Medical Biotechnology Law in South Africa: A Human Rights Analysis of Selected Topics

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Declaration

I, Donrich W Jordaan, hereby declare that the work on which this thesis is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university. I authorise the University of Cape Town to reproduce for the purpose of research either the whole or any portion of the contents in any manner whatsoever.

Signed on the 1st day of July 2012 at Pretoria.

Donrich W Jordaan

Abstract

In this thesis I analyse the human rights dimensions of the South African law on four topical medical biotechnology subjects, namely human embryo research, the use of human gametes, autologous stem cell therapy, and private stem cell banking. In all four cases, my analyses give specific prominence to two research themes: first, human dignity as touchstone of the South African human rights regime, and secondly legal certainly. The analyses show that the legal rules governing three of the four selected medical biotechnology subjects are not aligned with the country's human rights regime:

- The respect-for-the-embryo paradigm that dominates human embryo research encroaches on human dignity as expressed in the freedom of scientific research. The prominent arguments in favour of the respect-for-the-embryo paradigm, namely that the embryo has intrinsic value and that the embryo has symbolic value, are both shown to be indefensible in the context of the South African human rights system.
- The current outlawing of the use for non-medical purposes of gametes that are removed from the human body encroaches on human dignity as expressed in the right to privacy, again without reasonable justification.
- Autologous stem cell therapy constitutes a welcome exception to the trend in South African medical biotechnology law of suppressing human dignity: The current regulation of autologous stem cell therapy, which relies on scientifically constructed clinical trials – similar to the regulation of medicines in general – is supportive of human dignity.
- Although the current hyper-regulation of private stem cell banking does not per se constitute a human rights violation such as in the case of embryo research, the debate on private stem cell banking has served to expose a levelling-down conception of equality in government, as evident from a

version of draft regulations that were published for public comment. This conception of equality is shown to be in conflict with human dignity.

Similar to the position with the primary research theme of measuring alignment with human rights, the legal rules governing the selected medical biotechnology subjects also leave much to be desired in terms of the secondary research theme of legal certainty:

- Even within the respect-for-the-embryo paradigm that overtly aims to hyper-regulate embryo research, there is a lack of substantive criteria for approving human embryo research.
- The section in the National Health Act that purports to regulate the use of gametes suffers from an ambiguous formulation that is capable of divergent interpretations.
- Although the law regarding autologous stem cell therapy does not suffer from intrinsic legal uncertainties, legal uncertainty in the public's mind has been caused by extrinsic factors, namely the ill-informed, alarmist pronouncements of influential role-players in the field.
- The government's intentions with the regulation of private stem cell banking is uncertain, given inter alia the substantial differences between consecutive versions of draft regulations relating to stem cell banking, and the profit-ban on particular services that are associated with private stem cell banking that will be introduced by Chapter 8 of the National Health Act.

Finally, I make detailed recommendations on how to align the law on the selected medical biotechnology topics with South Africa's human rights regime, and on how to create legal certainly in these legal spheres.

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Preface

This thesis is based on ideas derived from a selection of my published articles, which I have rewritten specifically to address the research themes of this thesis. Accordingly, certain parts of the thesis have similarities with the corresponding parts in my published articles, while other parts throughout the thesis will be entirely new or substantially changed.

One of the published articles that I am using in this thesis was co-authored. In this regard, letters from my co-authors have been obtained that confirm that I was the primary author and conceptualised and drafted the bulk of the legal analyses, and that I have their permission to use the article for purposes of this thesis.

The law regarding medical biotechnology is of course ever-evolving, and new developments are in fact expected in the immediate future, such as the entering into force of Chapter 8 of the National Health Act, which will finally repeal the Human Tissue Act. In this light it should be noted that the content of the thesis was finalised in December 2011 and accordingly reflects the legal status quo it this point in time.

Chapter 1

Introduction

1 The biotechnology revolution

The dramatic surge in biotechnological progress that the world has been witnessing over the past generation is seen as the part of the knowledge economy (together with information and communication technology) that will impact society – and the law – in ways similar to the agricultural and industrial revolutions.[1] The concept 'biotechnology' is defined by the Organisation for Economic Cooperation and Development (OECD) with a 'single definition' complemented by a 'list-based definition'.[2] The single definition defines biotechnology as:[3]

> The application of science and technology to living organisms, as well as parts, products and models thereof, to alter living or nonliving materials for the production of knowledge, goods and services.

Because this single definition is broad enough to also cover traditional and borderline activities, the OECD developed a list-based definition to complement the single definition and that effectively limits biotechnology to modern biotechnology.[4] This list-based definition is as follows:[5]

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1 Cf: Ben Ngubane 'Foreword' in Iqbal Parker et al *A National Biotechnology Strategy for South Africa* (2001) v–vi available at *http://www.esastap.org.za/download/sa_biotechstrat_jun2001.pdf*; Steve Prentis *Biotechnology: A New Industrial Revolution* (1984).

2 Organisation for Economic Cooperation and Development *Statistical Definition of Biotechnology* (Undated) available at *http://www.oecd.org/document/42/0,3746,en_2649_34537_1933994_1_1_1_1,00.html*; Brigitte van Beuzekom & Anthony Arundel *OECD Biotechnology Statistics – 2006* (2006) 7 available at *http://www.oecd.org/dataoecd/51/59/36760212.pdf.*

3 Ibid.

4 Ibid.

5 Ibid.

DNA/RNA: Genomics, pharmacogenomics, gene probes, genetic engineering, DNA/RNA sequencing/synthesis/amplification, gene expression profiling, and use of antisense technology.

Proteins and other molecules: Sequencing/synthesis/engineering of proteins and peptides (including large molecule hormones); improved delivery methods for large molecule drugs; proteomics, protein isolation and purification, signaling, identification of cell receptors.

Cell and tissue culture and engineering: Cell/tissue culture, tissue engineering (including tissue scaffolds and biomedical engineering), cellular fusion, vaccine/immune stimulants, embryo manipulation.

Process biotechnology techniques: Fermentation using bioreactors, bioprocessing, bioleaching, biopulping, biobleaching, biodesulphurisation, bioremediation, biofiltration and phytoremediation.

Gene and RNA vectors: Gene therapy, viral vectors.

Bioinformatics: Construction of databases on genomes, protein sequences; modelling complex biological processes, including systems biology.

Nanobiotechnology: Applies the tools and processes of nano/microfabrication to build devices for studying biosystems and applications in drug delivery, diagnostics etc.

Although an analysis of the exact parameters of the definition of the concept 'biotechnology' is not relevant for purposes this thesis, the above list-based definition is indicative of the impressive breadth of the application of modern biotechnology, ranging from fermentation using bioreactors to embryo manipulation and tissue engineering.

2 Medical biotechnology: an emotionally loaded subject

Biotechnology is generally divided into three categories, namely medical biotechnology, agricultural biotechnology, and industrial biotechnology. (These categories are also often denoted by colours: medical biotechnology as red; agribiotech as green; and industrial biotechnology as white.) Although agribiotech is certainly controversial – think of the genetically modified (GM) food debate and the

highly publicised BioWatch court cases in South Africa[6] – *medical* biotechnology touches on even more emotionally loaded issues, such as gamete and embryo (including stem cell) research, private stem cell banking, and – looking into the future – the genetic engineering of 'designer babies'. Surprisingly, white biotechnology has not engendered the same agonising debate, even though its products appear in food (for example, ascorbic acid) and it is used in producing bio-fuels from food crops.

The emotions that medical biotechnology incites are not limited to the present time, but have been a social phenomenon at least since the advent of assisted reproductive technologies in the form of artificial insemination. Foley gives the following interesting background:[7]

> In 1960, a report by the British Feversham Committee on Human Artificial Insemination concluded that AID [artificial insemination by donor sperm] posed such serious emotional dangers to the sperm donor, impregnated woman, her husband, and the resulting child that it should not be considered an ethically acceptable reproductive option under any circumstances. Another common objection is that AID may pose a threat to genetic diversity if individuals are allowed to donate sperm without limitation. By 1980, the negative image of AID persisted, one commentator opining that AID posed serious psychological risks to the husband whose wife was inseminated by donor sperm, concluding, 'The physician is saying to the male partner that he is inadequate to properly inseminate his wife whereas the physician, with his technology, can do the job better.'
>
> IVF [in vitro fertilisation] initially did not fare much better in its quest for public acceptance. Many objected to the procedure on the grounds that it caused the creation of too many waste embryos. Others worried that the procedure posed serious risks of birth defects to the embryo and both psychological and physical risks to the woman and resulting child. Still

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6 *Biowatch Trust v Registrar Genetic Resources & others* (23005/2002) [2005] ZAGPHC 135; *Biowatch Trust v Registrar Genetic Resources & others* (A831/2005) [2007] ZAGPHC 270; *Biowatch Trust v Registrar Genetic Resources & others (Open Democracy Advice Centre as Amicus Curiae)* (A831/2005) [2008] ZAGPHC 135; *Biowatch Trust v Registrar Genetic Resources and Others* 2009 (6) SA 232 (CC).

7 Elizabeth P Foley 'The constitutional implications of human cloning' (2000) 42 *Ariz L Rev* 647. Footnote references removed.

> others labeled IVF 'morally irresponsible' on grounds that its inherent segregation of procreation from marital sex 'violates the reverence due to human life in its generation.'

However, despite these objections, the first human baby was born as a result of in vitro fertilisation ('IVF') in 1978. By 2005 – about a generation later – an estimated half million humans on our planet had been born through IVF.[8] The emotionally loaded nature of medical biotechnology informs the research themes of this thesis, which I will discuss next.

3 Research themes

Given the revolutionary nature of biotechnology – moreover, given the extraordinary anxiety surrounding medical biotechnology in certain sections of the populace – the possibility of legislative efforts being informed by prevailing emotional sentiments that may be contrary to the values enshrined in our Constitution is significantly higher than usual and therefore requires proper, *rational* constitutional scrutiny of the relevant law. The first – and most important – research theme that will be explored in this thesis is therefore whether the relevant law regarding medical biotechnology is aligned with the Bill of Rights. Answering this question will entail a human rights analysis of the relevant law.

A meta-theme of the human rights analysis will be the classic freedom-suppression conflict: In the present context, the classic freedom-suppression will take the form of a conflict between the liberal nature of the constitutional dispensation on the one hand, and the apprehension-informed socially conservative attitudes towards medical biotechnology on the other hand.

The cliché of the law dragging behind technology may be relevant to the present subject. The revolutionary nature of biotechnology – especially the rapid pace of its development – may leave lacunae of uncertainty in the law. A second research theme is therefore the *development of legal certainty* in the law regarding medical biotechnology where the possibility of uncertainty exists. The degree to which this

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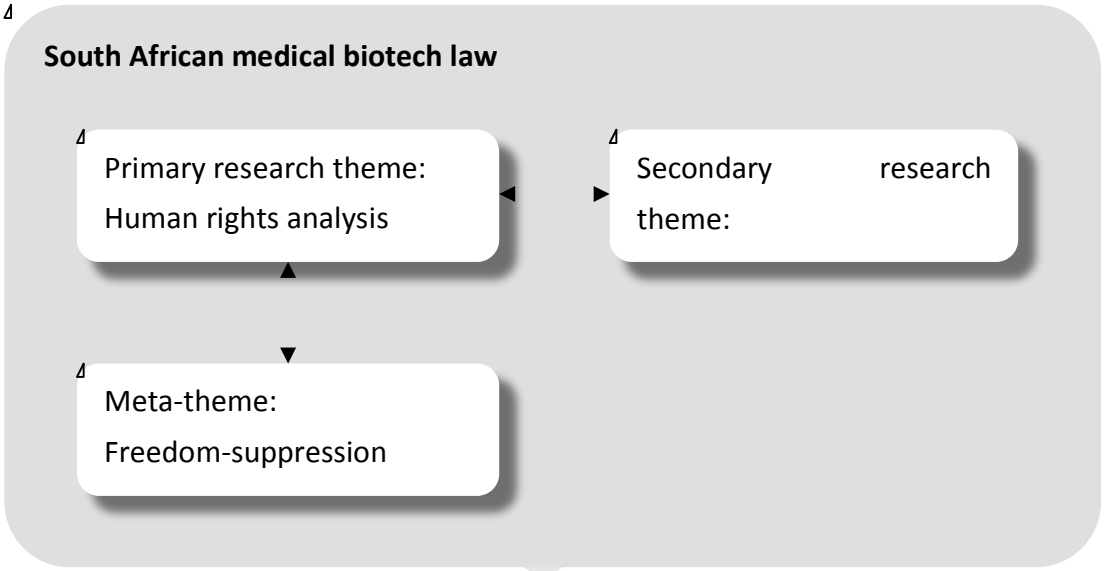
[8] Lee M Silver *Remaking Eden* paperback ed (1999) 69.

legal-certainty theme will be interwoven with the primary human rights analysis will depend on the nature of a specific medical biotechnology law subject.

The various research themes are schematically illustrated in Figure A.

Figure A: Research themes



4 Research design

This thesis will analyse four topical subjects within the scope of medical biotechnology law from the perspective of the research themes. These four subjects are:

- Human embryo research
- The use of human gametes
- Autologous stem cell therapy
- Private stem cell banking

5 What is 'relevant law'? The dynamic between current law and anticipated law

The 'relevant law' presents an interesting dynamic, in that the Human Tissue Act[9] ('HTA') – which is relevant to many, if not most medical biotechnology subjects – was supposed to be replaced by Chapter 8 of the National Health Act[10] ('NHA') and regulations in terms of Chapter 8 as long ago as mid-2005. Although the NHA, including Chapter 8, was enacted by parliament, Chapter 8 was not signed into force by the President.[11] The reason given by the Department of Health was that it first wanted certain regulations relating to Chapter 8 to be in place before Chapter 8 would come into effect and repeal the HTA. In 2004, the Minister of Health commented as follows:[12]

> We are busy drafting regulations . . . This is going to take a bit of time. We foresee that this section will be implemented around the middle of next year and in the meantime, the Tissue Act will remain in force until the new regulations are effective.

As this long-anticipated transition has not yet taken place, the HTA has continued to stay in force under the shadow of NHA Chapter 8 and the draft regulations published in terms of it. The analyses of the 'relevant law' therefore require consideration not only of the *current* legal position as per the HTA, but also of the *anticipated* legal position as per the already enacted, yet not in force NHA Chapter 8.

There is another source of complexity and uncertainty, namely that no less than nineteen draft regulations have been published through the years in terms of the NHA – later drafts apparently replacing earlier drafts, and none relating to Chapter

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9 Act 65 of 1983.

10 Act 61 of 2003.

11 With the exception of s 53 that deals with the establishment of a blood transfusion service.

12 Nkosazana Dlamini-Zuma *Briefing by Minister of Health on the National Health Act* (2004) available at *http://web.archive.org/web/20050505063820/http://www.doh.gov.za/docs/pr/2004/pr0819.html.*

8 in force at the time of writing. In order to avoid overbroad parameters for this thesis, the analyses of *anticipated* law will in general be limited to the NHA itself as enacted, and will not include any of the draft regulations in terms of it. The only exception to this rule will be the chapter on private stem cell banking, as the purpose of this chapter is, inter alia, to conduct a human rights analysis of a hypothetical ban on private stem cell banks, and such a ban has indeed been contemplated in the draft regulations.

6 Human dignity: to whom does it belong?

Human dignity is the preeminent value of South Africa's new constitutional political order.[13] However, as will be shown in this thesis, human dignity has been used to support various divergent points of view, giving rise to an international intellectual battle to claim the standard of human dignity. This situation has caused valid fears that an appeal to human dignity can easily serve to camouflage unconvincing arguments and unarticulated biases.[14] The renowned bioethicist John Harris provides a colourful analogy:[15]

> Appeals to human dignity are, of course, universally attractive; they are the political equivalents of motherhood and apple pie. Like motherhood, if not apple pie, they are also comprehensively vague.

'Human dignity' is ex facie not an esoteric concept and is therefore easily employed in arguments by non-lawyers. However, in South Africa 'human dignity' is a legal technical term with a legal technical content.[16] Given the essential role that human

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[13] *S v Makwanyane & another* 1995 (3) SA 391 (CC) para 329.

[14] Adam Schulman *Bioethics and Human Dignity* (Undated) available at *http://bioethics.georgetown.edu/pcbe/background/human_dignity.html.*

[15] John Harris 'Clones, genes, and human rights' in Justine Burley (ed) *The Genetic Revolution and Human Rights* (1999) 66.

[16] Should any non-legal interpretation of the term differ from the legal interpretation, such interpretation is in any case irrelevant for purposes of this thesis and any serious rights-based arguments.

dignity is set to play in the analyses of the four medical biotechnology subjects, and given the intellectual battle currently raging to claim human dignity for each side along the bioethical divides, this thesis will commence with a thorough analysis of the concept 'human dignity', before moving the attention to the four specific medical biotechnology subjects.

Chapter 2[*]

Human dignity

1 Introduction

In this chapter, I will introduce the reader to the concept 'human dignity' by giving an overview of the concept's philosophical evolution. Once the philosophical background has been established, I will analyse the meaning of the concept in the constitutional context with reference to case law. Specific attention will be paid to how *autonomy* gradually culminated in South Africa's human rights case law as a distinct element of human dignity.

2 The concept 'human dignity': a philosophical overview

Firstly, a conceptual distinction must be made between 'human dignity' and 'dignity'. As this discussion will show, various philosophical traditions give different interpretations to dignity. *Human* dignity denotes a specific kind of dignity that is perceived as the objective value *inherent* to all humans. Other notable kinds of dignity in Western philosophy are:

[*] The content of this chapter is based on: Donrich W Jordaan 'Autonomy as an element of human dignity in South African case law' (2009) 9 *J Philos Sci Law* available at: *http://www6.miami.edu/ethics/jpsl/archives/all/Autonomy-human-dignity.html#_ednref1*.

The support of the Mercator Foundation (through the *Humanism in the Age of Globalization* project) in the research and drafting of this chapter is gratefully acknowledged.

This chapter does not purport to present a comprehensive moral-philosophical analysis of human dignity; it presents a legal analysis of human dignity in South Africa's constitutional context with reference to case law. It is deliberately different from existing approaches in bioethics. Deryck Beyleveld & Roger Brownsword *Human Dignity in Bioethics and Biolaw* (2001) was identified as a source, but is not referred to, as the concepts addressed in this source, important in their own right, are outside the focus of this work – the stress here is on the South African Constitution and South African case law on human dignity.

- A behavioural conception of dignity, which denotes the objective value that an individual possesses based on certain behavioural qualities that are associated with dignity, such as composure, calmness, a noble manner[17]
- An aspirational conception that denotes the objective value that an individual possesses based on her or his accomplishments in life[18]
- Dignity as subjective self-value

In the broader societal context, these kinds of dignity are not necessarily mutually exclusive, but can be supplementary. One can, for instance, consistently support both the following positions:

- Person X must enjoy the *same* basic rights as other members of society based on her or his (inherent or human) dignity.
- Person X must be accorded *higher* respect in social interactions based on her or his (aspirational) dignity as a world-renowned scholar.

However, once the context is delineated more narrowly, such as the specific context of human rights law or biolaw, the incompatibility of the various kinds of dignity increases – especially between the various renderings of dignity as objective value.

The development of human dignity in philosophy is now considered. The interpretation of dignity as inherent value can trace its origin to the ancient Stoic tradition.[19] *Reason* is posited as a property of all humans – slave and free alike – which enables them to know the universe and improve themselves; this ability gives all humans dignity, which is equated to immeasurable value.[20] The advent of Christianity transferred the source of humankind's inherent worth to its belief that man was created by God in His divine image.[21] The Renaissance once again saw the celebration of humankind's free will and power of self-realisation as the source of

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17 Cf Aurel Kolnai 'Dignity' (1976) 51 *Philosophy* 251 at 253.

18 Aristotle famously said: 'Dignity does not consist in possessing honours, but in deserving them.'

19 Schulman op cit note 14.

20 Ibid.

21 Ibid.

dignity, albeit thoroughly rooted within the Christian religious worldview. As Giovanni Pico della Mirandola energetically exclaims in his *Oration on the Dignity of Man*, which became the manifesto of the Renaissance: 'Oh unsurpassed generosity of God the Father, Oh wondrous and unsurpassable felicity of man, to whom it is granted to have what he chooses, to be what he wills to be!' This idea was secularised in the elaborate metaphysical system that Immanuel Kant developed during the Enlightenment.[22] This philosophical tradition continues to be massively influential in our conceptual understanding of dignity in the human rights context, namely as inherent to every human being. In contemporary human rights law, this inherent kind of dignity has become commonly denoted as *human* dignity. The positioning of human dignity as a central value in any moral or legal system is therefore a moral or legal vindication of the idea that humanness per se is valuable. Against this philosophical background, the discussion will focus on human dignity as it has been applied in South African law.

3 Human dignity in the Constitution

As mentioned in Chapter 1: Introduction, the Constitutional Court singled out human dignity as the 'touchstone' of the new constitutional political order.[23] In all the cases that dealt with controversial and sensitive socio-political matters, such as the death penalty,[24] termination of pregnancy,[25] gay rights,[26] the wearing of

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22 Ibid.

23 *Makwanyane* supra note 13 para 329.

24 *Makwanyane* supra note 13.

25 *Christian Lawyers Association of South Africa & others v Minister of Health & others* 1998 (4) SA 113 (T).

26 Consensual sexual conduct between adults in private has been freed from criminal restriction, not only because sexual orientation is specifically listed in the Bill of Rights as a characteristic that may not be the grounds for unequal treatment, but on wider grounds of dignity and privacy (*National Coalition for Gay and Lesbian Equality & another v Minister of Justice & others* 1999 (1) SA 6 (CC), hereafter referred to as '*National Coalition I*', paras 28–32, per Ackermann J for the court; paras 108–129, per Sachs J with whose sentiments Ackermann J associated himself – para

religious symbols at public schools,[27] and commercial sex,[28] human dignity has played a vital role in the Constitutional Court's judgments.

Human dignity has a dual function in the South African constitutional dispensation: as a foundational *value* that informs the interpretation of all other specific rights, and as a justiciable and enforceable *right.*[29] Human dignity as a foundational value is provided for in three places in the Bill of Rights chapter of the Constitution:[30] the

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78). Same-sex partners have been held to be entitled to access to statutory health insurance schemes (*Langemaat v Minister of Safety and Security* 1998 (3) SA 312 (T)). The right of permanent same-sex partners to equal spousal benefits provided in legislation has been asserted (*Satchwell v President of the Republic of South Africa* 2002 (6) SA 1 (CC)). The protection and nurturance same-sex partners can jointly offer children in need of adoption have been put on equal footing with heterosexual couples (*Du Toit v Minister of Welfare and Population Development* 2003 (2) SA 198 (CC)). The right of a same-sex partner not giving birth to a child conceived by artificial insemination to become the legitimate parent of the child has been confirmed (*J v Director General: Department of Home Affairs* 2003 (5) SA 621 (CC)). The equal right of same-sex partners to beneficial immigrant status has been established (*National Coalition for Gay and Lesbian Equality & others v Minister of Home Affairs & others* 2000 (2) SA 1 (CC), hereafter referred to as '*National Coalition II*'). The common law has been developed by extending the spouse's action for loss of support to partners in permanent same-sex life relationships (*Du Plessis v Road Accident Fund* 2004 (1) SA 359 (SCA)). Finally, same-sex partners' right to conclude a marriage has been established – first by the Supreme Court of Appeal (*Fourie & another v Minister of Home Affairs & another* (232/2003) [2004] ZASCA 132 (30 November 2004), hereafter referred to as '*Fourie* (SCA)') and subsequently by the Constitutional Court (*Minister of Home Affairs & another v Fourie & another* 2006 (1) SA 524 (CC), hereafter referred to as '*Fourie* (CC)').

27 *MEC for Education: Kwazulu-Natal & others v Pillay* 2008 (1) SA 474 (CC).

28 *S v Jordan & others (Sex Workers Education and Advocacy Task Force & others as Amici Curiae)* 2002 (6) SA 642 (CC).

29 *Dawood & another v Minister of Home Affairs & others; Shalabi & another v Minister of Home Affairs & others; Thomas & another v Minister of Home Affairs & others* 2000 (3) SA 936(CC) para 35.

30 Chap 2 of the Constitution of the Republic of South Africa, 1996.

introductory section of the Bill of Rights,[31] as well as the all-important limitation[32] and interpretation[33] clauses of the Bill of Rights. Human dignity as an enumerated right in the Bill of Rights is stated as follows:[34]

> **Human dignity**
>
> Everyone has inherent dignity and the right to have their dignity respected and protected.

In its application of human dignity, the Constitutional Court has consistently emphasised the interdependency and mutually reinforcing relationship between human dignity and other enumerated rights, such as freedom,[35] privacy,[36] equality,[37] the right to life.[38]

4 Applicability of human dignity to the unborn?

It is also important to note that human dignity is specifically only applicable to persons *in esse* and not to the unborn. In *Christian Lawyers Association of South*

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[31] The Constitution s 7(1) reads: 'This Bill of Rights is a cornerstone of democracy in South Africa. It enshrines the rights of all people in our country and affirms the democratic values of human dignity, equality and freedom.'

[32] The Constitution s 36(1) reads: 'The rights in the Bill of Rights may be limited only in terms of law of general application to the extent that the limitation is reasonable and justifiable in an open and democratic society based on human dignity, equality and freedom, taking into account all relevant factors…'

[33] The Constitution s 39(1) reads: 'When interpreting the Bill of Rights, a court, tribunal or forum (a) must promote the values that underlie an open and democratic society based on human dignity, equality and freedom…'

[34] The Constitution s 10.

[35] *Ferreira v Levin NO & others; Vryenhoek & others v Powell NO & others* 1996 (1) SA 984 (CC) para 49.

[36] *National Coalition I* supra note 26 para 30.

[37] *National Coalition I* supra note 26 para 30; *National Coalition II* supra note 26 paras 41, 54; *Fourie* (CC) supra note 26 paras 50, 114, 151–152.

[38] *Makwanyane* supra note 13 para 84.

Africa v Minister of Health the court held that the Constitution does not change the common law position of the fetus as *not* being a legal persona.[39] The court per McCreath J commented that:[40]

> One of the requirements of the protection afforded by the *nasciturus* rule is that the foetus be born alive. There is no provision in the Constitution to protect the foetus pending the fulfilment of that condition.

The South African legal position is therefore distinguishable from the European position, which does apply human dignity to the embryo.[41]

5 The meaning of human dignity

At its broadest meaning, human dignity refers to the *intrinsic worth of all human beings.*[42] Beyond this frequently-used phrase, the Constitutional Court has not attempted to provide a comprehensive definition of human dignity and has in fact remarked that human dignity 'is a difficult concept to capture in precise terms.' [43] However, certain *elements* of human dignity have clearly crystallised in case law. The first of these positivist elements is the universal and egalitarian character of human dignity.[44] The Constitutional Court has at times used the typical Dworkinian

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[39] *Christian Lawyers* supra note 25 at 1443B–C, 1437C–D. Although the court used the archaic spelling 'fœtus', I will use the more standard spelling 'fetus' (*Oxford Dictionaries Online* (Undated) available at *http://www.oxforddictionaries.com*).

[40] Ibid at 1441I.

[41] *Oliver Brüstle v Greenpeace eV* 2011 Court of Justice of the European Union, case C-34/10, paras 33–34.

[42] *Makwanyane* supra note 13 para 328; *Dawood* supra note 29 para 35.

[43] *National Coalition I* supra note 26 para 28.

[44] *Makwanyane* supra note 13 para 329; *National Coalition I* supra note 26 para 28; *Fourie* (SCA) supra note 26 para 24; *National Coalition II* supra note 26 para 54; *Fourie* (CC) supra note 26 paras 50, 61; *Hoffmann v South African Airways* 2001 (1) SA 1 (CC) para 37.

formulation of 'equal concern' in the context of human dignity.[45] This egalitarian quality of human dignity confirms its roots in the philosophical tradition of inherent dignity, to the logical exclusion of the aspirational or behavioural tradition.[46]

The second positivist element of human dignity relates to the protection of personality rights, namely self-worth and reputation. At common law, the legal concept 'dignity' was equated with self-esteem or self-worth,[47] which included privacy.[48] Common law dignity was differentiated from reputation, although the classic Roman law actio iniuriarum was common to all the personality rights.[49] While self-worth as the common law meaning of dignity was clearly associated with human dignity from the onset of the constitutional dispensation,[50] the position with reputation was less clear. After divergent judgments by the provincial high courts on the inclusion of reputation in the ambit of the constitutional concept 'human

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45 *National Coalition II* supra note 26 para 54; *Fourie* (CC) supra note 26 paras 95, 112; *City Council of Pretoria v Walker* 1998 (2) SA 363 (CC) para 130.

46 Cf Nick Bostrom 'Dignity and Enhancement' in *Human Dignity and Bioethics: Essays Commissioned by the President's Council on Bioethics* (2008) 173–206 available at *http://bioethics.georgetown.edu/pcbe/reports/human_dignity/human_dignity_and_bioethics.pdf*; and the accompanying commentary by Charles Rubin at 207–210 of the same publication.

47 *University of Pretoria v Tommie Meyer Films (Edms) Bpk* 1979 (1) SA 441 (A) is the locus classicus on common law dignity in South African law. Common law dignity has been defined as 'that valued and serene condition in his social and individual life which is violated when he is, either publicly or privately, subjected by another to offensive and degrading treatment, or when he is exposed to ill-will, ridicule, disesteem or contempt' (*S v Umfaan* 1908 TS 62 67); 'self-respect' (*S v Holliday* 1927 CPD 395 400); 'right to tranquil enjoyment' (*S v Holliday* at 401); 'his proper pride in himself' (*S v Tanteli* 1975 (2) SA 772 (T) 775).

48 *Bernstein & others v Bester NO & others* 1996 (2) SA 751 (CC) para 68.

49 *Khumalo & others v Holomisa* 2002 (5) SA 401 (CC) para 27.

50 *S v Williams & others* 1995 (3) SA 632 (CC) paras 47, 77; *City Council of Pretoria v Walker* supra note 45 paras 113, 132; *Prince v President of the Law Society of the Cape of Good Hope* 2002 (2) SA 794 (CC), hereafter referred to as '*Prince* (CC)', para 47.

dignity',[51] the Constitutional Court has in *Khumalo v Holomisa* unanimously indicated that human dignity includes all personality rights, including reputation.[52] It is therefore clear that *human* dignity, or dignity in the *human rights context*, includes but also transcends common law dignity.

A decade ago, Haysom[53] proposed a third positivist element of human dignity, namely *autonomy*.[54] At the time, he only cited the (celebrated) concurring opinion of Ackerman J in *Ferreira v Levin* to support his analysis, in which Ackerman J only implicitly refers to autonomy.[55] Recent developments in South African case law have, however, clearly vindicated autonomy as an element of human dignity, and will be analysed below. These legal developments concerning autonomy and human dignity cannot be analysed in isolation from the developments concerning autonomy and human rights in general – the interrelation between human dignity and other human rights has already been mentioned.

The purpose of this chapter is to create more clarity regarding human dignity. The interpretation of human dignity as including autonomy does not only promise to contribute to clarifying the concept, but can also make a valuable – if not decisive – contribution to the current international intellectual battle to claim the banner of human dignity for divergent bioethical points of view. I will therefore trace – within the South African legal system – the emergence of autonomy as an element of

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[51] *Mandela v Felati* 1995 (1) SA 251 (W); *Gardner v Whitaker* 1995 (2) SA 672 (E); *Potgieter v Kilian* 1996 (2) SA 276 (N).

[52] *Khumalo* supra note 49 para 27.

[53] Nicholas Haysom was chief legal advisor to President Nelson Mandela, after which he was appointed as Director for Political Affairs in the office of the Secretary General of the United Nations. For Haysom's biographical notes, refer to United Nations *Secretary-General Appoints Nicholas Haysom of South Africa Executive Office Political Affairs Director* (2007) *http://www.un.org/News/Press/docs/2007/sga1065.doc.htm*.

[54] Nicholas R L Haysom 'Dignity' in M H Cheadle, D M Davis & N R L Haysom (eds) *South African Constitutional Law: The Bill of Rights* (2002) 123 at 131.

[55] Haysom's citation refers to Ackermann J's opinion at para 146, while it is apparent from the context that he intended to refer to para 46. It is assumed that the '1' was a typographic error.

human dignity integrated with the emergence of autonomy in general human rights case law.

6 The rise of autonomy

6.1 Introductory remarks

The concept 'autonomy' originates from the Greek 'auto' (self) and 'nomos' (law), meaning to be one's own law. In its simplest meaning, autonomy can therefore be understood as *self-determination*.[56] In the context of individual human rights, there is considerable conceptual overlap between autonomy and freedom:[57] Freedom includes both political freedom (the Roman 'libertas', which includes various rights concerning participation in the political process), as well as individual or personal freedom (the right to personal self-determination, that is, choosing and pursuing one's own ends in life, as exemplified in Mill's essay *On Liberty*). In its contemporary usage, autonomy generally corresponds with the latter form of freedom, but also has a broader meaning as referring to one's personal psychological *capacity* for self-determination. One can therefore remark that a child must develop autonomy (but not freedom) as a precondition to be an autonomous (or free) person. In the liberal philosophical tradition, autonomy as individual freedom is intimately associated with personal development and self-actualisation, and perceived as a precondition for well-being and self-fulfilment.[58]

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[56] Joel Feinberg 'The child's right to an open future' in W Aiken & H LaFollette (eds) *Whose Child? Children's Rights, Parental Authority, and State Power* (1980) 124 at 140.

[57] Cf: Isaiah Berlin *Four Essays on Liberty* (1969) 131–34; Ian Carter 'Positive and negative liberty' in Edward N Zalta (ed) *The Stanford Encyclopedia of Philosophy* (2007) available at *http://plato.stanford.edu/archives/win2007/entries/liberty-positive-negative/*.

[58] In general, see John Stuart Mill *On Liberty* (1860) available at *http:// www.constitution.org/jsm/liberty.htm*; for a discussion in the context of the parent-child relationship, see Feinberg op cit note 56 at 143–44; for a discussion in the context of biolaw and bioethics, see Jacob Dahl Rendtorff 'Basic principles in bioethics and biolaw' paper delivered at

6.2 The role of autonomy

In the first five years since the inception of the Constitutional Court (1995–1999) the term 'autonomy' was used in association with several enumerated constitutional rights and values, including human dignity,[59] freedom,[60] privacy[61] and equality.[62] However, the *nature* of the relationship between autonomy and these rights and values was still inexact and vague at this stage. The only reference in case law during this period that sketches the nature of the relationship between human dignity and autonomy in clearer terms – namely of autonomy being an *element* of human dignity – is the following implicit reference to autonomy in *Ferreira*, on which Haysom based his hypothesis:[63]

> Human dignity cannot be fully valued or respected unless individuals are able to develop their humanity, their 'humanness' to the full extent of its potential. Each human being is uniquely talented. Part of the dignity of every human being is the fact and awareness of this uniqueness. An individual's human dignity cannot be fully respected or valued unless the individual is permitted to develop his or her unique talents optimally.

Haysom accordingly drew a connection between personal development and autonomy. This connection depends on and therefore implies adherence to the liberal philosophical tradition that perceives autonomy as a causally necessary condition for the achievement of the individual's own good through personal

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the *Twentieth World Congress of Philosophy*, Boston, Massachusetts (10–15 August 1998) available at *http://www.bu.edu/wcp/MainBioe.htm*.

59 *Ferreira* supra note 35 paras 98, 107; *Bernstein* supra note 48 para 150; *Gauteng Provincial Legislature In re: Gauteng School Education Bill of 1995* 1996 (3) SA 165 (CC) footnote 18 to para 51.

60 *Coetzee v Government of the Republic of South Africa; Matiso & others v Commanding Officer Port Elizabeth Prison & others* 1995 (4) SA 631 (CC) para 44; *Ferreira* supra note 35 para 251; *Bernstein* supra note 48 para 150.

61 *Ferreira* supra note 35 paras 98, 107; *National Coalition I* supra note 26 paras 32, 117.

62 *Bernstein* supra note 48 para 151; *National Coalition II* supra note 26 footnote 50 to para 41.

63 *Ferreira* supra note 35 para 46 per Ackermann J.

development or self-realisation.[64] Given this philosophical foundation, Haysom's implicit reasoning is therefore a simple syllogism:

- Personal development is an element of human dignity (as per *Ferreira*)
- Autonomy is integral to personal development
- Ergo: Autonomy must also be an element of human dignity

In the same concurring opinion of Ackermann J in *Ferreira*, autonomy is also associated with another core concept of the Constitution, namely the open society – the concept 'open society' is central in both the limitation and interpretation clauses of the Bill of Rights.[65] Again, the term 'autonomy' is not used by Ackerman J, but instead concepts such as 'personal development' and 'own conception of the good life' that are associated with autonomy:[66]

> An 'open society' . . . is a society in which persons are free to develop their personalities and skills, to seek out their own ultimate fulfillment, to fulfill their own humanness and to question all received wisdom without limitations placed on them by the State. The 'open society' suggests that individuals are free, individually and in association with others, to pursue broadly their own personal development and fulfillment and their own conception of the 'good life'.

In the footnote to this paragraph, Ackermann J approvingly quotes Popper from his magnum opus, *The Open Society and its Enemies,* in which Popper refers to an open society as 'the society in which individuals are confronted with personal decisions' that is contrasted with the closed society or 'the magical or tribal or collectivist society'. Since the concept of an open society suggests autonomy, and the open society is a core concept in the Constitution, autonomy is established as general constitutional value.

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[64] Haysom tellingly elaborates on autonomy by referring to self-actualisation (Haysom op cit note 54 at 131): 'In this sense [of respect for autonomy], the subject's worth as a self-actualising being must be protected.'

[65] *S v Lawrence; S v Negal; S v Solberg* 1997 (4) SA 1176 (CC) para 146, per Sachs J (concurring): 'The concept of an open society must indeed be regarded as one of the central features of the bill of rights…'

[66] *Ferreira* supra note 35 para 50.

Although Ackermann J's concurring opinion in *Ferreira* represents an important step in the emergence of autonomy in South African human rights law in general and as an element of human dignity in particular, the absence of the explicit use of the term 'autonomy' in these paragraphs renders it tentative in nature.[67]

In the period 2000–2004, autonomy was placed centre stage in *S v Jordan*,[68] a case that tested the constitutionality of the legal prohibition of commercial sex. Counsel for the applicants argued that the rights to human dignity, freedom and privacy should be clustered together under the global concept of autonomy. Underlying this argument is clearly the idea that autonomy is at the core of all three these rights. The applicants' argument was dealt with in the concurring opinion of Sachs and O'Regan JJ.[69] The court did not specifically comment on the relationship between autonomy and the rights to human dignity, freedom and privacy, but rejected applicants' argument on the grounds that positing an independent right to autonomy would neither be 'useful' for the purposes of constitutional analysis, nor would it be 'appropriate' to base constitutional analysis on a right not expressly included within the Constitution. By rejecting the applicants' argument purely on these formal grounds and not addressing the underlying substantive claim that autonomy is at the core of the rights to human dignity, freedom and privacy, the judgment can be interpreted as an implicit confirmation of this substantive claim.

In 2007, this implicit confirmation was made explicit by O'Regan J in her dissenting opinion in *NM v Smith*.[70] This case dealt with the unauthorized publication of the identities of three HIV-positive women in the biography of a high-profile politician. The three women were successful in claiming damages for infringement on their privacy, dignity and psychological integrity. It should be noted that the dissent primarily relates to the majority's finding on the facts and not the interpretation of

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[67] In his concurring opinion in *Ferreira* supra note 35 para 251 Sachs J uses 'autonomy' explicitly as an element of freedom and personal security, not as an element of human dignity.

[68] *Jordan* supra note 28.

[69] Ibid para 52.

[70] *NM & others v Smith & others* 2007 (5) SA 250 (CC).

constitutional rights.[71] O'Regan J clearly posits autonomy as a constitutional value that underlies human dignity, freedom and privacy:[72]

> Underlying all these constitutional rights [human dignity, privacy and freedom] is the constitutional celebration of the possibility of morally autonomous human beings independently able to form opinions and act on them. . . . Our Constitution seeks to assert and promote the autonomy of individuals…

Finally, a majority opinion of the Constitutional Court that explicitly confirms autonomy as a core element of human dignity was realised in *Barkhuizen v Napier*[73] – coincidentally delivered on the same day as the *NM* judgment. *Barkhuizen* concerns the constitutionality of a time limitation clause in a short-term insurance policy that prevents an insured claimant from instituting legal action if summons is not served on the insurance company within the time limit set out in the clause. Although it has been contended that such a clause is unconstitutional in that it violates the right to approach a court for redress, the court upheld the principle of pacta sunt servanda (agreements must be honoured) as an embodiment of the constitutional values of human dignity and freedom. The majority per Ngcobo J (as he then was) deals specifically with autonomy and states unequivocally that autonomy 'is the very essence of freedom and a vital part of dignity.' [74] This judgment therefore marks an important milestone in the legal development surrounding human dignity in South African law.

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[71] Ibid para 125. In his concurring opinion, Langa CJ at para 92 is therefore able to associate himself with the analyses of constitutional rights by both Madala J for the majority and by O'Regan J: 'I … associate myself with the discussions of the rights to privacy and dignity in both Madala and O'Regan JJ's judgments…'

[72] Ibid paras 145–146.

[73] *Barkhuizen v Napier* 2007 (5) SA 323 (CC).

[74] Ibid para 57. The court employed the term 'self-autonomy', which is an unnecessary tautology. It does not seem that the court intended 'self-autonomy' to mean anything different from 'autonomy'.

This position is echoed in other cases, such as *MEC for Education: Kwazulu-Natal v Pillay*[75] that concerned the wearing of cultural and religious symbols at public schools. In this case the majority of the Constitutional Court per Langa CJ stated that an 'entitlement to respect for the unique set of ends that the individual pursues' is a 'necessary element of freedom and of dignity of any individual.' [76] Applying once again the classic liberal position that autonomy is a conditio sine qua non for the individual's pursuit of her or his 'unique set of ends', autonomy is confirmed as a 'necessary element' of human dignity.

In conclusion, I have indicated how autonomy emerged: tentatively initially, then gradually drawing more attention, and in 2007 eventually culminating in the clear recognition of its status and role in South Africa's human rights law. In particular, the *Barkhuizen* judgment finally provides clear binding authority that autonomy is an element of human dignity.

6.3 Defining autonomy

Apart from its authoritative role in illuminating the *role* of autonomy (as an element of human dignity), the *Barkhuizen* judgment also authoritatively provides the *meaning* of autonomy: the Constitutional Court defines autonomy as 'the ability to regulate one's own affairs, even to one's own detriment.' [77] This definition firstly confirms that autonomy corresponds with personal self-determination or what in philosophy is generally called personal or individual freedom; and secondly, also implies – logically, and through the use of the word 'ability' – the personal psychological *capacity* for self-determination. This conceptual overlap between autonomy and personal or individual freedom is confirmed by the Constitutional Court's reference to autonomy as the 'very essence of freedom.'

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[75] *MEC for Education: Kwazulu-Natal v Pillay* supra note 27.

[76] Ibid para 64 footnote omitted.

[77] *Barkhuizen* supra note 73 para 57.

In *NM,* O'Regan J also provides two descriptions of autonomy, both of which will be considered. The first *NM* definition describes autonomy as 'human beings choosing how to live their lives within the overall framework of a broader community.' [78] The first part of this definition (human beings choosing how to live their lives) is essentially similar to the *Barkhuizen* definition, while the second part (within the overall framework of a broader community) expands on it by explicitly imbedding autonomy in its wider social context. This socially integrated nature of autonomy has gradually been established as an important part of the court's conception of autonomy. This gradual establishment deserves attention and will be considered next.

Initially some concurring opinions dating from 1995 and 1996 endeavoured to separate autonomy from social interdependence in an effort to differentiate between autonomy and freedom, the latter being posited as a socially integrated enabler of autonomy.[79] While freedom was posited as what Berlin termed 'positive freedom' – as requiring positive state intervention – autonomy was used to denote 'negative freedom'. This atomistic rendering of autonomy had cracks of incoherence, as it admitted to the socially dependent nature of at least the *development* of autonomy.[80]

An important turning point came in the 1998 judgment of *National Coalition of Gay and Lesbian Equality v Minister of Justice* which released autonomy from its atomistic confines into a social context, and effectively did away with the

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[78] *NM v Smith* supra note 70 para 131.

[79] *Coetzee* supra note 60 para 44 per Sachs J (concurring); *Ferreira* supra note 35 paras 250–51 per Sachs J (concurring); and *Bernstein* supra note 48 para 150 per O'Regan (concurring).

[80] Cf the quote from Nedelsky in the footnote to *Ferreira* supra note 35 para 251 per Sachs J (concurring).

independence-interdependence distinction between autonomy and freedom. Sachs J's concurring opinion is a clear statement of this position:[81]

> Viewed this way autonomy must mean far more than the right to occupy an envelope of space in which a socially detached individual can act freely from interference by the state... While recognising the unique worth of each person, the Constitution does not presuppose that a holder of rights is as an isolated, lonely and abstract figure possessing a disembodied and socially disconnected self. It acknowledges that people live in their bodies, their communities, their cultures, their places and their times.

This socially integrated conception of autonomy does not imply that autonomy can be limited by dominant social values any more than would an atomistic conception of autonomy; what differentiates a socially integrated conception from an atomistic conception is that the former realises the necessity for positive state action to enable autonomy in its social context. Sachs J rationalises this approach of positive state intervention in his concurring opinion in *Ferreira*:[82]

> The reality is that meaningful personal interventions and abstinences in modern society depend not only on the state refraining from interfering with individual choice, but on the state helping to create conditions within which individuals can effectively make such choices.

In this way the state enhances autonomy and human dignity,[83] and therefore fulfils its duty to promote the values of the Constitution.[84] This is perhaps most vividly illustrated by the series of gay rights cases, in which the Constitutional Court specifically pointed out legal and social recognition of gay and lesbian people's personal relationships as vital to their human dignity.[85] This entailed not only a

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81 *National Coalition I* supra note 26 para 117 footnote omitted. Cf *Jordan* supra note 28 para 82 per Sachs and O'Regan JJ (concurring) and *Volks NO v Robinson & others* 2005 (5) BCLR 446 (CC) paras 154 and 156 per Sachs J (dissenting).

82 *Ferreira* supra note 35 para 251.

83 *Bernstein* supra note 48 para 150.

84 The Constitution s 7(2) reads: 'The state must respect, protect, promote and fulfil the rights in the Bill of Rights.'

85 Refer to note 26.

negative duty on the state to refrain from interfering with personal relationships (decriminalisation of sodomy),[86] but also a positive duty to grant the social benefits of legal recognition of personal relationships (for instance the legalising of gay adoption and same-sex marriages).[87]

The first *NM* definition can therefore be welcomed as an explicit confirmation of the socially integrated nature of autonomy, which is evidently an important consideration when interpreting and applying autonomy. This socially integrated conception of autonomy is also perfectly compatible with the *Barkhuizen* judgment, which indeed applies and protects autonomy within the highly socially interdependent context of contractual relations.

I now turn to the second definition expounded by O'Regan J in her dissenting opinion in *NM*. A few paragraphs after providing the first definition, she also describes autonomy by quoting a passage from Scanlon:[88]

> As Scanlon described in his seminal essay on freedom of expression, an autonomous person –
>
> '. . . cannot accept without independent consideration the judgment of others as to what he should believe or what he should do. He may rely on the judgment of others, but when he does so he must be prepared to advance independent reasons for thinking their judgment likely to be correct, and to weigh the evidential value of their opinion against contrary evidence.' [89]
>
> Our Constitution seeks to assert and promote the autonomy of individuals in the sense contemplated by Scanlon.

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86 *National Coalition I* supra note 26 para 32.

87 *National Coalition II* supra note 26 para 54; *Du Toit* supra note 26; *Fourie* (CC) supra note 26 para 50.

88 *NM v Smith* supra note 70 paras 145–146.

89 Thomas Scanlon 'A theory of freedom of expression' (1972) 1 *Philos Public Aff* 204 at 216 available at *http://philosophyfaculty.ucsd.edu/faculty/rarneson/courses/SCANLONfreeexpression.pdf.*

The second *NM* definition – the Scanlon quote – is in a significant way a departure from the *Barkhuizen* definition: it idealistically insists that an autonomous individual may rely on the judgment of others, but when he does so he *must* be prepared to advance independent reasons for thinking their judgment likely to be correct. The reality is that most of the values with which people are brought up are seldom, if ever, the subject of rational evaluation – most people tend to accept the core values with which they are brought up and only spend mental energy on rationally evaluating certain life decisions within a largely given value-context. What is important from a liberal perspective is that an individual must have the *ability* to challenge any received wisdom and essentially make up her or his own mind, as expressed in the *Barkhuizen* definition as well as more elaborately in Ackermann J's reference to the open society in *Ferreira*.[90] The ability to regulate one's own affairs (or choose one's own life) indeed implies that one is allowed to make decisions without being (morally or legally) obliged to rationalise such decisions – it implies that one does *not* need to have any rational awareness in such regulation (or choosing). Although it is a statement of the ideal, the second *NM* definition per the Scanlon quote is therefore not compatible with the majority position in *Barkhuizen*.

To conclude this discussion on the meaning of autonomy, I look at a remark that O'Regan J makes in *NM* that may point the direction for further legal analysis. She makes an important connection between autonomy and the meaning of human dignity as inherent worth, stating that the protection of autonomy 'flows from our recognition of individual human worth.' [91] Though this causality is not logically apparent, it is not explained further. Similar to the earlier references in *Ferreira* to personal development, the application of classic liberal political theory is implied to complete the logic.[92] The causality depends on at least the following two values:

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[90] Refer to 6.2 The role of autonomy supra.

[91] *NM v Smith* supra note 70 para 131.

[92] A non-liberal state may, for instance, promote (or even enforce) specific versions of the good life *because* it perceives these as protecting and advancing its citizens' inherent worth.

- Recognition of every individual's inherent value means that the individual's *own good* or well-being is allocated great value.
- Every individual's own good is *best provided* for by empowering her to take her own means of pursuing it.

In the future application and conceptual refinement of autonomy in case law, it will be essential that these values that underlie autonomy and bind it to human dignity, be given due consideration by the courts.

7 Conclusion

Since its introduction to law through the interim Bill of Rights in 1993, human dignity has been at the centre of South African constitutional analysis. Although it was clear from the onset that human dignity is a broader concept than common law dignity, the parameters of this conceptual breadth were to crystallise gradually in case law: while inherent (and equal) worth and self-worth were recognized early on as elements of human dignity, binding authority for autonomy as an element of human dignity was only attained in 2007, following a steady increase in case law of analysis of autonomy as concept. This conceptual clarity marks a certain coming of age of human dignity in South African law.

Chapter 3[*]

Human embryo research

1 Introduction

Throughout this thesis, the concept 'embryo' will refer to the union of a sperm and egg cell until the start of organogenesis (the formation of organs) at the end of the eighth week after conception, from which time the conceptus is known as the 'fetus'.[93] Subcategories of the embryo are discussed below.

Embryo research initially focused on solving reproductive problems, such as improving IVF success rates, but has since radically expanded due to the advent of

[*] The content of this chapter is based on: Donrich W Jordaan 'Science versus antiscience: the law on pre-embryo experimentation' (2007) 124 *S Afr Law J* 618; Donrich W Jordaan 'Criteria for pre-embryo research in South Africa: an analysis within the paradigm of respect for the pre-embryo' (2008) 27 *Med Law* 417.

Many commentators around the world assert that human embryos qualify as 'human beings' or 'members of the human species' at the moment of conception, and therefore need protection within the ambit of human dignity. This has been addressed in Chap 2, 4 Applicability of human dignity to the unborn supra. This chapter further canvasses this issue. In particular, the legal subjectivity of the embryo is analysed in this chapter, 4.1 The common law and the nasciturus fiction, and the averment that the embryo qualifies as a 'human being' (or 'human life', etc) is analysed in this chapter, 6.4 Can the limitations be justified by the respect for the embryo paradigm?

[93] The inclusion of the preimplantation stages of the conceptus (such as fertilisation, cleavage, compaction, differentiation, cavitation and zona hatching, that occur during the first six days after the sperm meets the egg) in the definition of 'embryo' follows the reasons advanced by: Susan Kimber 'IVF and manipulating the human embryo' in Anthony Dyson & John Harris (eds) *Ethics and Biotechnology* (1994) 94. Cf *Brüstle v Greenpeace* supra para 41, which adopts a similar understanding of 'embryo' in a 'wide sense'.

embryonic stem cell research,[94] the revolutionary aims of which include creating substitute organs and limbs. How does our law deal with embryo research?

First, I present the reader with a historic background of the regulation of embryo research. Next, I analyse the current international legal position on embryo research, before moving to an analysis of the relevant South African law. I then analyse the current legal-ethical paradigm regarding embryo research and endeavour to develop improvements to the law within this paradigm. Lastly, I adopt a more revisionist approach and challenge the current paradigm from a human rights platform.

2 Background

Embryo research was propelled on the public agendas around the world following the birth of the first baby by in vitro fertilisation in 1978. This landmark event took place in the United Kingdom, and it would also be the United Kingdom that would lead with public policy regarding embryo research: in 1984 the *Report of the Committee of Inquiry into Human Fertilisation and Embryology*,[95] named the *Warnock Report* after its chairperson, Mary Warnock, was published. The work

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[94] The advent of embryonic stem cell research complements the reasons proposed by Kimber op cit note 93 for the inclusion of the preimplantation stages of the conceptus in the definition of 'embryo' (or 'embryonic'): the concept 'embryonic stem cell' is a well-known reference to a stem cell derived from an embryo during the blastocyst stage four to five days after fertilisation; accordingly, to exclude the preimplantation stages of the conceptus from the definition of 'embryo' (or 'embryonic') would be inconsistent with the meaning of the concept 'embryonic stem cell'.

[95] Committee of Inquiry into Human Fertilisation and Embryology, United Kingdom *Report of the Committee of Inquiry into Human Fertilisation and Embryology* (1984) available at *http://www.hfea.gov.uk/docs/Warnock_Report_of_the_Committee_of_Inquiry_into_Human_Fertilisation_and_Embryology_1984.pdf*. Hereafter referred to as the '*Warnock Report*'.

done by the Warnock Committee was groundbreaking in the sense that they ventured into moral terra incognita. In retrospect Warnock comments thus:[96]

> Here lay the greatest difficulty in the beginning. For there was no received wisdom about the use of embryos in the laboratory; there could be none, since the first such embryo had come into existence only a few years before the debate started.

The *Warnock Report* became not only the basis for the Human Fertilisation and Embryology Act of 1990 in the United Kingdom, but the international standard for benchmarking embryo research policy. Perhaps the most important element of the *Warnock Report* is the line that it draws at fourteen days from fertilisation – the transition between the *pre*-embryo and the embryo *proper*. While *regulated* research would be allowed on the pre-embryo, research on the embryo proper would be prohibited. The *Warnock Report* established fourteen days as the barrier beyond which research could not proceed. The rationale behind the fourteen days distinction is explained by Warnock in her own words as follows:[97]

> Fourteen days was decided on as the limit because of the great change in the development of the embryo heralded by the development of the primitive streak. It is only after that that an individual exists with its own now quickly developing central nervous system, its own limbs, its own brain. Even though before that an embryo has a genetic individuality, it has no pattern of human identity, any more than human tissue has. The history of each person who is born can be traced back to the development of the primitive streak and not before.

The global influence of the *Warnock Report* is reflected in the fact that it would now take primary legislation to permit research using human embryos of more than fourteen days from fertilisation in those jurisdictions around the globe where embryo research is not totally prohibited.[98] However, the fourteen-day rule and especially the closely associated concept 'pre-embryo' are not uncontroversial, with the concept 'pre-embryo' remaining in the legal-ethical sphere and not being

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96 Mary Warnock 'Experimentation of human embryos and fetuses' in Helga Kuhse & Peter Singer (eds) *A Companion to Bioethics* (2001) 392.

97 Ibid at 394.

98 Ibid.

adopted by the scientific community.[99] Where I employ the concept 'pre-embryo' in this thesis, it is therefore purely to denote the embryo during its first fourteen days of development in the context of the fourteen-day rule; my use of the concept should be interpreted neither as an endorsement of an implied moral boundary between the pre-embryo and the embryo proper, nor as an endorsement of the concept 'pre-embryo' qua linguistic tool to emotionally remove the embryo during its first fourteen days of development from the moral connotations of the 'embryo'.

3 An overview of international legal and policy instruments

The Universal Declaration on Bioethics and Human Rights[100] is the international legal instrument that aims to provide a universal framework of principles and procedures to guide states in the formulation of their legislation, policies or other instruments in the field of bioethics; as well as to guide the actions of individuals, groups, communities, institutions and corporations, public and private. It recognises the importance of the freedom of scientific research and the benefits derived from scientific and technological development, while stressing the need to conduct such research within a framework of human dignity and human rights. The Universal Declaration on Bioethics and Human Rights does not, however, apply its abstract value statements to embryo research in particular – embryo research is not even mentioned. This therefore leaves the door open to different interpretations in the context of each state's legal culture.

The official international body that deals specifically with bioethics is the International Bioethics Committee, which functions under the auspices of UNESCO.

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[99] Kimber op cit note 93; Luis Vivanco et al 'Bibliometric analysis of the use of the term preembryo in scientific literature' (2011) 62 *J Am Soc Inform Sci Tech* 987.

[100] Adopted by acclamation on 19 October 2005 by the 33rd session of the General Conference of UNESCO.

Its report[101] on the ethical aspects of human embryonic stem cell research[102] is relevant to embryo research in general and therefore instructive, yet not conclusive: the report recognises that there are 'very marked differences of opinion' relating to embryo research[103] and that it is therefore impossible to articulate a uniform international position:[104]

> [This report] recognises that the solutions adopted by national ethical committees or national legislatures may well be different. Such differences are inevitable in a pluralistic world where people may sometimes adopt ethical positions which are unacceptable to others.

The report takes specific cognisance of philosophical and religious views on the subject and concludes that these are also widely diverse and hence inconclusive. The stereotype of religion as a conservative force in society is therefore anything but universally applicable in this case:[105]

> On the basis of religious beliefs, there is a broad range of positions on the status of the embryo and on the permissibility of using the embryo for any form of research . . . some of these consider permissible the use of embryos for therapeutic purposes, or for the purposes of research, while others do not accept the use of embryos for such purposes.

For systematic reasons I categorise the report's conclusions regarding embryo research in a substantive and a formal category. On the level of substantive policy the report concludes that every state will have to decide for itself whether or not and the degree to which to allow or prohibit embryo research; the report completely refrains from suggesting a preferred substantive solution in this regard

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101 International Bioethics Committee, UNESCO *The Use of Embryonic Stem Cells in Therapeutic Research* (2001) available at *http://portal.unesco.org/shs/en/files/2144/10541312311StemCells_en.pdf/StemCells_en.pdf*.

102 Embryonic stem cell research is a species of the genus embryo research.

103 International Bioethics Committee, UNESCO op cit note 101 para 1.

104 Ibid.

105 Ibid para 25.

and merely indicates the desirability of informed debate on a national level.[106] All the subsequent recommendations – both substantive and formal – are secondary to this primary substantive policy question that is left unanswered by the report, in the sense that the subsequent recommendations only become relevant should the decision taken on the primary level allow embryo research to some degree.

The only substantive policy recommendation that the report makes is that, in a scenario where a state allows embryo research, the human dignity and rights of both parental donors must receive particular attention, necessitating prior, free and informed consent by both parental donors to such research.[107]

Should a state allow embryo research to some degree, the report makes the following recommendations in the formal policy category:[108]

- The state must establish a regulatory regime to enforce 'appropriate' ethics guidelines, the content of which is once again completely up to each state to decide. The recommendation is therefore entirely formal, relating purely to the existence of a regulatory regime and ethics guidelines, regardless of its substantive rules.
- The purposes for which embryo research is conducted, and the way of its performance, must be subject to assessment by appropriate ethics committees, which must be independent of the researchers involved. This assessment must include ex post facto ethical evaluation of such research. This recommendation is also entirely formal, relating to the existence of a regulatory regime that provides for assessment by ethics committees, regardless of its substantive criteria used by these ethics committees.

After analysing the relevant international legal and policy instruments on the subject of embryo research, namely the Universal Declaration on Bioethics and Human Rights and UNESCO's International Bioethics Committee's report on the

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106 Ibid para 55.A.

107 Ibid para 55.B.

108 Ibid.

ethical aspects of human embryonic stem cell research, it must be concluded that there is simply no international legal position on the permissibility of embryo research.

4 Relevant South African law

4.1 The common law and the nasciturus fiction

In his informative, pre-constitutional era article[109] on the legal position of cryopreserved human embryos in the United States, Lupton speculates as to how a South African court would have ruled on the legal position of cryopreserved human embryos. He subsequently submits that South African law perceives human life to start at conception and cites the appellate division's decision in *S v Collop*[110] as authority for this submission. For reasons of a legal nature I must differ from Lupton's submission: the *Collop* case dealt with the definition of 'foetus' in terms of the now repealed Abortion and Sterilization Act 2 of 1975. The fact that the court interpreted 'foetus' to encompass the whole period of gestation for purposes of the Abortion and Sterilization Act, cannot provide a basis to infer that human life starts at conception. Nowhere did the court equate 'foetus' with 'human life' or 'personhood'. A valid inference that *can* be made in this context is that the conceptus was (conditionally[111]) perceived as morally and legally protection-worthy irrespective of the stage of prenatal development. However the moral-legal status of the conceptus was still not on par with that of the neonate qua legal subject: killing the latter would constitute murder which was a capital offence, while killing the former would constitute a lesser statutory offence with a maximum five-year sentence and/or R 5 000 fine. The inference made by Lupton that the court in casu ruled that human life or personhood starts at conception is therefore unfounded.

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[109] M L Lupton 'The legal position of cryopreserved human embryos' (1992) 3 *J S Afr Law* 466.

[110] *S v Collop* 1981 (1) SA 150 (A).

[111] Exceptions applied in the case of incest and rape.

Supplementing the human-life argument, Lupton proceeds to apply the nasciturus fiction to the cryopreserved embryo and states: 'This well established principle of our common law, stipulates that whenever it is to the foetus' advantage it is deemed to have already being born.' [112] He concludes that the court would therefore treat the cryopreserved embryo as a person. Also on this point I differ from Lupton's submission: It has already convincingly been argued in academic literature that the application of the nasciturus fiction beyond the scope of the law of succession is unfounded in South Africa's common law.[113] Moreover, even the proponents of the fiction's expansion beyond the law of succession acknowledge that the conditio sine qua non of the nasciturus fiction is *live birth* – only *if* and *once* a child has been born (alive), does the legal fiction kicks into action and does South African law deem the child to have acquired rights from the time of its conception.[114] A more accurate construction of the nasciturus fiction is therefore that certain rights can be held *in abeyance* for the nasciturus and acquired by it at birth:[115]

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

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[112] Lupton op cit note 109 at 473.

[113] W A Joubert 'Pinchin & Ano NO v Santam 1963 (2) SA 254 (W)' (1963) *J Contemp Roman-Dutch Law* 295.

[114] M J de Waal, M C Schoeman & N J Wiechers *Erfreg Studentehandboek* (1992) 171; J D van der Vyver & D J Joubert *Persone- en Familiereg* 3rd ed (1991) 62.

[115] P C Smit *Die Posisie van die Ongeborene in die Suid-Afrikaanse Reg, met Besondere Aandag aan die Nasciturus-Leerstuk* (1976) LLD thesis, University of the Orange Free State 212–13.

This construction is supported in subsequent academic literature and case law.[116] On legal grounds Lupton's nasciturus argument therefore also fails to convince that the embryo should be treated as human life or as a person.[117] In the new constitutional dispensation, this issue has conclusively been settled in the *Christian Lawyers* case to which I referred to above,[118] in which the court held that the Constitution does not change the common law position of the fetus as *not* being a legal persona.[119]

It should be clear from my analysis above that, as our law currently stands, the embryo does not qualify as a legal subject and can accordingly not be the bearer of any rights.

4.2 The Human Tissue Act

The relevant sections of the HTA read as follows:

> **18. Consent to removal of ... gametes from bodies of living persons**
>
> No ... gamete shall be removed or withdrawn from the body of a living person for a purpose referred to in section 19 –
>
> (a) except in accordance with the prescribed conditions; ...
>
> [...]
>
> **19. Purposes for which ... gametes of bodies of living persons may be used**
>
> Any ... gamete removed or withdrawn from the body of a living person shall, subject to the regulations, only be used for medical or dental purposes, including –

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[116] C J Davel 'Christian League of South Africa v Rall 1981 (2) SA 821 (O)' 1981 *De Jure* 361 at 362; *Christian League of South Africa v Rall* 1981 (2) SA 821 (O) 829–30, obiter dictum per L C Steyn J; the status of the prenate qua not a legal subject was confirmed in the ratio decidendi of *G v Superintendent, Groote Schuur Hospital, & others* 1993 (2) SA 255 (C).

[117] It is interesting to note that if Lupton's nasciturus argument is accepted and the court should deem the embryo to be a person, our current pro-choice abortion regime would be highly challengeable to say the least.

[118] Refer to Chap 2: Human dignity, 4 Applicability of human dignity to the unborn? supra.

[119] *Christian Lawyers* supra note 25 at 1441I, 1443B–C, 1437C–D.

[...]

(c) in the case of such gamete, the artificial fertilization of another person...

[...]

37. Regulations

(1) The Minister may make regulations regarding –

[...]

(e) the regulation and the control (including the imposition of duties on any person and of restriction and prohibitions in connection with such control) of –

[...]

(vii) the bringing together outside the human body of a male and a female gamete or gametes, and research of whatever nature with regard to the product of the union of such gametes, irrespective for what purpose such product has been or is being produced...

The reference in section 37(1)(e)(vii) to 'irrespective for what purpose such product has been or is being produced' implies that the list of 'medical or dental purposes' in section 19 is not a numerus clausus. If regulations are made regarding the creation of embryos for research, section 18(a) would accordingly in principle allow the withdrawal of gametes for such purpose; however, as no such regulations have been made, gametes cannot be withdrawn *for the purpose* of creating embryos for research. However, this does not constitute a ban on embryo research, but it does limit the source of embryos for research to 'excess' embryos: Current in vitro fertilisation protocols typically create about 10–12 embryos that are then implanted in utero in batches of 2–3 per implantation cycle until a successful pregnancy ensues. Should there still be in vitro embryos left after a successful pregnancy has ensued, the prospective parents – or single parent, depending on the situation – can exercise one of the following choices:

- cryopreserve the remaining embryos for later use
- donate the remaining embryos for implantation by other prospective parents
- donate the remaining embryos for research

- have the remaining embryos destroyed

In other words, an embryo may initially be created *for the purpose of artificial fertilisation* – and accordingly comply with the HTA – but eventually not be needed for such artificial fertilisation and then *allocated a new purpose* by the person or persons having the rights over such embryo, namely to aid in research. This is how embryos may become available for research without contravening sections 18 and 19. And as no regulations were made regarding 'research of whatever nature with regard to the product of the union of such gametes', research on excess embryos is therefore not regulated by the HTA or its secondary legislation. The legal regulation of this space is left to the MRC's ethics guidelines, which I will analyse next.

4.3 The MRC's ethics guidelines

The MRC is a creature of statute[120] and is responsible for regulating and controlling research on, or research with, humans or animals; human or animal research performed by employees of the MRC; and research or research performed by persons for or on behalf of the MRC or with the MRC's research aid.[121] The board of the MRC is empowered to determine ethical directives which must be followed in research or research in the above contexts and to take whatever control measures it may deem necessary to ensure that such ethical directives are complied with.[122] The board is advised by the MRC's ethics committee, which committee is also responsible for implementing the board's policy.

At first glance it would seem that the binding force of the MRC's ethics guidelines is limited to medical research undertaken by employees of the MRC and persons acting on behalf of the MRC or with the financial assistance of the MRC. Yet, in practice other research institutes in South Africa benchmark their own ethics guidelines against that of the MRC. Should such other institution's ethics guidelines

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[120] South African Medical Research Council Act 58 of 1991.

[121] Ibid s 17(1).

[122] Ibid s 17(2).

conflict with the MRC's, Van Oosten submits that the MRC's guidelines should be followed, provided that the rule concerned accords with those adhered to in international medical research.[123] The MRC's ethics guidelines therefore in effect have comprehensive national authority.

Following the latest revision (fourth edition), the MRC's ethics guidelines are thematically divided into five books. The second book, entitled *Guidelines on Ethics for Medical Research: Reproductive Biology and Genetic Research* [124] is relevant to embryo research. The *Guidelines* commence its bioethical pronouncements regarding 'Research on pre-embryos' with the following foundational statement:[125]

> The pre-embryo should be treated with the utmost *respect* because it is a genetically unique, viable human entity… [My emphasis]

This sentiment is later repeated with emphasis on the embryo's potential to become human life:[126]

> A human embryo is special because of its potential for human life. The recognition of this potential has traditionally *limited research on human embryos*, regardless of the legal determinations of when life begins. [My emphasis]

The MRC's *Guidelines* is therefore overt about its adherence to the value of 'respect-for-the-embryo', and that this value provides the basis for certain limitations on embryo research. Apart from a prohibition on research on the embryo proper in line with the *Warnock Report*,[127] the *Guidelines* effectively prohibit the creation of embryos for the purpose of research by 'discouraging' it and describing it as an unethical practice:[128]

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[123] F F W van Oosten 'The law and ethics of information and consent in medical research' (2000) 63 *J Contemp Roman-Dutch Law* 5 at 9.

[124] Medical Research Council *Guidelines on Ethics for Medical Research: Reproductive Biology and Genetic Research* 4th ed (2002) available at *http://www.kznhealth.gov.za/research/ethics2.pdf*.

[125] Ibid s 2.2.

[126] Ibid s 3.4.3.2.

[127] Ibid s 2.14.

[128] Ibid s 2.2; s 2.17.

> The production of excess embryos for the sole purpose of research should be discouraged.
>
> [...]
>
> Pre-embryo manipulation and research . . . can be regarded as ethical only if the embryos are not specifically produced for the purpose of research.

The *Guidelines* also require written consent from the embryo donors and their spouses for their embryos to be used for purposes of research.[129]

4.4 The National Health Act

The relevant sections of Chapter 8 of the NHA read as follows:

> 57(4) The Minister may permit research on stem cells and zygotes which are not more than 14 days old on a written application and if –
>
> (a) the applicant undertakes to document the research for record purposes; and
>
> (b) prior consent is obtained from the donor of such stem cells or zygotes.
>
> [...]
>
> 68(1) The Minister may make regulations regarding –
>
> [...]
>
> (k) the bringing together outside the human body of male and female gametes, and research with regard to the product of the union of those gametes...

Note that 'zygote' is defined by the NHA as 'the product of the union of a male and a female gamete.' The NHA's reference to 'zygotes which are not more than 14 days old' therefore corresponds with the concept 'pre-embryo'.

4.5 Conclusion on the relevant law

While scientists currently have a narrowly demarcated space – defined mainly by the use of only excess embryos and keeping within the fourteen-day limit – within which to conduct embryo research, the NHA will impose the additional regulatory

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[129] Ibid s 2.11.

burden of requiring ministerial approval. However, in essence, the HTA, the MRC's ethics guidelines and the NHA are all clearly carved from the same tree: They all adopt a paradigm of limiting embryo research – a paradigm that implies that, although the embryo is not a person, the embryo does possess a certain moral status that makes it worthy of some level of legal protection, which is articulated by the MRC's ethics guidelines as 'respect' for the embryo.

5 Recommended legal development within the respect-for-the-embryo paradigm

In this subchapter, I will explore the respect-for-the-embryo paradigm in more detail. Cognisant of the reality that paradigm shift is not an easy feat to accomplish, I will save my critique of the respect-for-the-embryo paradigm for the next subchapter, and will here instead endeavour to make recommendations on how to develop the relevant law within the conceptual confines of this paradigm.

5.1 Problem statement

Section 57(4) of the NHA[130] will grant the Minister of Health the discretion to allow an embryo research project or not. This discretion is limited by one substantive and three formal requirements: The only substantive requirement is the general Warnockian criterion that the embryo must not be older than fourteen days; the formal requirements are:

- a written application for permission to conduct embryo research
- prior consent by the donors
- an undertaking by the researcher to record-keeping

Apart from the criterion that limits embryo research to the first fourteen days, there are no other *substantive* criteria according to which the Minister (or a delegated authority) must exercise her or his discretion. This lack of proper substantive criteria constitutes the main problem that this subchapter will address. It is imperative that

[130] As quoted in 4.4 The National Health Act supra.

this lacuna that is left by the anticipated primary legislation be filled by regulations, or by an amendment to section 57(4). Should both the primary and secondary legislation fail to provide such substantive criteria, it would amount to plain bad law: such a situation will create legal uncertainty in the scientific community and will hence inhibit scientific progress.

5.2 Objective and methodology

The objective of this subchapter is to address the problem by developing a *comprehensive set of substantive criteria* to be incorporated in the regulations that are currently being drafted. This will be done by first analysing the value that justifies and informs the regulative paradigm, namely respect-for-the-embryo; and secondly by a comparative legal analysis.

5.3 The respect-for-the-embryo paradigm

The debate on embryo research is informed by opinions on the moral status of the embryo during its first fourteen days – the 'pre-embryo' – being the period during embryonic development when embryo research is in principle permissible. On the one side of the opinion-spectrum are those who do not perceive the pre-embryo as possessing any moral value and who therefore view any special regulation of research that involves pre-embryos as unnecessary and obstructive; on the other extreme of the spectrum are those who perceive the pre-embryo as morally en par with persons and who therefore oppose any research that involves the destruction of pre-embryos. In an effort to define a moral status for the pre-embryo, the concept 'respect' for the pre-embryo has emerged as a potential catalyst for building consensus and has thus increased in currency. The reasons are obvious: the concept 'respect' per se has strong universal appeal, but is also sufficiently vague to allow for different interpretations by people holding divergent views in the context of pre-embryo research. The spectrum of views that can be accommodated by this consensus-seeking measure is however limited.

In practice, the respect-doctrine typically allows certain forms of embryo research, within a regulated environment. It therefore neither gives carte blanche, nor does it

prohibit all embryo research. This middle-road approach has been adopted by several countries as the legal-ethical paradigm regarding embryo research. South Africa's adoption of the respect-doctrine is evident from the MRC's *Guidelines*, which state that '[t]he pre-embryo should be treated with the utmost respect'.[131] What exactly does this value entail for embryo research? How can this value influence the development of substantive criteria for permitting embryo research?

5.3.1 The conventional approach to respect

I open this philosophical overview with a question posed by Callahan more than a decade ago:[132]

> I have always felt a nagging uneasiness at trying to rationalize the killing of something for which I claim to have a 'profound respect.' What in the world can that kind of respect mean? An odd form of esteem – at once high-minded and altogether lethal…
>
> I have wondered for twenty-five years whether this is profound wisdom or profound self-deception. How does one tell?

Is respect for an entity compatible with the entity's destruction, and if so, under what circumstances? The appropriate place to start looking for an answer is the influential British Chief Medical Officer's Expert Group's *Stem Cell Research: Medical Progress with Responsibility*.[133] This report builds on the tone-setting *Warnock Report* and sums up the ethical principles underpinning embryo research as follows:

- The embryo of the human species has a special status but not the same status as a living child or adult.
- The human embryo is entitled to a measure of respect beyond that accorded to an embryo of other species.

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131 MRC *Guidelines* op cit note 124 s 2.2.

132 Daniel Callahan 'The puzzle of profound respect' (1995) 25 *Hastings Cent Rep* 39.

133 Chief Medical Officer's Expert Group, United Kingdom *Stem Cell Research: Medical Progress with Responsibility* (2000) available at *http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4065085.pdf*.

- Such respect is not absolute and may be weighed against the benefits arising from proposed research.

Using this summary as a point of departure, it is clear that 'respect' for the human embryo implies a moral status inferior to personhood, but superior to the embryos of other species; and it implies a direct horizontal competition with the benefits of research. Strong confirms this consequentialist competition:[134]

> In deciding whether particular actions should be carried out in order to show respect for preembryos, we . . . should consider the consequences of performing and not performing those actions.

In this context, any consequentialist argument must include a comparison between the value of the anticipated consequences of the proposed research on the one hand and the value of 'respect' for the pre-embryo on the other. Respect is therefore a relative value that can be overridden by other considerations. From this follows that respect and destruction are not in principle incompatible, provided that the destruction is for a purpose that out-competes respect.

However, without telling us more about what 'respect' means in this context, the consequentialist approach just begs the question: when, in this consequentialist competition will the benefits of research outweigh the 'respect' due to the embryo? Highlighting the vagueness regarding the meaning of 'respect', Kuhse argues that policy decisions in this context will essentially be an irrational process of subjective intuitions and compromises:[135]

> The notions of value and respect are very imprecise, and thus cannot be easily used in a utility calculus that weighs benefits against harms associated with a particular policy option . . . in the end, concrete policy guidelines are going to depend on more subjective and variable intuitions regarding whether a particular type of policy is appropriate . . . Where the line gets drawn thus depends simply on the intuitions and compromises of those involved in the process of negotiation that leads to concrete policy recommendations.

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[134] Carson Strong 'The moral status of preembryos, embryos, fetuses, and infants' (1997) 22 *J Med Philos* 457 at 475.

[135] George Khushf 'Embryo research: the ethical geography of the debate' (1997) 22 *J Med Philos* 495 at 512–513.

This of course does not mean that consequentialism is not used in the policy-making process; it is just that it is a consequentialism informed by intuition – policy makers often tend to fall back on a context-specific consequentialist approach, in which the balancing of interests tends to be intuitive.[136] Is it not possible to get more precise insight into the meaning of 'respect-for-the-embryo'?

Davidson presents a lucid analysis of the concept 'respect' and argues that respecting embryos implies that there are certain 'limits to what we may do to them.' [137] She elaborates as follows:

> [T]o create and destroy an embryo is not necessarily inconsistent with respecting embryos. However, respecting embryos means that if an embryo is to be destroyed, its destruction should only be for *worthwhile purposes*. [My emphasis]

She concludes that destroying the embryo for 'improving health' is 'likely to be consistent with respecting the embryo'; while 'non-therapeutic uses' will be 'less likely to be consistent with respecting the embryo, unless, of course, they are equally beneficial for society, parents or the future child'. Medical purposes are therefore likely to be considered worthwhile purposes.

Meyer and Nelson[138] add an additional dimension to respect, namely that the researcher working with embryos must perform her or his actions in a fundamentally respectful *manner*. They argue that researchers' attitudes and practices can demonstrate respect for the embryo and accordingly suggest the following restrictions on the treatment of embryos in order to show respect for them in the course of destruction for research:

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[136] Rogeer Hoedemaekers 'Human embryos, human ingenuity, and government policy' (2003) 19 *Ethics Med* 75.

[137] Helen Davidson 'Using embryos to make people better' Paper delivered at the *New Zealand Bioethics Conference 2006: Making People Better*, University of Otago, Dunedin, New Zealand (10–12 February 2006).

[138] Michael J Meyer & Lawrence J Nelson 'Respecting what we destroy: reflections on human embryo research' (2001) 3 *Hastings Cent Rep* 16.

a) Extracorporeal embryos should be used in research only if the research goals cannot be obtained by other methods.
b) Only the minimum number of embryos required to achieve the research goals should be acquired.
c) Researchers should avoid considering extracorporeal embryos as property, and should avoid buying and selling them.
d) Researchers should recognise that the destruction of extracorporeal embryos provides a reason for them to have and demonstrate some sense of regret or loss.
e) Disposal of the remains of used embryos should be done in a way that is respectful of their status (for example burial or cremation).

I submit that suggestions (a), (b) and (c) can be implemented in an objective way and can therefore be used fruitfully in the development of substantive criteria. Suggestion (c) is, however, already given effect to by section 60 of the NHA, which criminalises trade in human tissue, and will therefore not be considered further. In contrast with the first three suggestions, suggestion (d) is, however, not susceptible to effective implementation since it requires a subjective emotion: how does one legislate and enforce a sense of regret? Regarding suggestion (e), I submit that the prescribed method of handling of an embryo that has been destroyed as part of a termination of pregnancy procedure should serve as a guideline in order to ensure consistency: if such an abortus was already viable, it is cremated; if the abortus was not yet viable, it is handled as medical waste and disposed of through incineration. Since research embryos are not yet viable – they are *pre*-embryos – I submit that they should therefore be disposed of through incineration. For these reasons I will not give suggestions (d) and (e) further consideration.

5.3.2 Respect as a detached value

Davis argues that the consequentialist question requires reframing to allow productive discussion. She proposes a focus on the goals of the proposed research to determine whether the goals are trivial or whether they are so inherently entwined with the care of human suffering and happiness that using embryos for

this purpose 'exhibits a moral seriousness that points to a respect for the sanctity of human life'.[139] In this proposed reframing Davis echoes Dworkin's insight[140] that issues of reproductive bioethics are best understood in the context of *detached* values – values that have intrinsic value and that are detached from the interests of specific people. Possible candidates for detached values in this context would be 'the sanctity of human life' and 'a culture of life'. The opposite are *derivative* values, being values that are derived from the interests of specific people, such as the human dignity of a specific person, or the right of equality of a specific group in society. Since, as we have already seen, the respect-paradigm accepts that the embryo is *not* a person, it cannot have rights; since the embryo is not even sentient, it cannot have interests in any sensible way. Accordingly, derivative values are inapplicable to the embryo and the framing of ethical rules regarding the embryo in the language of derivative values is therefore inaccurate and counterproductive. Talking about 'respect for the embryo' can be misleading, as it can be interpreted to imply that the embryo has a *right* to respect, or at least *interests* of its own – both implications which are incoherent with the respect-paradigm.

What the embryo does possess in the respect-paradigm is a certain symbolic value:[141] as potential human life it is a 'potent symbol of human life.' [142] This symbolic value has intrinsic worth and does not imply or depend on the embryo having interests or rights. The concept 'respect-for-the-embryo' is therefore best understood as 'respect-for-human-life-as-symbolised-by-the-embryo', as opposed to 'respect-for-value-inherent-to-the-embryo'. According to this conceptual approach, legislation that aims to regulate embryo research is perceived as promoting the detached value of human life and human dignity rather than

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139 Dena S Davis 'Embryos created for research purposes' (1995) 5 *Kennedy Inst Ethic J* 343 at 351.

140 Ronald Dworkin *Sovereign Virtue: The Theory and Practice of Equality* 1st paperback ed (2002) 429.

141 Bonnie Steinbock 'Respect for human embryos' in Paul Lauritzen (ed) *Cloning and the Future of Human Embryo Research* (2001) 21 at 22, 24.

142 John A Robertson 'Symbolic issues in embryo research' (1995) 25 *Hastings Cent Rep* 37.

protecting the embryo per se.[143] From this it follows that, if the potential benefits of destroying an embryo in research have an equal or stronger nexus with human life and human dignity (through the potential of improving of the human condition) than the embryo's *symbolic* nexus with human life, the symbolic value of the embryo cannot serve to keep it from being destroyed in such research. The detached-value conceptual approach to 'respect' therefore leads to the same practical conclusions as the conventional approach discussed above, with trivial or frivolous destruction of embryos been ruled out, but research with the potential for improving of the human condition – such as medical scientific research – being allowed.

It is on a level of theoretical structuring and coherence that the detached-value approach claims its ascendancy: The apparent respect-destruction paradox that Callahan has highlighted evaporates in the detached-value approach, dispensing the need to rationalise this paradox as in the case of the conventional approach. In the detached-value conceptual structuring it is the value of human life that is the proper object of 'respect', not the embryo itself; the embryo is only respected qua symbol of human life. Therefore, when embryos are destroyed in research – provided that the research objectives are not trivial or frivolous but have the potential to improve the human condition – 'respect' per se is not compromised or out-competed by the benefits of the research in a consequentialist showdown, but actually promoted by it.

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[143] In *Brüstle v Greenpeace* supra note 41 para 34 the Court of Justice of the European Union states:

'The context and aim of the Directive thus show that the European Union legislature intended to exclude any possibility of patentability [related to the use of the human embryo] where respect for human dignity could thereby be affected. It follows that the concept of "human embryo" . . . must be understood in a wide sense.'

While the judgement in the *Brüstle* case did not attempt to elevate the embryo to the status of legal persona (and therefore bearer of rights), the judgement did imply that the legal treatment of the embryo affects human dignity. Accordingly, I suggest that the *Brüstle* case is aligned with the detached value conceptual approach, although not relating to embryo *research*, but the use of embryos in *patenting*.

5.3.3 Conclusion on the respect doctrine

From this philosophical overview of respect-for-the-embryo I propose the following succinct, systematic version: There are two dimensions of respect-for-the-embryo – one relating to the *ends* of embryo research, the other relating to the *means* of such research:

- *The ends of embryo research*. Respect is a relative value and therefore not en par with the, in principle, absolute value of human dignity.[144] Being of relative value, respect must compete with other interests in the consequentialist balancing process. If such other interest qualifies as a worthwhile purpose,[145] the destruction of the embryo in pursuit of such purpose would be justified. Medical purposes are likely to qualify as worthwhile.
- *The means of embryo research*. The respect doctrine requires not only that embryo research must be for good ends, but also that the use of embryos qua means must reflect the (relative) value of the embryo. This means that a worthwhile purpose does not give carte blanche to the researcher in the use of embryos, but rather that embryos should be used in a judicial fashion. This entails two rules:
    - *The rule of general necessity*. The use of embryos (in general) must be necessary, in the sense that there must be no alternative to the use of embryos that will achieve the same ends within the same timeframe and using the same resources.

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144 In Kantian philosophy, dignity is defined as absolute, incomparable value.

145 Meyer & Nelson's version of the consequentialist approach uses the concept of 'reasonable justification' instead of 'worthwhile purpose'. The use of 'reasonable justification' in the context of pre-embryo research should be rejected: reasonable justification is a legal technical term that implies a right and therefore implies that the pre-embryo is a legal subject, which is firstly contrary to law and secondly contrary to the respect doctrine. In the context of pre-embryo research the term 'worthwhile purpose', which does not have a fixed legal technical meaning, should therefore be preferred.

- *The rule of specific necessity*. The specific number of embryos to be used must be limited to that necessary to achieve the purpose.

I have thus far dealt with the non-legal, philosophical aspects of the respect doctrine. In the following subchapter, the focus shifts to the law. My aim is to show how the philosophical values that were identified in this subchapter have found expression in legal instruments.

5.4 Comparative legal analysis

The comparative legal analysis will include three foreign jurisdictions, namely the United Kingdom, the Netherlands and Belgium. All three share South Africa's alignment with the respect doctrine, but are ahead of South Africa in embodying the values associated with the respect doctrine in specific substantive criteria in their statute law. Embryo research is regulated by the following legislation in each of these jurisdictions respectively: in the UK, the Human Fertilisation and Embryology Act of 1990,[146] supplemented by the Human Fertilisation and Embryology (Research Purposes) Regulations of 2001; in the Netherlands the Embryo Act;[147] and in Belgium the Act regarding research on embryos in vitro.[148] Each of these countries' legal instruments provides a distinct, yet significantly overlapping set of criteria, as illustrated in Table A on the next page. I submit that *four general principles* can be identified in order to constitute an integrated conception of all three jurisdictions, each of which will be subsequently discussed:

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[146] Hereafter referred to as the 'UK Human Fertilisation and Embryology Act'. The relevant criteria are in s 3(2) and s 3(6) of Sch 2 of the Act.

[147] Wet van 20 juni 2002, houdende regels inzake handelingen met geslachtscellen en embryo's (Embryowet). Hereafter referred to as the 'Dutch Embryo Act'. The criteria are enumerated in s 10.

[148] Wet van 11 mei 2003 betreffende het onderzoek op embryo's in vitro. Hereafter referred to as the 'Belgian Act regarding research on embryos in vitro'. The criteria are enumerated in s 3.

Table A: Comparative of the criteria for deciding on pre-embryo research[149]

Criterion – general principle	**United Kingdom**	**Netherlands**	**Belgium**
1) Medical scientific purpose	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, or 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. Additional criteria specified in the 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.	If it is reasonable to assume that the research will lead to the establishment of new insights in the field of medical science.	If [the embryo research] has a therapeutic purpose or contributes to a better knowledge of fertility, infertility, organ or tissue transplant, or the prevention or treatment of diseases.

[149] The criteria of the Netherlands and Belgium are my translation of the original Dutch text.

Criterion – general principle	United Kingdom	Netherlands	Belgium
2) No equally effective alternative	No licence under this paragraph shall be granted unless the Authority is satisfied that any proposed use of embryos is necessary for the purposes of the research.	If it is reasonable to assume that the establishment, as intended [above], cannot transpire through other forms or methods of scientific research than research with the relevant embryos or through research of a less invasive nature.	If no other research method exists that is equally effective.
3) Sound methodology	-	If the research fulfils the requirements of a sound methodology of scientific research.	If [the embryo research] rests on the most recent scientific findings and fulfils the requirements of a sound methodology of scientific research.
4) Expertise of researchers	-	If the research is conducted by or under the supervision of persons who are experts on the relevant area of scientific research.	If [the embryo research] is conducted under the supervision of a medical specialist or doctor in the sciences and by relevantly qualified persons.

5.4.1 Medical scientific purpose

'Medical science' can be defined as the science of dealing with the maintenance of health and the prevention and treatment of disease in humans.[150] Good health is a vital component of a persons capacity for self-actualisation and autonomy, and hence fundamental to human dignity. The more debilitating a disease, the more a person's *de facto*, substantive autonomy is compromised, and human dignity undermined. Research that has as its objective to contribute to the maintenance of health, or the prevention or treatment of disease is therefore evidently strongly aligned with human dignity and should consequently (according to the respect doctrine) justify the use of embryos.

While the Dutch have adopted a medical scientific purpose as a general criterion, and the Belgians have largely done the same by reference to 'prevention and treatment of disease', the British have followed a more restrictive approach of enumerating only specific medical scientific purposes. Yet, the door was left open to the possibility of expanding on the original nomenclature through delegated legislation, which indeed happened about a decade later with the promulgation of regulations that specifically made provision for the (current) objectives of embryonic stem cell research. This promising and rapidly developing field of medical scientific research could of course not be foreseen by the British legislature in 1990.

In the light of the rapid pace of development in the biological sciences, I submit that it is more prudent to adopt the general criterion of a *medical scientific purpose* that would be inclusive of new medical scientific purposes that may yet emerge, as per the Dutch (and effectively the Belgian) example, than to limit embryo research to a nomenclature of presently known purposes: to expand such a nomenclature either via legislative or executive means is likely to be a slow process that could retard scientific progress in South Africa, frustrate the South African scientific community,

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[150] *Wordnet* (2012) available at *http://wordnet.princeton.edu/.*

make us less competitive internationally and make us even more dependent on foreign knowledge and intellectual property.

Finally, it should be noted that medical scientific research includes both basic and applied research. This is also made very explicit in the wording of the British specific criteria.

5.4.2 No equally effective alternative

The laws of all three of the comparative jurisdictions give expression to what I termed the rule of general necessity,[151] namely that the use of embryos must be *necessary* to achieve the purpose of the research. This poses a question of interpretation regarding necessity: is necessity *absolute,* in the sense that there may be absolutely no alternative means to achieve the purpose – even if such alternative means is far less effective, or is necessity *relative,* in the sense that there may be no *equally effective* alternative means to achieve the purpose? While the British and Dutch formulations do not explicitly qualify necessity, the Belgian formulation qualifies necessity with equal efficacy ('even doeltreffend' in Dutch). In the absence of such qualification, how should necessity in the British and Dutch law be interpreted? I submit that, whether necessity is explicitly qualified as relative to efficacy or not, the relative interpretation is the only reality-based interpretation of necessity in the scientific research context. The problem with the absolute interpretation is that there are seldom, if ever, any true absolutes in scientific research methodologies, making it practically impossible to ever meet the absolute necessity standard. It is always possible to think of alternative methodologies to achieve a research purpose – however creative or bizarre such alternative means might be. In the case of the use of embryos, it could for instance be argued that an alternative methodology for achieving certain research purposes could be to rather do research on the embryos of another species, after which predictions regarding the human embryo could be made using modelling software; such alternative methodology would possibly yield the same results as working with human embryos

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[151] Refer to 5.3.3 Conclusion on the respect doctrine supra.

in vitro – it would, however, take considerably longer (decades compared with years) and consume vastly more resources. The absolute interpretation of necessity would effectively constitute a blanket *prohibition* on embryo research, rather than a *criterion* for embryo research, hence defeating its own purpose. The absolute interpretation of necessity is therefore not aligned with the respect doctrine and should be rejected.

It is suggested that South Africa should specifically qualify necessity with efficacy, as per the Belgian formulation, in order to avoid any controversy as to its interpretation.

5.4.3 Good scientific practice

The last two criteria that can be identified from the comparative analysis are a sound methodology and the expertise of the researchers. These criteria can be grouped together as good scientific practice, which in my submission is essential for showing respect for the embryo; destroying embryos as part of research conducted according to substandard scientific practice would constitute disrespect for the embryo qua symbol of human life. I subsequently discuss each of the good scientific practice criteria:

- *Sound methodology*. While the British law is silent on this aspect, the laws of the two Low Countries require that the proposed embryo research must have a sound methodology. I would suggest that, apart from being good scientific practice, there is also a more philosophical dimension to this criterion: The rule of special necessity[152] is, in my submission, incorporated within this criterion. A sound methodology should entail the destruction of the smallest number of pre-embryos necessary to achieve the purpose of the research. (Note that necessity should once again be interpreted as relative, for the same reasons as already discussed.[153]) The rule of special necessity should therefore be seen as an integral element of the sound-

[152] Ibid.

[153] Refer to 5.4.2 No equally effective alternative supra.

methodology criterion. The additional requirement in the Belgian law that the methodology must be in line with the most recent scientific findings on the subject can also be seen as a component of the sound-methodology criterion, since any sound methodology must by definition always be based on the latest scientific findings. I suggest that the fact that this component of a sound methodology is specifically mentioned should be interpreted as an intention to highlight its particular importance and to ensure that the proposed research is not simply an uninformed replication of research that has already been done.[154] The sound-methodology criterion can therefore be perceived as a general criterion that includes specific aspects, *inter alia* the destruction of the smallest number of embryos necessary to achieve the purpose of the research and alignment with the latest scientific findings.

- *Expertise of researchers*. This criterion is once again explicit in the laws of the two Low Countries, though not in the British law. The expertise of researchers who are to conduct the research according to the methodology is just as important as the soundness of the methodology itself. If the researchers are not competent to execute the methodology, the whole research project is destined for failure from the start, rendering it a waste of embryos, which is obviously contrary to the respect doctrine. While the Belgian law prescribes that the research must be conducted under the supervision of either a medical specialist or a doctor in the sciences, the Dutch law does not prescribe such specific academic qualifications. Why exclude a non-specialised medical doctor or a scientist with a master's degree from leading a research project? The ability to conduct the proposed research should rather be evaluated on an *ad hoc* basis, comparing the actual skill of the research leader with the skill required by the research. For instance, a person might well have a doctoral degree and many years' experience – the question is, however, whether the degree and the

[154] *Knowingly* repeating certain research for purposes such as validation, is of course highly relevant and aligned with a sound methodology.

experience are relevant to the research at hand. I submit that the Dutch approach, requiring expertise in general, without prescribing specific qualifications, is preferable.

5.4.4 Conclusion

It should be noted how the statutory instruments of the three comparative jurisdictions give direct expression to the ethical values associated with the respect doctrine. In addition, the statutes also add a good measure of practicality by including criteria that pertain to good scientific practice. The subsequent concrete policy recommendations encapsulate in concise formulations the essence of this comparative legal analysis.

5.5 Recommendations

Based on the above analysis, the following concrete policy recommendations are proposed:

- *Medical scientific purpose.* The proposed research must have a medical scientific purpose.
- *No equally effective alternative.* There must be no alternative to the proposed research methodology that will not entail the use of embryos and still be equally effective in achieving the purpose of the proposed research.
- *Good scientific practice.* The proposed research must be aligned with good scientific practice, measured by the following criteria:
- *Sound methodology.* The proposed research must have a sound research methodology. This entails inter alia that:
    - the research methodology must entail the destruction of the smallest possible number of embryos necessary to achieve the research purpose without compromising the efficacy of the research.
    - the research methodology must be based on the latest scientific findings.

- *Expertise of researchers.* The key research team members must have the expertise necessary to conduct the proposed research.

5.6 Additional observations: regulatory structures

Apart from the issue of substantive criteria, there is also the structural issue as to who will apply these criteria in practice – to what legitimate, knowledgeable entity will the Minister delegate her authority to evaluate applications to conduct research involving embryos? Although the focus of this subchapter is specifically on substantive criteria for allowing embryo research, it would be informative to briefly look at this related aspect of regulatory structures for embryo research.

5.6.1 Comparative analysis

While the British and the Dutch have very centralised systems for regulating embryo research, the Belgians have a more decentralised system. In Britain, licences to conduct embryo research are issued by the Human Fertilisation and Embryology Authority[155] and in the Netherlands the Central Commission for Medical Scientific Research[156] must approve all research protocols. In Belgium, proposed research must first be submitted to local ethics committees.[157] Such a committee must take a decision within two months.[158] Only if the decision is positive can the applicant approach the Federal Commission for Medical and Scientific Research on Embryos in Vitro.[159] Should this Federal Commission not make a negative decision within two months, the application to conduct embryo research is deemed to be approved.[160]

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[155] Established by the UK Human Fertilisation and Embryology Act.

[156] The Dutch Embryo Act s 10. The commission was established by s 14 of another act, namely the Wet van 26 februari 1998, houdende regelen inzake medisch-wetenschappelijk onderzoek met mensen (Wet medisch-wetenschappelijk onderzoek met mensen).

[157] The Belgian Act regarding research on embryos in vitro s 7.

[158] Ibid.

[159] Ibid.

[160] Ibid.

This is an important rule of the Belgian law, which ensures that researchers are not kept in limbo for undetermined periods of time, at the mercy of the system – a rule that could certainly be very applicable in South Africa.

The *composition* of these regulatory authorities is also of significance. The Belgian Act regarding research on embryos in vitro provides for the inclusion of medical practitioners, natural scientists, jurists, ethicists and social scientists on the Federal Commission.[161] The Dutch Central Commission deals with all research involving humans and therefore requires the inclusion of a wider variety of experts than the Belgian law.[162] The British law does not mention all the various professional categories as specified by the Low Countries, but does place a minimum and maximum limit on the number of medical practitioners to be included, and completely precludes medical practitioners from becoming chairman or deputy chairman of the Authority.[163] In addition to the quotas according to profession, the Belgian law also stipulates that the composition of the Federal Commission must be representative of different ideological and philosophical opinions.[164] Both the Belgian and British laws also address gender inclusivity.[165]

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161 Ibid s 9.

162 The Dutch Wet medisch-wetenschappelijk onderzoek met mensen s 14.

163 Sch 1 of the UK Human Fertilisation and Embryology Act s 4(3), s 4(4).

164 The Belgian Act regarding research on embryos in vitro s 9: 'Bij de samenstelling van de commissie wordt ervoor gezorgd dat de verschillende ideologische en filosofische strekkingen evenwichtig vertegenwoordigd zijn.'

165 The Belgian Act regarding research on embryos in vitro s 9: 'De commissie mag niet minder dan een derde leden van hetzelfde geslacht tellen.' Sch 1 of the UK Human Fertilisation and Embryology Act s 4(2): 'In making appointments the Secretary of State shall have regard to the desirability of ensuring that the proceedings of the Authority, and the discharge of its functions, are informed by the views of both men and women.'

5.6.2 Evaluation

The decentralised system employed by Belgium for evaluating research proposals could distribute workload and streamline the regulatory approval process. It could be argued, on the other hand, that the number of applications in South Africa will – at least initially – not be so numerous as to necessitate the distribution of workload. An important element of the Belgian law is the two-month timeframe for decision making. Scientific research is internationally very competitive, and the loss of time is not only personally and professionally disruptive to the researchers involved, but might be crucial for the success of the research. It is in South Africa's national interest that decision making on proposed embryo research be swift.

The subject of embryo research has ethical and legal ramifications; this necessitates the expertise of not only people with medical and scientific expertise, but also people with ethical and legal expertise. The high level of expertise of the appointees is essential for the efficacy of the regulatory authority.

The gender composition of the regulatory authority is vital for the authority's legitimacy – especially in the South African context, with its history of gender discrimination. Provision should be made to ensure gender equality in representation in appointee selection.

The regulatory authority's ideological composition might be less tangible than the other dimensions of its composition, but just as important to its legitimacy. In present-day South African this would entail first and foremost a balance of appointees from academia vis-à-vis private business.

5.7 Conclusion

It must be re-emphasised that the analyses and recommendations of this subchapter have been made within the current politically dominant value paradigm of respect-for-the-embryo. This paradigm is the essential raison d'être of substantive criteria for allowing embryo research as well as the associated regulatory structures. As such, this regulatory system (such as criteria and structures) should be seen as the expression in law of the ethical viewpoints that

the embryo is a potent symbol of human life and that it therefore deserves respect. Moreover, the proposed regulatory system aims to express the underlying ethical values as a body of specific legal rules that can be applied objectively, hence avoiding arbitrariness and ensuring legal certainty.

6 A human rights challenge to the respect-for-the-embryo paradigm

In this subchapter, I argue that the banner of human dignity should properly be claimed for the cause of freedom of scientific research; I further argue that the current law limits embryo research and per implication therefore infringes on the right to freedom of scientific research and on human dignity. Next, I analyse whether the respect-for-the-embryo paradigm can serve as a justification for these limitations – how strong is the respect-for-the-embryo paradigm's claim to human dignity qua detached value?

6.1 Human dignity and the right to freedom of scientific research

The right to freedom of scientific research is explicitly protected in the Constitution:

> **16. Freedom of expression**
>
> 1. Everyone has the right to freedom of expression, which includes
>
> [...]
>
> d. academic freedom and freedom of scientific research.

I submit that the right to freedom of scientific research is fundamentally connected to and derived from human dignity: Freedom of scientific research is a species of individual autonomy and self-actualisation, both on the level of the individual scientist qua exerciser of this freedom and on the level of society qua beneficiary of science, where the autonomy and opportunity for self-actualisation of individual members of society are enhanced by scientific advances qua result of this freedom. The cardinal importance of science qua enabler of individual autonomy and self-actualisation for millions of individuals across the board in society cannot be overemphasised. What would our lives be like without science? The list of science's

gifts to humanity is endless: anaesthetics, organ transplants, motorcars, information and communication technology – in short everything that differentiates us from our cave-dwelling ancestors. Just contemplate the scientific advances of the past century and how it contributed to improve our lives: we now have a vast array of career choices to actualise our talents; modern medicine has vastly reduced infant mortality over the past century saving innumerable families from pain and tragedy; and on the subject of pre-embryo research, science has made it possible for thousands of couples that are not able to conceive children through sexual intercourse to have the children they so wish for.

The purpose here, however, is not to probe the moral nature of science – of course science also produced the atom bomb, as well as various other new, more effective ways for people to destroy each other and our planet – but only and specifically to demonstrate how science is a principal contributor to the improvement of the human condition and enabler of greater individual autonomy and self-actualisation in society, and hence an essential promoter of human dignity. In the relationship between society and science, the right to freedom of scientific research is the lifeblood of scientific progress and the conditio sine qua non for the continued improvement of the human condition.

6.2 Limiting the freedom of scientific research

The two most salient limitations imposed by current law on embryo research are:

- The Warnockian rule that research must be limited to the pre-embryo, and exclude the embryo proper; and
- That embryos may not be created for research purposes, but must rely on excess embryos that may be donated for research.

A challenge to the fourteen-day limit will demand in-depth analyses of concepts such as sentience, consciousness, viability (in the context of rapid technological advances), and the value that society attaches to these. As these extensive analyses are beyond the scope of this thesis, I will for present purposes not challenge the fourteen-day limit, but rather focus on the embryo creation ban. In addition, I will

also challenge the requirement of ministerial approval that the NHA aims to introduce.

A scientist who wishes to engage in embryo research has an interest in obtaining the subject of the research (id est embryos) easily and in sufficient quantities. The creation-ban is clearly anathema to this interest, as it makes a scientist's supply of embryos *entirely dependent* on externalities such as when and if there are excess embryos after IVF, and the will of the person or persons having rights over such excess embryos. Furthermore, a scientist who wishes to engage in embryo research has an interest in being able to engage in such research without bureaucratic hindrances, such as having to request permission from nobody less than the Minister of Health.

I submit that both these interests – the interest in being able to obtain the subject of one's research easily and in sufficient quantities, and the interest in being able to engage in one's research without bureaucratic hindrances – clearly fall within the ambit of the right to freedom of scientific research, and accordingly that the right to freedom of scientific research is limited by the creation-ban and the ministerial approval requirement.

6.3 When can a right be limited?

The Constitution's limitation clause reads as follows:

> **36. Limitation of rights**
>
> 1. The rights in the Bill of Rights may be limited only in terms of law of general application to the extent that the limitation is reasonable and justifiable in an open and democratic society based on human dignity, equality and freedom, taking into account all relevant factors, including
>
> a. the nature of the right;
>
> b. the importance of the purpose of the limitation;
>
> c. the nature and extent of the limitation;
>
> d. the relation between the limitation and its purpose; and
>
> e. less restrictive means to achieve the purpose.

> 2. Except as provided in subsection (1) or in any other provision of the Constitution, no law may limit any right entrenched in the Bill of Rights.

It is not necessary to engage in a comprehensive analysis of the limitation clause for purposes of this thesis. However, a brief comment regarding *rationality* will suffice: Although rationality is implicit from the list of 'relevant factors', it is also required by the concepts 'reasonableness' and 'open society': Rationality is both a minimum requirement of reasonableness,[166] as well as a constituent element of the open society.[167] In *The Open Society and its Enemies*, Popper states:[168]

> [T]he closed society is characterised by the belief in magical taboos, while the open society is one in which men have learned to be to some extent critical of taboos, and to base decisions on the authority of their own intelligence (after discussion).

6.4 Can the limitations be justified by the respect-for-the-embryo paradigm?

If the purpose of the limitations is to give effect to the value of respect-for-the-embryo, the critical question is: Why must the embryo be respected? In the discussions above, two rationales for respect-for-the-embryo were explored, namely that the embryo has *intrinsic value* – a 'special status'; and that the embryo possesses *symbolic value* qua symbol of human life. In the following paragraphs, these two rationales are critically analysed.

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166 'The question that inevitably arises is what is meant by "reasonableness"? Part of the answer is that it, at a minimum, encompasses rationality.' Jonathan Klaaren & Glenn Penfold 'Just administrative action' in S Woolman, T Roux & M Bishop (eds) *Constitutional Law of South Africa* 2nd ed (2002) 63. Cf *Bato Star Fishing (Pty) Ltd v Minister of Environmental Affairs and Tourism and Others* 2004 (4) SA 490 (CC) para 43, where reasonableness and rationality are used as synonyms.

167 Donrich W Jordaan 'The open society' (2001) 64 *J Contemp Roman-Dutch Law* 107.

168 Karl R Popper *The Open Society and Its Enemies. Vol 1: The Spell of Plato* 5th ed (1971) notes 202.

6.4.1 Intrinsic value

In support of the 'utmost respect' due to and the 'special' nature of the pre-embryo, the MRC proposes the following indicia of intrinsic value of the pre-embryo, namely potential for human life, genetic uniqueness, and viability:[169]

- *Potential*. To this indicium I reply as follows: Similar to the pre-embryo, the gametes also have potential to become human life. Does a sperm cell's potential also make it 'special' and worthy of the 'utmost respect'? Such a contention would be absurd in a society such as ours where sperm are regularly destroyed in their millions for no more elevated a purpose than sexual pleasure. If the pre-embryo aspires to a higher moral status than the gametes, it must therefore possess some *morally significant property* – not merely arbitrarily chosen – that the gametes do not. I will subsequently analyse the properties suggested by the MRC, namely genetic uniqueness and viability.
- *Genetic uniqueness*. The argument based on genetic uniqueness need not detain us long. Consider a scenario in which twins are born: if an embryo has a monozygotic twin, it simply *lacks* genetic uniqueness. Is it justifiable to give such an embryo a moral standing different from other embryos solely based on its lack of genetic uniqueness? Since all pre-embryos do not possess a unique genotype, it cannot serve as a general criterion to differentiate between gametes and pre-embryos.
- *Viability*. The usual meaning of 'viable' in the context of the unborn denotes a fetus that can survive outside the womb. Since it is currently impossible for a pre-embryo to survive outside the womb and develop into a fully fledged human, the MRC's pronouncement of the pre-embryo as a 'viable human entity' seems to be factually incorrect. However, when 'viable' is interpreted

[169] MRC *Guidelines* op cit note 124 ss 2.2, 3.4.3.2. For a more comprehensive analysis of the moral status of the pre-embryo, refer to Donrich W Jordaan *A Policy Model for Human Preimplantation Screening and Selection* (2002) Master of Political Policy Studies dissertation, University of Pretoria, 37–51.

in its general meaning as pertaining to something that is possible or feasible, the MRC's phrase 'viable human entity' can be taken to mean that the pre-embryo has everything that it takes – on a genetic level – to become a human being; that in contrast to the gametes, the pre-embryo has a *complete genotype*. The Achilles-heel of this argument (and the previous one of uniqueness) is that the pre-embryo is not a biological individual, because there is no subordination of parts to a whole, but rather an unorganised aggregate of precursor cells that lies within a cellular peripheral layer.[170] Seen in this light, the property of a complete genotype is not located on the level of the pre-embryo qua aggregate, but on the level of each of the individual pre-embryonic cells. In the early pre-embryo, each one of these cells can be split from the aggregate to create new potential human beings. Theoretically, the process of cell division and splitting could be repeated ad infinitum – as is indeed been done with so-called 'immortal' stem cell lines. A pre-embryo is therefore an indeterminate, infinite number of potential human beings. In order for a human being to develop eventually, the pre-embryonic cells will have to 'sacrifice' their individual potential by beginning to differentiate and thereby becoming subordinate parts of a whole, or even extra-embryonic material, for instance the placenta. It is therefore impossible to protect the potential of each individual pre-embryonic cell. To encapsulate: a complete genotype may be a factual distinction between the gametes and the pre-embryo, but it cannot constitute a morally relevant distinction, since this distinction is located in each cell of the pre-embryo and it is factually impossible to protect (or respect in any meaningful way) the potential of each cell to become a human person.

Moreover, each old skin cell that falls off a person's face has a complete genotype and can possibly in the near future – with nuclear substitution

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[170] Clifford Grobstein *Science and the Unborn: Choosing Human Futures* (1988) 59. UNESCO's International Bioethics Committee op cit note 101 para 35 also acknowledges the fact that the pre-embryo does not possess biological individuality.

> cloning techniques – become a potential human being and is therefore a 'viable human entity'. Should every old skin cell that falls off one's face be treated as 'special' and with the 'utmost respect'?

I have thus far argued that the indicia of the pre-embryo's intrinsic value – a moral status of 'utmost respect' – are unconvincing based on *practical* grounds: they either lead to inconsistencies (the non-uniqueness of twins) or to impossibilities (protecting infinite potentials) when applied to practice. On a level of theoretical principle the *fundamental question* still remains: What is *morally relevant* about genetic uniqueness or a complete genotype? The MRC does not provide any answer. From a moral perspective, these are purely arbitrary phenomena – it can only be when the proponent already *assumes* conception to be a morally relevant occurrence (based on personal conviction) that the moral relevance of potential coupled with genetic uniqueness and a complete genotype seems 'self-evident'. This is however no argument. It must accordingly be concluded that the pre-embryo does not possess any intrinsic value.

This conclusion does not close the door on allocating extrinsic value to a pre-embryo: For prospective parents who wish to get a child from a few pre-embryos in a petri-dish, each of these pre-embryos have great value; once a successful pregnancy has ensued and the parents do not wish to have another child, the excess embryos' extrinsic value to these parents will be reduced, if not nullified. The same with a scientist in the field of embryo research: Given the scarcity of embryos for research,[171] each pre-embryo will surely have significant extrinsic value for the scientist.

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[171] The scarcity of research embryos throughout the world is illustrated by the following: Ashreena Salpekar et al 'The use of amplified cDNA to investigate the expression of seven imprinted genes in human oocytes and preimplantation embryos' (2001) 7 *Mol Hum Reprod* 839 (scarcity of research embryos in the United Kingdom); Jeanne S Freeman 'Arguing along the slippery slope of human embryo research' (1996) 21 *J Med Philos* 61 (scarcity of research embryos in the United States); Jeff Nisker et al 'Development and investigation of a free and informed choice process for embryo donation to stem cell research in Canada' (2006) 28 *J Obstet Gynaecol Can* 903 (scarcity of research embryos in Canada).

6.4.2 Symbolic value

An averment of symbolic value – that the embryo is a potent symbol of human life – does not take the case for respect-for-the-embryo further – *why* is the embryo a potent symbol of human life? As all the indicia have already failed, symbolic value is exposed as nothing more than an ipse dixit, which certainly falls short of the rationality requirement of the Constitution's limitation clause.

Symbolic value essentially becomes the last refuge after all efforts to support an opinion with rational arguments have failed, as vividly illustrated by following statement by the MRC:[172]

> The fact that the source is a human embryo is itself problematic . . . because the extraction of stem cells from the human embryo eliminates that embryo's potential for life. It is not possible to completely rationalise this response. However, the objection must be treated with respect as the genuine response of a portion of the population, which believes that the right to life and dignity is applicable to human embryos. It does not help to enter into a legal debate as to when the embryo acquires the status and concomitant rights of a human being. The issue is not one of legality, but of mores.

After the stunning admission that 'It is not possible to completely rationalise this response', the MRC still persists in advancing this 'response' that the right to life and human dignity are applicable to the embryo by placing reliance on such response being the 'genuine response of a portion of the population'. In an open society the question is not whether it is a 'genuine' response, but rather whether it is a *rational* response.

Why, in any event, must a 'genuine response' be treated with respect? A portion of the population may be very racist and very sexist and hence have genuinely racist and genuinely sexist responses – must these also be treated with respect? Prejudice is more often than not a 'genuine response'. The Constitutional Court has made a clear distinction between the following two kinds of morality:[173]

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[172] MRC op cit note 124 s 3.4.3.2.

[173] *Jordan* supra note 28 para 113; *National Coalition I* supra note 26 para 136.

- Views of morality that, even though they might be popular in society, are not based on the Constitution
- The morality that is embodied in the Constitution

While the Constitutional Court has made it abundantly clear that a limitation cannot be justified by the former kind of morality, the state can and must however enforce the latter, constitutional morality.[174] The value of respect-for-the-embryo has no *rational* connection with human dignity or any other constitutional value. Accordingly, the value of respect-for-the-embryo falls in the category of views of morality that, even though they might be popular in society, are not based on the Constitution, and can as such not justify the limitations.

Furthermore, the MRC's argument that embryonic stem cell research is not an issue of legality, but of mores, is baffling and misleading. Baffling because the *Guidelines* continuously refer to concepts such as human dignity specifically in a constitutional, *legal* context, and even cite a section of the Constitution;[175] misleading because the *Guidelines* effectively have the power of law and are therefore in the legal domain.[176] This rejection of legal arguments in favour of perceived mores is a sad effort to escape the demands of reason.

Another ipse dixit example is an article by Slabbert entitled 'Are the human embryo and the foetus extra uterum sufficiently protected in terms of South African law?'[177] In her article, Slabbert condemns a wide range of new reproductive technologies and research associated therewith and proposes new legislation to ban these technologies and research. As reflected in the article's title, the essential premise of her article is that the embryo and the fetus are protection-worthy. Why

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[174] *Jordan* supra note 28 paras 86, 105; *National Coalition I* supra note 26 para 37.

[175] MRC op cit note 124 s 3.4.4.1.1.1.

[176] Jonathan M Burchell 'Non-therapeutic medical research on children' (1978) *S Afr Law J* 193 at 194. Cf Van Oosten op cit note 123 who also follows Burchell's position.

[177] Melodie N Slabbert 'Are the human embryo and the foetus extra uterum sufficiently protected in terms of South African law?' (2001) 3 *J S Afr Law* 495.

are the embryo and the fetus protection-worthy? The only apparent substantiation provided for this protection-worthy status is the 'inherent dignity of human life'.[178] Slabbert's implied argument regarding the pre-embryo can accordingly be systematically stated as follows:

- Premise A: All human life has inherent dignity
- Premise B: The human pre-embryo is human life
- Ergo: the human pre-embryo has inherent dignity (and should accordingly be respected/protected, which constitutes the essential premise for Slabbert's condemnations and proposals to ban certain technologies and research)

The silent assumption in Slabbert's article, which is essential for her argument, is Premise B: The human pre-embryo is human life. I suggest that Premise B is not only a silent assumption, but also a false one: Slabbert does not attempt to define what she means with 'human life'. A human pre-embryo qualifies as human life to the same degree as a human appendix or a human hair: all are *human* (in the sense that it is not a dog appendix or cat hair), and all are *alive*, but none of these entities qualify as *human life* in the relevant legal or moral sense of a conscious human individual; none of these entities possess any neurological attributes that are ascribed to human life.[179] I accordingly suggest that Premise B is a tacit ipse dixit – nothing more than an axiomatic 'I just believe it to be so'.

6.4.3 Conclusion on respect-for-the-embryo

The two rationales that are advanced for respecting the embryo both fail the test of rational analysis. The proposed indicia of inherent value give illogical results, while symbolic value is nothing more than an irrational 'I just believe it to be so' pronouncement. Respect-for-the-embryo can accordingly not be a valid purpose for the limitations on the freedom of scientific research. In our constitutional

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[178] Ibid at 510.

[179] For descriptions of what constitute human life, refer to *Clarke v Hurst NO & others* 1992 (4) SA 630 (D).

dispensation that requires rationality, the respect-for-the-embryo paradigm is completely impotent to justify any kind of limitation of rights – not even to the smallest degree.

6.4.4 Respect-for-the-embryo degrades human dignity

The argument can be taken further: The respect-for-the-embryo paradigm is not only impotent qua justification to limit human dignity as expressed in the right to freedom of scientific research, the paradigm per se – in as far as it makes a nexus between the pre-embryo and human dignity qua detached value – is an assault on the integrity of the value of human dignity. The respect-doctrine effectively introduces a form of quasi-human-dignity, where it is admitted that the embryo is not a person, but that the embryo is sufficiently proximate to the metaphorical tree of human dignity (either because of its inherent value or its symbolic value) to be halfway under its shade. However, human dignity, in the Kantian tradition, is *absolute*, incomparable worth. It is therefore per definition impossible to have a little bit of human dignity – either human dignity is applicable, or it is not – either under the shade of the tree, or not. To aver that a microscopic entity without any sentience, without any consciousness, without intellect or emotion, even without biological individuality – in short without any property that we associate with being human – has a claim to human dignity qua detached value is to make a mockery of human dignity. The pre-embryo is simply so far removed from being an autonomous individual with self-worth, that an averment that the pre-embryo has any connection to human dignity is clearly absurd and degrading to human dignity.

On the subject of Kant: The well-known Kantian maxim to always treat a person (equivalent of legal subject) as an end and never only as a means is often incorrectly applied to embryo research and therefore only needs mention in order to be rectified. Neither in our law nor in Kantian ethics does the embryo qualify as a person; in Kantian ethics, the embryo is manifestly not an autonomous moral agent and can therefore be used purely as a means to another end, such as the advancement of science.

6.5 Can the limitations be justified by relying on internationally recognised standards of research?

The Preamble of the NHA states that the purpose of the NHA is, inter alia, to 'establish a health system based on . . . internationally recognised standards of research and a spirit of enquiry . . . which encourages participation'. Accordingly, an argument can potentially be formulated that the purpose of the limitations of the right to freedom of scientific research is to bring the South African regulation of embryo research in line with internationally recognised standards of research. This argument assumes that the limitations are in fact in line with 'internationally recognised standards of research'. However, this assumption is false:

- Ministerial approval of embryo research is not mentioned in the international legal and policy instruments that I have discussed above, namely the Universal Declaration on Bioethics and Human Rights and UNESCO's International Bioethics Committee's report on the ethical aspects of human embryonic stem cell research. If one turns to foreign law, the law the three jurisdictions that I have analysed above in fact make provision for committees of diverse experts – not a minister of state – to decide on the approval or not of proposed embryo research.
- The ban on creating embryos for research is also not mentioned in the international legal and policy instruments that I have discussed above. Turning to foreign law, the Netherlands[180] and Belgium[181] have in fact

[180] The Dutch Embryo Act s 11 provides as follows (the entering into force of this provision has been suspended for 5 years): 'Het is verboden wetenschappelijk onderzoek te verrichten met embryo's die speciaal daarvoor tot stand worden gebracht. Dit verbod is niet van toepassing op wetenschappelijk onderzoek waarvan redelijkerwijs aannemelijk is dat het zal leiden tot de vaststelling van nieuwe inzichten op het terrein van onvruchtbaarheid, het terrein van kunstmatige voortplantingstechnieken, het terrein van aangeboren aandoeningen of het terrein van de transplantatiegeneeskunde en dat niet dan met gebruikmaking van in de eerste volzin bedoelde embryo's kan worden verricht.'

enacted legislation to specifically make provision for the creation of embryos for research purposes.

Accordingly, the argument based on 'internationally recognised standards of research' ricochets even before the question can be asked: What is the importance to the present human rights analysis of internationally recognised standards of research? In subsequent chapters, this question will become more relevant to answer.

It should be noted that in the same sentence the Preamble of the NHA also declares the aim to establish a health system based on 'a spirit of enquiry . . . which encourages participation'. These rhetorical questions must be posed: How does placing the bureaucratic mountain of ministerial approval in the path of embryo research contribute to a spirit of enquiry which encourages participation? How does maintaining a ban of the creation of embryos for research contribute to a spirit of enquiry which encourages participation?

6.6 Paradoxes in the legal status quo

The lack of justifiability of the limitations is highlighted by the paradoxes that are present in the legal status quo when the right to freedom of scientific research is compared to the right to reproductive freedom in the context of the embryo:

6.6.1 Embryo creation

A couple can hypothetically produce innumerable embryos as the by-products of their sexual lust (and each time just terminate its existence with a 'morning-after pill') without any trouble from a legal regulatory perspective, while the creation of embryos for scientific research purposes is prohibited by the MRC's *Guidelines*. In the context of creating pre-embryos, the legal status quo therefore allows for unlimited exercise of the right to reproductive freedom, but paradoxically

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[181] The Belgian Act regarding research on embryos in vitro s 4(1) provides as follows: 'Het aanmaken van embryo's in vitro voor onderzoeksdoeleinden is verboden, behalve indien het doel van het onderzoek niet kan worden bereikt door onderzoek op overtallige embryo's . . .'

completely limits the right to freedom of scientific research. There is no rational reason for this untenable legal inconsistency. A society – like ours – that allows recreational sex has no moral or philosophical basis to prohibit the creation of embryos for research, except if such society values the satisfaction of immediate sexual needs more than the long-term improvement of the human condition.[182]

6.6.2 Embryo destruction

Subsequent to successful IVF, a couple (the gamete donors) can hypothetically just decide to destroy the excess embryos without applying for anybody's permission, but should the gamete donors decide to donate the embryos for research, the NHA will require that the scientist who plans to use such donated pre-embryos will first have to obtain ministerial approval. While people's reproductive decisions and control over their genetic material are allocated high value and consequently free from societal interference, science is either allocated low value or perceived with immense suspicion.

6.7 Conclusion on the human rights challenge

A valid purpose for regulating embryo research would be to protect the rights of real people – embryo donors, for instance. In this regard, institutional ethics committees can ensure that embryo research – similar to all other research – proceeds within a value-framework that upholds human rights. However, protecting the rights of real people does not necessitate either ministerial approval, or the ban on creating embryos for research. It must be concluded that these limitations are not justifiable and hence unconstitutional.

One of the express objectives of the MRC is the promotion and improvement of the health and quality of life of the South African population through research development and technology transfer.[183] However, the MRC's current *Guidelines* do

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[182] I by no means want to attack or degrade the complete human experience that includes recreational sexual intercourse – on the contrary. It does, however, set an important precedent.

[183] South African Medical Research Council Act s 3.

the opposite with regards to embryo research: it *inhibits* research, rather than fulfilling its objective to promote it.

6.8 Recommendation

Section 57(4) of the NHA, which makes requires ministerial approval, must be deleted in its entirety; the offending parts of sections 2.2 and 2.17 of the MRC's *Guidelines*, which provide that the creation of embryos for the sole purpose of research is unethical, must be deleted.

7 Conclusion

In this chapter, I have set out to approach the subject of embryo research in two ways: First, I analysed the current legal-ethical paradigm of respect-for-the-embryo, and from a pragmatic perspective of acknowledging that paradigm shift may be an ambitious project, I made recommendations for piecemeal legal development. My second approach was indeed more ambitious, and entailed a principled challenge to the current paradigm. This duality is not an approach that I intend to follow in the rest of this thesis. However, given the exceptional and immediate socio-economic relevance of embryo research – embryonic stem cell research in particular – the recommendations within the paradigm of respect-for-the-embryo can potentially make an immediate and significant positive impact, and avoid paralysis brought about by the entrenched nature of the existing paradigm.

However, the pragmatism of the duality should not detract from the core principled conclusion of this chapter: The limitations on embryo research are unconstitutional. Similar to cadaver research at the beginning of modernity, embryo research is essential to scientific progress, progress that promises to revolutionise medical care and in so doing greatly improve the human condition and hence serve human dignity. The irrational values that currently inform the unconstitutional limitations on embryo research and inhibits progress must be boldly challenged from the granite platform of human dignity and its expression in the freedom of scientific research.

Chapter 4[*]

The use of human gametes

1 Introduction

While the previous chapter challenged the hegemony of the respect-doctrine regarding embryos, this chapter will explore the way in which aspects of this doctrine –particularly the use *only* for medical purposes, and a general tendency to hyper-regulate – are also present in the law relating to gametes: sperm and egg cells. Essentially, where the gametes are not used during sexual intercourse, the use of gametes is juridically medicalised and regulated. (The possible non-medical, non-sexual-intercourse purposes for which gametes can be used are plentiful, but I will leave it to the reader's imagination.) In contrast to the previous chapter that focused on human dignity as expressed in the freedom of *scientific research*, this chapter will focus on the connection between human dignity and privacy. Using gametes for whatever one's heart desire is admittedly not the most pressing social problem facing the world, yet, on a level of principle this is vital.

2 The relevant law

2.1 The Human Tissue Act

The HTA makes it clear that gametes removed from a living person may only be used for medical or dental purposes:

> **19. Purposes for which tissue, blood or gametes of bodies of living persons may be used**
>
> Any tissue, blood or gamete removed or withdrawn from the body of a living person shall, subject to the regulations, only be used for medical or dental purposes...

[*] The content of this chapter is based on: Donrich W Jordaan 'The boy and his microscope: interpreting section 56(1) of the National Health Act' (2009) 2 *S Afr J Bioeth Law* 12.

It should also be noted that, as this section of the HTA is only applicable to gametes *after they have been removed*, this section is not applicable to the use of gametes for the purpose of sexual intercourse.

2.2 The National Health Act

In contrast with the clear formulation of the HTA, the NHA presents the following formulation:

> **Use of tissue, blood, blood products or gametes removed or withdrawn from living persons**
>
> 56 (1) A person may use tissue or gametes removed or blood or a blood product withdrawn from a living person only for such medical or dental purposes as may be prescribed.

What is clear, is that this section is only applicable to gametes *after it has been removed*, and is therefore not applicable to the use of gametes for sexual intercourse. What is *not* clear, however, is whether such removed gametes may only be used for medical or dental purposes, or whether this section only applies to the *kinds* of medical and dental purposes that such gametes may be used for and therefore does not apply to the use of such gametes for non-medical, non-dental purposes. The qualification 'medical or dental' renders the sentence a classical textbook example of ambiguity:

- Does 'medical or dental' qualify the *prescription*, id est that the regulations are only intended to prescribe within the parameters of medical and dental use and that use outside those parameters is per implication not prescribed and hence permissible (the restrictive interpretation)? Stated differently, if a person wants to use gametes for medical or dental purposes, the use of the gametes must be in accordance with the regulations, but if a person wants to use gametes for purposes other than medical or dental, the use of such gametes falls outside the ambit of the section and is hence permissible.
- Or does 'medical or dental' qualify *use*, id est that use is confined to medical or dental use on a general level and that the regulations will be an additional

layer of specific limitations (the extensive interpretation) – in other words retaining the position of section 19 of the HTA?

If the intention of the legislature was the restrictive interpretation, the following clearer formulation is proposed:

> A person may use . . . gametes removed . . . from a living person, where such use is ~~only~~ for ~~such~~ medical or dental purposes, only as ~~may be~~ prescribed.

If, however, the intention of the legislature was the extensive interpretation, id est to retain the HTA's position, a clearer formulation of such intention would have been:

> A person may use . . . gametes removed . . . from a living person only for ~~such~~ medical or dental purposes, and only as ~~may be~~ prescribed.

2.3 Conclusion

While the HTA is clear that gametes removed from a person may only be used for medical or dental purposes, the NHA has lapsed into ambiguity in this regard. In the following, I employ the common law presumptions of statutory interpretation to suggest which interpretation of section 56(1) of the NHA should be accepted. This is followed by a human rights challenge to section 19 of the HTA and the corresponding extensive interpretation of section 56(1) of the NHA.

First, however, I present a hypothetical case study to assist in the analyses of this chapter.

3 The boy and his microscope: a hypothetical case study

A certain fourteen-year-old boy, who loves biology as a subject at school, receives a microscope as a present. Alone in his room, he decides to take some of his sperm and look at it under the microscope. He does this purely out of curiosity with no medical or dental purpose in mind. I submit that there is certainly an element of *use*, the object of which is *removed gametes*; further that it would be a highly strained argument to aver that the boy's actions are for medical or dental purposes, since it is neither the subjective intention of his actions, nor does he have the level

of medical or dental knowledge that would reasonably be expected from somebody who intends to engage in research for medical or dental purposes.

- Assuming the restrictive interpretation: the boy's experiments would fall outside the ambit of section 56(1) and would hence not constitute a contravention of the NHA.
- Assuming the extensive interpretation: the boy would be guilty of contravening section 56(1).

This case study can easily be expanded on: Quite fascinated by this new living microscopic world, the boy starts doing primitive experiments with his sperm, such as adding ordinary household chemicals and studying their reaction and how long they survive. The boy's friends – all his age and educational level – also soon take a keen interest in his experiments. All of them donate sperm for the experiments that they conduct under the microscope.

- Assuming the restrictive interpretation: similar to the initial case study, the boy and his friends' experiments would fall outside the ambit of section 56(1) and would hence not constitute a contravention of the NHA.
- Assuming the extensive interpretation: all the boys would be in contravention of section 56(1).

The case study of the boy and his microscope and its alternative legal implications will, in the subsequent analyses, serve as a reference to illustrate the abstract concepts of the NHA in an applied, concrete manner.

4 The common law presumptions of interpretation

In cases of statutory ambiguity such as the present, the common law presumptions of interpretation are called in aid.[184] Although some commentators[185] have expressed pessimistic views regarding the future of the presumptions in the new

[184] *Adampol (Pty) Ltd v Administrator, Transvaal* 1989 (3) SA 800 (A) 809.

[185] Christo J Botha *Statutory Interpretation: An Introduction for Students* 3rd ed (1998); Yvonne Burns *Administrative Law under the 1996 Constitution* (1999).

constitutional dispensation, arguing that the presumptions have 'now largely been supplanted' by the Constitution in general and the Bill of Rights in particular,[186] De Ville suggests that the courts' reliance on the presumptions in statutory interpretation has not visibly declined since the onset of the new constitutional dispensation.[187] It should be noted that although the Constitutional Court has on occasion expressed the opinion that 'a question mark has to be placed over the usefulness of common law presumptions in interpreting the Constitution',[188] no such reservation has been expressed regarding the role of the presumptions in statutory interpretation.[189] I therefore agree with Du Plessis' submission[190] that the presumptions could still fulfil a number of useful functions, of which the following bear relevance to the current analysis:

- They can supplement, facilitate and mediate resort to constitutional values in statutory interpretation, in accordance with the requirements of section 39(2) of the Constitution
- they can advance values that are implicit in the Constitution
- they can amplify values that are, although explicit in the Constitution, fragmented

In the following analysis, I will consider the following presumptions:

- The presumption that statute law is not unjust, inequitable and unreasonable; and
- The presumption that the legislature does not intend to alter the existing law more than necessary.

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186 Burns op cit note 185.

187 Jacques R de Ville *Constitutional and Statutory Interpretation* (2000) 166.

188 *S v Mhlungu & others* 1995 (3) SA 867 (CC) para 115 per Sachs J.

189 Lourens M du Plessis *Re-interpretation of Statutes* (2002) 152.

190 Ibid at 153.

4.1 The presumption that statute law is not unjust, inequitable and unreasonable

This presumption is well established in our law and is still relied on by the courts in the new constitutional era.[191] Du Plessis submits, however, that the Constitution can be perceived as a codification of the values of justice, equity and reasonableness as they are encountered in an open and democratic society based on human dignity, equality and freedom; and that the more specific and clearly articulated provisions of the Constitution have subsumed much of the presumption.[192] He therefore suggests the following:[193]

> At present the 'clear language' of the statute cannot trump the Constitution, and constitutional jurisprudence on many exigencies for which the presumption has traditionally catered, is forceful and to the point. In these instances it is desirable that constitutional provisions, as expounded in the case law, take the place of the presumption.

In the light of the ambiguous formulation of section 56(1) – the *lack* of 'clear language' – I submit that reliance on the presumption is suitable. This will be complemented in the next subchapter by a comprehensive human rights analysis of section 56(1).

Two specific applications of this presumption are relevant to the present analysis: first, onerous provisions and, secondly, preference for the most beneficial interpretation:

4.1.1 Onerous provisions

What are the criminal law implications of section 56(1) – what would be the penal consequences of the boys' actions if the extensive interpretation of section 56(1) is followed? In contrast with section 57 of the NHA, which deals with human cloning,

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[191] Cf *Ndebele v Mutual & Federal Insurance Co Ltd* 1995 (2) SA 699 (W) 704; *Nguza & others v Minister of Defence* 1996 (3) SA 483 (TkA) 488; *Rutenberg v Magistrate, Wynberg* 1997 (4) SA 735 (C) 754; *Road Accident Fund v Smith NO* 1999 (1) SA 92 (SCA) 102.

[192] Du Plessis op cit note 189 at 155.

[193] Ibid.

and which creates a criminal norm[194] and criminal sanction[195], section 56 provides for neither; it only creates a *legal norm*. Contravention of section 56(1) per se would therefore not be a criminal offence.[196] The NHA does, however, make provision for the appointment of so-called health officers[197] who have the duty to monitor and enforce compliance with the NHA.[198] Contravention of the legal norm created by section 56(1) would therefore expose a person to administrative action by a health officer, who could issue a compliance notice to such a person. Should the person who is in contravention of section 56(1) fail to comply with the *compliance notice*, such person would be guilty of an offence[199] and liable to a fine or to imprisonment for a period not exceeding five years or to both a fine and such imprisonment.[200] The valid execution of a prior, very specific administrative act by the state is therefore a conditio sine qua non for each instance of enforcement of section 56(1). Therefore: the boys in the case study can be exposed to administrative action by a health officer, and should they still persist they could be criminally prosecuted.

Accordingly, since section 56(1) has a penal nature, the common law maxim in poenis strictissima verborum significatio accipiendi est (in the case of penal laws the

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194 For example: 'act X constitutes an offence'.

195 For example: 'offence X is liable on conviction to imprisonment for a period of Y years'.

196 *S v Bornman* 1912 TPD 66; *S v Mills* 1927 CPD 133; *S v Bethlehem Municipality* 1941 OPD 230; *S v La Grange* 1991 1 SASV 276 (K). *Contra S v Forlee* 1917 TPD 52 – for critique of this judgement: C R Snyman *Strafreg* (1992) 42–43; J C de Wet *Strafreg* (1985) 46–47; M A Rabie & S A Strauss *Punishment: An Introduction to Principles* 4th ed (1985) 79–80.

197 NHA s 80.

198 NHA s 81.

199 NHA s 89(1)(f).

200 NHA s 89(2).

strictest interpretation of their terms should be accepted)[201] is applicable. This maxim very clearly determines in favour of the restrictive interpretation of section 56(1).

4.1.2 Preference for the most beneficial interpretation

The common law maxim semper in dubiis benigniora praeferenda sunt (in cases of doubt the most beneficial interpretation is to be preferred)[202] suggests the same result: with reference to the case study of the boy and his microscope it should be clear that the restrictive interpretation which allows the boy to conduct his experiments is the most beneficial interpretation of section 56(1). The court states it clearly in *Rossouw v Sachs*:[203]

> If a statute is couched in ambiguous language, the court will give it the meaning which least interferes with the liberty of the individual.

4.1.3 Conclusion

It is therefore submitted that the presumption that statute law is not unjust, inequitable and unreasonable clearly favours the restrictive interpretation of section 56(1), namely that outside the sphere of use for medical or dental purposes

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[201] *R v Milne and Erleigh* (7) 1951 (1) SA 791 (A) 823; *R v Sachs* 1953 (1) SA 392 (A) 399; *R v Sisilane* 1959 (2) SA 448 (A) 454; *S v Fazzie* 1964 (4) SA 673 (A) 680; *S v Stessen* 1965 (4) SA 131 (T) 134; *SA Breweries Ltd v Food and Allied Workers Union* 1990 (1) SA 92 (A) 97, 100; *S v Martinez* 1991 (4) SA 741 (Nm) 752–753; *Hira v Booysen* 1992 (4) SA 69 (A) 78, 81, 83.

[202] *Principal Immigration Officer v Bhula* 1931 AD 323 at 336–337; *Arenstein v Secretary of Justice* 1970 (4) SA 273 (T) 281A–D; *Cornelissen v Universal Caravan Sales (Pty) Ltd* 1971 (3) SA 158 (A) 175C; *Du Plessis v Skrywer* 1980 (2) SA 52 (SWA) 59D–G; *Sigaba v Minister of Defence and Police* 1980 (3) SA 535 (Tk) 541H; *Tshwete v Minister of Home Affairs (RSA)* 1988 (4) SA 586 (A) 612F–G; *SA Geneeskundige en Tandheelkundige Raad v Strauss* 1991 (3) SA 203 (A) 214H–J.

[203] *Rossouw v Sachs* 1964 (2) SA 551 (A). Cf *R v Sachs* supra note 201; *United Democratic Front v Acting Chief Magistrate, Johannesburg* 1987 (1) SA 405 (W); *Nkwentsha v Minister of Law and Order* 1988 (3) SA 99 (A); *S v Genu* 1988 (3) SA 974 (W); *Government of the Republic of Bophuthatswana v Segale* 1990 (1) SA 434 (BA); *Minister van Justisie v Hofmeyr* 1993 (3) SA 131 (A).

the use of gametes that removed from a person is *not* prohibited, in contrast with the extensive interpretation that prohibits all uses of gametes that are removed from a person, such as the boy's experiments in our case study.

4.2 The presumption that the legislature does not intend to alter the existing law more than necessary

Let us now consider the applicability of the presumption that the legislature does not intend to alter the existing law more than necessary. The purpose of this presumption is to enhance legal certainty[204] and has been described as the 'most fundamental of all the presumptions'.[205] The existing law, namely the HTA, is quite clearly aligned with the extensive interpretation of section 56(1) and could therefore be used to argue for such interpretation. Such an argument would however be critically flawed, as the NHA intends to *repeal* the HTA. The nature of the presumption, insofar as it relates to statute law which is the current case, was explained as follows in *Kent NO v South African Railways and Harbours*:[206]

> [I]t is necessary to bear in mind a well-known principle of statutory interpretation, viz, that statutes must be read together and the later one must not be so construed as to *repeal* the provision of an earlier one, or to take away rights conferred by an earlier one unless the later statute expressly alters the provisions of the earlier one in that respect or such alteration is a necessary inference from the terms of the later statute. The inference must be a necessary one and not merely a possible one. [My emphasis]

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[204] *Hlatswayo v Hein* 1999 (2) SA 834 (LCC) 840.

[205] G E Devenish *Interpretation of Statutes* (1992) 159; *Makholiso & others v Makholiso & others* 1997 (4) SA 509 (Tk) 516; *Commissioner of Taxes v First Merchant Bank of Zimbabwe Ltd* 1998 (1) SA 27 (ZS) 30.

[206] *Kent NO v South African Railways and Harbours & another* 1946 AD 398 at 405. Cf *Chotabhai v Union Government (Minister of Justice) and Registrar of Asiatics* 1911 AD 13 at 24; *New Modderfontein Gold Mining Co v Transvaal Provincial Administration* 1919 AD 367 at 400; *Durban Corporation v R* 1946 NPD 109 at 115; *Harris v Minister of the Interior* 1952 (2) SA 428 (A) 459; *R v Tucker* 1953 (3) SA 150 (A) 162; *R v Vos*, *R v Weller* 1961 (2) SA 743 (A) 749; *Wendywood Development (Pty) Ltd v Rieger* 1971 (3) SA 28 (A) 38.

This is not a case where statutes can be 'read together': Once Chapter 8 of the NHA, which includes section 56(1), comes into force, the HTA will simply cease to be law; the HTA can therefore not be 'existing law' for the purposes of the presumption that the legislature does not intend to alter the existing law more than necessary, rendering this presumption not applicable to the interpretation of section 56(1).

Prefacing my subsequent human rights analysis of section 56(1), a reference to Du Plessis's submission regarding the present presumption might be noteworthy: Du Plessis opines that, under the Constitution, the 'necessary' element of the presumption has become a concept different to what it used to be – that 'necessary' has now acquired a meaning equivalent to 'required to be in line with the Constitution'. This interpretation of the necessary element of the presumption therefore creates the opportunity to use this common law artefact to promote the values of the Constitution and prevents it from impeding the advance of these values by entrenching existing (probably pre-constitutional) law. Du Plessis states his position as follows: [207]

> [I]f the maximisation of the [existing] law through statutory interpretation comes to a result at odds with the Constitution, there can be no question: it is *necessary* to interpret the statute in a manner altering the [existing] law. . . [W]hen a statute dealing with the exercise of public power is construed, it is *necessary* that the [existing] law does not enjoy any possible 'advantage' that the conventional presumption could afford it.

Anticipating the conclusion of the subsequent human rights analysis that the extensive interpretation of section 56(1) of the NHA and its equivalent in section 19 of the HTA are unconstitutional, it is therefore according to Du Plessis *necessary* to interpret section 56(1) in a manner altering the previous position as per the HTA; moreover, since section 56(1) deals with the exercise of public power, it is *necessary* that the hypothetical existing law (which does not even exist in the present case, as it will be repealed) does not enjoy any possible advantage that the conventional presumption could afford it.

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[207] Du Plessis op cit note 189 at 181.

4.3 Conclusion on the presumptions

In the analysis of common law presumptions I have considered two presumptions that ex facie seemed to be relevant:

- The presumption that statute law is not unjust, inequitable and unreasonable clearly indicated the restrictive interpretation of section 56(1).
- The presumption that the legislature does not intend to alter the existing law more than necessary was indicated to be not relevant since it requires existing law, which will be repealed in the present case.

It must therefore be concluded that the common law presumptions of interpretation determine that the restrictive interpretation of section 56(1) – namely that outside the sphere of use for medical or dental purposes the use of gametes that are removed from a person is *not* prohibited – must be adopted.

5 The human rights dimensions

What are the human rights dimensions of the ban on the use of gametes for non-medical, non-sexual-intercourse purposes as per section 19 of the HTA and its equivalent in the extensive interpretation of section 56(1) of the NHA (the 'gamete-use ban')? In the following, I argue that the gamete-use ban infringes on at least one constitutionally guaranteed right, namely privacy,[208] and that such infringement is not justifiable in terms of the limitation clause[209]; the restrictive interpretation, in contrast, does not constitute any such infringement.

5.1 Interpreting privacy

South African case law has interpreted the right to privacy as admitting to degrees of protection depending on proximity of the relevant interest to the personal sphere in contrast with the communal sphere, and as largely instrumental in achieving further values – primarily human dignity. A comprehensive basis for this

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[208] The Constitution s 14.

[209] The Constitution s 36.

interpretation was laid in *Bernstein v Bester*.[210] Ackermann J, for the majority of the Constitutional Court, defined the scope of privacy to those aspects in regard to which a 'legitimate expectation of privacy' can be harboured. This 'legitimate expectation of privacy' consists of both a subjective expectation of privacy as well as an objectively reasonableness component.[211] A useful 'tool' to ascertain the reasonableness is the 'continuum of privacy interests' [212] that has been explained in *Bernstein* as follows:[213]

> Privacy is acknowledged in the truly personal realm, but as a person moves into communal relations and activities such as business and social interaction, the scope of personal space shrinks accordingly.

The continuum-of-privacy-interests doctrine therefore establishes a direct correlation between the proximity of an interest to the personal sphere and the degree of protection it will be afforded under the right to privacy.

As Currie and De Waal point out, the continuum-of-privacy-interests doctrine does not completely flesh out the concept of reasonableness and that the concept of reasonableness needs to be linked to other values to measure it against.[214] On this conception, the protection of privacy does not have intrinsic value, but serves an instrumental function in promoting these other values that are the measure of reasonableness.[215] In *Bernstein*, this end-value is articulated as 'one's own autonomous identity'.[216] In the subsequent case of *Hyundai Motor Manufacturers* 'autonomous identity' is substituted for the more conventional value of 'human

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[210] *Bernstein* supra note 48.

[211] Ibid para 75.

[212] The phrase was coined by Sachs J in *Mistry v Interim National Medical and Dental Council of South Africa* 1998 (4) SA 1127 (CC) para 27.

[213] *Bernstein* supra note 48 para 67.

[214] Iain Currie & Johan de Waal. *The Human Rights Handbook* 5th ed (2005) 318.

[215] Ibid 319.

[216] *Bernstein* supra note 48 para 65.

dignity'.[217] The two concepts 'identity' and 'human dignity' are of course very closely linked: The German Constitutional Court has in its interpretation of the meaning of human dignity specifically included 'own identity' as a constituent element.[218] The concept substitution of 'autonomous identity' with 'human dignity' qua end-value in *Hyundai Motor Manufacturers* must therefore be seen as substance broadening of privacy's end-value rather than substance substitution: 'human dignity' includes the original concept 'autonomous identity' qua constituent element.

Human dignity qua end-value of privacy requires more attention: I suggest that another constituent element of human dignity, namely autonomy,[219] is of particular relevance to the current analysis. Qua element of human dignity, autonomy can serve as a specific measure of the reasonableness of a subjective expectation of privacy, and hence the legitimacy of the privacy expectation. A direct conceptual nexus between privacy and autonomy was established by the Constitutional Court in *NM v Smith*:[220] Madala J, for the majority observes that 'Privacy encompasses the right of a person to live his or her life as he or she pleases',[221] and also that 'the nature and the scope of the right envisage a concept of the right to be left alone.' [222]

Beyond South African case law, other values than human dignity have also been suggested as end-values of privacy. The conception of privacy as an instrumental

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[217] *Investigating Directorate: Serious Economic Offences v Hyundai Motor Distributors (Pty) Ltd: In re Hyundai Motor Distributors (Pty) Ltd v Smit NO* 2001 (1) SA 545 (CC) para 18.

[218] Katz *Staatsrecht: Grundkurs im Offentlichen Recht* (1991) at 308 cited in Lourens M du Plessis & Jacques R de Ville 'Personal rights: life, freedom and security of the person, privacy and freedom of movement' in Dawid H van Wyk et al *Rights and Constitutionalism: The New South African Legal Order* (1994) 212.

[219] Refer to Chap 2: Human dignity supra.

[220] *NM v Smith* supra note 70.

[221] Ibid para 33.

[222] Ibid para 32.

right that serves other end-values is common in international jurisprudence. Edmundson identifies several such end-values, inter alia: inquiry; learning, creativity and relaxation; personhood and moral ownership of one's body.[223]

I now apply the theory to the case study of the boy and his microscope: I submit that the boy's interest in conducting his experiments is located very proximate to the core of the personal sphere on the continuum of privacy interests. In general, what one studies under one's own microscope in the privacy of one's own home should fall squarely within the protection of privacy. The fact that the object of the study is the boy's own sperm makes the case for privacy protection even stronger. The personal nature of any male's sperm to himself – and the possible extrinsic value that he may allocate to it[224] – should be apparent and is in my observation widely acknowledged in our society:

- Sperm become distinct from the body through – and are therefore associated with – the very intimate act of sex.
- Sperm are the designated carriers of one's genetic heritage.
- Sperm represent the means to building a family of one's own.

Sex, one's genetic heritage, and one's family are all deeply personal matters. The use of one's sperm is certainly a personal matter – certainly within the 'inner sanctum of a person', to cite Ackermann J in *Bernstein*.[225]

When privacy is approached as an instrumental right, I submit that the boy's interest in conducting his experiments is intimately linked with human dignity qua end-value of privacy: the experiments are an expression of curiosity, exploration and discovery, hence contributing to the development of an autonomous identity; moreover, the experiments are an expression of autonomy that contributes to self-

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[223] William A Edmundson 'Privacy' in M P Golding & W A Edmundson (eds) *The Blackwell Guide to the Philosophy of Law and Legal Theory* (2004).

[224] *Extrinsic* value must be distinguished from *intrinsic* value. In this regard, refer to Chapter 3: Human embryo research, 6.4.1 Intrinsic value supra.

[225] *Bernstein* supra note 48 para 67.

actualisation by answering and feeding the boy's fascination with microscopic life. The boy's actions are therefore strongly dignity-affirming.

When we turn to other possible end-values of privacy, as identified by Edmundson, the case for the boy's interest in conducting his experiments to be afforded privacy protection grows even stronger:

- *Inquiry*. The boy's experiments are certainly not cutting-edge science, but are inquiring par excellence. As such, privacy protection will clearly serve this end-value.
- *Learning, creativity and relaxation*. The boy might well teach himself quite a few things through his observations, such as how long sperm survive outside the human body. By occupying his time in this way – experimenting and learning – the boy will also be forming a habit of self-learning that may further contribute to his development of an autonomous identity.
- *Personhood and moral ownership of one's body*. The boy's experiments with his own sperm are confirmation of his moral ownership of his own body. Also in this case privacy protection will clearly serve this end-value.

I have now analysed the case study of the boy and his microscope from both the continuum-of-privacy-interests perspective and the instrumental perspective and must conclude that the boy's interest in conducting his experiments clearly falls within the ambit of privacy protection. I will now venture to the next step, namely the expanded case study:

Is the inner sanctum compromised when the case study is expanded to include the boy's friends? I submit that it is not. Similarly to family life that can be shared by multiple individuals but still remains private, so can the experiments by the boy and his friends. The fact that they are in the same (private) physical space when conducting the experiments instead of all acting in isolation is secondary to the personal nature of their activity. Sharing in this activity with a common goal may well contribute to fostering the friends' inter-personal relationships and hence touch on another end-value of privacy. The nurturing of human relationships has crystallised in our case law as a prominent aspect of privacy. Ackermann J

articulates it as follows in *National Coalition for Gay and Lesbian Equality v Minister of Justice*:[226]

> Privacy recognised that we all have a right to a sphere of private intimacy and autonomy which allows us to establish and nurture human relationships without interference from the outside community.

The value of establishing and nurturing human relationships has subsequently been used fruitfully by Sachs J and O'Regan J in their minority decision in *S v Jordan.*[227] They posit the establishing and nurturing human relationships as the end-value of privacy protection in the case of sexual relationships and consequently find that the sexual aspect of prostitution that would otherwise qualify as being in the intensely personal sphere, falls 'far away from the inner sanctum of protected privacy rights', since sex for sale in the (impersonal) open market has nothing to do with establishing and nurturing human relationships.[228] The boys in the case study may be sharing in a personal experience, but they are clearly far removed from entering the impersonal sphere of 'strangers in the marketplace' contemplated in *S v Jordan*[229] (which could have been the case had they for instance sold their sperm on the open market). It must therefore be concluded that the inner sanctum of privacy protection is not compromised by the boy in the case study involving some of his friends in his experiments; on the contrary, with the value of establishing and nurturing human relationships that comes into play, arguably incidentally, the argument for privacy protection might even be strengthened.

Given the above analysis, it must be concluded that the boy's (and his friends') interest in conducting his (their) experiments falls within the ambit of privacy protection. Accordingly, the gamete-use ban constitutes an infringement on the right to privacy.

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226 *National Coalition I* supra note 26 para 32.

227 *Jordan* supra note 28 para 82.

228 Ibid para 83.

229 Ibid para 83.

5.2 Limitation

Is it possible to justify the infringement on privacy posed by the gamete-use ban? One reaction can be that the infringement is simply so trivial that the de minimis rule should apply. Alternatively, an argument for limitation can also be based on the purpose of bringing South Africa in line with internationally recognised research standards. In the following, these two lines of argument will be analysed:

5.2.1 De minimis?

Is the subject of non-medical, non-sexual-intercourse uses of gametes not a matter so inconsequential that it should just be dismissed as a triviality according to the maxim de minimis non curat lex? I will argue that the application of de minimis is as a matter of principle not appropriate and, moreover, offers anything but a certain outcome in practice.

First, what is at stake here is the *principle* that South Africa is a rechtsstaat; that the law must conform to the values and rights entrenched in the Constitution. If these values and rights – however trivial the particular concrete application or exercise of these values and rights might seem to the observer – are to be limited by law, there must be reasonable justification. If the subject of non-medical, non-sexual-intercourse uses of gametes is swept under the carpet of de minimis, it not only devalue these constitutional values and rights, but create a dangerous precedent: avoid confronting and dealing with constitutional values and rights (such as privacy and its legitimate sphere), but rather opt for apparent expedient solutions (such as categorising an aspect of privacy as trivial and calling upon de minimis). De minimis is not a proper defender of constitutional values and rights.

Although the principle-argument is sufficient to rule out de minimis as a solution to the legal position of non-medical, non-sexual-intercourse uses of gametes, it can in addition also be argued that on a practical level de minimis offers a very uncertain solution. Judging by the case law history, the chance of successfully arguing for the application of the de minimis maxim in the case of statutory offences is slim:

although the maxim has been argued with varying degrees of success in cases dealing with common law crimes,[230] in the case of statutory crimes our courts have been consistently reluctant to apply the maxim.[231] If the case law proves anything, it is that there is a distinct possibility that the state may prosecute for trivialities and likewise that especially the lower courts will pass guilty judgements in such cases.

On a legal comparative note, it has been established as a general rule in American law that the de minimis maxim will not excuse trifling irregularities in complying with statutory requirements.[232] With reference to contemporary Dutch law, Labuschagne has suggested that triviality should only impact on sentencing and not on guilt.[233]

All of the above considered, applying de minimis firstly avoids addressing the principle at stake, and secondly does not offer a sure escape from the criminal law implications of contravening the HTA, or the NHA if the extensive interpretation of section 56(1) be adopted.

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230 Cf: *R v Herbert* (1900) 10 CTR 424 (The accused has lifted the complainant's cap from his head and has been charged with assault and found guilty; on appeal the court finds that the matter is indeed 'most trivial' yet does not set aside the court a quo's judgment.); *S v Bester* 1971 (4) SA 28 (T) (The accused, a grown man, slaps an eleven-year-old boy; conviction set aside on appeal based on the application of the de minimis maxim.); *S v Schwartz* 1971 (4) SA 30 (T) (The accused, a man, pushes a woman over; he is convicted of assault after the court rejects the application of the de minimis rule.); *S v Tshabalala* 2002 (1) SACR 605 (W) (Theft of goods to the value of R59,66 is not de minimis.)

231 Cf: *S v Arenstein* 1964 (1) SA 361 (A); *S v McChezney* 1967 (2) SA 382 (N); *S v Makwasie* 1970 (2) SA 128 (T); *S v Shangase* 1972 (2) SA 410 (N); *S v Van Wyk* 1974 (1) SA 36 (A); *De Reuck v Director of Public Prosecutions, Witwatersrand Local Division* 2003 (1) SACR 448 (W); *Director of Public Prosecutions, Eastern Cape v Klue* 2003 (1) SACR 389 (E).

232 Annotation to *Kane v Porter* 44 ALR 165 (Colorado Supreme Court 1925) 168. Cf *Montgomery Light and Traction Co v Avant* 3 ALR 384 (Alabama Supreme Court 1918); *Knoke v Swan* 97 ALR 841 (California Supreme Court 1935).

233 J M T Labuschagne 'De minimis non curat lex' (1973) *Acta Juridica* 291 at 304.

5.2.2 Internationally recognised standards of research

As mentioned in the previous chapter on embryo research, the Preamble of the NHA states that the purpose of the NHA is, inter alia, to 'establish a health system based on . . . internationally recognised standards of research and a spirit of enquiry . . . which encourages participation'. As with the subject of embryo research, an analogous argument can potentially be formulated in the current context, namely that the purpose of the limitation of the right to privacy is to bring the South African regulation of the use of gametes in line with internationally recognised standards of research. Although less spectacular that in the case of embryo research, in the current case of the use of gametes the argument's premise that the limitation is in fact in line with 'internationally recognised standards of research', is also false: First, on the echelon of international law, the relevant legal instrument, the Universal Declaration on Bioethics and Human Rights, does not even mention gametes; second, on the echelon of foreign law, a reading of the comparative legislation of four comparative foreign jurisdictions gives a mixed result, further indicating the lack of any international standard:

- The UK Human Fertilisation and Embryology Act does not regulate the use of gametes in general. Only specific uses of gametes, namely cryopreservation (storage), mixing with animal gametes, and fertility treatment are regulated.[234]
- The Dutch Embryo Act prohibits all uses of gametes for purposes other than the purposes specifically enumerated in the act.
- The Belgian Act regarding research on embryos in vitro has no general provision on the use of gametes – it only prohibits commercial use of gametes and specifically regulates the use of gametes to create embryos.

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[234] Ian Kennedy & Andrew Grubb, *Medical Law* 3rd ed (2000) 1224, 1246. Cf Margaret Foster Riley & Richard A Merrill 'Regulating reproductive genetics: a review of American bioethics commissions and comparison to the British Human Fertilisation and Embryology Authority' (2005) 6 *Colum Sci Tech L Rev* 1 available at *http://www.stlr.org/html/volume6/riley.pdf*.

The omission in international law and the divergence in foreign law render it impossible to conceive of internationally recognised standards regarding the use of gametes. The reference to internationally recognised standards in the Preamble is not superfluous in the context of the NHA as a whole: there are certainly internationally recognised standards regarding other important aspects with which the NHA deals, such as human reproductive cloning, which is beyond the scope of this thesis. But in the case of the use of gametes, the purpose of attaining internationally recognised standards of research is evidently meaningless and hence not applicable.

In the context of the use of gametes, the 'internationally recognised standards of research' argument can also be refuted with a semantic analysis centring on the difference between 'research' and 'use'. Although the two concepts overlap, 'research' is clearly a species of the genus 'use' and not vice versa; 'research' is therefore a specific kind of 'use', while the generic 'use' includes 'research', but also has a wider meaning and can include other conceivable 'uses' in the context of gametes, such as the creation of embryos for reproductive purposes. Seen against this background, the purpose of attaining internationally recognised standards of *research* has a far narrower, more specific ambit than the limitation imposed by the gamete-use ban. The causal connection between the limitation and its purpose is therefore insufficient, as the limitation is significantly wider than its purpose. The limitation imposed by the gamete-use ban therefore fails the test of the Bill of Rights' limitation clause; the limitation on privacy imposed by the gamete-use ban cannot be justified.

5.2.3 Conclusion on limitation

There is clearly no reasonable justification for the gamete-use ban. Similar to the subject of embryo research that is analysed in the previous chapter, I suggest that society's sense of propriety is the actual reason behind the limitation. But as I conclude in the previous chapter, a certain moral position that is not based on constitutional values – even if it supported by a majority in society – cannot justify the limitation of constitutional rights. Analogous to the paradoxes that I highlight in

the previous chapter, consider the following: The enforcement of any moral position that objects to the use of sperm as per the case study of the boy and his microscope would be absurdly inconsistent in a society that tolerates – and in mainstream youth culture celebrates – the destruction of gargantuan numbers of sperm for pure recreational sex. Also, to the degree that a male ejaculation per se is experienced as a medium to the sexual satisfaction of the parties involved, and not only a side-product of sex, such *use* of gametes is allowed for the private purpose of recreational sex – why not for the private purpose of studying it under a microscope?

I will conclude my analysis of the limitation of privacy by paraphrasing the Constitutional Court's memorable dictum on privacy in *Case v Minister of Safety and Security*:[235] What I may choose to do with my own sperm in the privacy of my home is nobody's business but mine.

5.3 Conclusion on the human rights dimensions

Insofar as it prohibits the use of gametes for non-medical, non-sexual-intercourse purposes, section 19 of the HTA is unconstitutional and invalid. The same would apply to its equivalent according to the extensive interpretation of section 56(1) of the NHA.

A section 56(1) interpretation redux is appropriate at this stage: Section 39(2) of the Constitution places a general duty on the court to promote the spirit, purport and objects of the Bill of Rights when interpreting any legislation. This duty is valid, irrespective of whether any of the parties to the litigation raised or relied on any section of the Bill.[236] De Ville suggests that the constitutional era has supplemented the nomenclature of common law presumptions of interpretation with a new

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[235] 'What erotic material I may choose to keep within the privacy of my home, and only for my personal use there, is nobody's business but mine.' *Case v Minister of Safety and Security* 1996 (3) SA 617 (CC) para 91.

[236] *Batchelor v Gabie* [1999] 2 All SA 65 (C).

presumption of interpretation: the presumption that a statute is constitutional.[237] Accordingly, section 56(1) of the NHA must be constructed as per the restrictive interpretation, namely that outside the sphere of medical and dental research, the use of gametes is *not* prohibited.

6 Conclusion: a spirit of enquiry

A last note on the interpretation of section 56(1): The NHA's stated purpose of attaining a spirit of enquiry clearly provides a powerful argument in favour of the restrictive interpretation: A spirit of enquiry, as embodied by the boy and his microscope in our case study, would be *actively countered* by the extensive interpretation. Although the restrictive interpretation is not the polar opposite of the extensive interpretation in the sense that it will actively promote a spirit of enquiry, it will at least passively allow it and is hence more proximate to the NHA's purpose of attaining a spirit of enquiry and therefore the preferable interpretation.

However, as the law regarding the use of gametes currently stands in the HTA, the scales tip against freedom in favour of suppression. As illustrated by the case study of the boy and his microscope, freedom is the essential enabler of a spirit of enquiry, which in turn is the very key to scientific discovery and ultimately the improvement of the human condition. If we are a humane society – a society that strives towards the improvement of the human condition – we should guard freedom and award the spirit of enquiry.

7 Recommendation

To give expression to the conclusions of this chapter and avoid any legal uncertainty, section 56(1) of the NHA should be amended to clearly reflect the restrictive interpretation. Furthermore, if the HTA is not going to be repealed very soon, its section 19 should be amended to reflect the restrictive interpretation of section 56(1) of the NHA.

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[237] De Ville op cit note 187 at 223.

Chapter 5[*]

Autologous stem cell therapy

1 Introduction

Although we all hope that newly developed therapies will prove to be miracle cures, many newly developed 'therapies' that enter clinical trials turn out to have limited efficacy, or worse, turn out to be unsafe and are therefore never released to the public at large.[238] This underscores the strong public policy rationale for regulating the introduction of new medicines in order to protect the general public. However, as biomedical science progresses, our regulatory frameworks are confronted with new medicines that are sometimes strikingly different from the medicines that we have known in the past, and that may even fall outside the defined ambit of the existing regulatory frameworks. Cutting-edge biomedical science may therefore often seem to be teetering on the edge of the regulated flat world, just inches from plunging into the unregulated abyss. A case in point, that will be the subject of this chapter, is autologous stem cell therapy ('ASC therapy').

Stem cells are cells that have the ability to *renew* themselves through numerous cycles of cell division, and *differentiate* into specialised cell types.[239] All the various

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[*] The content of this chapter is based on: Donrich W Jordaan 'Autologous stem cell therapy: an analysis of the South African regulatory regime' (2012) 28 *S Afr J Hum Right* 31; Donrich W Jordaan 'Regulatory crackdown on stem cell therapy: what would the position be in South Africa?' (2012) 102 *S Afr Med J* 226.

[238] Joseph DiMasi 'Risks in new drug development: approval success rates for investigational drugs' (2001) 69 *Clin Pharmacol Ther* 297.

[239] Cf: National Institutes of Health *Stem Cell Basics: Introduction* (2009) available at *http://stemcells.nih.gov/info/basics/basics1.asp*; California Institute for Regenerative Medicine *Stem Cell Definitions* (2009) available at *http://www.cirm.ca.gov/StemCellBasics_Definitions*; Biology Online *Stem Cell – Definition* (2008) available at *http://www.biology-online.org/dictionary/Stem_cells*. *Oxford Dictionaries Online* op cit note 39 defines 'stem cell' as 'an undifferentiated cell of a multicellular organism which is capable of giving rise to indefinitely

kinds of human tissue can track their origin to stem cells. Many biomedical researchers therefore believe that the use of stem cells in therapy can revolutionise the practice of medicine by regenerating damaged or sick human tissue.[240] Research in this field is, however, still in its infancy.[241]

Because stem cells are alive, they can be perceived as having more in common with blood transfusions and organ and tissue transplants than with conventional medicine such as the oral medications that are typically dispensed by a pharmacist. This raises the question of whether stem cell therapy can be regulated as medicine. The complexity of the question is increased if the stem cell therapy uses the

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more cells of the same type, and from which certain other kinds of cell arise by differentiation.' Note that stem cells admit of various types with different characteristics, such as embryonic stem cells and adult stem cells. These types of stem cells will be discussed further in Chap 6: Private stem cell banking, 3.2.1 Simplification of authorisation infra.

[240] M Mimeault, R Hauke & S K Batra 'Stem cells: a revolution in therapeutics – recent advances in stem cell biology and their therapeutic applications in regenerative medicine and cancer therapies' (2007) 82 *Clin Pharmacol Ther* 252 ('Basic and clinical research accomplished during the last few years on embryonic, fetal, amniotic, umbilical cord blood, and adult stem cells has constituted a revolution in regenerative medicine and cancer therapies by providing the possibility of generating multiple therapeutically useful cell types.'); regarding heart repair: Noel Caplice & Bernard Gersh 'Stem cells to repair the heart: a clinical perspective' (2003) 92 *Circ Res* 6 ('...the revolutionary potential of myocardial regeneration...'); Donald Orlic, Jonathan Hill & Andrew Arai 'Stem cells for myocardial regeneration' (2002) 91 *Circ Res* 1092 ('...we are about to enter a revolutionary period in stem cell biology and regenerative medicine.').

[241] *California Family Bioethics Council v California Institute for Regenerative Medicine & others* 55 Cal Rptr 3d 272 (California Court of Appeal, 1st Appellate Dist, 3rd Div 2007) 287 ('Research into stem cell therapy is in its infancy. As the understanding of the biology and biochemistry of stem cells expands it is to be expected that research will draw upon and overlap with studies in related fields of medicine, science, and technology.'); cf: Rosario Isasi & Thu Minh Nguyen 'The rationale for a registry of clinical trials involving human stem cell therapies' (2008) 16 *Health Law Rev* 56 at 56; Abdallah Daar & Lorraine Sheremeta 'The science of stem cells: some implications for law and policy' (2002) 11 *Health Law Rev* 5 at 9 ('The science of stem cells, while at a very early stage, is developing rapidly and creating enormous challenges for ethicists and policy-makers.').

patient's own stem cells – id est if the stem cell therapy is *autologous*. While autology has the medical benefit of ensuring perfect compatibility, it also adds the issues of a) patient-specific, individualised therapy in contrast with mass-produced conventional medicine, and b) the human rights dimension of control over one's own body parts that are used in one's own therapy.

This chapter explores the regulatory ramifications of the unique characteristics of ASC therapy – do these characteristics push ASC therapy over the edge of the regulated landscape into the unregulated abyss?

2 A closer look at autologous stem cell therapy

In order to aid the reader's comprehension of the legal analysis of ASC therapy that follows, I briefly sketch some essential context, focusing on the process of ASC therapy and role players involved in ASC therapy.

I suggest that the process of ASC therapy can be structured in the following five steps:

- *Prescription*. The process of ASC therapy commences with a prescription by a medical practitioner.
- *Harvesting*. Tissue containing stem cells, such as bone marrow or peripheral blood is removed (harvested) from the patient. Umbilical cord blood is also a source of stem cells, but is of course only available if the patient's umbilical cord blood was in fact stored after birth.[242] (The issue of umbilical cord blood banking brings with it its own array of legal issues, which is the subject of the next chapter. As such, the analysis in this chapter excludes umbilical cord blood as source of stem cells, and leaves it over for separate proper analysis in the next chapter.)
- *Preparation*. At its most basic level, this step entails the extraction of stem cells from the harvested tissue. In the case of more complex preparation processes, this may be followed by additional preparation protocols, such as

[242] Refer to Chap 7: Private stem cell banking infra.

culturing the stem cells (cell culture refers to the cultivation of living cells outside the body, typically in specially designed containers and under precisely controlled conditions that allow the cells to grow and multiply) and mixing them with other (therapeutic) substances. The physical output of the preparation step I refer to an 'autologous stem cell preparation' ('ASC preparation').

- *Storage*. In order to avoid repeating the whole cycle from harvesting each time more of the ASC preparation is needed for therapy, stem cells are sometimes cryopreserved for later use. When needed, the cryopreserved stem cells are thawed and can then enter the preparation process.
- *Administering*. Lastly, the ASC preparation is administered to the patient. This is currently typically done through injection, also often referred to as engraftment, transplantation, or – specifically in the present autologous scenario – implantation.

In the future the preparation step is set to become far more sophisticated and will involve intricate bioengineering to grow new tissue and organs in a laboratory from a person's own stem cells in order to guarantee perfect compatibility and availability.[243] Such ASC therapy will therefore not even contain stem cells in the final therapeutic product, as the new tissue or organ will be a collection of differentiated cells *originating* from the stem cells. For purposes of this article, however, the scope of the enquiry will be limited to therapy that administers autologous stem cells per se to a patient.

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[243] Overviews of the potential of stem cells as the biological basis for tissue engineering is given by: Paolo Bianco & Pamela Gehron Robey 'Stem cells in tissue engineering' (2001) 414 *Nature* 118; J Polak & L Hench 'Gene therapy progress and prospects: in tissue engineering' (2005) 12 *Gene Ther* 1725; for some examples of recent progress with stem cell-based tissue engineering in other species: Fraser W H Sutherland et al 'From stem cells to viable autologous semilunar heart valve' (2005) 111 *Circulation* 2783 (sheep heart valve engineered from stem cells); A Ohazama et al 'Stem-cell-based tissue engineering of murine teeth' (2004) 83 *J Dent Res* 518 (mouse teeth engineered from stem cells).

The purpose of the following brief discussion is to familiarise the reader with the role-players in ASC therapy and to explore briefly the possible structure of their legal relationships without evaluating or making a judgement on the ethical desirability of such structures.

The typical role-players involved in ASC therapy would be the patient, his or her medical practitioner, and the laboratory that does the preparation and storage ('the preparation laboratory'). The patient's medical practitioner is the person who must prescribe the relevant ASC therapy, and who is also likely the person who will do the harvesting and the eventual administering of the ASC preparation. However, the driving force behind the introduction and use of a new ASC therapy will likely be the preparation laboratory: Given the high cost associated with the research and development (R&D) of new ASC therapies, the R&D institution that has researched and developed a new ASC therapy – whether it is a private company or a university – will presumably make sure that it patents such new ASC therapy internationally with the view of receiving a return on its R&D investment. Such return can be obtained in several ways, but the most likely route would be to exclusively license the new ASC therapy to an international network of entrepreneurs who each has the required laboratory infrastructure, technical expertise and marketing capacity to successfully commercialise the new ASC therapy in his or her region of the world. The preparation laboratory is therefore likely to be a local South African entrepreneurial venture that has the rights to prepare the relevant ASC preparation in terms of a geographically exclusive licence from a foreign patent-holder. The preparation laboratory qua ASC therapy licensee will have to create awareness of its offering and convince medical practitioners to prescribe it much like other manufacturers of medicines and their sales representatives. The preparation laboratory can also be expected to market its offering to patients and the wider public as potential customers. The scenario of the preparation laboratory being an entrepreneurial commercial entity is of course not a given, but for the reasons given above a likely scenario.

Other scenarios can also be contemplated, such as the new ASC therapy being researched and developed with funds from philanthropic donors and placed in the

public domain, rather than patented. In the alternative, the new ASC therapy can be patented with free licences to prepare the new ASC therapy be given to non-profit organisations acting as preparation laboratories.

In the above, I have endeavoured to familiarise the reader with the context of ASC therapy by exploring the process entailed by ASC therapy, as well as the typical role-players involved in ASC therapy. The stage is now set to lift the curtains on the analysis of in the South African regulatory regime with reference to ASC therapy.

3 The relevant law

The legal framework for the introduction to the South African market of a new medicine is established by the Medicines and Related Substances Control Act[244] ('the Medicines Act'). Given that ASC preparations are derived from a patient's own tissue, the relevant law will also include the HTA and the NHA Chapter 8.

3.1 The Medicines Act

Whether ASC preparations fit into the legal framework of the Medicines Act depends on a two-tier inquiry: Do ASC preparations qualify as 'medicine' in terms of the Medicines Act; and if so, have ASC preparations been called up for registration by a notice in terms of the Medicines Act?

3.1.1 The definition of medicine; the medicine hypothesis

Section 1 of the Medicines Act provides the following definition of 'medicine':

> 'medicine' means any substance or mixture of substances used or purporting to be suitable for use or manufactured or sold for use in -
>
> (a) the diagnosis, treatment, mitigation, modification or prevention of disease, abnormal physical or mental state or the symptoms thereof in man; or
>
> (b) restoring, correcting or modifying any somatic or psychic or organic function in man,
>
> and includes any veterinary medicine;

[244] Act 101 of 1965.

The definition of 'medicine' was the object of a constitutional challenge of being overbroad in *Reitzer Pharmaceuticals v Registrar of Medicines*.[245] It was argued that the definition is overbroad as 'restoring somatic function in man' can be interpreted as including 'water used merely to quench thirst'.[246] The court refused to strike down the definition, but instead ruled that the definition is reasonably capable of a more restricted interpretation that 'does not exceed the limits of any of the entrenched rights' [247] namely 'a substance used for a therapeutic or medicinal purpose'.[248] The words 'therapeutic' and 'medicinal' in the restricted interpretation should, however, not be interpreted according to their ordinary dictionary meanings, as there are several instances in the *Reitzer* judgement where the court makes it clear that it intends these words to have a broader-than-ordinary meaning:

- The court equates 'therapeutic purpose' with the content of paragraph (a) of the definition, which includes concepts that are ordinarily not included in the meaning of therapy, such as prevention and diagnosis.[249] However, the content of paragraph (b) of the definition seems to be less suggestive of a therapeutic purpose:[250]

> I would venture to say that in para (a) of the definition of 'medicine' a so-called 'therapeutic purpose', if one may call it that, comes to the fore. When a substance is used in the diagnosis, treatment, mitigation, modification or prevention of disease, abnormal physical or mental state or the symptoms thereof in man, one can hardly envisage that the substance is being used other than for a therapeutic or medicinal purpose. The words employed in para (a) of the definition all suggest this. In para (b) of the definition of 'medicine' the words employed do not perhaps as strongly suggest a therapeutic or medicinal purpose as those in para (a).

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245 *Reitzer Pharmaceuticals (Pty) Ltd v Registrar of Medicines & another* 1998 (4) SA 660 (T).

246 Ibid at 662.

247 Ibid at 686.

248 Ibid at 688.

249 Ibid at 685.

250 Ibid at 685–6.

The Afrikaans version of the Medicines Act is the authoritative version for purposes of interpretation, as this is the version signed by the State President. While paragraph (b) in English employs the words 'restoring, correcting or modifying', the Afrikaans version uses 'genesing, regstelling of matiging'. 'Genesing' has a distinctly therapeutic connotation that 'restoring' lacks. Accordingly, had the court considered the Afrikaans text, the court would in all probability have perceived paragraph (b) in a similar 'therapeutic purpose' light as paragraph (a).

- With reference to the Medicines Act's original definition of 'medicinal purpose', which has subsequently been deleted, the court finds that it was the intention of the legislature that both treatment (therapy) and prevention be included in the definition of 'medicinal purpose':[251]

> The relevant part of the definition of 'medicinal purpose' provides that it means 'in relation to a scheduled substance, . . . the treatment or prevention of a disease or some other definite curative or therapeutic purpose . . .'.

- As mentioned above, the Afrikaans version of the Medicines Act is the authoritative version for purposes of interpretation. The court notes that although the Afrikaans word 'geneeskundige' has been translated as 'therapeutic' in the English text, 'geneeskundige' has a broader meaning than the ordinary meaning of 'therapeutic':[252]

> The word 'geneeskundige', used in the Afrikaans text on two occasions as a translation of 'therapeutic', is defined by Bosman, Van der Merwe and Hiemstra Bilingual Dictionary as meaning 'medical, medicinal, therapeutic(al)'. 'Geneeskundige' indicates, to my mind, the broader concept of a substance used not only to treat illness and disease, but also to prevent it.

Note the first (and in my view the most appropriate) word with which 'geneeskundige' is translated into English: 'medical', which is defined as

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[251] Ibid at 687.

[252] Ibid at 688.

> 'relating to the science or practice of medicine'.[253] 'Medical' clearly overlaps in meaning with 'therapeutic' and 'medicinal' (in their ordinary meanings), but is also a significantly broader concept. Although the court has focused on 'prevention' that is included in the term 'geneeskundige' – assumedly because of the specific subject matter of the case – the court's use of the term 'geneeskundige' as informative of the meaning of 'therapeutic', effectively expands the meaning of 'therapeutic' for purposes of the court's restrictive interpretation of the definition of 'medicine' to 'medical' – 'relating to the science or practice of medicine'.

The clear purpose of the *Reitzer* interpretation of the definition of 'medicine' is to keep the definition as broad as possible – according to the court 'it is reasonable and justifiable for "medicine" to be defined widely' as its purpose is 'to achieve the widest and most efficient form of regulation and control of medicines in the interests of the public' [254] – while excluding the everyday eating of food ('water used merely to quench thirst') from inclusion in the definition by setting *medical* parameters to the definition. The *Reitzer* judgement accomplishes this purpose not by reformulating or deleting any aspect of the statutory definition of 'medicine', but by establishing a general *threshold criterion* for a substance to qualify as a medicine, namely an actual or purported *medical* use.

The word 'substance' also merits attention. The *Reitzer* judgement does not set out to define it, nor is it defined in the Medicines Act. In order to ascertain the ordinary meaning of 'substance', the following dictionary definitions are informative:[255]

> [A] particular kind of matter with uniform properties: a steel tube coated with a waxy substance [or] an intoxicating, stimulating, or narcotic chemical or drug, especially an illegal one: he was suspended for using a banned substance[256]

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[253] *Oxford Dictionaries Online* op cit note 39. Similar definitions are given by other dictionaries such as: *American Heritage Dictionary* (Undated) available at *http://ahdictionary.com*; *Collins English Dictionary* (Undated) available at *http://www.collinsdictionary.com*.

[254] *Reitzer* supra note 245 at 684.

[255] I only quote the relevant parts of the definitions.

> That which has mass and occupies space; matter [or a] material of a particular kind or constitution.[257]
>
> [T]he tangible matter of which a thing consists [or] a specific type of matter, [especially] a homogeneous material with a definite composition[258]
>
> [T]hat of which a thing consists; physical matter or material: form and substance [or] a species of matter of definite chemical composition: a chalky substance.[259]
>
> [P]hysical material from which something is made or which has discrete existence [or] matter of particular or definite chemical constitution[260]
>
> [T]he physical matter of which a thing consists; material [or] matter of a particular kind or chemical composition.[261]

The following strands of meaning can be identified from the dictionary quotes above:

a) substance as matter in general

b) substance as a specific type of matter

c) substance as matter of a specific chemical composition

ASC preparations would without controversy qualify in strands (a) and (b): ASC preparations are per definition *stem cell-based* and hence matter of a specific type. Strand (c) can however be the seed for an argument that an ASC preparation cannot constitute a substance: It can be argued that the purpose of the Medicines Act is specifically to regulate *inorganic chemical substances* and *not* biological matter such as cells or (organic) molecules, given the language employed by the Medicines Act, such as 'active component' and 'compound' with relation to medicine; and that these words point towards an assumption underlying the Medicines Act that

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256 *Oxford Dictionaries Online* op cit note 39.

257 *American Heritage Dictionary* op cit note 253.

258 *Collins English Dictionary* op cit note 253.

259 *Dictionary.com* (Undated) available at *http://dictionary.reference.com*.

260 *Merriam-Webster Dictionary* (Undated) available at *http://www.merriam-webster.com*.

261 *Webster's New World College Dictionary* (Undated) available at *http://www.yourdictionary.com.*

medicine is of an inorganic chemical nature, as inorganic chemical substances can be compounded and have active components,[262] while these concepts are not common terms in biology. However, the exclusion-of-biological-matter argument is stillborn for at least two reasons:

- In *Reitzer* the court ruled that *Saccharomyces boulardii*, which is a live micro-organism (and hence biological matter, being a complex combination of cells), is medicine. Per implication therefore, 'substance', as part of the definition of medicine, include biological matter.
- The regulatory framework that evolved in terms of the Medicines Act through consecutive versions of regulations and notices published in the *Government Gazette*, categorises medicines in various ways, one of these categories being 'biological medicine'. In principle, therefore, biological matter must be able to qualify as medicine and per implication 'substance' therefore includes biological matter. Biological medicine is the subject of the next subchapter, where it will be discussed in detail.

From the analysis above it must be concluded that 'substance' is not limited to strand-of-meaning (c); and consequently that 'substance' must include either or both strands (a) and (b).

To conclude the analysis of 'substance', it is elucidating to look at the Afrikaans version of the Medicines Act. 'Substance' is the translation of 'stof', which is defined[263] as 'alles wat ruimte beslaan en gewig het'[264] (everything that occupies

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[262] The generally accepted terminology is actually 'active ingredient'. I assume this is what was intended with 'active component'.

[263] I only quote the relevant parts of the definitions. 'Stof' can for instance also mean 'dust', which is clearly not relevant in the current context.

[264] F F Odendal & R H Gouws (eds) *Verklarende Handwoordeboek van die Afrikaanse Taal* 4th ed (2000).

space and has mass)[265] and 'alles wat grootte en gewig het, wat uit iets bestaan'[266] (everything that has size and mass, that consists of something).[267] Accordingly, the only meaning of 'stof' and 'substance' that overlaps, is strand-of-meaning (a) – 'substance as matter in general'.

To conclude this section: Given that an ASC preparation is matter, it constitutes a substance. Furthermore, given that an ASC preparation is a substance that purports to be suitable for therapeutic uses, it prima facie falls within the statutory definition of 'medicine' (the medicine hypothesis). In the following, I will first delve deeper into the nature of ASC preparations qua medicine in more detail, after which I will consider possible arguments *contra* the medicine hypothesis.

3.1.2 Delving deeper into the nature of autologous stem cell preparations; the biological medicine hypothesis

As briefly mentioned above, the regulatory framework that evolved in terms of the Medicines Act provides for various categories of medicine, inter alia 'biological medicines'. Within the Medicines Act's regulatory framework 'biological medicines' is used interchangeably with 'biological medicinal products' and 'biological products'. Using the medicine hypothesis as working hypothesis, and given the organic or biological nature of ASC preparations – in contrast with traditional inorganic medicines – ASC preparations would prima facie fall within this category of 'biological medicines' (the biological medicine hypothesis).

The MCC's *Guidance Document: Good Manufacturing Practice for Medicines in South Africa*[268] defines 'biological medicines' as follows:

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265 My translation.

266 M S B Kritzinger & F J Labuschagne (eds) *Verklarende Afrikaanse Woordeboek* 7th ed (1980).

267 My translation.

268 Published under GN 609 *GG* 24785 of 2 May 2003. Hereafter referred to as '*Good Manufacturing Practice*'.

15.1.1 Biological medicines comprise those *derived or extracted from living* organisms or *tissues* and those which contain living or inactivated organisms in the end product. [My emphasis]

15.1.3 The methods employed in the manufacture of biological medicinal products are a critical factor in shaping the appropriate regulatory control. Biological medicinal products can be defined therefore largely by reference to their method of manufacture. Biological medicinal products prepared by the following methods of manufacture will fall under this chapter.

(a) Microbial cultures, excluding those resulting from r-DNA techniques.

(b) Microbial and *cell cultures*, including those resulting from recombinant DNA or hybridoma techniques. [My emphasis]

(c) *Extraction from biological tissues*. [My emphasis]

(d) Propagation of live agents in embryos or animals.

(Not all aspects of this chapter may necessarily apply to producers in category (a).)

The MCC's *General Information* for human medicines[269] is very similar to the *Good Manufacturing Practice* quoted above, and reads as follows:

2.7.5 Biological medicines: Biopharmaceuticals and Biosimilars

Biological medicine: A medicine where the active ingredient and/or key excipients have been derived from living organisms or tissues, or manufactured using a biological process. Biological medicines can be defined largely by reference to their method of manufacture (the biological process). These include inter alia medicines prepared from the following substrates:

(i) Microbial cultures (fermentation);

(ii) Plant or Animal Cell cultures (including those resulting from recombinant DNA or hybridoma techniques);

(iii) Extraction from biological tissues; and

(iv) Propagation of live agents in embryos or animals.

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[269] Medicines Control Council *Registration of Medicines: General Information* (2011) available at *http://www.mccza.com/genericDocuments/2.01_General_information_Mar11_v7_track_changes.doc*. Hereafter referred to as '*General Information'.*

> The living substrate may be genetically modified in a number of ways to provide the required active ingredient, including recombinant DNA technology or hybridoma techniques**.**
>
> Biological Medicines include, but may not be limited to the following:
>
> (i) Plasma-derived products, e.g. Clotting factors, Immunosera, etc;
>
> (ii) Vaccines;
>
> (iii) Biotechnology-derived medicinal products (rDNA products) e.g. rHu-antihemophilic factors, Hormones, Cytokines, Enzymes, Monoclonal antibodies, erythropoietins;
>
> (iv) Human Gene therapy.

Before proceeding, the meaning of 'tissue' deserves attention. In contrast with the HTA which specifically defines the term, 'tissue' is neither defined in the Medicines Act, which is the primary legislation under which the *Good Manufacturing Practice* has been published, nor in the *Good Manufacturing Practice* or *General Information* documents. As such, the term must be interpreted in its ordinary meaning in the present context. In order to ascertain the ordinary meaning of 'tissue', the following dictionary definitions are instructive:[270]

> [A]ny of the distinct types of material of which animals or plants are made, consisting of specialized cells and their products: inflammation is a reaction of living tissue to infection or injury [and] the organs and tissues of the body[271]
>
> An aggregation of morphologically similar cells and associated intercellular matter acting together to perform one or more specific functions in the body. There are four basic types of tissue: muscle, nerve, epidermal, and connective.[272]
>
> A large mass of similar cells that make up a part of an organism and perform a specific function. The internal organs and connective structures (including bone and cartilage) of vertebrates, and cambium, xylem, and phloem in plants are made up of different types of tissue.[273]

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[270] I only quote the relevant parts of the definitions.

[271] *Oxford Dictionaries Online* op cit note 39.

[272] *American Heritage Dictionary* op cit note 253.

[273] *American Heritage Science Dictionary* (Undated) available at *http://www.thefreedictionary.com*.

> [A] part of an organism consisting of a large number of cells having a similar structure and function[274]
>
> [A]n aggregate of similar cells and cell products forming a definite kind of structural material with a specific function, in a multicellular organism[275]
>
> [A]n aggregate of cells usually of a particular kind together with their intercellular substance that form one of the structural materials of a plant or an animal[276]
>
> An aggregate of cells in an organism that have similar structure and function.[277]
>
> Tissues that work in unison to carry out a specific set of functions form an organ.[278]

What is clear from the above definitions is that tissue does not equate to either cells or organs, but that organs are *made up* of tissues, and that tissue in turn are *made up* of cells.

The ordinary meaning of 'tissue' must be clearly differentiated from the technical meaning ascribed to the term in the HTA:

> 'tissue' means -
>
> (a) any human tissue, including any flesh, bone, organ, gland or body fluid, but excluding any blood or gamete; and
>
> (b) any device or object implanted before the death of any person by a medical practitioner or dentist into the body of such person;

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[274] *Collins English Dictionary* op cit note 253.

[275] *Dictionary.com* op cit note 259.

[276] *Merriam-Webster Dictionary* op cit note 260.

[277] Biology Online *Tissue – Definition* (2008) available at *http://www.biology-online.org/dictionary/Tissue.*

[278] Ibid.

While 'tissue' in the context of the HTA is clearly intended as catch-all term for all human bodily components save blood and gametes – even including medical devices![279] – 'tissue' in its ordinary meaning has a significantly narrower, less encompassing meaning. For the reasons stated above, the current analysis of the MCC's guideline documents will employ the ordinary meaning of 'tissue'.

I now return to the biological medicine hypothesis: The definition of 'biological medicines' in the MCC's guideline documents specifically includes extractions or derivatives *from* tissues, but not tissue per se. The evident inference is therefore that tissue (and organs as combination of tissues) are not included in the definition of 'biological medicines'. On the other hand, cells are components of tissue and can therefore be extracted or derived from tissue; cells are therefore included in the definition of 'biological medicines' – provided, of course, that such cells in the first place qualify as medicine. Therefore, given the medicine hypothesis as working hypothesis, and given that ASC preparations consist of cellular extractions or derivatives from tissue, the biological medicine hypothesis is confirmed: ASC preparations would qualify as biological medicine.

3.1.3 The Transplantation Argument: Autologous stem cell preparations are the objects of transplantation or transfusion, not medicine

The transplantation of various human bodily components, such as organs, tissues, and cells, are well-known medical procedures, as is blood transfusion. A healthy organ, tissue, or cells that are transplanted, or the blood (or blood product) that is transfused, can be perceived as a substance that is used for a medical purpose, hence qualifying as medicine. It should be noted that the Medicines Act provides no explicit exclusion of transplants or transfusions from the definition of medicine. However, it can be argued that the *purpose* of the Medicines Act is not to regulate

[279] It is interesting to note that the inclusion of medical devices was omitted from the definition of 'tissue' in the NHA. The NHA's definition roughly corresponds with part (a) of the HTA's definition, and is as such still intended as a catch-all term for all human bodily components save blood and gametes.

transplants or transfusions, for two reasons: First, these procedures are specifically regulated by another act, namely the HTA (or its anticipated successor, NHA Chapter 8) and, secondly the language of the Medicines Act is inconsistent with the inclusion of these procedures.

I will analyse both of these reasons:

- The argument that transplants and transfusions are specifically regulated by the HTA (or its anticipated successor, NHA Chapter 8) and that transplants are therefore excluded from the ambit of the Medicines Act is weak as the Medicines Act is not contradicted by the HTA (or NHA Chapter 8), but rather provide supplementary layers of rules.[280] It is not uncommon in the world that a therapeutic agent can meet the definitions of several different kinds of regulated substances or acts and hence be subject to several layers of regulation.[281]
- The argument that the choice of words of the Medicines Act indicates that the Medicines Act does not purport to regulate transplants and transfusions, can be formulated as follows: The Medicines Act speaks of the 'administering' of a medicine.[282] Using 'administering' in the context of organ transplants would clearly be linguistically awkward: one does not 'administer' a new heart to a patient. However, the same does not apply across the board to transplants, nor does it apply to transfusion. On the other side of the transplantation spectrum, in the case of the transplantation of cells, such as bone marrow transplants, I submit that it would *not* be linguistically awkward to refer to 'administering new, healthy cells to a patient through injection', or 'administering an ASC preparation to a patient through injection'. The same would apply to blood transfusion, which can be

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[280] Cf *Minister of Police v Haunawa* 1991 (2) SA 542 (Nm).

[281] D G Halme & D A Kessler 'FDA regulation of stem-cell–based therapies' (2006) 355 *N Engl J Med* 1730.

[282] Medicines Act ss 1, 19(2), 22A(10), 22A(16)(c), 22A(17)(b), 22B(1), and 28(1)(b).

> referred to as 'administering blood to a patient intravenously'. While it can therefore be inferred from the language of the Medicines Act that *organ transplants* should fall outside the intended meaning of medicine, the same does not apply to transplantation on the level of cells or to blood transfusion. The language of the Medicines Act is in fact consistent with the inclusion qua medicine of cells that are to be used in transplantation or transfusion. This conclusion is also aligned with my analysis of biological medicines above, where I have found that while organs and tissue are outside the MCC's definitional scope of 'biological medicines', cells that have a medical purpose or use – that qualify as medicine – fall within the MCC's definitional scope of 'biological medicines'.

The argument that the purpose of the Medicines Act is not to regulate transplantation therefore fails with regards to the transplantation of cells. Whether a cellular substance is used in transplantation or not is therefore irrelevant for purposes of determining whether such cellular substance constitutes medicine. From this follows that whether any specific autologous ASC therapy in fact constitutes transplantation, does not impact on the medicine hypothesis.

3.1.4 The Precedent of Non-Regulation Argument: The current non-regulation by the MCC of a certain autologous stem cell therapy sets a precedent for autologous stem cell therapy in general

In response to my analysis of the Transplantation Argument, an argument *contra* the medicine hypothesis can be made by pointing out examples of transplantation of cellular substances that are commonly accepted medical practice and that are in fact *not* regulated by the MCC; and given this fact it can then be argued that these examples of non-regulation set a precedent for cellular substances – such as ASC therapy – in general. The apparent example would be bone marrow transplantation: Bone marrow transplantation can be autologous or allogeneic (provided there is histocompatibility with the patient, of course); in the case of autologous transplantation the patient's bone marrow – or nowadays more commonly his or her peripheral blood – is harvested; stem cells are isolated from

such harvested tissue *ex vivo* and suspended in a medium; the stem cells are cryopreserved until needed; once needed the stem cells are thawed and engrafted in the patient. Bone marrow transplantation is therefore an example of stem cell therapy that entails very elementary preparation, in contrast with others that may entail more sophisticated preparation procedures.

Based on this analogy, an argument can be constructed that, as autologous bone marrow transplants are commonly accepted medical practice, and the stem cells that are used to engraft in patients are not registered qua medicine with the MCC, this sets a precedent that the use of ASC preparations are not regulated qua medicine.

The counterargument would be that the fact that a certain medical practice has become commonly accepted rather points to failure on the side of the statutory regulator, the MCC, and does not change the law. Comparable to the effort to employ commonly accepted medical practice as camouflage to evade regulation in terms of the Medicines Act, legally valid registration of a substance as a food supplement was the camouflage employed in *Treatment Action Campaign v Rath*:[283] The argument was advanced that certain vitamins that were used by the 'Rath respondents' to treat HIV patients cannot be regulated qua medicines as these vitamins have already been registered qua food supplements in terms of another statutory framework. However, the court ruled as follows:[284]

> The Rath respondents aver that VitaCell does not need to be registered as it is currently registered as a "food supplement for distribution and importation into South Africa in terms of the Foodstuffs, Cosmetics and Disinfectants Act 54 of 1972 ("the Foodstuffs Act")". They accordingly contend that the call up notice issued and published by the MCC in 2002 does not apply to VitaCell.
>
> I agree with Mr Budlender that a substance which is a medicine under the Medicines Act is not governed by the Foodstuffs Act. In the light of the fact that I have already found that VitaCell is a medicine within the definition of the Medicines Act, the Rath respondents may not rely on the provisions of the Foodstuffs Act as a basis for their argument that VitaCell is

[283] *Treatment Action Campaign & another v Rath & others* [2008] 4 All SA 360 (C).

[284] Ibid paras 56–57.

> not covered by the provisions of the Medicines Act. The provisions of the Medicines Act apply to VitaCell and not the Foodstuffs Act.

Commonly accepted medical practice – even explicit or tacit approval by health profession councils and ethics committees – can therefore not camouflage a substance that has a medical purpose from regulation by the Medicines Act. The Precedent of Non-Regulation Argument's vulnerability is that its point of reference is practice, and not the law. However, this argument does highlight practical shortcomings in the MCC execution of its regulatory mandate, which should be addressed.

3.1.5 The Autologous Argument: Autologous stem cell preparations are patient-specific and can therefore not be medicine

A possible argument that ASC preparations are not medicine can be based on the autologous nature of ASC preparations: In *Reitzer* the court found that the legislature intended that a particular substance must be used 'relatively widely' for therapeutic purposes and not only on a 'single occasion' in order for the substance to qualify as a medicine in terms of the Medicines Act.[285] Given that ASC preparations will always be patient-specific, it can be argued that the *Reitzer*-criterion of relative wide use is not met by ASC preparations and that they therefore do not qualify as medicine.

The counterargument would be that the subject-matter of the *Reitzer* judgement should be differentiated from ASC therapy: The *Reitzer* judgement specifically dealt with the de facto use of a substance for therapeutic purposes *in the absence of therapeutic claims* made regarding the substance by a person with an interest in such substance. An example would be the belief held by some members of society that Coca-Cola can help for stomach ailments, even though no such therapeutic claims are made by Coca-Cola's manufacturers, distributors, or retailers. According to the *Reitzer*-criterion, should Coca-Cola be 'relatively widely' used for its perceived abdominal healing powers, it will qualify as medicine. In contrast, in the

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[285] *Reitzer* supra note 245 at 682–683.

case of ASC preparations, therapeutic claims are indeed made, which therefore places ASC preparations outside of the ambit of the *Reitzer* enquiry and renders the *Reitzer*-criterion irrelevant for purposes of determining whether ASC preparations qualify as medicine.

3.1.6 Purposive interpretation of the Medicines Act; conclusion on the hypotheses

After considering various arguments contra the medicine hypothesis, I suggest that none of these arguments could succeed in disproving the hypothesis. The final touchstone for accepting the hypothesis is its alignment with the general purpose of the Medicines Act.

The purpose of the Medicines Act is eloquently formulated by the court in *Administrator, Cape v Raats Röntgen and Vermeulen:* [286]

> It would be advisable to pause for reflection lest the wood become obscured by the trees. Manifestly the Act was put on the statute book to protect the citizenry at large. Substances for the treatment of human ailments are as old as mankind itself; so are poisons and quacks. The technological explosion of the twentieth century brought in its wake a flood of pharmaceuticals unknown before and incomprehensive to most. The man in the street – and indeed many medical practitioners – could not cope with the cornucopian outpourings of the world-wide network of inventors and manufacturers of medicines. Moreover, the marvels of advertising, marketing and distribution brought such fruits within the grasp of the general public. Hence an Act designed, as the long title emphasises, to register and control medicines. The enactment created a tightly meshed screening mechanism whereby the public was to be safeguarded: in general any medicine supplied to any person is, first, subject to stringent certification by experts; then it has to be clearly, correctly and comprehensively packaged and labelled and may only be sold by certain classes of persons and with proper explanatory information; to round it out detailed mechanisms for enforcement are created and ancillary measures are authorised.

A shorter version of the above formulation is employed by the court in *Treatment Action Campaign,* namely that the purpose of the Medicines Act is to 'protect the

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[286] *Administrator, Cape v Raats Röntgen and Vermeulen (Pty) Ltd* 1992 (1) SA 245 (A) 254B–E.

public against quackery through assessing and controlling the quality [and] efficacy of ... medicines'.[287]

The fact that ASC therapy per definition makes therapeutic claims is decisive to bring ASC preparations within the definition of medicine in terms of the Medicines Act. Moreover, given the purpose of the Medicines Act, I suggest that the court will feel obliged to include ASC preparations in the definition of medicine *in order to protect the public*. This is illustrated by the court's rationale in *Treatment Action Campaign*:[288]

> The substances are medicines in that the first and second respondents distribute them for use for medicinal purposes. It is therefore necessary to bring them under the ambit of the definition of 'medicines' in order to control and regulate their use. Members of the public, because of statements about their medicinal efficacy, will start using the substances on the basis that, when taken, they will cure or reverse the course of [the relevant medical condition]. The control and regulation of these substances is necessary in order to prevent confusing messages being sent out to the public about the treatment of [the relevant medical condition].

Lastly, I have already concluded that, assuming the correctness of the medicine hypothesis, the biological medicine hypothesis would also be true. As I have now concluded that the medicine hypothesis should indeed be accepted, it follows that the biological medicine hypothesis should similarly be accepted as the correct interpretation of the law.

3.1.7 Are autologous stem cell preparations registrable?

As mentioned earlier, regulation of a substance by the Medicines Act depends on a two-tier inquiry: Does a substance qualify as medicine; and if so, does such substance fall within a category of medicine that has been called up for registration by a notice in terms of the Medicines Act? We have now established that ASC preparations qualify as biological medicine. All 'biological products' have indeed

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[287] *Treatment Action Campaign* supra note 283 para 42.

[288] Ibid para 45.

been called up for registration[289] and are listed as scheduled substances under Category A, Classification 30. As discussed above, the terms 'biological medicine' and 'biological medicinal product' are used interchangeably in the MCC's *Good Manufacturing Practice*. As such, I suggest that 'biological products' is equivalent to these terms. Accordingly, ASC preparations are subject to registration with the MCC.

3.1.8 Conclusion: successful clinical trials would be required for autologous stem cell therapy

The conclusion reached above that ASC preparations qualify qua registrable medicine in the subclass of biological medicine has a simple consequence: Section 14 of the Medicines Act prohibits the *sale* of medicines that are subject to registration but which are not registered. This immediately poses the question of whether the legal transaction between a patient and the preparation laboratory qualifies as *sale*. ASC preparations must per definition be custom prepared using the patient's own stem cells. Given that the patient is therefore providing the essential component of the ASC preparation, the contract between the patient and the preparation laboratory would prima facie constitute locatio conductio operis, and not a contract of sale (emptio venditio) involving a ASC preparation qua object of the sale (merx). This common law distinction could indeed have been a knock-out argument to place ASC preparations outside the ambit of section 14 of the Medicines Act, had it not been that the term 'sale' has been given a definition in the Medicines Act that is decidedly broader than its common law meaning:

> 'sell' means sell by wholesale or retail and includes import, offer, advertise, keep, expose, transmit, consign, convey or deliver for sale or authorize, direct or allow a sale or prepare or possess for purposes of sale, and barter or exchange or supply or dispose of to any person whether for a consideration or otherwise; and 'sale' and 'sold' have corresponding meanings;

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[289] Call-up notice for registration of biological products (GN 2085 *GG* of 21 September 1984).

In *Raats Röntgen and Vermeulen* the court interpreted the definition of 'sell' as follows:[290]

> Notwithstanding the wide ambit of the words and the ostensibly diverse range of acts enumerated, there is an identifiable common denominator characterising the whole. That is some transaction or action of a commercial or quasi-commercial nature related, albeit remotely, to selling – or delivery pursuant thereto – with a view to consumption. That the word 'supply' was not intended to apply – to the administration of an injection by a nurse at the bedside of the hospital or to a mother cajoling her offspring to gulp a proffered spoonful of cough syrup.

I suggest that locatio conductio operis is not merely 'remotely' related to emptio venditio, but very closely related, as the only differentiating element between these two species of contract is whether the source material is provided by the customer (locator/emptor) or not.[291]

In the recent *Treatment Action Campaign* case the court ruled that a donation of medicine falls within the definition of 'sale'.[292] If donatio, which is a unilateral contract – in contrast with emptio venditio and locatio conductio operis that are both bilateral – is judged as sufficiently related to emptio venditio,[293] then locatio conductio operis is highly likely to be judged similarly.

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[290] *Raats Röntgen and Vermeulen* supra note 286 at 258A.

[291] *Tulloch v Marsh* 1910 TPD 453. Cf: *SA Wood Turning Mills v Price Bros* 1962 (4) SA 263 (T); *Stassen v Stofberg* 1973 (3) SA 725 (C); *JK Jackson v Salisbury Family Health Studio* 1974 (2) SA 619 (RAD).

[292] *Treatment Action Campaign* supra note 283 para 51.

[293] Cf *General Finance Co (Pvt) Ltd v Robertson* 1980 (4) SA 122 (ZA) in which the court differentiated emptio venditio from donatio in that if one of the two main obligations of an alleged emptio venditio is missing, the contract is donatio. Id est if a supposedly bilateral contract is in fact unilateral, it must be enforced qua unilateral contract.

An alternative argument on this issue can be formulated based on section 36 of the HTA:

> **36. Exclusive rights in respect of bodies of deceased persons, tissue, blood and gametes**
>
> Any person who acquires the body of a deceased person or any tissue, blood or gamete by virtue of any provision of this Act, shall, subject to any restrictions in terms of this Act or any other law and provided he uses the body, tissue, blood or gamete for the purposes for which it has been donated, handed over or supplied to him, on receipt of that body, tissue, blood or gamete acquire exclusive rights in respect thereof.

It is interesting that the legislature used the words 'exclusive rights' and not 'ownership'. The reason, I assume, was that ownership (dominium) has set components, such as the right to use the thing (res) which is the object of ownership, which would clearly not be consistent with the provisions of the HTA, and that the use of the words 'exclusive rights' was an attempt to avoid this potential contradiction, as the concept 'exclusive rights' does not imply any specific rights that may be in conflict with the provisions of the HTA, but still convey that any real rights in the relevant tissue, which rights can exist within the framework of the HTA, will vest in the legal possessor of such tissue. The legal technical question of whether ownership passes to the possessor is essentially irrelevant, as the 'ownership' that is hypothetically not transferred will only be nominal and without any rights – empty ownership.

What is clear therefore is that once a patient whose tissue has been harvested transfers possession of her or his tissue to the preparation laboratory, she or he ceases to have any rights in such tissue and the preparation laboratory will acquire all relevant rights in the tissue. This means that when the preparation laboratory supplies the patient with an ASC preparation, the patient will not be receiving a res in which she or he already had any *real* rights; the patient only has a *personal* right against the preparation laboratory. This situation clearly approximates more to emptio venditio than to locatio conductio. Again, it must be concluded that the transaction between the patient and the preparation laboratory qualifies as 'sale' per its statutory definition.

Lastly, it should be noted that NHA Chapter 8 does not contain a provision similar to HTA section 36. Under NHA Chapter 8, the contract between the patient and the preparation laboratory would simply constitute locatio conductio operis. As already concluded above with reference to relevant case law, locatio conductio operis is highly likely to qualify as 'sale' in terms of the Medicines Act.

Accordingly, it must be concluded that the prohibition of section 14 of the Medicines Act applies to ASC therapy. The requirement in section 14 that a registrable medicine must be registered with the MCC deserves elaboration: Before registering a new medicine, the MCC requires that the safety, efficacy and quality of such medicine must have been proven through well-constructed clinical trials with the necessary scientific controls.[294] Accordingly an ASC therapy has to successfully pass through the rigorous process of clinical trials before qualifying to be offered to the South African public. This, in my submission, constitutes the core of the regulation of ASC therapy in South Africa. Apart from this core requirement of registration with the MCC that in turn requires successful clinical trials, ASC preparations will of course also have to comply with all other legal rules relating to medicines in general as prescribed in secondary legislation to the Medicines Act[295] and its preparation processes must be benchmarked to the MCC's *Good Manufacturing Practice*.

3.2 The Human Tissue Act

As mentioned in the introduction, ASC preparations contain stem cells that are derived from tissue (in its general meaning), such as bone marrow, fat and peripheral blood, which are harvested from the patient. When analysing the provisions of the HTA, it should therefore be kept in mind that 'tissue' as defined in the HTA excludes blood, and that the HTA often deals separately with 'tissue' and blood. The legal rules established by the HTA that are relevant to ASC therapy can be summarised as follows:

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[294] MCC *General Information* op cit note 269.

[295] Medicines Act s 19.

- Patient consent is required.[296]
- The harvesting of stem cells must serve a medical purpose.[297] In the case of 'tissue' (as defined in the HTA), such medical purpose can include the *production* of a therapeutic, diagnostic or prophylactic substance; in the case of blood, such medical purpose can include the *production* of a blood product. Given that I have concluded that ASC preparations are biological medicine or biological medicinal *products* that are *derived from* tissue (in its general meaning), the HTA's medical purpose requirement is clearly met.
- In the case of stem cells that are derived from 'tissue' (as defined in the HTA):
    - The removal of such 'tissue' from the patient's body must be performed by a medical practitioner or dentist or a person acting under his or her supervision.[298]
    - The preparation laboratory must be designated as an 'authorised institution' by the Minister of Health, as a requirement for acquiring and storing such 'tissue', and preparing and supplying ASC preparations.[299]

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[296] HTA s 18(b).

[297] HTA s 18, s 19.

[298] HTA s 23(a).

[299] HTA s 24. 'Use' in the context of s 24 will include inter alia storage through cryopreservation and the process of preparing ASC preparations: the term 'use' is defined by the HTA s 1 to specifically include 'preserve'; the HTA s 19 provides that 'the production of a therapeutic . . . substance' is one of the '[p]urposes for which tissue . . . may be used'. Also note that 'tissue'-derived ASC preparations as such would also qualify as 'tissue' in terms of the HTA, as it contains 'tissue' as defined by the HTA.

- Similarly, the preparation laboratory must be designated as an 'authorised institution' by the Minister of Health, as a requirement for receiving payment for supplying ASC preparations.[300]

- In the case of stem cells that are derived from blood, regulations must be in place that allow for preparation laboratories to acquire blood from a patient and supply ASC preparations qua 'blood product' to the patient as a requirement for preparation laboratories to receive payment for supplying such ASC preparations.[301] I suggest that the Regulations relating to Blood and Blood Products in principle make provision for such activities.[302] A preparation laboratory will of course have to obtain a licence in terms of these regulations.

3.3 The National Health Act

The position of the NHA relating to ASC therapy generally corresponds with that of the HTA. One welcome development is that the NHA adopts a more uniform approach to both 'tissue' (as defined in the NHA) and blood. For instance, the scope of operations of a designated 'authorised institution' has been expanded in the NHA to include not only the acquisition, use and supply of 'tissue', but also blood and blood products.[303]

The ambiguity inherent in the NHA section 56(1), namely whether the section bans non-medical uses or does not apply to such uses, is irrelevant in the present context as ASC therapy per definition has a medical purpose; accordingly, the ambiguity does not lead to multiple possible interpretative outcomes.

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300 HTA s 28(1)(a).

301 HTA s 28(1)(b).

302 Published under GN 1935 *GG* 12695 of 17 August 1990.

303 NHA s 54(2)(d).

3.4 Conclusion

I have argued that ASC therapy is indeed subject to legal regulation: At its core, the current regulatory regime requires an ASC therapy to pass the rigorous test of clinical trials – success with clinical trials being a precondition for the relevant ASC preparation to qualify to be registered with the MCC; and registration with the MCC in turn being a precondition for prescribing and/or supplying the ASC therapy to a patient. Around this regulatory core there exist various layers of additional regulatory rules pertaining to the harvesting, storage and preparation activities of the ASC therapy process.

4 The human rights dimensions

Are the conclusions reached above aligned with our country's commitment to human rights? In this part of the analysis, I explore a possible human rights challenge to the regulation of ASC therapy. As will be shown, such a challenge is likely to fail.

4.1 Conceiving a human rights challenge

The only ex facie credible line of attack on the current regulation of ASC therapy would be to argue that a person should have the right to use her or his own stem cells in an individualised therapy prepared for her or his own use, based on the right to control over one's own body as enumerated in section 12(2)(b) of the Constitution. This is an argument for a *special exemption* from the general regulation of medicine: While not challenging the general rationale for regulating medicines, this argument aims to *differentiate* ASC preparations from medicines in general based on the *autologous* nature of ASC preparations – the fact that it is produced with the patient's *own tissue* – and allocating special value to this differentiation: A challenger of the current regulation of ASC therapy will accordingly argue that the use of the patient's own tissue qualifies ASC preparations for protection within the ambit of the constitutional right to control one's own body, while other non-autologous medicines do not qualify as such.

The special exemption argument has to overcome three crucial obstacles: first, it must be demonstrated that the use of a patient's own tissue in ASC therapy does in fact fall within the ambit of the constitutional right to control one's own body; secondly, it must be demonstrated that the right to control one's own body is in fact violated (or limited) by the impugned provision, namely the definition of medicine that includes the autologous use of cells derived from human tissue; thirdly it must be demonstrated with reference to the Constitution's limitation clause, section 36, that the limitation of the right to control one's own body by the impugned provision is not justifiable. In the following, I analyse these respective obstacles.

4.2 Does the interest fall within the ambit of the right?

A person may have an *interest* in using her or his own stem cells in an individualised medicine prepared for her or his own use, but does this particular interest fall within the ambit of the *right* to control one's own body? In this hypothetical human rights challenge, it cannot be assumed that the relevant 'medicine' has passed through clinical trials – in fact, given that successful clinical trials is core to the regulatory regime that is being challenged, and given that clinical trials are usually also the most expensive and time-consuming part of new medicine development,[304] a reluctance on behalf of the developer of a new ASC therapy to conduct clinical trials would be the most likely reason to launch a human rights challenge to the current regulatory regime. Therefore, assuming the lack of clinical trials, the question posed earlier should be reformulated as follows: a person may have an *interest* in experimenting with using her or his own tissue to produce a new, unproven 'medicine' for her or his own use, but can such interest enjoy protection under the *right* to control one's own body? The answer to this question is debatable, but in order to allow further analysis of the special exemption argument

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[304] Pharmaceutical Research and Manufacturers of America *Pharmaceutical Industry Profile 2011* (2011) 45 available at *http://www.phrma.org/sites/default/files/159/phrma_profile_2011_final.pdf*.

I assume an affirmative answer. As the further analysis will conclusively show, the answer to this question is ultimately inconsequential, rendering superfluous an in-depth and potentially inconclusive analysis of the ambit of the right to control one's own body in the current context.

At this juncture mention should also be made of section 12(2)(c) of the Constitution, which provides that a person may not be subjected to medical experimentation without his or her informed consent. Depending on one's subjective point of view, the right to control one's own body (section 12(2)(b)) is therefore either enhanced or constrained by the informed consent requirement. In order not to be side-tracked by this potential dichotomy, informed consent will be assumed.

4.3 Is the right limited by the impugned provision?

The next question is whether the right to control one's own body has been limited by the impugned provision (the definition of medicine that includes the autologous use of cells derived from human tissue). Given that the impugned provision causes the autologous use of cells derived from human tissue to be prohibited subject to registration of such cells as a medicine with the MCC, which in turn is subject to clinical trials which are hugely expensive and take years,[305] I suggest that the right to control one's own body has indeed been limited by the impugned provision.

4.4 Can the limitation be justified?

This brings me to the last obstacle, namely the section 36 analysis. I suggest that the state should rightly argue in favour of justifying the limitation that the limitation is based on the important government purpose[306] to protect the public from unsafe and ineffectual 'medicines'; that the limitation is not a blanket prohibition on the use of new medicines, but only requires that such new medicines must first be proven safe and effective prior to being made available for use; and that there are

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[305] Ibid at 10, 12, 45.

[306] Refer to 3.1.6 Purposive interpretation of the Medicines Act; conclusion on the hypotheses supra.

no less restrictive means available to achieve the purpose of protecting the public from unsafe and ineffectual 'medicines'.

In answer to the state's argument, the challenger of the current regulatory regime can argue that this general rationale only holds true when dealing with mass-manufactured medicines, and that the present case deals with a new class of medicine that is produced on an individual basis using the patient's own stem cells as basis. Given this differentiation, the challenger will further argue that the state's interest in protecting the public is not compromised by allowing individual patients to use unproven autologous 'medicines', as the actions of these individual patients only have consequences for themselves. Moreover, allowing individual patients to use unproven autologous 'medicines' allows such individual patients to exercise the right to control their own bodies – essentially using the potential healing power of one's own stem cells in an effort to heal oneself. Accordingly, the challenger's argument concludes that the purpose of protecting the public from unsafe and ineffectual 'medicines' can indeed be achieved through less restrictive means, namely to interpret medicine as excluding the *autologous* medical use of cells derived from human tissue.

A case that is comparable to our present analysis is *Prince v President of the Law Society of the Cape of Good Hope*,[307] in which the constitutionality of the prohibition of cannabis by inter alia the Medicines Act was challenged. It was argued that cannabis is used for religious purposes by Rastafarians and that the general prohibition of cannabis therefore violates various constitutional rights of Rastafarians. The court found that the relevant provisions of the Medicines Act indeed limit certain constitutional rights of Rastafarians, but that such limitations were justified in terms of section 36 of the Constitution and should accordingly be upheld:[308]

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[307] *Prince v President of the Law Society of the Cape of Good Hope & others* 1998 (8) BCLR 976 (C).

[308] Ibid at 988.

> Balancing the right to religious freedom against the evils which the legislature sought to combat through the enactment of [the relevant legislation], applicant's right to practise his religion must, in my judgment, be subordinate to the provisions of the [relevant legislation].

The decision of the court a quo was confirmed by a unanimous Supreme Court of Appeal (SCA)[309] and a majority of the Constitutional Court.[310] The SCA delved deeper into the validity of the special exemption based on freedom of religious practice argument made by the appellant, which is analogous to the special exemption based on the right to control one's body in our current analysis. The SCA states:[311]

> The appellant's case turns entirely on the submission that a general ban on the use and possession of cannabis is unnecessary since the abuse of illegal drugs can be equally effectively suppressed without banning the use of cannabis by Rastafarians for the observance of their religion. This is plainly wrong. Legalizing the use of a forbidden substance by one section of the community for a particular purpose cannot possibly prevent its abuse within that section... And there are other socially harmful consequences, so notorious, that we need not dwell on them. The prevention of drug abuse is plainly a legitimate governmental aim and an effective prohibition thereof a pressing social purpose... It is beyond doubt that the ban on the use and possession of cannabis in both Acts was imposed to protect society as a whole... Lifting it partially to allow its uncontrolled use by one section of the community cannot leave society unaffected and adequately protected.

Analogous to the reasoning of the SCA, to argue for a special exemption for autologous medicine based on the constitutional right to control one's own body, would amount to an argument that harm and exploitation caused by the sale and use of unproven 'medicines' to and by the general public can be equally effectively avoided without regulating the use of unproven *autologous* 'medicines'. Such an argument would be 'plainly wrong' (to paraphrase the SCA), given that allowing the unregulated use of unproven 'medicines' if such 'medicines' are *autologous,* cannot

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309 *Prince v President of the Law Society of the Cape of Good Hope & others* 2000 (3) SA 845 (SCA), hereafter referred to as '*Prince* (SCA)'.

310 *Prince* (CC) supra note 50.

311 *Prince* (SCA) supra note 309 para 12.

possibly prevent harm to and exploitation of those persons who will use their own tissue for producing the unproven autologous 'medicine' with which they wish to experiment. The fact that a medicine is autologous may have various benefits, but it does not establish (in the same way as a clinical trial) the safety, quality and efficacy of the medicine – similarly, Rastafarianism has certain protocols for the use of cannabis, but provides no guarantee against abuse. The purpose of the regulation of medicine is to protect the public as a whole from harm and exploitation caused by the sale and use of unproven 'medicines' – including persons who wish to use their own stem cells in autologous medicine. The special exemption argument in favour of deregulating autologous medicine will accordingly fail the section 36 analysis.

4.5 Concluding remarks on the human rights dimensions

It must be concluded that, even if the special exemption argument in favour of deregulating autologous medicine overcomes the earlier obstacles, it is certain to fail the last one. Moreover, a strong pro-regulatory argument can be made based on human dignity – the 'touchstone' [312] of our country's constitutional political order: The purpose of government's protecting the public from unsafe and ineffectual 'medicines' is in itself clearly promoting the value of human dignity – in particular human dignity qua intrinsic worth of each person; the system of requiring clinical trials in order to prove or disprove the actual safety, quality and efficacy of a new medicine is designed to ensure that the public at large is not degraded to the status of sacrificial objects in arbitrary, unscientific human experiments or hoodwinked into investing financially and emotionally in snake oil.

The conducting of clinical trials of new medicines is a tightly controlled process to limit risk to human subjects – first conducting various safety tests, including tests on animals, prior to introducing the new medicine to human subjects. Clinical trials then proceed cautiously while continuously monitoring the health the human subjects and gradually scaling up. These volunteers who participate in such trials

[312] *Makwanyane* supra note 13 para 329.

give informed consent and – very important – *know* that they are part of a clinical trial process. Being part of a clinical trial process means that one is taking personal risk to contribute to science and ultimately the improvement of the human condition. This is qualitatively different from taking similar risk with experimenting with a new medicine outside the context of a clinical trial. Accordingly, no kind of 'informed consent' can compensate for a departure from the rigorous scientific controls and ethical rules of clinical trials. Lastly, the scientific data produced by clinical trials is an enabler of autonomy – and hence human dignity – by allowing sound, scientifically informed decision-making regarding a person's own health.

I therefore suggest that the current regulatory regime applicable to ASC therapy in South Africa is well aligned with the country's commitment to human rights and accordingly withstands constitutional scrutiny.

4.6 Distinguishing the regulation of ASC therapy from the regulation of embryo research and the use of gametes: hard versus soft paternalism

My conclusion above on the alignment of the regulation of ASC therapy with human rights may ex facie seem discordant with my conclusions in the previous chapters on the regulation of embryo research and the use of gametes: In the previous two chapters I argue that the relevant regulatory rules constitute unjustifiable limitations on human rights, while in the present chapter I argue that the relevant regulatory rules are indeed justifiable. The key to unravelling this apparent paradox lies in the conceptual distinction between 'hard paternalism' and 'soft paternalism':

- Hard paternalism *imposes one particular set of values and judgements* on everybody in a polity and hence violates the autonomy of individual members of the polity.[313]

[313] Joel Feinberg *Harm to Self: Moral Limits of the Criminal Law* (1986) 12–15; Danny Scoccia *In Defense of Hard Paternalism* (Undated) 6–7 available at *http://web.nmsu.edu/~dscoccia/research/defenseofhardpattolaw%26phil.pdf*.

- Soft paternalism, by contrast, is interference on behalf of a person's *own will, preferences, and values*, and hence does not violate such person's autonomy.[314] Soft paternalism is relevant when a person's choices are substantially non-voluntary,[315] or in other words when the person's autonomy (in the sense of *capacity* for self-determination) is substantially compromised. Typical indicia of autonomy compromise would be a lack of relevant knowledge, a lack of control, and undue influence.[316]

An alternative, contractarian distinction between hard and soft paternalism is proposed by Gerald Dworkin, who describes soft paternalism as a 'social insurance policy' to which rational individuals would hypothetically consent (while in a rational frame of mind).[317] This social insurance policy would preserve and enhance autonomy:[318]

> I suggest that we would be most likely to consent to paternalism in those instances in which it preserves and enhances for individuals their ability to rationally consider and carry out their own decisions.

The regulation of embryo research qualifies as hard paternalism: The hyper-regulation of embryo research and the coersice legislation against creating embryos for research are clear attempts to impose *one particular set of values and judgements*, namely the respect-for-the-embryo paradigm, on all in society; this is not a case of acting on behalf of the will and values of a scientist who intends to conduct embryo research – the intention with the regulation of embryo research is clearly not to protect the *scientist* who intends to conduct embryo research, nor for that matter any other person.

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[314] Ibid.

[315] Ibid.

[316] Chin Liew Ten *Chapter Seven: Paternalism – Weak Paternalism* available at http:// *www.victorianweb.org/philosophy/mill/ten/ch7a.html*.

[317] Gerald Dworkin 'Paternalism' in Gerald Dworkin (ed) *Mill's On Liberty: Critical Essays* (1997) 61 at 75.

[318] Gerald Dworkin 'Paternalism' in Rolf E Sartorius (ed) *Paternalism* (1983) 19 at 33.

Similarly, the regulation of the use of gametes qualifies as hard paternalism: As illustrated by the hypothetical case study of the boy and his microscope, it cannot be argued that the ban on the use of gametes for non-medical purposes is an intervention on behalf of the will and values of the boy who studies his own sperm under his microscope; rather, the ban is a textbook example of the imposition of society's sense of propriety on all its members.

In contrast with the subjects of the previous chapters, the regulation of ASC therapy qualifies as *soft* paternalism: Consider the combined effect of the following factors on a patient's autonomy (in the sense of the patient's psychological *capacity* for self-determination):

- *Lack of relevant information*. Absent clinical trials, relevant information about the actual safety, quality and efficacy of a 'medicine' would simply be non-existent.
- *Lack of control*. A patient is in an emotionally vulnerable position: the fact that a patient suffers from an illness may compromise the patient's ability to rationally consider the consequences to her- or himself of taking an unproven 'medicine'.
- *Undue influence*. Therapeutic claims regarding an unproven 'medicine' can unduly influence a person suffering from an ailment to risk taking such 'medicine'. Medical science is a highly specialised field; accordingly, most patients cannot be expected to verify therapeutic claims in authoritative scientific sources.

The purpose of the regulation of ASC therapy is therefore to interfere *on behalf of a patient's own will* for her or his own benefit – to paraphrase Gerald Dworkin, it is a social insurance policy to preserve and enhance a patient's autonomy. Pope encapsulates the position well:[319]

[319] Thaddeus Mason Pope 'Is Public Health Paternalism Really Never Justified? A response to Joel Feinberg' (2005) 30 *Okla City Univ L Rev* 121 at 123.

> The core idea of the soft paternalism liberty limiting principle is that only substantially autonomous decisions, decisions free from cognitive and volitional defects, are worthy of respect. In soft paternalism, there is no usurpation of autonomy because there is none to usurp. You cannot take control away from someone who doesn't have it. Indeed, instead of counteracting autonomy, soft paternalistic regulation actually helps to protect and promote it by ensuring that an individual's choices reflect her true preferences. Prescription drug laws, for example, do not bar access to therapeutic drugs. They just say, 'Hold on! Is your decision to take that drug substantially informed and voluntary?'

While hard paternalism should be opposed, soft paternalism is acceptable in the Millian liberal tradition and – judging from my analyses thus far in this thesis – in the context of the South African human rights regime.

5 Conclusion: this regulatory world is round

At the beginning of this chapter I used the image of a flat world with defined edges as metaphor for the ambit of the regulatory frameworks relevant to new biomedical advances, such as ASC therapy, with the implication that if certain new biomedical advances fall outside the regulatory scope, such advances would find itself tipping off the edge of the metaphorical world and freefalling into the unregulated abyss. However, with reference to ASC therapy in South Africa, it must be concluded that the flat world-metaphor does not hold: there is no unregulated abyss. The South African regulatory framework is both sufficiently comprehensive to encompass ASC therapy, and also solidly in sync with human rights – our country's regulatory world is round, after all.

6 Postscript: rectifying the perception of a regulatory vacuum

Contrary to my conclusion above, a perception has recently been propagated that stem cell therapy finds itself in a regulatory vacuum in South Africa: In a recent article,[320] Pepper highlights the problem of the proliferation of untested 'stem cell therapies' around the world and advocates an ethical stance of protecting the

[320] Michael S Pepper 'Cell-based therapy – navigating troubled waters' (2010) 100 *S Afr Med J* 286.

public from potential abuses in this regard. Any person of conscience must agree with this position. However, Pepper then proceeds to declare a 'legislative vacuum' in South Africa and sketch our country as attractive for companies looking for a slack stem cell therapy regulatory regime. I strongly differ from this opinion of Pepper's. As I have indicated in this chapter, new stem cell therapies would be subject to the same safety, efficacy and quality requirements as any other new medicine. Pepper states:

> Chapter 8 of the National Health Act (the major part of the legislation in South Africa that deals with the issue of cell-based therapy) has not been promulgated. This is a serious hiatus, since we have to rely on the outdated Human Tissue Act of 1983 to provide the necessary legislation.

The reason for Pepper's conclusion that there exists a legislative vacuum in our country is clearly his failure to take cognisance of the Medicines Act, which is in fact the primary legislation that regulates cell-based therapy and all other therapies, and his failure to consider any relevant case law.

The fallacy of a regulatory vacuum was also taken up and perpetuated by the National Biotechnology Advisory Council (NBAC), of which Pepper is a member. In an official position paper NBAC states:[321]

> The NBAC wishes to bring to the attention of the relevant authorities the precarious situation that our country finds itself in by perpetuating an *unregulated environment with regard to stem cells*. [My emphasis]

While Pepper's article focuses on cell-based *therapy*, the NBAC position paper speaks of stem cells in general, which includes stem cell therapy. The NBAC position paper does not attempt any legal analysis of whether stem cell therapy is in fact regulated or not, it simply *states* that it is not. The position paper makes only a single mention of the NHA, and – similar to Pepper's article – no mention of the Medicines Act or any relevant case law.

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[321] National Biotechnology Advisory Committee *Position Statement on Stem Cell Regulations in South Africa* (Undated) available at *http://www.nacinnovation.biz/wp-content/uploads/NBAC-Stem-Cell-Regulatons-Position-Statement.pdf*.

These publications are by high-profile role-players in the South African biotechnology environment and are readily available on the Internet. Accordingly, legal certainty regarding the regulation of ACS therapy is compromised in the eyes of the public. Moreover, given that NBAC is an official government body that gave what purports to be a legal opinion, should any person anywhere in the world acted on the strength of the NBAC opinion to her or his detriment, delictual liability may be arise. Accordingly, I recommend that the Minister of Science and Technology, to which NBAC reports, should as a first step publicly and immediately rectify the perception of a regulatory vacuum.

In conclusion, I can only remark that there is wide consensus that the public must be protected against unethical medical practices. However, making the right legal diagnosis is the essential first step to addressing social ills and averting the potential proliferation of such social ills.

Chapter 6[*]

Private stem cell banking

1 Introduction

In the previous chapter, the subject of analysis was stem cell therapy. A promising source of stem cells for therapy – both autologous and allogeneic – is neonatal blood harvested immediately after birth from the placenta (via the umbilical cord) – commonly referred to as umbilical cord blood. The subject of the present chapter, stem cell banking, is the practice of storing such umbilical cord blood, or storing the stem cells isolated from such blood. Internationally, stem cell banks have elicited much ethical and legal debate.[322] The subject is multi-facetted with specific interesting sub-topics, such as ownership of umbilical-cord-blood-derived stem cells.[323]

[*] The content of this chapter is based on: Donrich W Jordaan, Christopher Woodrow & Michael S Pepper 'Banning private stem cell banks: a human rights analysis' (2009) 1 *S Afr J Hum Right* 126.

[322] George J Annas 'Waste and longing – the legal status of placental-blood banking' (1999) 340 *N Engl J Med* 1521; M Zilberstein, M Feingold & M M Seibel 'Umbilical-cord-blood banking: lessons learned from gamete donation' (1997) 349 *Lancet* 642; G R Burgio, E Gluckman & F Locatelli 'Ethical reappraisal of 15 years of cord-blood transplantation' (2003) 361 *Lancet* 250; J L Ecker & M E Greene 'The case against private umbilical cord blood banking' (2005) 105 *Obstet Gynaecol* 1282; F L Johnson 'Placental blood transplantation and autologous banking – caveat emptor' (1997) 19 *J Pediatr Hematol Oncol* 183; Jennifer Gunning *Umbilical Cord Cell Banking: A Surprisingly Controversial Issue* (2004) available at *http://www.ccels.*cf.*ac.uk/archives/publications/2004/gunningpaper.pdf.*

[323] From one perspective there seems to be support for the fact that such stem cells belong to the child, since they contain the DNA of the baby and not the mother; from another perspective this should belong to the mother, as the placenta is part of the mother's body. Cf: Annas op cit note 322; N Kirby 'Treatment or crime? The status of stem cell therapies and research in South African law' (2007) 26 *Med Law* 95; C Witte 'Cord blood storage: property and liability issues' (2005) 26 *J Leg Med* 275; T McIntire 'Legal issues of stem cell transplantation and the family'

In this chapter, I first provide an overview of the salient aspects of stem cell banking, before analysing the relevant South African law on the subject. With reference to certain draft regulations that were published for public comment in terms of the NHA, I argue that a total *prohibition of private stem cell banking* is a distinct policy option that is within government's contemplation. Accordingly, I analyse the human rights dimensions of such a possible ban, and make appropriate recommendations.

2 A closer look at stem cell banking

2.1 Umbilical cord blood as a source of stem cells

In the previous chapter, I defined stem cells as cells that have the ability to a) *renew* themselves through numerous cycles of cell division, and b) *differentiate* into specialised cell types. For purposes of this chapter, the concept 'stem cells' deserve some further analysis: The earlier in human development the stem cells are harvested, the greater is their capacity to develop into the entire repertoire of cells that constitute the human body. A broad distinction can be made between embryonic stem cells and adult stem cells. Embryonic stem cells, which are derived from an early stage embryo,[324] can develop into every cell type in the body, and

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(2002) 32 *Univ Memphis Law Rev* 3; J D Munzer & F O Smith 'Limited property rights in umbilical cord blood for transplantation and research' (2001) 23 *J Pediatr Hematol Oncol* 203.

In South Africa, the Draft Regulations regarding the Use of Human DNA, RNA, Cultured Cells, Stem Cells, Blastomeres, Polar Bodies, Embryos, Embryonic Tissue and Small Tissue Biopsies for Diagnostic Testing, Health Research and Therapeutics that were published for public comment under GN 7 *GG* 29526 of 5 January 2007, intend to settle the issue of ownership: Regs 9(c) and 10(c) provide that the ownership of umbilical cord blood and the stem cells derived from umbilical cord blood vest in the parents. These draft regulations appear therefore to create parental co-ownership. Ambiguous situations may result from situations in which children are born from rape, for example, or in which the father cannot be identified. This is an area that needs further deliberation.

[324] Stem cells are typically derived from the embryo during the blastocyst stage four to five days after fertilisation.

therefore have the potential to be used for the treatment of many diseases.[325] Embryonic stem cell research is, however, still in its infancy and has to date not produced any success in humans. The first clinical trial using embryonic stem cells for the treatment of patients with spinal cord injury has recently been approved by the United States Food and Drug Administration.[326]

Adult stem cells on the other hand have the capacity to develop essentially into cells of the tissue from which they were derived. Under certain conditions in an experimental setting they may also be induced to differentiate into cells from other tissues.[327] Adult stem cells have been used successfully for several decades in bone marrow transplantation for the treatment of many diseases. Adult stem cells have traditionally been derived from the bone marrow or from peripheral blood (following growth factor mobilisation of bone marrow cells). Umbilical cord blood is a third and rapidly expanding source of adult stem cells.[328] Stem cells from umbilical cord blood today form one of the most commonly banked forms of human tissue. Originally stored for the treatment of haematological disorders, in pre-clinical studies these stem cells have now been found to be more versatile, and have the potential to be used for the treatment of a broader range of diseases.[329]

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[325] Paul J Gokhale & Peter W Andrews 'Human embryonic stem cells: 10 years on' (2009) 89 *Lab Invest* 259.

[326] Nayanah Siva 'US stem cell climate improves raising concerns elsewhere' (2009) 15 *Nature Med* 224.

[327] M R Alison & S Islam 'Attributes of adult stem cells' (2009) 217 *J Pathol* 144.

[328] K Bieback et al 'Critical parameters for the isolation of mesenchymal stem cells from umbilical cord blood' (2004) 22 *Stem Cells* 625; J Kurtzberg 'Update on umbilical cord blood transplantation' (2009) 22 *Curr Opin Pediatr* 21.

[329] R K Burt et al 'Clinical applications of blood-derived and marrow-derived stem cells for nonmalignant diseases' (2008) 299 *J Am Med Assoc* 925.

2.2 The medical uses of stem cells

In the previous chapter, reference was already made to bone marrow transplantation as an example of the transplantation of cellular substances that are commonly accepted medical practice. In fact, bone marrow transplantation is *currently* the only clinically accepted and routinely applied form of *stem cell therapy*, and has been practiced successfully in many countries for several decades. The potential for stem cells to be used in the treatment of a much broader spectrum of diseases is one of the principal factors driving activity in this area, and has led to the emergence of the field of regenerative medicine.[330] For example, clinical trials are underway to assess the use of stem cells for the treatment of heart disease.[331] The most recent (December 2011) worldwide status of clinical trials using umbilical-cord-blood-derived stem cells is presented in Table B.

Table B: Currently active clinical trials using umbilical cord blood to treat different diseases and conditions[332]

Targeted disease/condition	**Status**	**Sponsor**	**ClinicalTrials.gov Identifier**
Hematologic Neoplasms; Bone Marrow Failure Syndromes	Recruiting participants	University of British Columbia, Canada	NCT00897260
Traumatic Brain Injury	Recruiting participants (phase II)	The University of Texas Health Science Center, Houston, USA	NCT01251003
Hematologic Malignancies	Recruiting participants (phase II)	Fred Hutchinson Cancer Research Center, USA	NCT01175785
Inborn Errors of Metabolism	Recruiting participants (phase I)	Duke University, USA	NCT00692926

330 Ibid.

331 V F M Segers & T L Lee 'Stem-cell therapy for cardiac disease' (2008) 451 *Nature* 937.

332 Hamad Ali & Fahd Al-Mulla 'Defining umbilical cord blood stem cells' (2012) 2 *Stem Cell Discov* 15.

Targeted disease/condition	Status	Sponsor	ClinicalTrials.gov Identifier
Cerebral Palsy	Recruiting participants (phase II)	Duke University, USA	NCT01147653
Leukemia Lymphoma Multiple Myeloma Aplastic Anemia	Recruiting participants (phase II)	Tufts Medical Center, USA	NCT00676806
Spinal cord injuries	Recruiting participants (phase II)	China Spinal Cord Injury Network, China	NCT01046786
Hematologic Malignancies	Recruiting participants (phase II)	Memorial Sloan-Kettering Cancer Center, USA	NCT00739141
Hearing Loss	Recruiting participants (phase I)	Memorial Hermann Healthcare System, USA	NCT01343394
Hypoplastic Left Heart Syndrome	Recruiting participants (phase I)	Duke University, USA	NCT01445041
Type 1 Diabetes	Recruiting participants (phase II)	University of Florida, USA	NCT00873925
Myelodysplastic Syndrome (MDS) Severe Aplastic Anemia (SAA)	Recruiting participants (phase II)	National Heart, Lung, and Blood Institute (NHLBI), USA	NCT00604201

2.3 The likelihood of using stem cells

Several studies have attempted to estimate the likelihood of using stem cells for therapeutic purposes. For example, it has been suggested that the cumulative probability of requiring any stem cell therapy (using either one's own (autologous) or someone else's (allogeneic) cells) over a lifetime up to age 70 years is approximately 1:200, while for an autologous stem cell therapy the figure is 1:400.[333] Two studies have addressed the need in humans up to age 20: The

[333] M C Pasquini et al 'The likelihood of hematopoietic stem cell transplantation (HCT) in the United States: implications for umbilical cord blood storage' (2005) 106 *Blood* 1330.

likelihood of needing any stem cell therapy (allogeneic or autologous) in this group was estimated to be from 1:925[334] to 1:1 700[335] while the probability of requiring autologous stem cell therapy is approximately 1:2 700[336] to 1:5 000[337]. These numbers are for *current* medical practices. Several other estimates ranging from 1:20 000 to 1:200 000 have been proposed, but none of these have been substantiated. I suggest that, given the anticipated progress with regenerative medicine technologies, there is a greater need for one's own stem cells in order to avoid the need for lifelong immunosuppressive therapy. For example, since 2005, several children have received transplants of their own umbilical cord blood in an effort to heal brain damage.[338]

However, the above estimates should be viewed with caution. Sullivan[339] for example has questioned the accuracy of these estimates, and this has stimulated debate on the subject.[340] Two additional factors need to be borne in mind: First, in terms of current medical practice, reliable alternative sources of stem cells are available, and include bone marrow and peripheral blood; second, with the advent of new stem cell technologies, the need for autologous stem cells may become obsolete as it may be possible to reprogram differentiated autologous adult cells into stem cells (for example, induced pluripotent stem cells, which have embryonic

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334 Johnson op cit note 322.

335 Pasquini et al op cit note 333.

336 Johnson op cit note 322.

337 Pasquini et al op cit note 333.

338 ClinicalTrials.gov *Cord Blood for Neonatal Hypoxic-ischemic Encephalopathy* (2012) available at *http://clinicaltrials.gov/ct2/show/NCT00593242?term=NCT00593242&rank=1*.

339 M J Sullivan 'Banking on cord blood stem cells' (2008) 8 *Nature Rev Cancer* 555; M J Sullivan 'Banking on cord blood stem cells' (2008) 8 *Nature Rev Cancer* 823 (author reply).

340 J J Nietfeld 'Opinions regarding cord blood use need an update' (2008) 8 *Nature Rev Cancer* 823; D T Harris 'Cord blood stem cells: worth the investment' (2008) 8 *Nature Rev Cancer* 823.

stem cell-like properties).[341] However, much work is still required in this field before firm conclusions can be drawn on their therapeutic potential.

2.4 Stem cell banking: public versus private

Umbilical-cord-blood-derived stem cells are currently stored by both public and private stem cell banks. Public banks store the cells for the benefit of the general public, while private banks store cells for private (personal or family) use. Private stem cell banks are therefore also often referred to as 'family' stem cell banks.[342] Most clients of private banks have a low-risk medical profile, and are motivated to use a private bank's service by the possibility – however remote – that they themselves or their next-of-kin might in the future have a medical need for the stored stem cells.[343] The ethical values associated with public banks are altruism and mutuality; the ethical values underpinning private banks are family obligation and consumer choice.[344]

Contractually, the difference between public and private banks is essentially the difference between donatio versus depositum: in the case of a public bank, umbilical cord blood is donated altruistically and is available for any histocompatible patient who needs an allogeneic transplant, while in the case of a private bank, the bank is paid to store umbilical-cord-blood-derived stem cells for autologous use or

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[341] N Maherali & K Hochedlinger 'Guidelines and techniques for the generation of induced pluripotent stem cells' (2008) 3 *Cell Stem Cell* 595.

[342] P Martin, N Brown & A Turner 'Capitalizing hope: the commercial development of umbilical cord blood stem cell banking' (2008) 27 *New Genet Soc* 127 at 138; 'Parents can also save their child's cord blood by contracting with a private bank to store it for the family. In this case the parents cover the cost of processing the stem cells and maintaining them in storage. We have an international list to help you to find a *family bank* by country. . . . In some countries it is possible to store cord blood in a *family bank* and simultaneously list it on a public registry in case a patient needs it.' My emphasis (Parent's Guide to Cord Blood Foundation *Reasons to Bank Cord Blood* (2012) available at *http://parentsguidecordblood.org*).

[343] Martin, Brown & Turner op cit note 342 at 138.

[344] Ibid at 136.

for use by next-of-kin. Private banks are contractually obliged to return the stored cells on request and at the bank's expense exclusively to their clients (or a contractually determined beneficiary). Private stem cell banks are generally for-profit organisations, but can also be not-for-profit.

Hybrid public-private models exist, the most prominent being the United States Cryobanks International, the Canadian Cord Blood Registry, and the United Kingdom's Virgin Health Bank.[345] The latter employs a unique model in terms of which it splits it units with 80 per cent of a unit going to a public bank and 20 per cent being retained for private use.[346] In 2006, Spain introduced a hybrid system effectively allowing the public to access privately stored stem cells.[347]

2.5 Private stem cell banking: Defining characteristics

Given the discussion above, the essential elements of a contract between a private stem cell bank and its client can be summarised as follows:

- The bank has a duty to acquire, purify, analyse, and safely store the umbilical cord blood stem cells for (typically) at least 20 years. This long minimum storage period is necessary in the light of the fact that most clients are low-risk, and the focus is on the future need and promise of stem cell therapy.
- The bank has a duty to return the stem cells to the client on request. Although the bank takes possession of the umbilical cord blood, the client remains the owner thereof. This duty follows from the client's motivation of possible future personal or family use.

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345 Ibid at 140.

346 Ibid.

347 Royal Decree 1301/2006, Spain, available at *http://parentsguidecordblood.org/content/media/m_pdf/RealDecreto_1301-2006.pdf*. Cf Gregorio Garrido 'Debate: is there a place for autologous cord blood banking?' Webcast from the *International Conference on Biology and Clinical Applications of Cord Blood Cells* (2008) available at *http://www.multiwebcast.com/eurocord-ed/2008/20th-cord-blood/listing*.

- The client has a duty to pay the bank the agreed amount. Private stem cell banking is essentially a service-for-a-fee industry.

These defining characteristics of private stem cell banking evoke certain ethical objections against the industry that I will discuss below.

2.6 The situation in South Africa

Bone marrow transplantation has been practised successfully in South Africa for many years. Sources of stem cells include the bone marrow and peripheral blood, which may be autologous, or allogeneic from siblings. South Africa also has a Bone Marrow Registry (SABMR) that sources stem cells from unrelated voluntary donors for allogeneic transplantation. South Africa does not at present have a public stem cell bank. Prior to 2011 private stem cell banking was offered by three for-profit banks, namely Netcells, Cryo-Save and Lazaron Biotechnologies; however, during 2011 this number decreased to two for-profit banks when Lazaron Biotechnologies merged into Cryo-Save.[348]

2.7 Stem cell banks internationally

A survey conducted in 2007 identified 194 stem cell banks internationally and concluded that stem cell banking had become a sizeable international industry with annual revenues of over US$200 million per year.[349] The locus of the global stem cell banking economy has also shifted away from Europe and North America through the emergence of new bioeconomies in East Asia and Latin America.[350]

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[348] Confirmed via informal correspondence with Kim Hulett, managing director of Netcells, 23 & 24 April 2012.

[349] Martin, Brown & Turner op cit note 342 at 141.

[350] Ibid. Cf European Group on Ethics in Science and New Technologies *Ethical Aspects of Umbilical Cord Blood Banking* (2004) Opinion No 19 to the European Commission available at *http://web.archive.org/web/20061114230031/http://ec.europa.eu/european_group_ethics/docs/avis19_en.pdf*.

Table C: Leading public and private cord blood banks (>5 000 units in 2007)[351]

Name of bank	Location	Founded	Public/Private	Units stored
Public banks				
New York Blood Centre National Cord Blood Programme	USA	1996	Public	33 000
Tzu Chi Stem Cells Centre	Thailand	1997	Public	15 000
University of Colorado Cord Blood Bank	USA	1997	Public	6 700
Leuven Cord Blood Bank	Belgium	1997	Public	6 500
Australian Cord Blood Bank (Auscord)	Australia	1995	Public	5 000
TOTAL				**66 200**
Private banks				
Cord Blood Registry	USA	1995	Private	180 000
Cryo-Cell International	USA	1992	Private	140 000
Cells Limited	UK	2004	Private	130 000
Cord Trust/ViaCord	USA	1994	Private	115 000
Cryogenesis International	UK	2005	Private	90 000
Cryo-Save	Belgium	2000	Private	50 000
Vita 34	Germany	1997	Private	43 000
StemCyte	USA	1997	Private	25 000
Golden Meditech	China	2004	Private	23 000
Insception Biosciences	Canada	1996	Private	23 000
Cryobanks International	USA	1994	Private	15 000
CorCell (Cord Bank America)	USA	1995	Private	12 000
StemCord Private	Singapore	2002	Private	10,000
Lifebank	USA/Canada	1996	Private	7 000
Stem Cell Institute	Japan	1999	Private	6 000
Babycord	Jordan	2002	Private	7 000
Virgin Health Bank	UK	2007	Private	5 000
TOTAL				**881 000**

[351] Martin, Brown & Turner op cit note 342 at 130.

3 The relevant law

There are obvious areas of overlap between private stem cell banks and preparation laboratories in the case of ASC therapy: both of these kinds of entities acquire, store, and supply stem cells. It may also be that a private stem cell bank in practice acts as a preparation laboratory for stem cell therapy. In abstracto, however, these two kinds of entities must be differentiated for purposes of proper analysis. The two most salient differences are as follows:

- While a preparation laboratory must produce a stem cell preparation for the explicit purpose of therapy, a private stem cell bank must only when so requested return the stem cells that have been deposited with it, and can steer completely clear of any therapeutic claims. The Medicines Act is accordingly not applicable to private stem cell banks.
- While a preparation laboratory may receive stem cells from any source, private stem cell banks per definition specifically deal with umbilical cord blood. In the previous chapter I stated that such chapter will not deal with umbilical cord blood as source of autologous stem cells, given that it will be the subject of this chapter. Accordingly, the specific aspects in the relevant law that deal with umbilical cord blood are analysed in the following subchapter.

3.1 The Human Tissue Act

The HTA provides that blood withdrawn from a living person may only be used for medical purposes, including the administering of such blood to another living person, or for blood products.[352] The placenta and umbilical cord may not be used for these purposes, except with the consent of the Minister of Health.[353] Since umbilical cord blood is withdrawn from the placenta via the umbilical cord, the Minister's consent is clearly necessary for a private stem cell bank to operate.

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[352] HTA s 19.

[353] HTA s 19(iv).

The HTA further provides that only an institution prescribed by regulation may receive payment in respect of the acquisition or supply of blood and blood products, and that any payment in respect of the acquisition or supply of blood made to an institution that may not receive such payment shall be refundable to the person who made it.[354] The Regulations relating to Blood and Blood Products make provision for a person to obtain a licence to acquire and supply blood and blood products. Accordingly, over and above having to obtain ministerial consent as discussed above, a stem cell bank must also obtain a licence in terms of the Regulations relating to Blood and Blood Products.

3.2 The National Health Act

The main changes effected by the NHA are that the process of obtaining authorisation to operate as a stem cell bank has been simplified, and that certain services rendered by private stem cell banks are subject to a profit-ban. These main changes will be discussed in the following paragraphs:

3.2.1 Simplification of authorisation

While the HTA effectively required a double layer of authorisation as discussed above, the NHA replaces the double layer with a single layer: As already mentioned in the previous chapter, the NHA brings blood and blood products under the umbrella of 'authorised institutions';[355] the NHA furthermore introduces the following *exemption* from the requirement of obtaining ministerial consent:

> 56. (1) A person may use tissue or gametes removed or blood or a blood product withdrawn from a living person only for such medical or dental purposes as may be prescribed.
>
> (2) (a) Subject to paragraph (b), the following tissue, blood, blood products or gametes may not be removed or withdrawn from a living person for any purpose contemplated in subsection (1):

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354 HTA s 28.

355 NHA s 54.

> […]
>
> (iv) placenta, embryonic or foetal tissue, stem cells and umbilical cord, *excluding umbilical cord progenitor cells.* [My emphasis]
>
> (b) The Minister may authorise the removal or withdrawal of tissue, blood, a blood product or gametes contemplated in paragraph (a) and may impose any condition which may be necessary in respect of such removal or withdrawal.

The concept 'progenitor cell' is controversial, as it can be used in the following ways:

a) As a concept distinct from stem cell, referring to an early descendant of a stem cell that can still differentiate, but which lost its ability of extended self-renewal[356]

b) As a synonym for adult stem cell, id est to denote stem cells that have already differentiated to a degree, such as multipotent stem cells, in contrast with totipotent or pluripotent stem cells that are found in embryos[357]

c) Simply as a synonym for stem cell[358]

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[356] Harvard Stem Cell Institute *Glossary* (Undated) available at *http://www.hsci.harvard.edu/glossary*. Susan Prohaska & Irving Weissman 'Biology of hematopoietic stem and progenitor cells' in Frederick R Appelbaum et al (eds) *Thomas' Hematopoietic Cell Transplantation: Stem Cell Transplantation* 4th ed (2009) 36.

[357] Medical Dictionary Online *What Is [a] Progenitor Cell?* (2008) available at *http://www.medicaldictionaryonline.info/medical-term/Progenitor+Cell*.

[358] Donald Venes (ed) *Taber's Cyclopedic Medical Dictionary* 21st ed (2009); *American Heritage Science Dictionary* op cit note 273.

According to meaning (a), both stem cells and progenitor cells are found in umbilical cord blood, but for therapeutic purposes this distinction is mostly irrelevant.[359] Accordingly, there is no conceivable policy rationale in the context of the NHA for distinguishing between umbilical-cord-blood-derived *stem* cells and umbilical-cord-blood-derived *progenitor* cells and making the removal of the one subject to special ministerial permission and not the other.

On the other side of the meaning spectrum, if progenitor cells is simply meant as a synonym for stem cells as per meaning (c), why did the legislature elect to use a different term – given that the term 'stem cells' is also used in the same sentence? The use of a different term implies that the legislature wanted to make some kind of distinction between stem cells and progenitor cells. In this regard, meaning (b) offers a solution: progenitor cell is conceptually differentiated from stem cell as being a *specific kind* of stem cell, namely the *kind* found in umbilical cord blood (and in some other tissue of postnatal humans) in contrast with the *kind* found in embryos.

Accordingly, I suggest that the legislative intent is to create an exemption from the requirement of obtaining special ministerial permission for what is generally referred to (also in this thesis) as umbilical-cord-blood-derived stem cells.

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[359] Where a distinction is made between stem cells and progenitor cells in the context of umbilical cord blood in academic literature, such distinction plays no part in these cells' therapeutic application: Hal E Broxmeyer et al 'Human umbilical cord blood: a clinically useful source of transplantable hematopoietic stem/progenitor cells' (1990) 8 *Int J Cell Clon* 76; Hector Mayani & Peter M Lansdorp 'Biology of human umbilical cord blood-derived hematopoietic stem/progenitor cells' (1998) 16 *Stem Cells* 153; L Lu et al 'High efficiency retroviral mediated gene transduction into single isolated immature and replatable CD34(3+) hematopoietic stem/progenitor cells from human umbilical cord blood' (1993) 178 *J Exp Med* 2089; Fernando Ramirez et al 'Umbilical cord stem cell therapy for cerebral palsy' (2006) 3 *Med Hypotheses Res* 679.

It should, however, be clear that the statutory drafting decision to employ a controversial term such as 'progenitor cell' without defining it, does not serve the principle of legal certainty. I recommend that 'umbilical cord progenitor cells' in the NHA section 56(2)(a)(iv) should be replaced with 'umbilical-cord-blood-derived stem cells'.

3.2.2 A profit ban?

At a conference on stem cell banking that was held in 2007 in Pretoria, the concern was raised that the profit banning provisions of the NHA section 60 will effectively ban for-profit private stem cell banking.[360] I suggest that this concern is based on an overbroad interpretation of this section. The relevant section reads as follows:

> 60. (1) No person, except–
>
> […]
>
> (b) a person or an institution contemplated in section 63 or an authorised institution, may receive any payment in respect of the importation, export or acquisition for the supply to another person of blood or a blood product.
>
> (2) The amount of payment contemplated in subsection (1) may not exceed an amount which is reasonably required to cover the costs involved in the importation, export, acquisition or supply of the tissue, gamete, blood or blood product in question.

One the hand it can be argued that the legislative intent was to include all acts by stem cell banks with the use of the words 'importation, export, acquisition or supply'. On the other hand it can be argued that 'importation, export, acquisition or supply' in fact constitute a numerus clausus of acts that are subject to the profit-ban, and that in their ordinary meaning these acts do not include all the essential services performed by private stem cell banks for their clients, such as purification, analysis, and storage of such stem cells. In addition, since section 60 has a penal

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[360] Dominique Schaub et al (comps) *Report: Bioethics Forum on Stem Cell Banking, Held at the Innovation Hub, Pretoria, on 15 June 2007* (2007) 7 available at *http:// www.docstoc.com/docs/3870941/Report-Bioethics-Forum-on-Stem-Cell-Banking-held-at-the*.

nature,[361] the common law maxim in poenis strictissima verborum significatio accipiendi est (in the case of penal laws the most restrictive interpretation of their terms should be accepted) is applicable.[362] This common law rule of interpretation clearly directs that section 60 should *not* be interpreted as encompassing any of the other services performed by private stem cell banks for their clients that fall outside the numerus clausus of acts specified in section 60.

It therefore follows that private stem cell banks will be limited to recovering reasonable costs regarding the process of acquiring the umbilical cord blood immediately after birth and eventually supplying the umbilical-cord-blood-derived stem cells to the client when needed; and will be free to make profit in respect of any service other than acquisition and supply of stem cells, such as the purification, analysis and storage of the cells.

3.2.3 Conclusion on the NHA: The direction of policy evolution

While apparently simplifying the bureaucratic requirements for operating a stem cell bank, the NHA's move towards market intervention by limiting the fees that may be charged for certain services related to stem cell banking signals a particular ethical and political vision of the health care sector (including stem cell banking), which is likely to be indicative of the direction of future policy evolution.

3.3 Draft regulations in terms of the National Health Act

The government's forays into the further evolution of policy regarding stem cell banking manifested in two consecutive versions of draft regulations that have been published for public comment in terms of the NHA: An initial version in 2007[363] and a revised version in 2011.[364] While the 2007-version has continued on the policy

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[361] NHA s 60(4), (5).

[362] Refer to the case law cited in note 201.

[363] Draft Regulations relating to Human Stem Cells (GN R376 *GG* 29840 of 4 May 2007).

[364] Draft Regulations relating to Stem Cell Institutions or Organisations (GN R265 *GG* 34159 of 1 April 2011).

evolution trajectory by, first, limiting access to private stem cell banking to high-risk families, and, secondly, instituting a comprehensive profit-ban on activities of stem cell banks, these two features were omitted from the 2011-version, therefore calling an apparent halt – if but temporary – to the policy evolution trajectory. However, it should be emphasised that the 2011-version of the draft regulations is but the *latest* version of *draft* regulations for public comment – it is not necessarily the final version, nor is it law as yet.

The policy measures that the 2007-version sought to introduce, namely, limiting access to private stem cell banking to high-risk families, and instituting a comprehensive profit-ban on activities of stem cell banks, merit analysis.

3.3.1 Access to stem cell banking limited to high risk families

Draft regulation 7 states that 'Stem cells obtained for later therapeutic use must only be obtained from high risk families.' Given that it is a defining characteristic of private stem cell banking that most clients of private stem cell banks are low-risk, this draft regulation will clearly constitute an effective ban on private stem cell banking in South Africa.

3.3.2 Comprehensive profit ban

In contrast to the NHA's limited profit ban on specific acts, the 2007-version of the draft regulations intend to subject private stem cell banks to a comprehensive profit ban. Draft regulation 3(4) states that 'An authorised stem cell establishment shall operate as a non-profit making entity.' All three of the private banks currently operating in South Africa are for-profit enterprises; there are no non-profit private banks in the country. The government argues that a profit-ban will not result in a ban on private stem cell banking in South Africa, since the profit-ban will only require the current stem cell banks to amend their business model to one of

sustainability instead of profitability.[365] This argument is supported by using the South African National Blood Service (SANBS) as an example of an organisation that does indeed operate on a non-profit basis. The government's argument and its reliance on the SANBS model merits analysis.

Changing the business model of any enterprise from for-profit to non-profit is a fundamental change that concerns the very raison d'être of such an enterprise. Economic common sense dictates that a guaranteed (legally enforced) zero return on investment would oblige shareholders to free what is left of their capital as quickly as possible for investment elsewhere. The two most likely ways to do this would either be liquidation of the company, or selling the shares to the company's staff, who obviously have a vested interest in the survival of the company and who can potentially get a return on their investment via salaries. However, since the latter solution moves the substantial financial risk of the stem cell bank qua business enterprise squarely from the investor(s) to the staff, its feasibility depends on the entrepreneurial sensibilities of the staff, which makes the solution speculative. The long-term sustainability of a stem cell bank in the staff-shareholder paradigm is also doubtable, since the lifespan of the company is linked to the career plans and personal agendas of the relevant staff. In the realm of speculation, non-staff shareholders may perhaps even have a strategic reason for keeping their capital in a non-profitable venture and keeping it afloat. Another possible scenario may be that non-profit private stem cell banks may be established as trusts with altruistic investments. However, speculation does not constitute a convincing argument. Furthermore, the example of the SANBS is not a valid comparison for the following reasons:

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[365] This was argued on behalf of the Department of Health at a workshop on the draft regulations relating to human stem cells, organised by the Department of Health, Pretoria, 3 October 2007, where I was present.

- *Constitution*. The SANBS is a non-profit company;[366] there are no shareholders who have invested into the setting up and running of the company, and who were willing to take the risks involved therein.
- *Function*. The SANBS's core business, namely the collection, storage and distribution of blood and blood products, relies on the voluntary donation of the products it sells.[367] Private stem cell banks, on the other hand, do not operate on the basis of donations, but receive umbilical cord blood units as deposits for safekeeping.
- *Market risk*. Since the SANBS is providing an essential health service,[368] its market risk-profile is virtually zero, which contrasts with private stem cell banks that are highly susceptible to fluctuations in the market, such as medical aid funds' willingness to pay for private stem cell banking, and potential clients' capacity and willingness to pay for private stem cell banking themselves. While the SANBS is therefore guaranteed to recuperate its costs from its market, stem cell banks are not. The capital needs of private stem cell banks require investment from entrepreneurs who are willing to take significant risks. To expect this of members of a non-profit organisation, or of the health professionals in the employ of private stem cell banks that operate on this basis is clearly unreasonable.

Does this exhaust the argument that the profit-ban will only require the current stem cell banks to amend their business model to one of sustainability instead of profitability? The Spanish legal position that makes provision for private stem cell banks, but limits stem cell banking contracts to cost-recovery, may potentially also be perceived as an example that private banks can indeed operate successfully

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366 South African National Blood Bank Service *About the SANBS* (Undated) available at *http://www.sanbs.org.za/*.

367 Ibid.

368 Ibid.

under a non-profit regime. Such an argument would however be unconvincing for at least two reasons:

- The example of Spain is decontextualised and ignores the current South African reality. For one, the incidence of stem cell banking per birth is reported to be significantly higher in Spain[369] than in South Africa,[370] which seriously impacts on the underlying risk-profile and feasibility of any private stem cell bank – whether for-profit or non-profit.
- There is a very important and fundamental difference between the Spanish non-profit limitation and draft regulation 3(4): While the Spanish non-profit provision only applies to the contract between the stem cell bank and its client, draft regulation 3(4) applies to the entire operation of the bank. Given the high popularity of stem cell banking in Spain and the highly developed medical and medical insurance industries that have an interest in stem cell banking, private stem cell banks in Spain can profit from contracts in these industries. One Spanish private stem cell bank reported profits before tax of €1,8 million for 2007.[371]

Given the above considerations, the most likely result of the comprehensive profit-ban as per draft regulation 3(4) would be the closure of the existing for-profit banks in South Africa and not their speculative 'evolution' into non-profit banks. Furthermore, given the South African reality of three for-profit private banks and no

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[369] The proportion of families in Spain that chooses to bank their newborn's stem cells is 12 per cent. (M Kirwin 'Stem cell collection: the banking crisis' (6 April 2009) *The Independent* (Ireland) available at *http://www.independent.ie/health/case-studies/stem-cell-collection-the-banking-crisis-1699539.html*.)

[370] The proportion of families in South Africa that chooses to bank their newborn's stem cells is estimated at about 0,16 per cent, which is a rate of 75 times less than in Spain. Refer to 4.2.2 The diversion-of-resources argument infra.

[371] Cryo-Save Group NV *Acquisition of Leading Spanish Distributor* (2008) available at *http://www.2.cryo-save.com/cms/bib/files/929_spanishacquisitionfinal.pdf*.

non-profit banks, the profit-ban therefore amounts to an effective ban on private stem cell banks.

3.3.3 Conclusion on the draft regulations: a ban on private stem cell banks is on the policy agenda

What the 2007-version of the draft regulations has accomplished is to overtly introduce the policy option of banning private stem cell banks to the policy agenda and to the political, legal and ethical discourse on the subject of stem cell banks. Despite its omission from the 2011-version, banning private stem cell banks remains a policy option that merits analysis – specifically an analysis of its human rights dimensions as per the main theme of this thesis.

It should further be noted that although the 2007-version of the draft regulations effectively bans private stem cell banking through limiting access to private banking to high-risk families; and banning profit-making by all stem cell banks, the same result could also be achieved by banning any other defining characteristic of private stem cell banking, such as banning private ownership of stem cells, or limiting the time for which stem cells may be stored. The possibilities abound. Because of the plethora of possible ways to effect a ban on private stem cell banking, and the possibility that subsequent versions of the draft regulations may still be amended in unforeseeable ways in order to achieve the same policy objective by other means, the subsequent human rights analysis will consider a hypothetical ban on private stem cell banks in abstracto, irrespective of the specific legislative means or formulation utilised to achieve this end.

3.4 Conclusion on the relevant law

The two main changes brought about by the NHA relative to the HTA are both dependent on at least a degree of legal interpretative construction, and as such contribute negatively to legal certainty in the area of private stem cell banking: the exemption for undefined 'progenitor cells' calls for clarification; and the profit-ban on particular services has already been interpreted by some as intended as a comprehensive profit-ban. The policy ping-pong that is apparent from the various

versions of the draft regulations further contributes negatively to legal certainty. Lastly, the uncertainty about when the NHA Chapter 8 will eventually come into force only serves to deepen the current morass of legal uncertainty.

4 Mounting a human rights challenge to a ban on private stem cell banks

4.1 Introduction

In the following, I analyse the human rights dimensions of a hypothetical ban on private stem cell banking. I first argue that the interests of the newborn and its next-of-kin to have the newborn's[372] umbilical-cord-blood-derived stem cells privately banked are protected by no less than four constitutionally protected rights. Subsequently, I analyse the arguments in favour of such a ban to ascertain whether a limitation of the relevant rights can be justified.

4.2 Four relevant rights

Four constitutionally protected rights are considered as potential launch pads for a human rights challenge to a hypothetical ban on private stem cell banks, namely the right to access to health care, the right to control over one's own body, the best interests of the child, and the right to freedom of economic activity.

4.2.1 The right to access to health care

The Constitution provides for the right to access to health care services.[373] The access to health care provision in our Constitution has both a positive and a

[372] The umbilical cord blood is referred to as the newborn's in the genetic sense, not necessarily the legal sense. Legal ownership of umbilical cord blood is a separate issue that will not be addressed in this thesis.

[373] The Constitution s 27(1).

negative component.[374] The positive component places a duty on the state to take measures to promote access to health care, while the negative component places a duty on the state to refrain from limiting access to health care. While the state's positive duty to 'achieve the progressive realisation' of access to health care is qualified by 'within available resources',[375] the state's negative duty is not similarly qualified.[376] The state's positive duty is therefore dependent on the state's health care priorities and its health care budget,[377] while the state's negative duty, on the other hand, is independent of such variables.

Consider the health-care-services-related interests that are at stake in the context of a ban on private stem cell banks: First, a newborn has an interest in the banking of its stem cells, since it may in future need these cells for therapeutic purposes (the current use for autologous cells is limited, but they may be useful for regenerative medicine in the future), in which case the banked material guarantees a suitable supply of autologous cells. Secondly, a newborn's parents and siblings, because of the higher possibility of histocompatibility relative to the general population, also have an interest in the private banking of the cells. Seen in the light of its therapeutic nature, it is evident that these interests fall within the ambit of health care. A ban on private stem cell banks would undermine these interests – the undermining effect is accentuated in the current South African context of a genetically diverse population – hence undermining the right to access to health care.

It must be stressed that the availability of state resources is not an issue in the case of the state's negative duty to refrain from limiting access to health care, since the

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[374] *Ex parte Chairperson of the Constitutional Assembly: in re Certification of the Constitution of the Republic of South Africa 1996* 1996 (4) SA 744 (CC) para 78.

[375] The Constitution s 27(2). Cf *Soobramoney v Minister of Health (Kwazulu-Natal)* 1998 (1) SA 765 (CC).

[376] *Jaftha v Schoeman* 2005 (2) SA 140 (CC) paras 31, 33. Cf *Residents of Bon Vista Mansions v Southern Metropolitan Local Council* 2002 (6) BCLR 625 (W).

[377] The state's positive duty will be considered in 4.2.2 The diversion-of-resources argument infra.

cost for private storage is covered by the family of the newborn child. A ban on private stem cell banks would constitute a breach of the state's negative duty to refrain from limiting access to health care, however limited the current and future use of stem cells may be.[378]

The state's positive duty in the context of stem cell banking is discussed below.[379]

4.2.1 The right to control over one's own body

As already discussed in the previous chapter on ASC therapy, the Constitution provides for the right to bodily and psychological integrity, which includes the right to control over one's body.[380] In the previous chapter this right is applied in an attempt to protect the interest of a patient in the autologous use of 'medicine' derived from her or his own stem cells. In the present analysis, the right to control over one's body is *not* applied to one's use of any medicine, but purely to *banking one's own stem cells* (or that of one's child on its behalf) that might in future be used as medicine. Although the banking of stem cells for possible future use as medicine and the actual use thereof as a specific medicine are related acts, it is important to draw a clear conceptual distinction between these two acts.

Control over one's body denotes bodily autonomy or self-determination.[381] Since umbilical cord blood is part of a human body – whether the mother's or the baby's – the right to control over one's body therefore in principle entails the autonomy to decide what to do with the umbilical cord blood, which autonomy is protected against unjustified state intervention. Assuming the umbilical cord blood belongs to the mother, the mother has this autonomy; assuming the umbilical cord blood belongs to the newborn child, it is obvious that such child will not be able to

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[378] Refer to the discussion of the current use of stem cells in 2.3 The likelihood of using stem cells supra.

[379] Refer to 4.2.2 The diversion-of-resources argument infra.

[380] The Constitution s 12(2).

[381] Currie & de Waal op cit note 214 at 308.

exercise this autonomy on its own and, depending on the circumstances, a parent would usually act on behalf of the child in exercising this autonomy. One particular autonomous decision in the contemporary health care environment is to privately bank the umbilical-cord-blood-derived stem cells. Accordingly, a newborn child's and its next-of-kin's interests in private stem cell banking, as identified in the analysis of the right to access to health care above, are protected within the ambit of the right to bodily integrity. As a ban on private stem cell banks would clearly undermine these interests, it also follows that such a ban would limit the autonomy to make decisions regarding one's own body.

4.2.3 Children's rights

The Constitution sets out the specific rights of children.[382] These enumerated rights are, however, not exhaustive of children's rights.[383] Of particular importance for present purposes is the constitutional provision that a child's best interests are of paramount importance in every matter concerning the child.[384] In South Africa, a 'child' means a person under the age of 18 years.[385]

The importance of the best-interests-of-the-child criterion is also reflected in the Convention on the Rights of the Child which South Africa signed and ratified in 1995. Article 3(1) of the Convention provides:

> In all actions concerning children, whether undertaken by public or private social welfare institutions, courts of law, administrative authorities or legislative bodies, the best interests of the child shall be a primary consideration.

The right of children to access to health care services is provided for in article 24(1) of the Convention:

> States Parties recognize the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health.

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[382] The Constitution s 28(1).

[383] *Minister of Welfare and Population Development v Fitzpatrick* 2000 (3) SA 422 (CC) 428 para 17.

[384] The Constitution s 28(2).

[385] The Constitution s 28(3).

> States Parties shall strive to ensure that no child is deprived of his or her right of access to such health care services.

The Children's Act[386] must guide all proceedings, actions and decisions by any organ of state in any matter concerning a child or children in general.[387] This Act further stipulates:

> 6 (2) All proceedings, actions or decisions in a matter concerning a child must -
>
> (a) respect, protect, promote and fulfil the child's rights set out in the Bill of Rights, the best interests of the child standard set out in section 7 and the rights and principles set out in this Act, subject to any lawful limitation…

Section 9 of the Children's Act reaffirms the constitutional directive that in all matters concerning the care, protection and well-being of a child, the standard that the child's best interest is of paramount importance must be applied.

How does private stem cell banking relate to children's rights and the best-interests-of-the-child criterion in particular? As discussed above, a newborn child has an interest in the private banking of its stem cells, since it may in future need stem cell therapy, in which case the banked stem cells guarantee a suitable supply of histocompatible cells. Provided that the child's parents are in a financial position to be able to afford the service without compromising other interests of the child, private stem cell banking is therefore directly in the best interests of the child. Since a child also has an interest in its family's health and lives, private stem cell banking can also indirectly be in the best interests of the child in that its next-of-kin may benefit. Therefore, while acknowledging both the current limited use of stem cells and the indefinable future promise thereof,[388] I suggest that a ban on private stem cell banking would constitute an infringement on children's rights, in particular the

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386 Act 38 of 2005.

387 The Children's Act s 6(1)(b).

388 Refer to the discussion of the current use of stem cells in 2.3 The likelihood of using stem cells supra.

best-interests-of-the-child criterion, as protected by the Constitution, legislation and international human rights instruments.

Should a ban on private stem cell banking be implemented, such a ban would impact both on children who presently have stem cells privately banked and on children who in the future would have had stem cells privately banked but for such a ban. In my opinion there would be an infringement both on the rights of individual children who have had stem cells privately banked and on the rights of children as a group of people in South Africa.[389]

4.2.4 The right to freedom of economic activity

I have thus far analysed the rights that are relevant to the interests of the newborn child and its next-of-kin qua users of the services of private stem cell banks. The discussion will now focus on private stem cell banks, which have a clear interest in their own continued existence.

Section 22 of the Constitution provides that every citizen has a right to choose her or his trade, occupation or profession freely.[390] Does a juristic person such as a private stem cell bank qualify as a citizen? High Court decisions in the Cape of Good Hope and the Eastern Cape have specifically limited the meaning of 'citizen' in the context of section 22 to natural persons to the exclusion of juristic persons.[391] In the absence of a Constitutional Court judgement on the matter, constitutional scholars

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389 Cf *Minister of Health v Treatment Action Campaign* 2002 (5) SA 721 (CC).

390 This is in contrast with the broader formulation of the right's predecessor, s 26(1) of the interim Constitution (of the Republic of South Africa, Act 200 of 1993), which provided that 'every person shall have the right to freely engage in economic activity and pursue a livelihood anywhere in the national territory.' There is clearly a difference in the wording of the current s 22 and its predecessor, from which it is clear that the current right is narrower in scope, *inter alia* as it only pertains to citizens of the Republic of South Africa.

391 *JR 1013 Investments CC & others v Minister of Safety and Security & others* 1997 (7) BCLR 925 (E); *City of Cape Town v Ad Outpost (Pty) Ltd & others* 2000 (2) SA 733 (C) at 747F; *First National Bank of SA Ltd t/a Wesbank v Commissioner for the South African Revenue Service & another* 2001 (3) SA 310 (C).

Currie and de Waal argue that section 22 should be interpreted as applying to juristic persons as well.[392] They refer to section 8(4) of the Constitution that provides that juristic persons are 'entitled to the rights in the Bill of Rights to the extent required by the nature of the right and the nature of the juristic person,' and argue that since juristic persons are capable of choosing and practising a trade, occupation or profession, it follows that the nature of the right protects the activities of a juristic person. As authority for their interpretation Currie and de Waal cite a Canadian Supreme Court case that indeed applied the right to gain a livelihood to juristic persons.[393] They suggest that juristic persons may be regarded as citizens for the purposes of section 22 if they are incorporated in South Africa, or, with reference to an Appellate Division (as it then was) case,[394] if they are controlled by South African citizens. Whether private stem cell banks' interest in pursuing their economic activities is protected by section 22 of the Constitution is therefore a matter of academic speculation.

Since an applicant in constitutional litigation is not expected to show that its interests are protected by a specific right, but only that it has sufficient interest in the outcome of the litigation,[395] private stem cell banks would be able to approach the court to challenge a ban on private stem cell banking, irrespective of the interpretation of section 22. Should a restrictive interpretation of section 22 be followed that excludes juristic persons, private stem cell banks qua hypothetical applicants would have to prove that the section 22 rights of their employees, qua natural persons and presumably mostly South African citizens, have been infringed. Since a ban on private stem cell banks would render it impossible to pursue careers within the field of private stem cell banking, it would limit free choice and practice

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[392] Currie & de Waal op cit note 214 at 489-490.

[393] *Black v Law Society of Alberta* [1989] 1 SCR 591.

[394] *T W Beckett & Co Ltd v H Kroomer Ltd* 1912 AD 324 at 334; cf *Dadoo Ltd v Krugersdorp Municipal Council* 1920 AD 530.

[395] *Ferreira* supra note 35.

of an occupation. An argument can therefore be made that such a ban would infringe on the section 22 rights of natural persons.

The significance of a citizen's interest to work in a particular field, which is protected by the section 22 rights, should not be underestimated. Its importance and interrelatedness with human dignity was elaborated on by the Constitutional Court per Ngcobo J (as he then was):[396]

> Freedom to choose a vocation is intrinsic to the nature of a society based on human dignity as contemplated by the Constitution. One's work is part of one's identity and is constitutive of one's dignity. Every individual has a right to take up any activity which he or she believes himself or herself prepared to undertake as a profession and to make that activity the very basis of his or her life.

4.2.5 Conclusion: The ban infringes on all four human rights

I have argued that the interests of the newborn child and its next-of-kin in the private banking of the newborn's stem cells are protected by the three constitutional rights that we have considered, namely the right to access to health care services, the right to bodily integrity, and children's rights. By undermining these interests, a ban on private stem cell banking would therefore infringe on these constitutional rights. Whether the interest of a private stem cell bank in its own continued existence is protected by the constitution, is possible but speculative; it does, however, ensure locus standi for a private stem cell bank in litigation regarding a ban on private stem cell banking. Although the constitutional protection of the interests of private stem cell banks is uncertain, the interests of private stem cell banks' employees to work in the field of private stem cell banking is likely to be protected by the constitutional right to freely choose a trade, occupation or profession. In addition to the infringements on the first mentioned three rights, a ban on private stem cell banking would accordingly also constitute an infringement on the right to freely choose a trade, occupation or profession. A ban on private stem cell banking evidently has wide human rights ramifications.

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396 *Affordable Medicines Trust & others v Minister of Health & another* 2006 (3) SA 247 (CC) 274.

4.3 Can the ban be justified?

Given the infringements established above, the human rights analysis must now enter its next phase, namely the evaluation of the justifications for the infringements in terms of the Bill of Rights' limitation clause. What is of particular importance to the subject of this chapter, is that in order to satisfy the limitation clause, the law in question must serve a purpose that is aligned with the core values of the constitution; furthermore the law in question must not invade the enumerated constitutional rights further than it needs to in order to achieve this purpose.[397] Four anti-private-stem-cell-bank arguments that enjoy prominence in South Africa[398] will be analysed, namely the equality argument, the diversion-of-resources argument, the low-recall argument, and the compromised-autonomy argument. In contrast to the last three arguments that are well-known in international literature on the subject, the first argument is characteristically (though not necessarily exclusively) South African.

4.3.1 The equality argument

Given the historic and persisting inequalities in South African society, the redistribution of social goods – especially regarding health care – is a principle theme in government policy. At the core of the policy stance that opposes the existence of private stem cell banks is the following perception of equality: a situation of unequal access to a certain social good can justifiably be remedied by denying access to this social good to everyone. This is an attractive concept for certain political groupings – especially in situations where there is an apparent low possibility of attaining equality through state intervention aimed at universal access to this social good. This is exactly the case with stem cell banking: The establishment of a public stem cell bank in South Africa would contribute

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397 The Constitution s 36.

398 Cf Michael S Pepper 'Stem cell banking scientific arguments' Paper delivered at the *Bioethics Forum on Stem Cell Banking*, held at the Innovation Hub, Pretoria (15 June 2007) 39 available at *http://web.up.ac.za/sitefiles/File/Unit%20for%20Policy%20Studies/Scientific%20arguments.pdf.*

significantly to increasing the access to stem cell therapy in the future; however, since the government's priorities do not appear to include stem cell therapy,[399] the state is unlikely to allocate financial resources to the establishment of a public stem cell bank aimed at increasing access to this health care service. Should the government move further on the policy evolution trajectory to ban private stem cell banks, such a policy decision would from the government's perspective be justified as a measure to address (redress) the current situation of unequal access to stem cell banking by levelling access down.

Although the levelling down conception of equality may be politically influential in South Africa and perhaps elsewhere, it has been unequivocally rejected by the Constitutional Court:[400]

> Levelling down . . . would not promote the achievement of the enjoyment of equality. Such parity of exclusion rather than of inclusion would distribute resentment evenly, instead of dissipating it equally for all. The law . . . calls for equality of the vineyard and not equality of the graveyard.

The levelling down conception of equality is incompatible with human dignity – in particular human dignity qua autonomy: The logical conclusion of levelling down is that the autonomy of those who can access a certain social good is negated for the sake of equal access to such social good at the level of the lowest common denominator – even at the level of zero access. Equality interpreted in alignment with autonomy requires a levelling up conception of equality. A ban on private stem cell banks in South Africa would therefore not survive constitutional scrutiny if argued from an equality platform.

4.3.2 The diversion-of-resources argument

The prohibition of private stem cell banks can be argued from a social solidarity platform: It has been suggested that private banking diverts umbilical cord blood

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[399] Department of Health *Strategic Plan 2010/2011–2012/2013* (2010) available at *http://www.doh.gov.za/list.php?type=Strategic%20Documents*.

[400] *Fourie* (CC) supra note 26 para 149.

samples away from public banks, hence limiting the establishment and maintenance of public banks.[401] Thus, instead of fostering the creation of a public bank that can benefit the whole populace, the existence of private banks results in the fact that only the wealthier portion of society that can pay for private banking would benefit from the ensuing therapeutic options.[402]

First, the fundamental logic of the above argument is flawed: If parents who intend to bank their newborn's stem cells privately are prohibited from doing so, it does not necessarily follow that they would now decide to donate it to a public bank – they might just as well decide not to donate it at all. If they are prohibited from advancing their family's own interests, why would they now advance an altruistic cause? There is no psychological research presented by the proponents of this argument to even suggest that a prohibition on private banks would promote donations to public banks. The opposite may even be the case.

Consider the following statistics: The estimated number of umbilical cord blood samples banked privately in South Africa per year is 2 100.[403] With a total of 1 294 694 live births registered with the Department of Home Affairs in South Africa in 2010,[404] this translates into 0,16 per cent of potential cord blood donations to a prospective public bank that are privately banked. Instead of banning private banking, a more constructive measure would be for the state to recruit donations from the estimated 99,84 per cent of neonates whose umbilical cord blood is discarded. A recent study in the UK found that women in antenatal clinics had very little knowledge about cord blood banking, and that while 14 per cent of those questioned would have elected to bank privately, 86 per cent would have been

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401 Johnson op cit note 322.

402 C Waldby 'Umbilical cord blood: from social gift to venture capital' (2006) 1 *BioSocieties* 55.

403 Confirmed via informal correspondence with Hulett op cit note 348.

404 Statistics South Africa *Key Findings* (Undated) available at *http://www.statssa.gov.za/publications/statskeyfindings.asp?PPN=P0305&SCH=5001*.

willing to donate altruistically to a public stem cell bank instead.[405] I therefore suggest that, if well managed and supported by a well-designed information campaign, a prospective public bank should not find it difficult to collect a critical number of umbilical cord blood samples (estimated to be at least 5 000 to 10 000 in South Africa)[406] initially required to establish a functional public bank.

Underlying the diversion-of-resources argument is the purpose of protecting the ability to create a public stem cell bank against the perceived negative impact of private stem cell banks. The Bill of Rights' limitation test requires inter alia that the relationship between the limitation and its purpose must be probed.[407] This entails that there must be a logical nexus between the purpose and the limitation – in casu between the purpose of protecting the feasibility of a public stem cell bank and the ban on private stem cell banks. As argued above, the nexus between the purpose of protecting the feasibility of a public stem cell bank and the ban on private stem cell banks is precarious, as its logic is fundamentally flawed. In addition, when the proportionality test is applied,[408] recruiting donations from the 99,87 per cent of neonates whose umbilical cord blood is currently discarded is evidently a less restrictive means to achieve the purpose. In the absence of a convincing nexus and with the availability of less restrictive means, the diversion-of-resources argument fails the Bill of Rights' limitation test and can therefore not justify the ban on private stem cell banks.

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[405] Conrad V Fernandez et al 'Knowledge and attitudes of pregnant women with regard to collection, testing and banking of cord blood stem cells' (2003) 168 *Can Med Assoc J* 695.

[406] Robert Crookes, Ernette du Toit & Machteld Oudshoorn *A Public Cord Blood Bank for South Africa?* (2007) Electronic Briefing Paper 42/2007, Centre for International Political Studies, University of Pretoria, available at *http://web.up.ac.za/default.asp?ipkCategoryID =3955&subid=3955&ipklookid=9*; Vernon Louw & Anthon du P Heyns *The Role of the State in Establishing a Public Cord Blood Stem Cell Bank* (2007) Electronic Briefing Paper 43/2007, Centre for International Political Studies, University of Pretoria, available at *http://web.up.ac.za/default.asp?ipkCategoryID=3955&subid=3955&ipklookid=9*.

[407] The Constitution s 36(1)(d).

[408] The Constitution s 36(1)(e).

Currently there is no public stem cell bank in South Africa. A public stem cell bank would enhance the public's access to health care services, and its establishment is aligned with the state's constitutional duty to take reasonable measures within its available resources to achieve the progressive realisation of access to health care.[409] Although government can legitimately allocate its limited resources to priority health care areas, such as primary health care, this certainly does not translate into zero ethical or legal duty regarding public stem cell banking. In the absence of action by the government, the private health sector may have an opportunity to take the initiative in this regard. In the South African context, where private banks have indeed offered to contribute their resources (intellectual property, staff, equipment, and cryopreservation space) towards the establishment and maintenance of a public bank,[410] the private banks are indeed a *contributory means* towards the end of a feasible public bank, rather than an impediment. Given the resources that are available for the establishment and maintenance of a public bank, we submit that 'reasonable measures' in the context of the state's constitutional duty regarding access to health care would at the very least entail institutional support in the form of championing and facilitating the process to establish and maintain a public bank in South Africa.

4.3.3 The low-recall argument

As discussed above,[411] given current medical technology, the likelihood of stem cells stored at a private stem cell bank actually being used is low: For instance, as of December 2011, the largest private bank in the United States, Cord Blood Registry,

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409 The Constitution s 27(2).

410 Michael S Pepper *A Model for the Co-existence of Public and Private Stem Cell Bank* (2007) Electronic Briefing Paper 44/2007, Centre for International Political Studies, University of Pretoria, available at *http://web.up.ac.za/default.asp?ipkCategoryID=3955&subid=3955&ipklookid=9.*

411 Refer to 2.3 The likelihood of using stem cells supra.

had released 182 samples[412] from an inventory of 400 000 samples stored.[413] This low incidence of recall led to various organisations taking positions of not recommending private stem cell banking. The Scientific Advisory Committee of the Royal College of Obstetricians and Gynaecologists, for instance, feels that there is 'insufficient evidence to *recommend* directed commercial cord blood storage in low-risk families'.[414]

The pro-ban lobby's argument is that, given the current low recall rate, for-profit private stem cell banking constitutes an exploitative practice – especially with regards to low-risk families. In other words, the argument is that profiting from a practice that currently offers a low chance of value-actualisation for the client is unethical. I respond to this argument in two ways:

- *The accuracy of the argument's factual premise*. Proponents of private stem cell banking argue that it would be unrealistic to only consider the current limited therapeutic use of autologous stem cells. Stem cells are typically stored for 20 years. During this time, stem cell research promises to revolutionise medical practice, likely causing wider use of stored stem cells and therefore increasing the frequency of recalls.
- *The reasoning based on the factual premise*. Even if the factual premise of a low incidence of recall is accepted arguendo, this fact per se does not necessarily constitute an exploitative contract. First, consensus is lacking on the disproportionate nature of the contractual obligations of a private stem cell bank on the one hand and the payment received on the other. Secondly, even if it is conceded that the performances are disproportionate, mere

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412 Cord Bank Registry *Cord Blood Released for Use by CBR Clients* (2012) available at *http://www.cordblood.com/best-cord-blood-bank/~/media/Files/FAQs/transplant_summary.pdf*.

413 Cord Bank Registry *CBR – The Best Stem Cell Bank Delivers More* (2012) available at *http://www.cordblood.com/en/best-cord-blood-bank/best-stem-cell-bank*.

414 Royal College of Obstetricians and Gynaecologists, Scientific Advisory Committee *Umbilical Cord Blood Banking* (2006) available at *http://web.archive.org/web/20080503093118/http://www.rcog.org.uk/index.asp?PageID=545*. My emphasis.

disproportionality of performances cannot constitute an exploitative contract, else donatio as a species of contract would per definition be exploitative. In order to constitute exploitation, additional elements such as being practically forced into the contract by circumstances, or lack of correct information regarding the objective values of any one or both of the performances, are necessary. This therefore points to a broader argument based on compromised autonomy, which will be analysed next. Without recourse to such a broader argument, the low-recall argument fails to convince.

4.3.4 The compromised-autonomy argument

The compromised-autonomy argument purports to be a soft-paternalism argument: It focuses on the psychological context in which private stem cell banking contracts are concluded to argue that the autonomy of clients of private stem cell banks is compromised, hence calling for intervention in the form of a ban on private stem cell banking. The concern with autonomy in the context of private stem cell banking is explained by Edozien as follows:[415]

> Some people would argue that the medical establishment's discouragement of 'just in case' collection of cord blood is an extension of medical paternalism. If parents want it and can pay for it, our duty should be to provide all the information we can. The decision whether to store cord blood should be taken by parents not by the healthcare providers. On the other hand, parents anxious to do the best they can for the unborn child are in a vulnerable position, and their autonomy is readily compromised by suggestive mailing, promotion, or advertising.

The psychological context in which private stem cell banking contracts are concluded is multi-faceted and will be analysed systematically. I start with the relationship between the health professional, typically a gynaecologist, involved in the newborn's delivery on the one hand, and the parent or parents qua potential private stem cell banking clients on the other. Given the position of authority in

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[415] L C Edozien 'Commercial banking of umbilical cord blood NHS maternity units should not encourage' (2006) 333 *Br Med J* 801.

which health professionals are held by the public, the potential certainly exists for undue influence by a health professional that could result in the autonomy of the parents being compromised. This potential with regard to stem cell banking is exacerbated by the future promise of stem cell therapies that may easily be blurred by advertising by private stem cell banks as well as attention in popular media. In principle, however, the relationship of health professional vis-à-vis parent in the private stem cell banking context is similar to all other services provided by the private health sector: a health professional recommends a medical intervention from which she or he may profit directly or indirectly. The primary protection against potential compromising of autonomy in the healthcare context is *informed consent* – a value that has become a cornerstone of bioethics and biolaw.[416] The Universal Declaration on Bioethics and Human Rights states the following in this regard:[417]

> Any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free and informed consent of the person concerned, based on adequate information.

There is a statutory duty on a health professional – and a stem cell bank qua legal person – to ensure that the potential stem cell banking client gives informed consent:

- Section 7 of the NHA makes informed consent a general prerequisite for the provision of all health services. I suggest that health services include stem cell banking, given that the purpose of stem cell banking is solely the potential *therapeutic* use of the banked cells.

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[416] Cf: *Castell v De Greef* supra note 367; D Welz 'The boundaries of medical-therapeutic privilege' (1999) *S Afr Law J* 299; F F W van Oosten 'Informed consent: patient rights and the doctor's duty of disclosure in South Africa' (1989) *Med Law* 443; F F W van Oosten 'The so-called "therapeutic privilege" or "contra-indication": its nature and role in non-disclosure cases' (1991) *Med Law* 31; F F W van Oosten '*Castell v De Greef* and the doctrine of informed consent: medical paternalism ousted in favour of patient autonomy' (1995) *De Jure* 164.

[417] Article 6(a).

- Section 55 of the NHA furthermore requires that consent for the removal of blood from a living person – which is the case with stem cell banking – must be given in *writing*.
- Section 6 of the NHA specifies the specific information that must be provided, but its applicability to stem cell banks is debatable.[418]

It is clear that the law already enforces informed consent in the context of stem cell banking. However, given the particular situation of stem cell banking with regard to the current limited therapeutic use of stem cells, I suggest that the provisions of the NHA can be supplemented by regulations on stem cell banking that provide guidelines as to what constitutes adequate information during informed consent, and also requires health professionals to disclose any financial interests.[419] The guidelines as to what constitutes adequate information should require that the low likelihood of using the stem cell unit and the indefinable and hypothetical nature of future therapeutic possibilities are communicated in all media used by private stem cell banks.[420] In addition, adequate information should also include information about the procedures followed for collection, processing, testing, storing, and use of

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[418] NHA s 6 specifies that 'health care providers' must inform the users of health services of, inter alia, the benefits, risks, costs and consequences of the treatment options. A 'health care provider' is defined by NHA s 1 as a person providing health services 'in terms of any law', such as the Health Professions Act. Although a gynaecologist (who may discuss the matter of stem cell banking with a patient *independent* of a stem cell bank) is thus clearly a 'health care provider', it is debatable whether a stem cell bank qua legal person would qualify as such and therefore be subject to the provisions of NHA s 6. It can be argued that a stem cell bank is indeed a person providing health services 'in terms of any law' – the relevant law being the NHA itself – and that a stem cell bank would therefore qualify as a health care provider. It can, however, be counter-argued that it is questionable whether it is the intention that a definition in the NHA referring to 'any law' would include the NHA itself. This uncertainty can be addressed by an amendment of the NHA.

[419] These suggested regulations are amongst recommendations made by: Mitchell S Cairo et al 'Cord blood banking for potential future transplantation' (2007) 119 *Pediatrics* 165.

[420] These guidelines as to what constitutes adequate information are amongst recommendations made by: European Group on Ethics in Science and New Technologies op cit note 350.

stem cells.[421] The clear purpose of such special informed consent measures would be to counter undue influence and lack of relevant information that could compromise a parent's autonomy in deciding to conclude a contract with a private stem cell bank.

A further crucial factor that colours the psychological landscape of private stem cell banking is pregnancy. Pregnancy per se does not influence an expectant mother or couple's legal capacity to conclude contracts. During the nine-month pregnancy-period parents might make fundamental life-altering decisions in several areas, without such parents' capacity to make these decisions being doubted. However, on the extreme side of the spectrum, such as when a woman is about to go into labour, caution is certainly justified. It must be conceded that such an extreme situation could potentially compromise autonomy and accordingly warrants protective measures. It has been suggested that written informed consent must be obtained during pregnancy prior to the onset of labour, followed by confirmation of consent after delivery.[422] Although I agree that informed consent should ideally be obtained as early during pregnancy as possible and that private stem cell banks should not actively market their services to women who are in labour, experience has shown that there are indeed cases where women who are in labour specifically request private stem cell banking. To deny a woman who has gone into labour the opportunity to conclude a private stem cell banking contract would be to penalise the very person who is supposed to be protected.

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[421] These guidelines as to what constitutes adequate information are amongst recommendations made by: Elena Salvaterra et al 'The ethics of cord blood banking in light of ownership, informed consent, and solidarity' (2006) 4 *Cell Preserv Technol* 91.

[422] Drawing the line at labour and also requiring post-natal confirmation are recommendations made by: American Academy of Pediatrics Working Group on Cord Blood Banking 'Cord blood banking for potential future transplantation' (1999) 104 *Pediatrics* 116; Jeremy Sugarman et al 'Ethical issues in umbilical cord blood banking' (1997) 278 *J Amer Med Assoc* 938.

The emotional vulnerability of the expecting parents during pregnancy can be addressed effectively through granting parents a cooling-off period after delivery.[423] Such a cooling-off provision would entail that written informed consent to a private stem cell banking contract must again be confirmed in writing after birth. Should confirmation not be obtained after birth, the private stem cell banking contract would be null and void. In such a case, provision should be made that the parents will only be liable for the private bank's reasonable costs relating to the acquisition of the stem cells.

Implementation of these special measures with regard to informed consent in the context of private stem cell banking will require informed consent at a higher level than is generally the case with health services in the private health care sector, and effectively address the concerns underlying the compromised-autonomy argument. The principle that the compromised-autonomy argument aims to promote, namely the autonomy of the potential clients of private stem cell banking, is certainly a purpose that is aligned with our constitutional ethos, and in particular human dignity. However, this purpose does not necessitate a ban on private stem cell banks. The Bill of Rights' limitation test requires inter alia that a limitation must be proportional to the purpose that it seeks to accomplish, entailing that the less restrictive means available must be employed to accomplish the purpose.[424] Such less restrictive measures are indeed available: first, providing guidelines regarding what constitutes adequate information; secondly, obliging health professionals to disclose any financial interests; and lastly, providing for a cooling-off period post-delivery. These measures are not only less restrictive, but would per se promote autonomy and hence human dignity. In the light of the availability of these less restrictive means to accomplish the purpose of promoting autonomy, the compromised-autonomy argument qua justification for a ban on private stem cell banks must fail the Bill of Rights' limitation test.

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[423] Cf K J Moise Jr 'Umbilical cord stem cells' (2005) 106 *Obstet Gynecol* 1393.

[424] The Constitution s 36(1)(e).

4.4 Conclusion on the human rights challenge: regulate rather than ban

It must be concluded that a ban on private stem cell banks would kill the proverbial goose that potentially lays the golden eggs. In South Africa's constitutional dispensation, a ban on private stem cell banking – whether effected through provisions such as those contained in the 2007-version of the draft regulations or in any other way – would constitute an unjustifiable infringement on no less than four enumerated rights and would hence be unconstitutional and void.[425] Instead of an unconstitutional ban, I have suggested that the objectives of, first, promoting autonomy and, secondly, establishing a public stem cell bank can indeed be attained in a constitutionally acceptable fashion through less restrictive regulatory means.

Finally, it may be noted that the crux of my conclusion is aligned with the official position of the South African Society of Obstetricians and Gynaecologists:[426]

> SASOG is in favour of freedom of choice and if patients have the resources and wish to store their baby's stem cells, the profession should comply with their wishes provided that there are no contra-indications and that the safety of the mother and baby are always the priority during labour.

4.5 Paternalism redux

Should a ban on private stem cell banks be instituted, it would constitute hard paternalism: A ban would have more to do with imposing a certain conception of equality on all of society, than with promoting autonomy. In contrast, the less restrictive means that I am proposing would constitute soft paternalism, as

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[425] Although generally skeptical about private stem cell banking, the European Group on Ethics in Science and New Technologies op cit note 350 has come to the conclusion that a strict ban would represent an undue restriction on the freedoms of enterprise and choice of individuals.

[426] South African Society of Obstetricians and Gynaecologists *Umbilical Cord Blood Banking* (Undated) available at *http://web.archive.org/web/20070924061110/http://www.sasog.co.za/B_drcnr_PosStatements_011.asp*.

potential private stem cell bank clients will first have to read (or listen to) specified information before they can enter into private stem cell banking contracts. Similarly, at the conclusion of the previous chapter of ASC therapy,[427] I conclude that the regulation of ASC therapy constitute soft paternalism. However, the kinds of intervention in the two cases (ASC therapy and private stem cell banking) are clearly dissimilar. Can such dissimilarity be justified? If, in the case of private stem cell banking, the autonomy-related concerns could be addressed through less restrictive measures than an outright ban, could *similar less restrictive measures* not also address the autonomy-related concerns in the case of ASC therapy? In the following, I will endeavour to answer this question:

- First, the regulation of medicines does not amount to a permanent ban on ASC therapy in general, only a temporary ban that is lifted on a case by case basis when and if a specific ASC therapy has passed through clinical trials.
- Secondly, the less restrictive means in the context of private stem cell banking entails special *informed consent* requirements. In the case a ASC 'therapy' for which therapeutic claims are made, but which has not passed through clinical trials, informed consent to use such a ASC 'therapy' qua therapy/medicine is simply not possible, as there is insufficient scientific information available. A person can at most give informed consent to become part of a clinical trial of such ASC 'therapy', which would in principle be legal.
- Thirdly, the potential harmful consequences of private stem cell banking on the one hand and submitting to ASC therapy on the other are qualitatively different: In the case of banking of stem cells for possible future use as medicine, potential harm is limited to the monetary cost to the client of the private banking; in the case of the actual use of stem cells qua 'medicine', potential harm extends far beyond wasted money, and includes health

[427] Refer to Chapter 5: Autologous stem cell therapy, 4.6 Distinguishing the regulation of ASC therapy from the regulation of embryo research and the use of gametes: hard versus soft paternalism supra.

complications that may be of a very serious nature. This difference also calls for the kind of soft paternalism intervention applied in the case of ASC therapy to be of a stronger nature. To illustrate: While a cooling-off provision is workable in the case of private stem cell banking, with the contractual obligations becoming null and void, a cooling-off provision would not assist a patient who developed an adverse reaction such as a malignant tumour following ASC 'therapy'.

5 Conclusion

It should be noted that it has not been the purpose of this chapter to make comprehensive recommendations on the regulation of stem cell banking, such as on quality assurance, accreditation, or even ownership of stem cells. The purpose, in line with the themes of this thesis, has specifically been to, first, analyse the current legal position regarding private stem cell banks and appraise its level of legal certainty; and, lastly, to conduct a human rights analysis of a hypothetical – yet entirely possible – ban on private stem cell banks and to make recommendations within this context. In summary, I have concluded that there is significant legal uncertainly in the current legal position regarding private stem cell banks; and that a hypothetical ban on private stem cell banks would be unconstitutional, and I have identified alternative policy options that should rather be considered.

Chapter 7

Conclusion

1 The analytical journey's end

The analytical journey of this thesis roughly followed the logical progression of the development of a new medicine, or a new stem cell therapy in particular: It all starts with research – and it is especially here where a spirit of free inquiry is essential for progress; research is followed by clinical trials to ensure the safety and efficacy of the new stem cell therapy; and lastly, a functional system of umbilical-cord-blood-derived stem cell banks may contribute to providing the stem cells required for such new stem cell therapies. Now, at the conclusion of this analytical journey, I integrate and discuss its main findings.

2 Discussion of results

This thesis analysed South African medical biotechnology law according to the two main research *themes*:

- The alignment of South African medical biotechnology law with the Bill of Rights, which is paralleled on a meta-level by the classic freedom-suppression conflict
- The level of legal certainly within South African medical biotechnology law

These analyses were conducted with specific reference to four topical *subjects* within the scope of medical biotechnology law, namely:

- human embryo research
- the use of human gametes
- autologous stem cell therapy
- private stem cell banking

Throughout these analyses, consideration was given not only to current law, but, given the peculiar situation of the NHA Chapter 8 being enacted in 2003 but ever

since hanging like the sword of Damocles over the HTA, just waiting to replace it, consideration was also specifically given to the NHA Chapter 8 – the anticipated law.

In the following, the results of the analysis of each subject are summarised in the light of the research themes.

2.1 Human embryo research

In stark contrast to the way our law deals with human pre-embryos that find themselves inside a woman's body – namely that the woman is given unregulated, absolute freedom to terminate the pre-embryo – the use (and consequent termination) of a pre-embryo to the benefit of science is hyper-regulated; while the pre-embryo creation-termination cycle is unregulated when it is a by-product of heterosexual sex, the same cycle is illegal when it is the intentional result of a scientist wishing to conduct research on such pre-embryo. This ban on creating human embryos for research is constitutionally indefensible and constitutes suppression of the freedom of scientific research. Moreover, the NHA will further suppress the freedom of scientific research by sinking human embryo research further into hyper-regulation with its requirement of ministerial approval. On the legal certainty dimension the situation is similarly dismal, given the lack of objective criteria for approving human embryo research.

2.2 The use of human gametes

The use of human gametes outside the context of sexual intercourse is juridically medicalised and regulated: The HTA outlaws the use of gametes 'removed or withdrawn' from a living person for non-medical purposes. As illustrated by the hypothetical case study of a boy and his microscope – a metaphor of a free (and harmless) spirit of enquiry – this ban of using human gametes for non-sexual, non-medical purposes unjustifiably infringes on privacy. As the relevant section of the NHA suffers from an ambiguous formulation that is capable of divergent interpretations, the door is opened to the possibility of tilting the scale in favour of freedom on this subject. However, whichever interpretation is favoured, the ambiguity inherent in the NHA constitutes a classical case of legal uncertainty.

2.3 Autologous stem cell therapy

In contrast to the previous subjects where the freedom of scientific research and the spirit of free enquiry are suppressed, the regulation of ASC therapy is based on and reinforcing science and human dignity. The regulation of ASC therapy harmonises the freedom of scientific research on the one hand, and the freedom to take decisions regarding one's own body and health in an informed way on the other.

However, legal certainty is not only determined by the relevant law per se, but also by public perceptions – whether accurate or not. In the case of ASC therapy, the NBAC, which ironically lacks any legal expertise amongst its members, has officially declared a legislative vacuum regarding stem cell therapy. This incorrect and alarmist interpretation of the law has thus far been unopposed. Accordingly I suggest that the legal certainty regarding ASC therapy is ambivalent.

2.4 Private stem cell banking

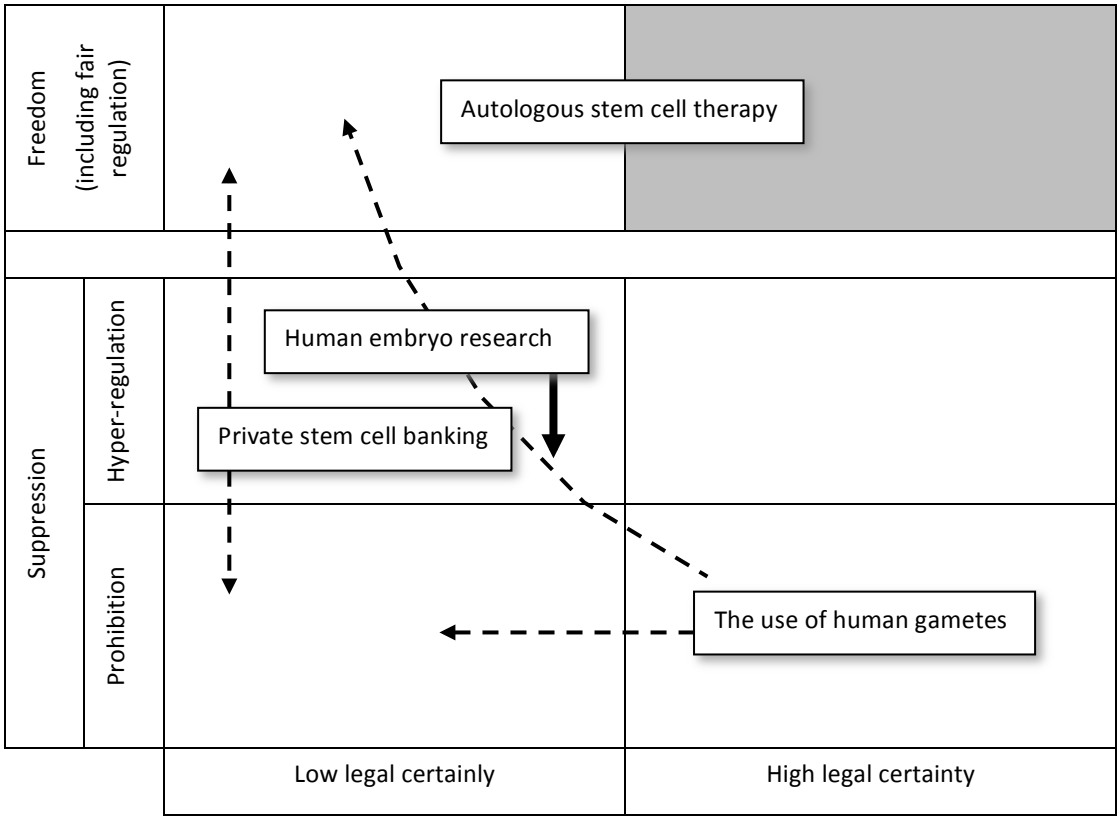
The issue of private stem cell banking is entangled in the politics of access to healthcare and the concomitant equality-of-the-graveyard mentality. Although the government's policy dance entailed a forward step away from hyper-regulation in one respect (the NHA apparently doing away with the requirement of ministerial consent), in another respect it has been followed by a backward step right into effective prohibition (the 2007-version of the draft regulations), and then a forward step again out of prohibition (the 2011-version of the draft regulations). Given this unpredictable policy dance, legal certainty is seriously compromised. This lack of legal certainty is worsened by a) the use in the NHA of the undefined concept 'progenitor cells'; and b) the NHA's profit-ban on particular services that are associated with private stem cell banking.

While the HTA requires ministerial approval without providing any criteria for such approval (similar to human embryo research), it is unclear in which direction the law regarding private stem cell banking will eventually evolve under the NHA.

2.5 Conclusion

The results of the analysis of each subject is summarised in Figure B, which visually plots the *current* legal position of each of these subjects onto the two dimensions of legal certainty-uncertainty and freedom-suppression, and indicates with arrows the *anticipated* position (in terms of the NHA) of each subject along these two dimensions. The top right-hand block on the diagram (indicated with a shaded background) represents the space where each subject *should* be, namely at the intersection of freedom and legal certainty. It should be noted that only one of the four subjects, autologous stem cell therapy, find itself *halfway* in this space, while the other three subjects are all currently in the suppression space. The *anticipated* positions of the latter three subjects on the freedom-suppression axis are either uncertain or, in the case of human embryo research, deepening the suppression. On the legal certainty-uncertainty axis, the anticipated positions of these three subjects all gravitate towards legal uncertainty.

Figure B: The subjects plotted on a landscape of the research themes



From a human rights perspective and from a legal policy perspective that favours legal certainty, the above conclusion should be cause for grave concern. Urgent and comprehensive legal reform is clearly necessary. This is addressed in the following paragraphs.

3 Recommendations

In the following, the recommendations made throughout this thesis are integrated, structured chronologically as per relevant section of the NHA, followed by regulations in terms of the NHA, the MRC *Guidelines* and lastly recommendations regarding executive actions. Importantly, the NHA Chapter 8 must enter into force as soon as the amendments detailed below have been effected by parliament, hence obviating the need to amend the HTA.

3.1 Chapter 8 of the National Health Act

The following amendments to Chapter 8 of the NHA are recommended:

> 56. (1) A person may use tissue or gametes removed or blood or a blood product withdrawn from a living person, where such use is ~~only~~ for ~~such~~ medical or dental purposes, only as ~~may be~~ prescribed.[428]
>
> (2) (a) Subject to paragraph (b), the following tissue, blood, blood products or gametes may not be removed or withdrawn from a living person for any purpose contemplated in subsection (1):
>
> […]
>
> (iv) placenta, embryonic or foetal tissue, stem cells and umbilical cord, excluding umbilical-cord-blood-derived stem ~~progenitor~~ cells.[429]

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[428] This amended version of NHA s 56(1) will clarify the current ambiguity in line with the Bill of Rights. Refer to Chap 4: The use of human gametes supra.

[429] This amendment will clarify the current uncertainty caused by the use of the controversial and undefined term 'progenitor cell'. Refer to Chap 6: Private stem cell banking, 3.2.1 Simplification of authorisation supra.

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

[...]

Establishment of the National Embryo Research Ethics Committee[430]

56A (1) A committee to be known as the National Embryo Research Ethics Committee is hereby established.

(2) The National Embryo Research Ethics Committee must consist of five to eight members, each appointed by the Minister for a non-renewable term of four years from nominations received following a call for nominations in a national newspaper.

(3) In appointing the members of the National Embryo Research Ethics Committee, the Minister must endeavour to promote a balanced representation in terms of industry vis-à-vis academia, gender, and fields of expertise including life sciences, medical law, and medical ethics.

(4) The National Embryo Research Ethics Committee will have the functions as provided for herein and as may be prescribed.

[...]

57 (4) The National Embryo Research Ethics Committee shall[431] ~~Minister may~~ permit research on stem cells and zygotes which are not more than 14 days old on a written application and if –

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[430] Similar to the comparative jurisdictions that were analysed in Chap 3: Human embryo research, namely the UK, Belgium and the Netherlands, it is recommended that South Africa also establishes a representative, knowledgeable entity to serve as regulatory authority for human embryo research. Refer to Chap 3: Human embryo research, 5.6 Additional observations: regulatory structures supra.

[431] Assuming the respect-for-the-embryo paradigm, regulation of human embryo research is required. However, the National Embryo Research Ethics Committee must only evaluate whether an application complies with the legal requirements; in the interest of legal certainty, the National Embryo Research Ethics Committee does not have any discretion beyond these objective legal requirements.

(a) the applicant undertakes to document the research for record purposes; ~~and~~

(b) prior consent is obtained from the donor of such stem cells or zygotes; and

(c) the application complies with the criteria for approving embryo research as prescribed.[432]

(4A) In the event that the National Embryo Research Ethics Committee fails to make a decision on an application as contemplated in subsection (4) in two months from receiving such application, such application will be deemed to be approved.[433]

[...]

60. (1) No person, except–

[…]

(b) a person or an institution contemplated in section 63 or an authorised institution, may receive any payment in respect of the importation, export or acquisition for the supply to another person of blood or a blood product.

(2) The amount of payment contemplated in subsection (1) may not exceed an amount which is reasonably required to cover the costs involved in the importation, export, acquisition or supply of the tissue, gamete, blood or blood product in question.

(2A) The activities contemplated in subsection (2) do not include the purification, analysis, or storage of umbilical-cord-blood-derived stem cells.[434]

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[432] As argued in Chap 3: Human embryo research, having objective, substantive criteria for approving embryo research is essential from a legal certainty perspective. These criteria are presented in this chapter, 3.2.1 Regulations regarding human embryo research infra.

[433] This is similar to the provision in Belgian law. Refer to Chap 3: Human embryo research, 5.6 Additional observations: regulatory structures supra.

[434] The purpose of this amendment is to clarify that the words the words 'importation, export, acquisition or supply' are not all-inclusive, but that certain essential services performed by private stem cell banks for their clients, such as purification, analysis, and storage of such stem

3.2 Regulations in terms of the National Health Act

In addition to the above amendments to the NHA, regulations must be made in terms of the NHA to provide for the following:

- Substantive criteria for approving human embryo research within the respect-for-the-embryo paradigm
- Special informed consent requirements in the case of private stem cell banking

In the following, recommendations regarding these two sets of regulations are presented:

3.2.1 Regulations regarding human embryo research

Regulations regarding human embryo research must be made to establish the following objective, substantive criteria for approving human embryo research:[435]

- *Medical scientific purpose.* The proposed research must have a medical scientific purpose.
- *No equally effective alternative.* There must be no alternative to the proposed research methodology that will not entail the use of embryos and still be equally effective in achieving the purpose of the proposed research.
- *Good scientific practice.* The proposed research must be aligned with good scientific practice, measured by the following criteria:
    - *Sound methodology.* The proposed research must have a sound research methodology. This entails inter alia that:
        - The research methodology must entail the destruction of the smallest possible number of embryos necessary to achieve

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cells, are not included in the profit ban of NHA s 60. Refer to Chap 6: Private stem cell banking, 3.2.2 A profit ban? supra.

[435] Refer to Chap 3: Human embryo research, 5.5 Recommendations supra.

the research purpose without compromising the efficacy of the research.

- The research methodology must be based on the latest scientific findings.

- *Expertise of researchers.* The key research team members must have the expertise necessary to conduct the proposed research.

3.2.2 Regulations regarding private stem cell banking

Regulations regarding private stem cell banking must be made to establish the following special informed consent requirements:[436]

- Adequate information must be communicated by a private stem cell bank to its prospective clients through informed consent. In addition to the information that must be communicated in terms of the NHA, adequate information in the context of stem cell banking entails the following:
  - Information about the procedures followed for collection and processing of umbilical cord blood, as well as testing, storing, and thawing out of umbilical-cord-blood-derived stem cells
  - Information pertaining to the low likelihood of using the umbilical-cord-blood-derived stem cells and the indefinable nature of future therapeutic possibilities, both autologous and allogeneic
- The information contemplated in the last sub-bullet above must be communicated in all printed and electronic media used by a private stem cell bank.
- Health professionals must disclose to a prospective client any financial interests relevant to the stem cell bank in question.

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[436] Refer to Chap 6: Private stem cell banking, 4.4 Conclusion on the human rights challenge: regulate rather than ban supra.

- Any private stem cell banking contract must be subject to a cooling-off period post-delivery.
- Should a public stem cell bank be established in South Africa, private stem cell banking clients must be informed of the benefit to wider society of donating to a public bank, and given the option to contribute to a public bank if they so desire.

Furthermore, in the context of regulations regarding private stem cell banking, no provision in such regulations may amount to an effective ban (or an explicit ban) on private stem cell banking.[437]

3.3 MRC's *Guidelines*

The MRC's *Guidelines* must be amended as follows:[438]

> **2.2 Research on pre-embryos**
>
> A pre-embryo is defined as the product of gamete union from the time of fertilisation to the appearance of the embryonic axis. The pre-embryonic stage is considered to last for 14 days. The pre-embryo should be treated with the utmost respect because it is a genetically unique, viable human entity. If pre-embryo transfer to the uterus is envisaged, special care should be taken to ensure the welfare of the potential fetus. ~~The production of excess embryos for the sole purpose of research should be discouraged.~~
>
> **2.17 Pre-embryo manipulation and research**
>
> Pre-embryo manipulation and research may yield valuable medical information. ~~However, it can be regarded as ethical only if the embryos are not specifically produced for the purpose of research. In addition, the~~ Where embryos have been the subjects of research, such

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[437] The regulatory measures presented here would sufficiently address the rationales of the promotion of autonomy and the public interest in the viability of a public stem cell bank; given the constitutional principle of proportionality, these rationales cannot justify a ban on private stem cell banks. Refer to Chap 6: Private stem cell banking, 4.4 Conclusion on the human rights challenge: regulate rather than ban supra.

[438] The ban on creating embryos for research cannot withstand constitutional scrutiny. Refer to Chap 3: Human embryo research, 6.7 Conclusion on the human rights challenge, and 6.8 Recommendation supra.

embryos should not be transferred to the uterus unless there is reasonable certainty that the manipulation carries no potential risks for the fetus.

3.4 Executive actions

Apart from the recommendations regarding legislative reform, I also recommend the following executive actions:

- *The MCC*. First, the MCC must take proactive steps to regulate bone marrow transplantation. The fact that bone marrow transplantation qualifies qua biological medicine, but is unregulated, sets an undesirable precedent.[439] Secondly, the MCC must issue a practice note on its website to the effect that the NBAC position paper entitled *Position statement on Stem Cell Regulations in South Africa*[440] is incorrect and that stem cell therapy indeed falls within the MCC's regulatory mandate.[441]
- *The Minister of Science and Technology*. Given the embarrassment that the NBAC position paper is plainly uninformed and wrong; given that the NBAC position paper may open the door on delictual liability; and given that NBAC reports to the Minister of Science and Technology, said Minister should publicly and immediately rectify the perception of a regulatory vacuum that was created by the NBAC position paper.[442]
- *The Department of Health*. In the light of the state's constitutional duty to take reasonable measures within its available resources to achieve the progressive realisation of access to health care, and given the private banks' commitment to contribute part of the necessary resources, I recommend

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[439] Refer to Chap 5: Autologous stem cell therapy, 3.1.4 The Precedent of Non-Regulation Argument: The current non-regulation by the MCC of a certain autologous stem cell therapy sets a precedent for autologous stem cell therapy in general supra.

[440] NBAC op cit note 321.

[441] Refer to Chap 5: Autologous stem cell therapy, 5 Conclusion: this regulatory world is round, and 6 Postscript: rectifying the perception of a regulatory vacuum supra.

[442] Ibid.

that the Department of Health should provide for the establishment of a public stem cell bank in South Africa through consultation with all relevant stakeholders, including private banks, and contractually secure the private banks' resource-contributions towards a public bank.[443] The public stem cell bank must have a clear mandate to actively recruit donations.

4 Conclusion: Final remarks on sentimental morality, human dignity and biolaw

In the introduction of this thesis I noted that medical biotechnology is an emotionally loaded subject, and as such that there exists a higher than usual possibility of legislative efforts being informed by prevailing emotional sentiments that may be contrary to the values enshrined in the Constitution. As has been evidenced throughout the thesis, this possibility has indeed materialised:

- The notion that an embryo is a 'symbol of human life' that is worthy of 'respect' to the degree that scientific research on embryos is legally inhibited to the detriment of human progress[444]
- The aversion to the idea of a boy playing with his own sperm, as evidenced by non-medical uses of gametes being outlawed in the HTA (and ambiguously reformulated in the NHA)[445]
- The unfounded fear that South Africa's regulatory framework regarding stem cell therapy is non-existent, hence allowing unscrupulous merchants of

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[443] Refer to Chap 6: Private stem cell banking, 4.3.2 The diversion-of-resources argument supra.

[444] The reader is reminded of the duality inherent in my analysis of the subject of human embryo research, and that while I have for pragmatic reasons made recommendations within the current dominant paradigm of respect-for-the-embryo, such pragmatism should not detract from the core principled conclusion of Chap 3: Human embryo research, namely that the limitations on embryo research demanded by the paradigm of respect-for-the-embryo are unconstitutional.

[445] Can it be the connotation with sex that occasions this antipathy to the spirit of enquiry when applied to sperm?

untested stem cell 'therapies' to mislead and even harm the unsuspecting South African public

- The levelling down conception of equality, entailing that if the all cannot have access to a certain medical service, no one should have such access

Through the rational process of human rights analysis, I have endeavoured to expose these prevailing emotional sentiments and their incompatibility with the values underlying the Constitution. In this regard, I have placed special emphasis on the value of human dignity for two reasons: first, because human dignity has universal appeal, but is lacking an authoritative construction in international biolaw and bioethics discourse, hence leading to the twisting of the meaning of human dignity to suit any particular bioethical position; and, secondly, because human dignity is the touchstone of the South African constitutional dispensation, with human dignity's meaning been extensively analysed and authoritatively established by the Constitutional Court, hence offering a beacon of light in the dark and stormy oceans of international biolaw and bioethics discourse.

The application of the value of human dignity to each of the biotechnology subjects that were analysed in this thesis can be summarised as follows:

- *Human embryo research.* Human dignity is expressed in the right to freedom of scientific research, entailing that scientists must be free to create embryos for research and to destroy such embryos during research without being stymied by regulations.[446]
- *The use of human gametes*. Human dignity is expressed in the right to privacy: What I may choose to do with my own sperm in the privacy of my home is nobody's business but mine.
- *Autologous stem cell therapy.* Human dignity requires the rigorous scientific methodology of and scientific data generated by clinical trials; any new medicine must be subjected to clinical trials before it may be provided to patients.

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[446] Refer to note 444.

- *Private stem cell banking.* Human dignity requires a levelling up conception of equality, and also that informed consent must include the communication of scientific data pertinent to private stem cell banking.

What appears clearly from the above summary is the *alignment of human dignity and science*: that human dignity supports freedom of scientific research and a free spirit of enquiry, and that human dignity requires and depends on a scientific methodology and scientific data. In international biolaw and bioethics discourse, the banner of human dignity should therefore rightly be claimed by those who are pro-science and who stand to oppose the irrational, emotional onslaught of sentimental morality.

Epilogue

Looking into the future

Looking into the future, the most far-reaching and controversial aspect of the biological revolution is certainly the possibility of human genetic engineering, id est, introducing genes from other species, or – more likely – artificially designed genes into the genome of human individuals – likely at pre-embryonic stage. In the debate about human genetic engineering, the human dignity platform has generally been monopolized by conservative commentators, who generally argue either for a comprehensive ban on such technology, or for only allowing such technology for therapeutic purposes. However, given my analysis of human dignity in Chapter 2: Human dignity of this thesis – and especially the prominent role of autonomy as an element of human dignity – the human dignity platform can offer strong arguments to the permissive side in the human genetic engineering debate. Consider for instance the following argument: Human genetic engineering will enable humankind to shape our own future on an entirely new level; we will *self-determine* the genetic characteristics of our species, instead of leaving such determination to the random forces of nature. From this perspective it can be argued that human genetic engineering radically enhances autonomy and hence human dignity.

However, the analysis of human dignity as autonomy also implies an important limitation on the use of human genetic engineering. Autonomy – the ability to regulate one's own affairs and to choose how to live one's live within the overall framework of a broader community – implies that one should have a *choice of a reasonable array of different life plans* available to members of one's society. Apart from societal and other environmental factors, a person's genetic endowment can obviously also heavily impact on the scope and content of the array of different life plans available to such person. Accordingly, human genetic engineering should not be used in such a way as to result in the reduction of this reasonable array of different life plans. Essentially, autonomy should not be used to compromise itself;

prospective parents' autonomy to use genetic engineering should be limited by the prospective child's future capacity for autonomy.

A question of relevancy is therefore posed and hangs above the therapy-versus-enhancement demarcation that characterises much of the current debate on human genetic engineering.[447] If human dignity is accepted as the paradigm for this debate, should the demarcation of ethical and legal permissibility not rather be drawn between those uses of genetic engineering that compromise the capacity for autonomy, and those that are neutral or enhancing towards the capacity for autonomy?

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[447] Cf Francis Fukuyama *Our Posthuman Future: Consequences of the Biotechnology Revolution* (2003).

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1.4.3 Spain

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