context of the EU's Sixth Framework Programme for Research, Technological Development and Demonstration Activities as a Contribution towards the Realization of the European Research Area (2002-2006)*' (ABC 2002).

[3] Full title: '*Interim Report on so-called reproductive cloning with regard to a detailed opinion on the application of human cloning, embryo protection and embryo research, preimplantation diagnosis as well as additional issues concerning reproductive medicine*' (ABC 2003).

National Fund for Scientific Research (FWO)[4]	Belgium	No published reports at present[5]. Statements are from personal communication.	Yes	Yes – provided national and local ethical review	Yes – provided national and local ethical review
Comité Consultatif de Bioéthique/ Belgian National Consultative Bioethics Committee (CCB)[6]	Belgium	Reports published in French on embryo research and human cloning; an opinion on stem cell research is planned[7]	Yes	Could not obtain report.	Could not obtain report.
Ad hoc Committee on Genetic Technology (CGT)[8]	Denmark	Fremtidens Bioteknologier – muligheder og risici (October 24 2002)	Yes[9]	X	X
Det Etiske Råd / Danish Council of Ethics (DCE)[10]	Denmark	'Statement on Cloning' (2002)	Yes	'…most …find there is no pressing need at present to allow embryonic stem cells to be produced for research or possible treatment of disease, either by cloning or by the in vitro technique …these members recommend that research …be confined to embryos left over from IVF treatment' (2002 p. 33)	A minority of the DCE approves in the use of therapeutic cloning in order to obtain stem cells (2002 p. 33).
Forsknings styrelsen/ Danish Research	Denmark	No relevant reports[12].	Yes	X	X

[4] *FWO - Vlaanderen* was founded in 1928 as an Institution of Public Interest for the support of scientific research. The FWO activities are aimed at a push back of the frontiers of knowledge in all disciplines, stimulating and funding fundamental academic research at the universities in the Flemish Community and at scientific research institutes. http://sun.fwo.be/.

[5] Personal communication 7/10/02.

[6] http://www.health.fgov.be/bioeth/.

[7] Personal communication 26/3/03.

[8] Created by the Danish Minister for Science, Technology and Innovation in 2002.

[9] The opinion states that research on embryonic stem cells and therapeutic research would not be supported under present Danish legislation. Should a political decision be made to pursue such research purposes, then the present Act on Medically Assisted Procreation would require amending.

[10] The DCE was established in 1988 to provide the Danish Parliament, official authorities and the public with ongoing advice and information about ethical problems raised by developments within the national health service and the field of biomedicine. The Council has 17 members. http://www.etiskraad.dk/.

Agency (DRA)[11]					
Valtakunn-allinen terveydenh-uollon eettinen neuvottelu-kunta/ National Advisory Board on Health Care Ethics (ETENE)[13]	Finland	No relevant reports[14].	Yes	X	X
National Advisory Board on Research Ethics (NABHCE)[15]	Finland	X	Yes[16]	X	X
Biotekniik-an neuvottelu-kunnan/ National Advisory Board for Biotechnol-ogy[17]	Finland	No information in English	No	X	X
National Consultati-ve Ethics Committee for Health and Life Sciences	France	'Opinion on the Establishment of Collections of Human Embryo Cells and their use	No	'...any creation *de novo* of human embryos for any purpose other than a parental project, is still not permitted' (1997; also see 2001).	'There is a majority in favour [of]...controlled authorisation to engage in 'therapeutic' cloning' (2001).

[11] The DRA is an independent institution under the Ministry of Research. The Agency houses the secretariats for The Board of Danish Research Councils, The Danish Research Councils, The Danish Research Training Council, the Central-Scientific Ethical Committee (see *supra* s. 3.1.1. p. 178), and the Danish Committees on Scientific Dishonesty. http://www.forsk.dk/eng/cvk/index.htm.

[12] Personal communication 8/11/02.

[13] ETENE was established in 1998 under the Act on the Status and Rights of Patients (785/1992, amendment 333/1998). The Board deals with ethical issues related to health care and the status and rights of patients from the point of view of principle. It can also take initiatives and issue advisory opinions and recommendations on ethical health care issues and foster discussion on them within Finnish society and provides expert assistance with the development of health care and relevant legislation, and collects and distributes information on ethical questions involved in health care and related international discussion, technological advances in health care and the ensuing ethical issues. (Decree on the National Advisory Board on Health Care Ethics 494/1998). http://www.etene.org/e/yourturn.shtml.

[14] Personal communication 2012/02.

[15] http://pro.tsv.fi/tenk/english1.htm.

[16] No competence in this field: Personal communication 24/9/02.

[17] http://www.biotekniikanneuvottelukunta.fi/.

[18] The CCNE was established by a decree signed by the President of the French Republic on 23rd February 1983. It is now enacted in the law of 29th July 1994. The Committee's mission is to *give*

(CCNE)[18]		for Therapeutic or Scientific Purposes' (Opinion 53; 1997); 'Opinion on the Parliamentary Draft Revision of the Laws on Bioethics' (Opinion 67; 2001).		'...research for medical purposes may ...be undertaken on human embryos that are no longer required for a parental project, with the agreement of the procreating couple' (2001)	
Centre national de la recherche scientifique (CNRS) (National Centre for Scientific Research) - Committee on Ethics for the Sciences (COMETS) & Comitié d'Ethique de CNRS)[19]	France	X	No	X	X
Enquete-Kommissi-on (EK)[20]	Germany	'Second Interim Report of the Study Commission on the Law and Ethics of Modern Medicine: Stem Cell research' (2001)	N/A	Objected in principle to the import of cells for research on the grounds that the utilisation of EC cells could not be distinguished from the destruction of the embryo. However, because of the conditions of the right to freedom of research, recommended an in-principle ban that could be relaxed under exceptional circumstances	X
Der Nationaler Ethikrat/ German	Germany	'The Import of Human Embryonic Stem Cells:	Yes	A majority (p. 54) of the Council support: 'The provisional import of human	X

opinions on ethical problems raised by progress in the fields of biology, medicine, and health, and to publish recommendations on this subject. http://www.ccne-ethique.fr/english/start.htm.

[19] The CNRS was created in 1939 by presidential decree. The aim was to merge all the non-specialised state organisations involved in basic and applied research into a single institution in order to co-ordinate research at the national level. http://www.cnrs.fr/index.html.

[20] Set up by the German Bundestag in 2000. http://www.bundestag.de/gremien/medi/.

National Ethics Council (NEC)[21]		Opinion' (2001)		embryonic stem cells, for a limited period only and subject to strict conditions' (2001 p. 48).	
Deutsche Forschung-sgemeinsc-haft (DFG) / German Research Foundation [22]	Germany	'Recommendati-ons of the DFG Concerning Research with Human Embryonic Stem Cells (2000); 'Recommenda-tions of the DFG Concerning Research with Human Embryonic Stem Cells' (2001).	Yes	'Active participation of scientists in Germany in the generation of embryonic stem cell lines is desirable' (2001). The DFG recommends provisions to establish new cell lines (over the next 5 years) or importing those created later than 1st January 2002 (2001). Only embryos derived from 'surplus' embryo can be imported (2001).	'The DFG holds the view that …therapeutic cloning by means of nuclear transplantation into enucleated human oocyteas can neither be justified scientifically nor can it be accounted for ethically and for that reason it is not permissible' (2001).
Εθνική Επιτροπή Βιοηθικής/ Hellenic National Bioethics Commission (HNBC)[23]	Greece	Comments on the Draft Bill Concerning Medically Assisted Human Reproduction (2001); Recommendati-on on the Use of Stem Cell in Biomedicine and Clinical Medicine (2001 per. co.);	Yes	'Most members …agree with the general principal of article 18, of the Convention on Human Rights and Biomedicine …that generally allows research under specified conditions on embryos in vitro. They consider though that further clarification is needed concerning the conditions for embryo research and	'Most members of Commission consider that embryo production for therapeutic purposes via cloning and derivation of stem cells from such embryos should not be precluded, in condition that there is no alternative …the Commission (by majority) reckons that therapeutic cloning is exempted from the general prohibition of article 18' (2001).

[21] Following the Federal Government's decision of 2 May 2001, the NEC was inaugurated on 8 June 2001 as a national forum for dialogue on ethical issues in the life sciences. The National Ethics Council has up to 25 members, who represent the scientific, medical, theological, philosophical, social, legal, ecological and economic worlds and are appointed for a four-year term by the Federal Chancellor. The National Ethics Council is independent and is bound solely by the function laid down in the decree that established it. http://www.nationalerethikrat.de/_english/index_e.html.

[22] The DFG is the central, self-governing research organisation that promotes research at universities and other publicly financed research institutions in Germany. http://www.dfg.de/en/index.html.

[23] The National Bioethics Commission is an independent advisory body of experts established by law 2667/1998. The Commission investigates the ethical, social and legal aspects that arise from scientific advances in biology, biotechnology, medicine and genetics, and outlines, in collaboration with the respective ministries, proposals of general policy and provides specific recommendations on related issues. It also collaborates with international organisations and related bodies, informs the public on issues related to biotechnological advances and the impact of their applications, and orientates and co-ordinates related governmental advisory bodies in the field of bioethics. The Commission is composed of nine academic members, appointed by the Prime minister for a term of five years. http://www.bioethics.gr/index.php.

		Report on the Use of Stem Cell in Biomedicine and Clinical medicine (2001 per. co.).		stem cells derivation' (2001).	
Commission on Assisted Human Reproduction (Department of Health and Children) [24]	Ireland	Opinion planned.	N/A	X	X
Comitato Nazionale per la Bioetica/ National Bioethics Committee (CNB)[25]	Italy	'Opinion of the NBC on the Therapeutic use of Stem Cells' (2000a).	Yes	It is '...ethically legitimate to derive stem cells for therapeutic purposes from embryos that it is no longer possible to implant ...nevertheless [the NBC] recommend performing investigations and rigorous verifications on a case by case basis concerning the suitability for implantation, the consent to donate and the therapeutic purpose of the experimentation' (2000a para 31).	' ...this line of research could produce therapeutic results of great significance and for the time being without any alternative such as to suggest evaluating the ethical aspects of future applications on a case by case basis' (2000a para 29).
Commission consultative national d'éthique pur les sciences de la vie et de la santé/ National Consultative Committee for Life and Health Sciences	Luxem-bourg	X	No	X	X

[24] http://www.doh.ie/aboutus/groups/cahr.html.

[25] The setting up of the NBC followed resolution no. 6-00038 approved on 5 July 1988, committed the Government to promoting an international level comparison on the state of the art of biomedical research and genetic engineering which might serve as a valid point of reference for future choices in which the progress of science can be reconciled with the respect for human freedom and dignity. It was established by a decree signed by the President of the Council of Ministers on 28 March 1990. The Committee publishes opinions for the purpose of preparing legislative acts, and addresses the ethical and legal problems that may emerge as a result of the progress of research and the emergence of possible new applications of clinical interest. http://www.palazzochigi.it/bioetica/.

(NCEC)					
Ministère de la Santé[26]	Luxem-bourg	X	Yes	Permissible for medical research; and subsequent to local and government review; consent from parents; and only IVF 'spare' embryos[27]	X
Gezondheid-sraad/ Health Council of the Netherlands (HCN)[28]	Netherl-ands	'Stem Cell for Tissues Repair: Research on Therapy using Somatic and Embryonic Stem Cells' (2002); 'IVF-Related Research' (1998).	Yes	'The committee *recommends*: permitting the isolation of stem cells from 'spare' embryos for the purposes of stem cell research' 2002 p. 18). 'The committee feels that the legal option of generating embryos specifically for scientific research should remain open …in the interests of acquiring important new knowledge [and] that cannot be obtained by any other means. The committee considers that …the distinction between conducting research on spare embryos and creating embryos specifically for the purpose of research is comparatively small' (2002 p. 58). '…while a given value should be assigned to the embryo in vitro …this value is relative and can be overridden when other, more imperative interests are involved …the Committee considers it	'The committee does not believe these trials [therapeutic cloning] are urgent, but does believe that they will be important when it becomes clear that cell therapy with embryonic stem cells is effective and no feasible alternatives have been developed. …[the HCN recommends] no ban …in advance on research into the possibility of nuclear transplants and the creation of new embryonic stem cell lines …in the view of the committee, this right to protection cannot be used to make a convincing *a priori* objection to the creation of such an embryo by means of cell nuclear transfer' (2002 p. 59).

[26] http://www.etat.lu/MS/.
[27] Personal communication 24/9/02.
[28] The HCN is an independent advisory body whose task is to advise Ministers and Parliament in the field of public health. Ministers ask the Health Council for advice on which to base policy decisions. In addition, the Health Council has an 'alerting' function, which also allows it to give unsolicited advice. The Standing Committee on Medical Ethics was set up in 1977 and has since 1983 been designated as the Standing Committee on Medical Ethics and Health Law. It consists of experts in the fields of medicine, medical ethics and health law. The committee gives advice on any ethical, legal or social matters that may arise in relation to draft advisory reports. The standing committee will itself sometimes produce advisory reports. http://www.gr.nl/index.php.

				acceptable for embryos to be created for research purposes only when such research cannot be carries out using surplus embryos' (1998 p. 12).	
Netherlands Organisation for Health Research and Development (ZonMw)[29]	Netherl -ands	Endorses the Reports of the ESF[30].	Yes	Yes	Yes
Conselho Nacional de Etica Para as Ciencias da Vida/ National Council on Ethics for the Life Sciences (CNEVC)[31]	Portugal	X	No	X	X
Observatory on Bioethics and Law, Barcelona (OBL)	Spain	Declaration on Embryonic Stem Cells (16 December 2001)	N/A	Permissible inc. creating embryos by IVF and CNR specifically for research; must have consent and approved by an 'ad hoc committee'[32]	Yes
National Commission of Human Assisted Reproduction (NCHAR)[33]	Spain	'Reproducción Humana Asistida: Informe Annual 1998' (1998)	N/A	Recommended that researches should be permitted to obtain stem cells from embryos stored for more than 5 years[34].	X
Advisory Committee on Ethics of Scientific and Technical	Spain	'Report: Stem Cell Research' (2003)	N/A	'...recommends that, as an alternative to the destruction of surplus embryos, these may be used to obtain embryonic stem cells ...The	X

[29] The new organisation covers the entire continuum in the areas of health, prevention and care, from basic scientific research to modernisation projects in practice. The main customers for ZonMw are the Ministry of Health, Welfare and Sport (VWS) and the Netherlands Organisation for Scientific Research (NWO). http://www.zonmw.nl/index.asp?s=3787.

[30] Personal communication 12/11/02; *infra* s. 5.2.

[31] The mandate of the CNEVC expired in 2003 and no new appointments have been made. http://www.cnecv.gov.pt/.

[32] See Malagrida 2003; & Holden 2003.

[33] Committee created under the Ministerio de Sanidad Y Consumo. http://www.msc.es/.

[34] Report in Spanish; contents and interpretation from Bosch (2003).

Research (ACE)[35]				creation of human embryos for the specific purpose of generating stem cells for research in not recommended …the Committee believes that the two lines of research (ES and AS cell) are not in competition and recommends that research be carried out with both' (2003 pp. 101-102)	
Kommitten om genetisk integritet/ Committee on Genetic Integrity (SCGI)[36]	Sweden	'Summary of the Genetic Integrity report concerning embryonic stem cell research' (2003)	Yes	'It is not proposed to implement a general prohibition against *producing fertilised eggs for research purposes*. It is the opinion of the committee that such production must take place in order for research to be carried out into fertility and the development of the fertilised egg …It is not possible to set a legal limit with sufficient clarity that would delineate what …would be forbidden. This delineation should rather be done on a case-by case basis within the framework of the ethical review of research' (2003 p. 14).	'*The transfer of somatic cell nuclei* should not be prohibited …No detailed regulation concerning research based on the transfer of somatic cell nuclei should be introduced (2003 p. 15)
Genteknik-nämnden/ Swedish Gene Technology Advisory Board[37]	Sweden	X	Yes[38]	X	X
Swedish Research	Sweden	'Guidelines for Research-	No	'The use of [spare] human embryos is	'Creation of embryos through somatic cell

[35] Created under the Spanish Foundation for Science and Technology and pursuant to the 27 April 2001 Resolution of the Spanish Council of Ministers at the initiative of the Ministry of Science and Technology. http://www.fecyt.es/index-flash.htm.

[36] Under the Ministry of Health and Social Affairs: http://www.social.regeringen.se/inenglish/index.htm.

[37] http://www.genteknik.se/.

[38] No competence in this area; recommended to contact Kommittén om Genetisk Integritet (personal communication 20/12/02).

Council (SRC)[39]		Ethical Review of Human Stem Cell research' (2001)		permissible [for ES cell research] if there are no acceptable alternative ways to achieve corresponding results and the project is judged necessary …Creation of embryos from eggs and sperm solely for research purposes cannot be allowed since there are less invasive methods of acquiring such embryos' (2001 p. 16).	nuclear transfer may be ethically defensible but cannot be allowed in the present legal situation' (2001 p 16); 'Such an activity …should be made contingent upon [setting up] a national authority …[and] be proceeded by a legal ban against implanting embryos in a woman's uterus' (2001 p. 15).
Statens Medicinsk-Etiska Råd/ Swedish National Council on Medical Ethics (SMER)[40]	Sweden	'Statement of Opinion on Embryonic Stem Cell Research' (2002)	Yes	'…embryonic stem cell research is ethically defensable on the condition that it is conducted in controlled forms and under public scrutiny, including legally regulated ethical examination of each individual project by a committee of research ethics; is permissible only if *there* are no scientifically well-founded and ethically acceptable alternatives for attaining the same goals of knowledge; does not justify the creation of embryos, through test-tube fertilisation, solely for research purposes (2002 sec 8).	'The Council has not, at this stage, taken a position on the issue of cell nuclear transfer. The medical-ethical and legal implications of allowing cell nuclear transfer to egg cells, or to fertilised eggs, are insufficiently elucidated at present. Consequently, the issue should remain open until the level of knowledge and understanding is adequate to provide a base for policy decision. For the time being, a ban against creation of embryos for research purposes should not be introduced to Swedish law' (2002 sec 8).
The Wellcome Trust (WT)[41]	UK	'Interim Position Statement on Stem Cell	Yes	'There are a number of sources of stem cells but to begin with it is likely that	Supported in 2000 Statement through endorsement of DoH Report 2000 (see

[39] The Swedish Research Council has national responsibility for developing the country's basic research towards attainment of a strong international position. The Council has three main tasks: research funding, science communication and research policy. Research is the foundation for the development of knowledge in society, and the basis of high-quality education. Research is also crucial as a means of enhancing welfare through economic, social and cultural development. http://www.hsfr.se/english/index.asp.

[40] The Swedish National Council on Medical Ethics is an advisory board to the Swedish government on ethical issues raised by scientific and technological advances in biomedicine. It has 23 members. http://www.smer.gov.se/.

[41] The WT is an independent research-funding charity established 1936. It is funded from a private endowment, which is managed with long-term stability and growth in mind. Its mission is 'to foster and promote research with the aim of improving human and animal health'. The WT seeks to raise awareness

		Research' (2000); 'Wellcome Trust response to the report of the House of Lords Select Committee on Stem Cell Research' (27 February 2002)		the greatest benefits will be realized [sic] by using those cells derived from very early-stage embryos …stem cell research for the benefit of human health is ethically justifiable' (2000) 'The Lords deserve congratulations on their clarity of thought on an issue that others have attempted to hijack with inflammatory and misleading interventions. It is crucial that stem cell research using both adult and early embryo stem cells is allowed to progress' (2002)	below).
Royal Society (RS)[42]	UK	Science and Society: A Response to the Inquiry by the House of Lords Science and Technology Select Committee (1999); Stem Cell Research and Therapeutic Cloning: An Update (2000a); Therapeutic Cloning: A Submission by the Royal Society to the	Yes	'the proposed new regulations …which would allow research on human embryonic stem cells, are scientifically necessary to realise fully the potential of stem cell therapies' (2000b); Creating embryos is supported by endorsing the DoH Report (2000) (see below).	'Very early human embryos cloned for legitimate research harnessing stem cells coupled help to improve or save the lives of millions of patient worldwide' (2003); Therapeutic cloning is endorsed by supporting the DoH Report (2000) (see below).

of the medical, ethical and social implications of research and promote dialogue between scientists, the public and policy makers. http://www.wellcome.ac.uk/en/1/hme.html.

[42] As the UK national academy of science founded in 1660, the RS plays a crucial role as the champion of top quality science and technology. By virtue of its independent status and its body of some 1300 Fellows and Foreign Members covering all scientific disciplines, the Society is uniquely placed to represent the interests of top quality science and technology in its interactions with government, the public and the media. It adopts a high profile on issues which are vital to scientific progress and is making an increasingly prominent position in furthering the role of science, engineering and technology in society by facilitating constructive dialogue between scientists and non-scientists. http://www.royalsoc.org/.

		Chief Medical Officer's Expert Group (2000b) Stem Cell Research: Second Update (2001). Human Reproductive Cloning: Statement by the Royal Society' (2003)			
Medical research Council (MRC)[43]	UK	No relevant reports[44].	Yes	X	X
Nuffeild Council on Bioethics (NCB)[45]	UK	'Stem Cell Therapy: The Ethical Issues – A Discussion Paper' (2000).	Yes	'We therefore recommend that research involving human embryos be permitted for the purpose of developing tissues to treat diseases from derived embryonic stem (ES) cells' (p.1); '...we consider that there are no compelling reasons to allow additional embryos to be created merely to increase the number of embryos available for ES cell research or therapy. However, we suggest that this issue be kept under review' (p. 11).	'...we consider that the proposed creation of embryos using SCNT for research into the derivation of stem cells offers such significant potential medical benefits that research for such purposes should be licensed' (p. 18).

[43] The MRC is a national organisation funded by the UK taxpayer and established in 1913. The Council works in close partnership with Health Departments, other Research Councils, industry and others to identify and respond to current and future health needs. http://www.mrc.ac.uk/.

[44] Personal communication 9/12/02; but note the MRC's role in the UK stem cell bank; see: http://www.mrc.ac.uk/prn/index/strategy-strategy/strategy-science_strategy/strategy-strategic_implementation/strategy-stem_cells/strategy-stem_cell_governance/public-stemcell_governance_steering.htm.

[45] The NCB is an independent body established by the Trustees of the Nuffield Foundation in 1991 to consider the ethical issues arising from developments in medicine and biology. The Council is funded jointly by the Nuffield Foundation, The Wellcome Trust and the Medical Research Council. The Council plays a major role in contributing to policy-making and stimulating debate in bioethics. Once the Council has identified a topic for investigation, it establishes a multidisciplinary group with the relevant expertise to examine and report on the issue. http://www.nuffieldbioethics.org/home/.

House of Lord's Select Committee on Stem Cell Research (Sel. Com.)	UK	'Stem Cell Research: Report' (2002)	N/A	'...there is a clear scientific case for continued research on ES cells ...To ensure maximum medical benefit it is necessary to keep both routes to therapy open' (ES, CBS and AS cell research) (*stem cell research* s. iv)[46] 'Embryos should not be created specifically for research purposes unless there is a demonstrable and exceptional need which cannot be met by the sue of surplus embryos' (*status of the embryo* s. ix)	'Although there is a clear distinction between an IVF embryo and an embryo produced by CNR (or other methods) in their method of production, the Committee does not see any ethical difference in their use for research purposes up to the 14 day limit (*cell nuclear replacement and cloning* s. xi).
Department of Health (DoH[47])	UK	'Stem Cell Research: Medical Progress with Responsibility : A Report from the Chief Medical Officer's Expert Group Reviewing the Potential of Developments in Stem Cell Research and Cell Nuclear Replacement to Benefit Human Health' (2000).	N/A	'Research using embryos (whether created by in vitro fertilisation or cell nuclear replacement) to increase understanding about human disease and disorders and their cell-based treatments should be permitted, subject to the controls in the Human Fertilisation and Embryology Act 1990' (Rec. 1; 2000).	'In licensing any research using embryos created by cell nuclear replacement, the Human Fertilisation and Embryology Authority should satisfy itself that there are no other means of meeting the objectives of the research' (Rec. 2; 2000).

2. International Bodies

Advisory Group	Affiliation	Title of Report(s)	Embryo Research	Therapeutic Cloning
European Group on Ethics in Science and	Euro Commi-ssion	'Ethical Aspects of Cloning Techniques' (Opinion 9 1997);	'...funding should no a priori exclude human embryo research' (1998 2.8) providing there is	Only for the objective of researching the causes of human disease/human suffering, and should not

[46] All quotes from *Summary of Conclusions and Recommendations* of the Report.
[47] Also see: *Human Genetics Advisory Commission/Human Fertilisation and Embryology Authority*: 'Cloning Issues in Reproduction, Science and Medicine' (1998). http://www.doh.gov.uk/.

New Technologies (EGE)[48]		'Ethical Aspects of Research Involving the use of Human Embryo in the Context of the 5th Framework Programme' (12 1998); 'Ethical Aspects of Human Stem Cell Research and Use' (15 2000)	ethical evaluation at the Community level (2.9) and national level (2.10) (also 2000 2.13); '...the creation of embryo ...for the purpose of stem cell procurement is ethically unacceptable (2000 2.7)	include the replacement of the embryo (1997 2.9); '...the creation of embryos by somatic cell nuclear transfer for research on stem cell therapy would be premature' (2000 2.7)
European Science Foundation (ESF)[49]	X	'Human Stem Cell Research: Scientific Uncertainties and Ethical Dilemmas' (Nos. 15 2001 and 18 Second edition 2002)	'It is essential to proceed with research on stem cells derived from embryos, foetal tissues and adults, in parallel' (2002 p. 4)	'...fundamental research involving this technique should be supported, but under strong regulatory control by national bodies' (2002 p. 5)
European Society of Human Reproduction and Embryology (ESHRE)	X	'The Moral Status of the Pre-Implantation Embryo' (2001); 'Stem Cells' (2002)	'...the creation and the possibility of research on pre-implantation embryos specifically created for the purpose is appropriate only if the information cannot be obtained by research on supernumerary zygotes' (2001 p. 1048); 'We do not object to embryo research on supernumerary embryos, nor do we find any major ethical differences with embryos created for research [including for therapeutic cloning]' (2002 p. 1410)	X
International Federation of Gynaecology and Obstetrics (FIGO)[50]	X	'Recommendations on Ethical Issues in Obstetrics and Gynaecology (1997)	'Research on pre-embryos is only ethically acceptable when its purpose is for the benefits of human health ...The Committee was unable to reach a consensus as to whether research should be limited to surplus pre-embryos or	X

[48] The Group is an independent, pluralist and multidisciplinary body which advises the European Commission on ethical aspects of science and new technologies in connection with the preparation and implementation of Community legislation or policies. In December 1997 the European Commission set up the European Group on Ethics to succeed the Group of Advisers on the Ethical Implications of Biotechnology. http://europa.eu.int/comm/european_group_ethics/index_en.htm.

[49] The European Science Foundation promotes high quality science at a European level. It acts as a catalyst for the development of science by bringing together leading scientists and funding agencies to debate, plan and implement pan-European initiatives. http://www.esf.org/.

[50] The mission of FIGO is to promote the well-being of women and to raise the standard of practice in obstetrics and gynaecology. FIGO is a non-profit organisation. http://www.figo.org/

			should also include pre-embryos specifically generated for research' (p. 15).	
Nordic Committee on Bioethics (NorCB)[51]	X	'The Ethical Issues in Human Stem Cell Research' (2000)	'The use of stem cells, derived from human spare embryos produced for in vitro fertilization [sic.] but no more needed, was considered acceptable until day 14 of embryonal development... The creation of human embryos solely for research purposes seemed not necessary at the present stage of research'	'...at this stage of embryonic stem cell research and waiting for more definite results on the potential of using adult stem cells it was felt that use of the somatic cell nuclear transfer technique in humans should not be allowed in the Nordic countries'
Steering Committee on Bioethics (CDBI)	Council of Europe	'The Protection of the Human Embryo in Vitro' (2003)	'...it seems possible and desirable with regards to the need to protect the embryo in vitro on which all countries have agreed, that common approaches be identified to ensure proper conditions for the application of procedures involving the creation and use of embryo in vitro' (p. 37).	X
Internation-al Bioethics Committee (IBC)	UNESCO United Nations[52]	'The Use of Embryonic Stem Cells in Therapeutic Research' (McCall Smith & Revel 2001)	'Human embryonic stem cell research – and embryo research in general – is a matter which each community will have to decide for itself. If the decision is reached after serious ethical debate ...then this must be accepted' (p. 13)	X
The Interacademy Panel on International	X	'Statement on Human Cloning' (2003)[54].	X	'Cloning for research and therapeutic purposes therefore has considerable potential

[51] To further promote Nordic co-operation and exchange of information between scientists, parliamentarians and opinion leaders on ethical aspects of biotechnological research, development and application a Nordic committee on Bioethics was formed in1989. The committee's mandate has been reviewed several times. The present mandate is for the years 2002-2004. The Committee has two members from each of the Nordic countries and represents broad-based knowledge in biotechnology and bioethics. Members are nominated by the national ministries for education/ research and they are appointed by the Nordic Council of Ministers for a period of three years that can be renewed once. Members shall, if possible, be members of their respective National Ethics Councils. The committee has adopted a system of yearly chair rotation between the member countries. http://www.ncbio.org/Html/eng_index.htm.

[52] UNESCO, United Nations Educational, Scientific and Cultural Organisation was established on 16th of November 1945. http://www.unesco.org/.

[53] To promote co-operation among national scientific academies, the IAP was created in January 1995. It has an informal advisory capacity to the UN.

Issues (IAP)[53]				from a scientific perspective, and should be excluded from the ban on human [reproductive] cloning. Both policies should be reviewed periodically in the light of scientific and social developments' (2003).

3. Groups Contacted

AUSTRIA (Groups contacted: 8; Responses: 0)
Bioethikkommission beim Bundeskanzleramt – Geschäftsstelle
Bundesministerium für Bildung, Wissenschaft und Kultur (bm:bwk) / Federal Ministry for Education, Science and Culture
Bundesministerium für soziale Sicherheit und Generationen / Federal Ministry for Labour, Health & Social Affairs
Bundesministerium für soziale Sicherheit und Generationen / Federal Ministry for Social Security and Generations
Büro für Internationale Forschungs- und Technologiekooperation (BIT) / Bureau for International Research and Technology Co-operation
Die Bioethikkommission / Austrian Bioethics Commission
Fonds zur Förderung der wissenschaftlichen Forschung (FWF) / Austrian Fund for the Promotion of the Scientific Research
Osterreichische Akademie der Wissenschaften / Austrian Academy Of Sciences
BELGIUM (9: 4)
Belgium Committee of Medical Ethics of the National Scientific Research Fund (FGWO-FNRS)
Centrum voor Biomedische Ethiek en Recht / Centre for Biomedical Ethics and Law
Comité Consultatif de Bioéthique de Belgique / Belgian National Consultative Bioethics Committee
Federal Ministry of Social Affairs, Public Health and the Environment
Federal Office for Scientific, Technical and Cultural Affairs
Fonds voor Wetenschappelijk Onderzoek –Vlaanderen / National Fund for Scientific Research - Flanders
La Commission d'éthique du FRSM Fonds National de la Recherche Scientifique (FNRS) / National Fund for Scientific Research
l'Association Belge de Bioéthique / Belgium Association of Bioethics
Ministere de la Sante
Senat de Belgique: Committee of the Belgian Senate on Bioethical Issues
DENMARK (14: 5)
ad hoc Committee on Genetic Technology
BIOSAM
Centrale Videnskabsetiske Komité / Central Scientific Ethical Committee
Danish Centre for Evaluation and Health Technology Assessment
Danish Medical Research Council
Danish Medicines Agency
Det Etiske Råd / The Danish Council of Ethics
Det Kongelige Danske Videnskabernes Selskab / Royal Danish Academy of Sciences and Letters

[54] The Report was endorsed by 63 of its 90 members, including (from the EU): *the Royal Danish Academy of Sciences and Letters*; the *Delegation of the Finnish Academies of Science and Letters*; *Académie des Sciences*, France; the *Academy of Athens*, Greece; the *Royal Netherlands Academy of Arts and Sciences*; the *Royal Swedish Academy of Sciences*; and the *Royal Society*, UK. http://www4.nationalacademies.org/iap/iaphome.nsf.

Forskningsstyrelsen / The Danish Research Agency
Ministeriet for Videnskab Teknologi og Udvikling / Ministry of Science Technology and Innovation
Ministry of Interior and Health
National Board of Health
National Institute of Public Health
Statens Sundhedsvidenskabelige Forskningsråd / National Institute of Public Health
Teknologirådet / The Danish Board of Technology
FINLAND (11: 2)
Biotekniikan neuvottelukunnan / National Advisory Board for Biotechnology
Board of Gene Technology
Finnish Office for Health Care Assessment (STAKES) / FinOHTA
Ministry of Social Affairs and Health
Tutkimuseettinen neuvottelukunta (TENK) / National Advisory Board on Research Ethics
Research Science and Technology Policy Council of Finland
Suomen Akatemia – Finlands Akademi / Academy of Finland
Suomen Tiedeakatemian Valtuuskunta/Delegationen / Delegation of the Finnish Academy of Sciences and Letters
Teknologia –tie Tulokseen (TEKES) / National Technology Agency of Finland
Tutkimuseettinen neuvottelukunta / National Research Ethics Council of Finland
Valtakunnallinen terveydenhuollon eettinen neuvottelukunta (ETENE) / National Advisory Board on Health Care Ethics
FRANCE (5: 1)
Comité Consultatif National d'Ethique piur les Sciences de la Vie et de la Santé (CCNE) / National Consultative Ethics Committee for Health and Life Sciences
Comite D'Ethique pour les Techniques de Procreation Artificielles
Institut National de la Santé et de la Recherche Médicale (Inserm) / The French Institute of Health and Medical Research
Le Comité d'éthique du Centre National de la Recherche Scientific (CNRS) / CNRS Committee on Ethics
State Secretat for Health / Ministere de L' Emploi et de la Solidarite / Ministry of Employment and Solidarity
GERMANY (16: 2)
Akademie für Ethic in der Medizin e.V. / Academy for Ethics in Medicine
Besucherdienst beim Deutschen Bundestag
Der National Ethikrat / German National Ethics Council
Deutsche Forschungsgemeinschaft (GFG) / German Research Association
Federal Institute for Drugs and Medical Devices
Georg-August-Universität Göttingen Bereich Humanmedizin
Geschäftsstelle der Akademie für Ethik in der Medizin e.V.,
Geschäftsstelle der Bioethik-Kommission Bayern Bayerisches Staatsministerium für Gesundheit,
Hermann von Helmholtz Association of National Research Centres / Hermann von Helmholtz-Gemeinschaft Deutscher
Institut für Wissenschaft und Ethik e.V.
Kommission fur Offentlichkeitsarbeit und Ethische Fragen der Deutschen Gesellschaft fur Humangenetik e.V. / Committee for Public Relations and Ethical Issues of the German Society of Human Genetics
Ludwig-Maximilians-Universität - Forum Medizinische Ethik
Max-Planck-Gesellschaft (MPG) / Max Planck Society
Universität Tübingen Interfakultäres Zentrum für Ethik in den Wissenschaften (IZEW)
Zentrale Ethikkommission Geschäftsstelle bei der Bundesärztekammer
Zentrum für Medizinische Ethik e.V. / Bochum Centre for Medical Ethics
GREECE (5: 1)
Greek National Bioethics Committee
National Hellenic Research Foundation (NHRF)
National Committee on Bioethics
Κέντρο ιοϊατρικής Ηθικής και Δεοντολογίας / Hellenic Center for Biomedical Ethics
Ταχυδρομική Διεύθυνση / National Bioethics Commission

IRELAND (6: 0)
Department of Health and Children
Health Research Board (HRB)
Royal College of Physicians of Ireland
Royal College of Surgeons of Ireland
Royal Irish Academy
Science Foundation Ireland
ITALY (3: 1)
Comitato Nazionale per la Bioetica / National Bioethics Committee
Consiglio Nazionale delle Ricerche (CNR) / National Research Council
Societa Italiana di Bioetica (SIB) / Italian Society of Bioethics
LUXEMBOURG (3: 1)
Commission consultative nationale d`éthique pour les science de la vie et de la sante / National Consultative Committee for Life and Health Sciences
Institut für Ethik in der Medizin e.V., Leipzig / Institute for ethics in the medicine e.V., Leipzig
Ministere de la Sante
NETHERLANDS (5: 2)
Gezondheidsraad / Health Council of the Netherlands
Ministry of Health, Welfare and Sport
Nederlandse Organisatie voor Wetenschappelijk Onderzoek (NWO) / Netherlands Organisation for Scientific Research
Netherlands organisation for health research and development (ZonMw)
Rathenau Institute
PORTUGAL (5: 0)
Academia das Ciências de Lisboa / Lisbon Academy of Science
Conselho Nacional de Ética Para as Ciências da Vida / National Ethics Council for Life Sciences
Fundação para e Ciência e a Tecnologia (FCT) / Foundation for Science and Technology
Ministero do Saude Direcac-Geral da Saude / General Directorate of Health
Instituto de Cooperaçao Ciêntifica e Tecnológica Internacional / Institute for International Scientific and Technological Co-operation
SWEDEN (8: 3)
Gentekniknämnden / Swedish Gene Technology Advisory Board
Kommittén om genetisk integritet/ Committee on Genetic Integrity
Kungliga° Vetenskapsakademien (KVA) / The Royal Swedish Academy of Sciences
Medicinska Forskningradet (MFR) / Swedish Medical Research Council
Ministry of Health and Social Affairs
Statens beredning för medicinsk utvärdering (SBU) / Swedish Council on Technology Assessment in Health Care
Swedish National Council on Medical Ethics
Vetenskapsrådet / Swedish Research Council
SPAIN (6: 0)
Consejo Superior de Investigaciones Cientificas
Council for Scientific Research / Consejo Superior de Investigaciones Cientificas (CSIC)
Fundación de Ciencias de la Salud / Foundation for Health Sciences
Ministero de Sanidady Consumo / National Institute of Health
Oficina de Ciencia y Tecnologia) (OCYT) / Office for Science and Technology
Sociedad Internacional de Bioética (SIBI) / International Society of Bioethics
UK (9: 4)
Biotechnology and Biological Sciences Research Council (BBSRC)
Central Office for Research Ethics Committees (COREC)
Human fertilisation and Embryology Authority (HFEA)
Human Genetics Commission (HGC)
Medical Research Council(MRC)
Nuffield Council on Bioethics (NCB)
The British Academy

The Royal Society
The Wellcome Trust

Notes

Bold = National Ethics Committee/ Regulatory Authority/ National Advisory Body
Italics = Groups that responded

Total sent = 114
Total Responses = 26