FLAWED LAW: A CRITICAL ANALYSIS OF THE FAULTS AND SHORTCOMINGS OF CHAPTER 8 OF THE NATIONAL HEALTH ACT OF 2003

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SUMMARY

During 2011 health law grew by the addition of eight new of Regulations dealing with stem cells and related matters. This added to the already existing six of Regulations which had been sporadically published since 2007. All these Regulations supplement the National Health Act of 2003. This legislative excess begs the question: Why has it been at all necessary to flood the legislative landscape surrounding the Act. The Act is a complex one and it entrenches various health policy principles. It is also framework-legislation meaning that only broad legal guidelines are provided and it must be "fleshed out" in Regulations. This however does not satisfy the question as to why this "fleshing out" has been done so overwhelmingly considering the period of time which the Act has been in force and keeping in mind these Regulations apply only to a single chapter of the Act. The aim of this article is thus an analysis of certain provisions in chapter 8 of the Act which will entail an explanation of its content, followed by a dissection thereof and suggestions. Ultimately, this article attempts to illustrate that stem cell research, therapy and technology in general is not sufficiently regulated by chapter 8 which is so fatally flawed that it is almost dead legislation. It is recommended that new and comprehensive, updated and corresponding Regulations be drafted to supplement and correct the Act.

1 INTRODUCTION

On 1 April 2011 the body of health-related legislation was, shall we say, enriched, or perhaps burdened, by the addition of eight new sets of Regulations dealing with stem cells and related matters.[1] This added to the six already existing Regulations sporadically published in the Government

[1] The Regulations are: the Regulations relating to Artificial Fertilisation of Persons; Regulations relating to the Use of Human Biological Material; Regulations relating to Stem Cell Institutions or Organisations; Regulations relating to the Import and Export of Human Tissue, Blood, Blood Products, Cultured Cells, Embryos, Zygotes and Gametes; Regulations relating to Tissue Banks; Regulations regarding the General Control of Human Bodies, Tissue, Blood, Blood Products and Gametes and the Regulations relating to Blood and Blood Products as published in *GG* R 34159 of 2012-04-01.

Gazette from 2007.[2] These fourteen Regulations as well as various Commencement Notices and Amendment Bills constitute (in the author's opinion) the excessive, supplementary legislative documentation to the National Health Act (NHA).[3] This is even more astonishing when considering that these documents supplement only chapter 8 of the NHA and that chapter 8 only fully came into force on 1 March 2012. This excessive supplementation may lead one to ask the question as to why it has been necessary to, proverbially, flood the legislative plain.

An answer to this might be found in the fact that the NHA is complex legislation in both its scope and objectives and entrenches various principles of health policy which have been developed over the years. It is also framework-legislation, meaning that it prescribes a broad legal and operational system of principles which are to be "fleshed out" in Regulations.[4] Although this is true it is still concerning that this has been done in such abundance since usually, the number of Regulations as supplementary documentation made in terms of an Act is smaller in number or at least occurs over a longer period of time or covers a larger scope than a mere chapter of an Act. The observation which could be made is that chapter 8 of the NHA is fatally flawed. As will be illustrated by this article, chapter 8 is *inter alia* outdated and lags behind scientific development and progress, it contains factual errors, creates *lacuna* and hands the Minister of Health excessive authority and power.

The objective of this article is therefore a critical analysis of certain sections of chapter 8. This will entail an explanation of the content of certain selected sections which will be followed by a dissection thereof as well as relevant recommendations. Ultimately, this article wishes to illustrate that development of stem-cell research and therapy as well as technology of this kind, cannot be properly regulated and controlled by inadequate legislation which is so fatally flawed that it is worthless and dead legislation. Firstly, however, it may be important to briefly discuss the history and background of the NHA as a whole.

2 A BRIEF HISTORY OF THE NHA

On 19 August 2004 the then Minister of Health, Manto Tshabalala-Msimang, delivered a briefing on the NHA wherein it was stated that the NHA replaced "the last vestige of apartheid in health policy", referring to the old Health Act.[5]

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2 The Regulations are: the 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 and the Regulations regarding Artificial Fertilisation and Related Matters in *GG* R 29526 of 2007-01-05. The Regulations relating to Research on Human Subjects; Regulations relating to the National Health Research Committee and the Regulations relating to the National Research Ethics Council in *GG* R 29637 of 2007-02-23 and lastly the Regulations relating to Human Stem Cells in *GG* R 29840 of 2007-05-04.

3 61 of 2003.

4 Department of Health "Briefing by the Minister of Health on the National Health Act" (19 August 2004) http://www.doh.gov.za/docs/pr/2004/pr0819.html (accessed 2010-08-06).

5 63 of 1977.

It was further stated that the NHA provides the framework for a structured and uniform health system under which the various elements of the South African national health system may be united in the common goal of improving universal access to quality health services by taking into account the obligations imposed by the Constitution of the Republic of South Africa, 1996 (the Constitution).[6]

The NHA relies heavily on the Constitution by directly drawing on some 50 constitutional sections and, according to the Minister's briefing, the inclusion of such constitutional provisions is what makes the NHA the single most important piece of legislation in the health sector. At the time of this statement, the NHA had not come into force and would only fully do so almost eight years later.

3 CHAPTER 8

Chapter 8 provides for some complicated issues such as the control of the use of blood, blood products, tissue and gametes in humans. The most

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[6] Department of Health http://www.doh.gov.za/docs/pr/2004/pr0819.html. The preamble to the NHA further eludes to the reformative spirit of the Act and reads as follows:

"**Preamble**

Recognising –

- the socio-economic injustices, imbalances and inequities of health services of the past;
- the need to heal the divisions of the past and to establish a society based on democratic values, social justice and fundamental human rights;
- the need to improve the quality of life of all citizens and to free the potential of each person;

Bearing In Mind That –

- the State must, in compliance with section 7(2) of the Constitution, respect, protect, promote and fulfil the rights enshrined in the Bill of Rights, which is a cornerstone of democracy in South Africa;
- in terms of section 27(2) of the Constitution the State must take reasonable legislative and other measures within its available resources to achieve the progressive realization of the right of the people of South Africa to have access to health care services, including reproductive health care;
- section 27(3) of the Constitution provides that no one may be refused emergency medical treatment;
- in terms of section 28(1)(c) of the Constitution every child has the right to basic health care services;
- in terms of section 24(a) of the Constitution everyone has the right to an environment that is not harmful to their health or well-being;

And In Order To –

- unite the various elements of the national health system in a common goal to actively promote and improve the national health system in South Africa;
- provide for a system of co-operative governance and management of health services, within national guidelines, norms and standards, in which each province, municipality and health district must address questions of health policy and delivery of quality health care services;
- establish a health system based on decentralised management, principles of equity, efficiency, sound governance, internationally recognised standards of research and a spirit of enquiry and advocacy which encourages participation;
- promote a spirit of co-operation and shared responsibility among public and private health professionals and providers and other relevant sectors within the context of national, provincial and district health plans."

important element of chapter 8 is, however, the fact that it is the proposed legislative tool whereby stem cells and related activities will be regulated in South Africa. As stem-cell research and therapy are becoming more prominent and are no longer science fiction but an actual medical reality, and due to the fact that these inherently entail not only great ethical issues[7] but also real health risks,[8] it is of immense importance that this technology is well regulated and controlled.

Chapter 8 was published with the title "Control of Use of Blood, Blood Products, Tissue and Gametes in Humans". It is recommended that the title be amended in some way, either directly or under an umbrella term, to include stem cells. After all, chapter 8 is the proposed regulatory tool for the regulation and control of stem cells.

3 1 Definitions

The first issue which is immediately obvious is the lack of certain relevant definitions. A shocking example of this is the fact that the NHA does not contain a definition of "stem cells". Definitions direct the user and interpreter of legislation as to the meaning of certain terms. A general rule of legal interpretation requires that words must be interpreted in accordance to their ordinary, grammatical meaning unless the words carry specialized or technical meanings. The term "stem cell" has a definite, specialized meaning and for this reason a definition of the term should be provided. Furthermore, as the NHA and chapter 8 in particular purport to regulate stem-cell research and therapy, it is naturally expected that a definition of the terms should be included. It is therefore recommended that such a definition be included under the NHA.

3 2 Section 55: Removal of tissue, blood, blood products or gametes from living persons

Section 55 states that a person may not remove tissue, blood, a blood product or gametes from another living person's body unless the person from whom the tissue, blood, blood product or gametes are removed has granted permission therefore in the prescribed manner[9] and such removal is done in accordance with the prescribed conditions.[10] The permission which section 55 refers to is consent.[11] Some clarity is necessary regarding the conditions surrounding consent, however. It is submitted that stem cells be expressly added to the ambit of section 55 in order to protect the person from whom

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7 See in this regard Prinsen *An Analysis of the Proposed Regulatory Framework for the Procurement and Distribution of Stem Cells* (2010) LLM dissertation UP 111–162.

8 Stem-cell research may in certain instances, such as during induced pluripotency, make use of cancer-causing genes. See Darr and Benvenisty in Starkeand and Freiburg (eds) *Handbook of Experimental Pharmacology volume 174: Stem Cells 2* (2006) 8–12. For more on the process of induced pluripotency, see Kastenberg and Odorico "Alternative sources of pluripotency: Science, ethics and stem cells" 2008 *Transplantation Review* 22 215.

9 S 55(1)(a).

10 S 55(1)(b).

11 Consent is specifically dealt with in chap 2 of the NHA.

such cells are removed. It would then be expressly required that such a person provide his/her consent to the removal or withdrawal and such removal or withdrawal will only be permitted under the prescribed conditions.

3 3 Section 56: Use of tissue, blood, blood products or gametes removed or withdrawn from living persons

Section 56 is an important section to be taken into account in any attempt at stem-cell regulation as it stipulates the permissible activities surrounding stem cells. It should be noted that the very first reference to stem cells is made in section 56(2)(iv). Section 56 states the following:

> "(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.
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> (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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> (i) Tissue, blood, a blood product or a gamete from a person who is mentally ill within the meaning of the Mental Health Care Act, 2002 (Act No. 17 of 2002);
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> (ii) Tissue which is not replaceable by natural processes from a person younger than 18 years;
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> (iii) A gamete from a person younger than 18 years; or
>
> (iv) Placenta, embryonic or fetal tissue, stem cells[12] and umbilical cord, excluding umbilical cord progenitor cells.
>
> (b) The Minister may authorise the removal or withdrawal of tissue, blood, a blood product or gametes contemplated in paragraph (a) and may impose any condition which may be necessary in respect of such removal or withdrawal."

It is submitted that section 56(1) should be broadened by amendment so that the Minister may permit a health-care professional or an authorized institution to use tissue, gametes or stem cells which have been removed or blood which has been withdrawn from a living person not only for medical and dental purposes, but also for research purposes. The ambit of sub-section (1) must, however, also be narrowed down. The removal of the materials must now be allowed as well as the removal of tissue and gametes and then for research purposes as well as medical or dental purposes. This would constitute a huge development in context of stem-cell research. It would *inter alia* allow for research to be conducted on embryos[13] as it could then be argued that an embryo is the product of fertilization. Fertilization is the union of the male and female gametes as mentioned in section 56. Research utilizing gametes may lead to fertilization and the creation of an embryo which

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[12] It is important to note that this is the first time that stem cells are mentioned in chap 8. Stem cells are not defined in the NHA and it is submitted that a definition thereof should be provided as chap 8 is after all the proposed regulatory tool for stem cells.

[13] S 1 of the NHA defines an embryo as "a human offspring in the first eight weeks from conception". The definition of "embryo" may perhaps be amended to read that it is "human offspring in the first fourteen days from conception". This would be done to bring the South African definition in line with internationally used definitions of embryos.

may be utilized in stem-cell research.[14] If stem cells were to be included under the regulatory scope of section 56, however, the above argument would be unnecessary as stem cells would be expressly regulated. In effect this would then further permit the use of embryonic and adult stem-cell research.

The ambit of this section should further also be narrowed down by the removal of "blood products". The inclusion of "blood products" is indicative of the legislators' lack of knowledge surrounding human biology. The NHA defines blood products as "any product derived or produced from blood, including circulating progenitor cells, bone marrow progenitor cells and umbilical cord progenitor cells". The medical definition thereof is, however, "the constituents of whole blood such as plasma or platelets that are used in replacement therapy".[15] A blood product may therefore not be removed from the human body. It must be removed from blood and blood may be withdrawn from a person's body and it is thus submitted that a separate provision must be made for an institution where blood products may be generated.[16] It is suggested that blood products should rather be defined as any processed or manufactured product derived from blood which is intended for therapeutic purposes, but excludes stem cells and genetic material.[17]

Sub-section (2) states that, unless permitted by the Minister, certain materials may in certain cases not be removed or withdrawn from a living person. These materials and circumstances are as follows:[18]

(i) Tissue, blood, a blood product or gametes from a person who is mentally ill as contemplated in the Mental Health Care Act.[19] It is submitted that this should include stem cells or biological material.

(ii) Tissue which cannot be replaced by natural processes from a minor.[20]

(iii) Gametes from a minor. Concerning sub-sections (ii) and (iii) it is worth taking note that stem cells may be removed or withdrawn from a minor as they do not technically constitute gametes, especially in the case of adult stem cells. Furthermore, stem cells are replaceable by natural processes as stem cells proliferate indefinitely.[21] The required consent must, however, be obtained.[22]

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14 Specifically, embryonic stem-cell research.

15 Farlex "The Free Medical Dictionary" (undated) http://medicaldictionary.thefreedictionary.com/blood+products (accessed 2010-11-15).

16 Such as a blood fractionation service.

17 Prinsen *An Analysis of the Proposed Regulatory Framework for the Procurement and Distribution of Stem Cells* (LLM dissertation, University of Pretoria, 2010) 238.

18 S 56(5)(a)(i)-(iv).

19 17 of 2002.

20 A minor is a person under the age of 18 years.

21 This means that stem cells will continuously self-renew and spread for an undetermined period of time.

22 In terms of s 129 of the Children's Act 38 of 2005 a child may provide consent themselves for any proposed medical treatment. The child's level of maturity as well as capacity to understand the implications of the treatment are taken into account. The NHA further deals with consent of a minor in s 71 and makes a distinction between the consent required for medical treatment and for participation in research. Research is then further categorized as therapeutic or non-therapeutic. Therapeutic research is governed by s 71(2) and s 71(3)

(iv) Placenta, embryonic or fetal tissue, stem cells and umbilical cord. This sub-section therefore, by stating that only with Ministerial approval will it be permissible, prohibits stem-cell removal or withdrawal. Section 56(2)(b) states that the Minister may approve such removal but only of tissue, blood and blood product or gametes. No mention is made of stem cells and it could seem to mean that stem-cell removal is not permitted.

The NHA causes more uncertainty than clarity or certainty regarding what is permitted regarding stem cells. It is strongly suggested that this sub-section be amended to include stem cells. This recommendation is supported by the fact that sub-section (2) functions as an internal limitation to chapter 8 of the NHA as it prohibits the removal or withdrawal of material from certain persons and also due to the additional Ministerial regulation.

It is further submitted that Ministerial approval is not ideal as the Minister, or the delegated person acting on his or her behalf, often lacks the necessary knowledge regarding stem-cell research and related matters. This may inhibit decision-making and ultimately has negative repercussions on the development of this branch of science in South Africa. It is thus submitted that an independent authority, such as the United Kingdom's Human Tissue Authority,[23] or a specialist regulatory board be established to deal with such matters.[24]

3 4 Section 57: Prohibition of reproductive cloning of human beings

Section 57 deals with the prohibition of reproductive cloning and is, in my opinion, rather perplexing. This section states that no person may manipulate genetic material such as gametes, zygotes[25] or embryos[26] and further that no person may partake in any activity with the purpose of reproductive cloning and this includes nuclear transfer and embryo splitting.[27] It is important to note that the more common name by which nuclear transfer is known, cloning. This prohibition is, it is submitted, thus unnecessarily discussed in this section as it only leads to confusion at this point. Reproductive cloning of humans is internationally and nationally prohibited and almost goes without saying. It was uncalled for to dedicate an entire section to this subject matter and could have simply and more economically been prohibited in a dedicated sub-section dealing exclusively with prohibitions and offences. This would then require that section 57 be renamed.

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regulates non-therapeutic research. For a discussion of consent of a minor in this context, see Prinsen *An Analysis of the Proposed Regulatory Framework for the Procurement and Distribution of Stem Cells* 197–200.

23 See in general Swanepoel *Embryonic Stem Cell Research and Cloning: A Proposed Legal Framework in Context of Legal Status and Personhood* (LLM dissertation, University of Pretoria, 2006) 218–279.

24 For more recommendations regarding s 56, see Prinsen *An Analysis of the Proposed Regulatory Framework for the Procurement and Distribution of Stem Cells* 240–241.

25 A zygote is "the product of the union of a male and female gamete" as defined in s 1 of the NHA.

26 S 57(1)(a).

27 S 57(1)(b).

What is even more vexing about this section, and another reason for stating that this prohibition is not suitably discussed here and lends itself to confusion, is that this section conflicts within itself as sub- section (2) allows for therapeutic cloning using adult or umbilical cord cells. Therapeutic cloning and reproductive cloning are done by the exact same process, that of nuclear transfer.[28] It is, however, the destined use of the cloned material which establishes whether a particular instance is a case of reproductive or therapeutic cloning.[29] Sub-section (1), however, prohibits such activity. It is submitted that this clearly indicates a lack of knowledge on the part of the legislator and strongly reiterates that regulatory control should not vest in a governmental branch but in an independent authority. This section of chapter 8 should thus be completely scrapped or amended in its totality.

Section 57 continues by stating that Ministerial approval is required for the importation or exportation of human zygotes or embryos[30] and that a contravention of these provisions could lead to a fine or imprisonment.[31] Definitions for reproductive and therapeutic cloning are provided for in the section itself.[32] A further anomaly exists in that the section 57 allows for research on stem cells and zygotes not older than 14 days.[33] Although the 14-day cut-off is a recognized limitation on the use of embryos and zygotes,[34] nowhere however, is it ever mentioned that a stem cell itself must be under 14 days old. In fact, one of the wondrous characteristics of stem cells is that they are seen as immortal and that their so called "age" is irrelevant.[35] This, once

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28 Nuclear transfer is the process whereby the nucleus from a cell is introduced into an enucleated, meaning its own nucleus has been removed, egg cell. The donor nucleus could come from an undifferentiated embryonic cell or from a differentiated adult or somatic cell in which case this process is referred to as somatic cell nuclear transfer. The egg cell which has been implanted with the nucleus of another cell now contains the exact DNA of the donor. See Clone Safety "Process of Cloning" (undated) http://www.clonesafety.org/cloning/facts/process/ (accessed 2013-06-06).

29 In the case of reproductive cloning, the egg cell containing the nucleus of a donor cell and therefore the DNA of the donor is allowed to develop to term meaning that a being is born with the exact same DNA as another being. In the case of therapeutic cloning, the egg cell is only allowed to develop up to a certain stage, the blastocyst stage, at which point the cells which have developed are harvested and therapeutically applied. See also fn 32 below.

30 S 57(3).

31 S 57(5).

32 S 57(6) holds that (a) reproductive cloning of a human being means "the manipulation of genetic material in order to achieve the reproduction of a human being and includes nuclear transfer or embryo splitting for such purpose" and (b) therapeutic cloning is "the manipulation of genetic material from either adult, zygotic or embryonic cells in order to alter, for therapeutic purposes, the function of cells or tissues".

33 S 57(4) states that "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".

34 The reason for this is that the primitive streak develops at this stage. The primitive streak later develops into the central nervous system and is seen as an ethical, medical and scientific line which must not be crossed. See Odendaal *Ginekologie* (1989) 21–23.

35 Stem cells, unlike other cells in the body have the ability to continuously replicate in a process referred to as proliferation. Owing to this, the argument may be made that the cells are immortal as a small subset of cells could produce millions of cells if allowed to proliferate for many months in culture. This immortality of cells is called homeostasis. See Laurie "Patenting Stem Cells of Human Origin" 2004 26(2) *European Intellectual Property Review* 59.

again, illustrates a lack of technical knowledge on the part of the legislator regarding the science surrounding stem cells. It is once again strongly recommended that a knowledgeable, independent authority must be established to regulate stem cells and related processes in South Africa.

3 5 Section 59: Removal, use or transplantation of tissue, and administering of blood and blood products by medical practitioner or dentist

Section 59 in a nutshell deals with who may undertake the permitted activities. Sub-section (1) reads that only a registered medical practitioner or dentist may remove tissue from a living person, use said tissue or transplant it into another living person. Sub-section (2) provides therefore that only a medical practitioner or dentist or a person under their instruction or supervision may administer blood or a blood product to a living person. It is submitted that this section should be amended to include that a person may act within his/her field of competency, for example a medical practitioner is competent to draw blood and a dentist is competent to derive dental pulp stem cells,[36] and may then remove any tissue, blood, gametes or other biological material from a living person or use the tissue, blood, or biological materials which have been removed for any of the purposes contemplated, or transplant the tissues or gametes into another living person. It is further submitted that "researcher" must be included under this section as a competent person, along with a medical practitioner or dentist, in order to facilitate stem-cell research.

3 6 Prohibitions and offences

It is submitted that an entirely new section dealing exclusively with prohibitions and offences under chapter 8 must be created as opposed to the scattered prohibitions and offences being provided in individual sections of chapter 8. Such a section may then include *inter alia* the prohibition of reproductive cloning, improper financial incentives or the trafficking of stem cells. The prescribed punishment may then be imprisonment for no more than 5 years or a fine or both.

4 THE REGULATIONS

As the above discussion of certain sections of the NHA illustrates, the Act is flawed. A person would thus wish to see these flaws addressed in the numerous Regulations made in terms of the NHA. This is, however, not the case as the Regulations have, rather than clarify some of the ambiguities and solved some of the issues, caused even further complications. A fully detailed discussion of these new issues fall outside the scope of this particular article but it is, however, important to briefly motivate why the Regulations are also

[36] For more on dental pulp stem cells see Kerkis, Kerkis, Dozortsev, Stukart-Parsons, Gomes, Sílvia, Pereira, Caplan and Cerruti "Isolation and Characterization of a Population of Immature Dental Pulp Stem Cells Expressing OCT-4 and Other Embryonic Stem Cell Markers" 2006 184 *Cells Tissues Organs* 105.

flawed and problematic. Firstly, the Regulations have not mitigated the factual, scientific flaws of the NHA. In some instances, it has only emphasized the lack of technical knowledge on the part of the legislator. For example, the 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[37] define a cell as "the basic structural and functional unit in people and all living things. Each cell is a small container of chemicals and water wrapped in a membrane". This is not a definition fit for binding legislative documents. In my opinion, the source of this definition is an unaccredited online website, rather than a scientific researcher, biologist or geneticist. Secondly, the Regulations do not provide certain pertinent definitions such as "adult stem cells" even though "embryonic stem cells" is provided for. Research and therapy is moving away from embryonic stem cells towards adult stem cells and thus clearly indicates that the Regulations, much like the NHA, are behind the newer trends in this field of research.[38] Thirdly, yet another issue exists surrounding the definitions and that is that the definitions do not correspond throughout the different Regulations. In contrast to the definition already discussed here, the later Regulations Relating to the Use of Human Biological Material[39] define a cell as "the smallest structural and functional unit of an organism, consisting of cytoplasm and a nucleus enclosed in a membrane in living things". This is truly disconcerting. Lastly, it should be mentioned that the Regulations greatly overlap and thus result in redundancy and a fragmented regulatory framework wherein a person attempting to understand stem-cell regulation is only left more confused and overwhelmed.[40]

5 CONCLUSION AND SUMMARY OF RECOMMENDATIONS

The following recommendations have been made in the course of this article concerning chapter 8 of the NHA:

(i) That "stem cells" must be included in the title of chapter 8.

(ii) A definition of "stem cells" must be provided as the NHA is the proposed regulatory tool in the attempted regulation of stem-cell technology in South Africa.

(iii) The scope of section 55 must be broadened to include stem cells in order to facilitate the removal or withdrawal thereof. This would also result in better protection of the patient or research participant and public.

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37 *GG* R 29526 of 2007-01-05.

38 Prinsen *An Analysis of the Proposed Regulatory Framework for the Procurement and Distribution of Stem Cells* 28.

39 GG R 34159 of 2011-04-01.

40 Eg, there are two Regulations pertaining to artificial fertilization. The Regulations regarding Artificial Fertilisation and Related Matters as published in GG R 29527 of 2007-01-05 and the Regulations relating to Artificial Fertilisation of Persons as published in GG R 34159 of 2011-04-01.

(iv) Research should be recognized as a permitted activity under section 56 of the NHA.

(v) The prohibition of reproductive cloning could be provided for in a section devoted exclusively to prohibitions and offences. This indicates a lack of understanding as to what must be regulated and what is jaded by the legislator. It further reiterates the fact that an independent body of regulatory authority is needed.

(vi) Who a competent person is, must be elaborated on to include a researcher and "research" must be added to the scope of section 59 in order to allow for the lawful removal and use of stem cells in a scientific context as this is currently not provided for.

(vii) A separate, new section should be brought into chapter 8 which deals exclusively with prohibitions and offences under this chapter.

Considering the vast amount of suggestions, it is safe to say that the NHA is very much lacking specifically when it comes to the regulation of stem cell technology in South Africa. It may even be said that it is fatally flawed. These flaws are stinting the development of stem cell technology in this country and further do not reflect international trends in stem cell research. Chapter 8 of the NHA is thus of a very low quality legislation and the entire chapter should be amended. Unfortunately, given the amount of time it has already taken for this chapter to simply come into force, it is strongly suggested that new and comprehensive, updated and corresponding Regulations be drafted. This process would be much faster and economic than a total rewriting of the relevant parts of legislation. At the very least it is suggested that scientifically, ethically and legally sound policy documents or practical guidelines be issued. Until such time however, the future of stem cell research and therapy control and regulation in South Africa seems bleak and perplexing. While the world is moving forward in this field of science, the flawed and flooded legislative plane of the NHA, has left the ideal of well controlled and regulated stem cell research and related activities, dead in the water.