

BANNING PRIVATE STEM CELL BANKS: A HUMAN RIGHTS ANALYSIS

DONRICH W JORDAAN^{*}
CHRISTOPHER WOODROW^{**}
MICHAEL S PEPPER^{***}

ABSTRACT

Stem cell banking is a complex and controversial subject. There are currently three private stem cell banks in South Africa. At present, South Africa does not have a public stem cell bank. The de facto legal vacuum in which the private banks have operated thus far will change at some point in the future following the publication, for public comment, of draft regulations relating to human stem cells in the Government Gazette. If promulgated in their present form, the draft regulations would effectively ban private stem cell banking. We argue that such a ban would constitute an unjustifiable violation of at least four constitutionally protected rights, namely, the right to access to health care, the right to bodily integrity, children's rights, and the right to freedom of economic activity. The traditional arguments against private banking that are based on the low recall rate of banked cells, and the diversion of resources away from public banks, may justify the regulation of private banks, but not their prohibition. Specific attention is given to the argument against private banking that is purportedly based on equality. This argument is shown to be based on an incorrect conception of equality, namely that equality justifies 'levelling down', in which unequal access to a certain social good can justifiably be remedied by denying everyone access to this social good. Less restrictive measures are proposed to regulate stem cell banking in South Africa for the public good and in a constitutionally acceptable fashion.

I INTRODUCTION: HOW TO UNTIE THE KNOT?

If you can untie a knot with your fingers, why should you use your teeth?¹ This metaphor corresponds to the well-established constitutional principle of proportionality: legislative measures should not limit rights more than is necessary to accomplish the objectives of these measures. Internationally,

* Advocate of the High Court of South Africa, CEO of Sylvean Biotech, and Head of the Unit for Policy Studies, Centre for International Political Studies, University of Pretoria.

** Advocate of the High Court of South Africa and a practising member of the Pretoria Society of Advocates.

*** Professor in the Unit for Advanced Studies and an Extraordinary Professor in the Department of Immunology, Faculty of Health Sciences, University of Pretoria, and Professeur Associé in the Department of Genetic Medicine and Development, Faculty of Medicine, University of Geneva, Switzerland.

1 This is a Persian proverb, recently employed in the context of the Iranian nuclear problem by Ali Larijani, Iran's top nuclear negotiator. 'US "Digs Its Own Hole"'. Interview with Ali Larijani' *Newsweek* (2 July 2007) 19.

private stem cell banks are the subject of much ethical and legal debate.² In May 2007, the South African National Department of Health (DoH) published Regulations relating to human stem cells³ in terms of the National Health Act 61 of 2003 for public comment. If maintained in their current form, these draft Regulations could constitute an effective ban on private stem cell banking.⁴ Is this ban necessary to protect the public interest, or is it a case of using teeth where fingers can easily untie the public policy knot?

The subject of private stem cell banks is complex and multi-faceted and continues to stimulate debate. There is for instance a rich (and growing) body of legal and ethical research on the specific sub-topic of ownership of stem cells in the context of private stem cell banking.⁵ In South Africa, the issue of ownership could be settled through other regulations in terms of the National Health Act.⁶ However, one aspect of private stem cell banks that has yet to receive the attention it merits is that of human rights. This article will specifically focus on a human rights analysis of the consequences of a ban on private stem cell banks in the South African legal context. This article does not intend to provide an opinion on the merits or demerits of stem cell banking per se. However, since there is a demand for private banking, and since a human rights argument might be used by interested persons or classes of persons to argue in favour of this service, we will first provide an overview of the subject of stem cell banking, and will thereafter proceed to an analysis of the human rights issues.

- 2 GJ Annas 'Waste and longing – the legal status of placental-blood banking' (1999) 340 *N Engl J Med* 1521; M Zilberstein, M Feingold & MM Seibel 'Umbilical-cord-blood banking: lessons learned from gamete donation' (1997) 349 *Lancet* 642; GR Burgio, E Gluckman & F Locatelli 'Ethical reappraisal of 15 years of cord-blood transplantation' (2003) 361 *Lancet* 250; JL Ecker & ME Greene 'The case against private umbilical cord blood banking' (2005) 105 *Obstet Gynaecol* 1282; J Gunning *Umbilical Cord Cell Banking: A Surprisingly Controversial Issue* (2004), <<http://www.ccels.cf.ac.uk/literature/publications/2004/gunningpaper.pdf>>; FL Johnson 'Placental blood transplantation and autologous banking – caveat emptor' (1997) 19 *J Pediatr Hematol Oncol* 183.
- 3 *Government Gazette* (4 May 2007).
- 4 The reason why the draft Regulations constitute an effective ban is set out below in part IV 'Private stem cell banks and the draft Regulations'.
- 5 See for instance Annas (note 2 above); 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 of Legal Medicine* 275; T McIntire 'Legal issues of stem cell transplantation and the family' (2002) 32 *Univ of Memphis LR* 3; JD Munzer & FO Smith 'Limited property rights in umbilical cord blood for transplantation and research' (2001) 23 *J Pediatr Hematol Oncol* 203.
- 6 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 were published for public comment in the *Government Gazette* (5 January 2007). From one perspective there seems to be support for the fact that such umbilical cord blood and stem cells belong to the child, since they contain the DNA of the baby and not the mother; from another perspective this may belong to the mother, as the placenta is seen as part of the mother's body. Regulations 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. The 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.

II AN OVERVIEW OF STEM CELL BANKING

(a) Umbilical cord blood as a source of stem cells

Stem cells are defined as undifferentiated cells capable of self-renewal that can differentiate into specialised cell types when exposed to appropriate environmental cues. 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. We can thus broadly distinguish between embryonic stem (ES) cells and adult stem cells. ES cells, which are derived from an early stage embryo, can develop into every cell type in the body, and therefore have the potential to be used for the treatment of many diseases.⁷ ES cell research is, however, still in its infancy and has to date not produced any successes in humans. The first clinical trial using ES cells for the treatment of patients with spinal cord injury has recently been approved by the United States Food and Drug Administration.⁸

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 the experimental setting they may also be induced to differentiate into cells from other tissues.⁹ Adult stem cells have been used successfully for several decades for 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). Neonatal blood harvested immediately after birth from the placenta (via the umbilical cord) – commonly referred to as umbilical cord blood – is a third and rapidly expanding source of adult stem cells.¹⁰ 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.¹¹

(b) The medical uses of stem cells

Bone marrow transplantation is the only clinically accepted and routinely applied form of stem cell therapy, and has been practised 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.¹² For example, clinical trials are underway to

7 PJ Gokhale & PW Andrews 'Human embryonic stem cells: 10 years on' (2009) 89 *Lab Invest* 259.

8 N Siva 'US stem cell climate improves raising concerns elsewhere' (2009) 15 *Nature Med* 224.

9 MR Alison & S Islam 'Attributes of adult stem cells' (2009) 217 *J Pathol* 144.

10 J Kurtzberg 'Update on umbilical cord blood transplantation' (2009) 21 *Curr Opin Pediatr* 22.

11 RK Burt, Y Loh, W Pearce et al 'Clinical applications of blood-derived and marrow-derived stem cells for nonmalignant diseases' (2008) 299 *J Am Med Assoc* 925.

12 *Ibid.*

assess the use of stem cells for the treatment of heart disease,¹³ and preclinical studies have highlighted the potential of stem cells for the treatment of diabetes, spinal cord injury and other central nervous system disorders, such as Parkinson's disease.

(c) 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 transplant, i.e. 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 transplant the figure is 1:400.¹⁴ Two studies have addressed the need in children up to age 20. Thus, the likelihood of needing any stem cell transplant (allogeneic and autologous) in this group was estimated to be from 1:925¹⁵ to 1:1 700¹⁶ while the probability of requiring an autologous transplant is approximately 1:2 700¹⁷ to 1:5 000.¹⁸ 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.) It is believed that with the future increase in regenerative medicine technologies, there will be 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 cord blood in an effort to heal brain damage.¹⁹

However, the above estimates should be viewed with caution. Sullivan²⁰ for example has questioned the accuracy of these estimates, and this has stimulated debate on the subject.²¹ 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 should be possible to reprogramme differentiated autologous adult cells into stem cells (for example through induced pluripotent stem (iPS) cells, which have ES-like properties).²² However, much

13 VFM Segers & TL Lee 'Stem-cell therapy for cardiac disease' (2008) 451 *Nature* 937.

14 MC Pasquini, BR Logan, F Verter, MM Horowitz & JJ Nietfeld 'The likelihood of hematopoietic stem cell transplantation (HCT) in the United States: implications for umbilical cord blood storage' (2005) 106 *Blood* 1330.

15 Johnson (note 2 above).

16 Note 14 above.

17 Ibid.

18 Ibid.

19 Phase I non-randomised study in progress at Duke University (NCT00593242), <<http://clinicaltrials.gov/ct2/show/NCT00593242?term=NCT00593242&rank=1>>.

20 MJ Sullivan 'Banking on cord blood stem cells' (2008) 8 *Nature Rev Cancer* 555; MJ Sullivan 'Banking on cord blood stem cells' (2008) 8 *Nature Rev Cancer* 823 (author reply).

21 JJ Nietfeld 'Opinions regarding cord blood use need an update' (2008) 8 *Nature Rev Cancer* 823; DT Harris 'Cord blood stem cells: worth the investment' (2008) 8 *Nature Rev Cancer* 823.

22 N Maherali & K Hochedlinger 'Guidelines and techniques for the generation of induced pluripotent stem cells' (2008) 3 *Cell Stem* 595.

work is still required in this field before firm conclusions can be drawn on their therapeutic potential.

(d) Stem cell banking: public versus private

Umbilical cord blood 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.²³ 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.²⁴ The ethical values associated with public banks are altruism and mutuality; the ethical values underpinning private banks are family obligation and consumer choice.²⁵

Contractually, the difference between public and private banks is essentially the difference between an anonymous donation versus storage for private use: in the case of a public bank, 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 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 to 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.²⁶ The latter employs a unique model in terms of which it splits its units with 80 per cent of a unit going to a public bank and 20 per cent being retained for private use.²⁷ In 2006, Spain introduced a hybrid system effectively allowing the public to access privately stored stem cells.²⁸

23 P Martin, N Brown & A Turner ‘Capitalizing hope: the commercial development of umbilical cord blood stem cell banking’ (2008) 27 *New Genetics and Society* 127, 138; see also <<http://parentsguidecordblood.org>>.

24 Ibid 138.

25 Ibid 136.

26 Ibid 140.

27 Ibid.

28 Royal Decree 1301/2006 (Spain), <http://parentsguidecordblood.org/content/media/m_pdf/RealDecreto_1301-2006.pdf>. See also G 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 online curriculum on Cord Blood Technology & European School of Haematology (EUROCOR-ED & ESH), <<http://www.esh.org>>.

(e) 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:

1. 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.
2. 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.
3. 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 we will discuss below.

(f) 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. Private stem cell banking is offered in South Africa by three for-profit banks, namely Netcells Cryogenics (Netcells), Cryo-Save and Lazon Biotechnologies. Cryo-Save stores its units in Belgium because, amongst other reasons, of the 'political risk' of 'restrictive legislation in this field' in South Africa.²⁹

(g) 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 \$200 million per year.³⁰ The locus of the global stem cell banking economy has also shifted away from Europe and North America through the emergence of new promissory bioeconomies in East Asia and Latin America.³¹

29 <http://www.cryo-save.co.za/why_offshore.htm>.

30 Martin et al (note 23 above) 141.

31 Ibid. Cf European Group on Ethics in Science and New Technologies *Ethical aspects of umbilical cord blood banking* Opinion No 19 to the European Commission (2004), <http://www.europa.eu.int/comm/european_group_ethics/docs/avis19_en.pdf>.

Table 1. Leading public and private cord blood banks (>5 000 units in 2007)³²

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
Inseption 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

III PRIVATE STEM CELL BANKS AND THE NATIONAL HEALTH ACT

Umbilical cord blood-derived stem cells as a ‘blood product’ are dealt with in chapter 8 of the National Health Act. The President will sign chapter 8 into effect once all the regulations relating to this chapter have been finalised.³³ In the following, we will give an overview of the relevant sections of chapter 8:

32 Martin et al (note 24 above) 130.

33 Statement by the DoH *National Health Act proclaimed by the President* (19 April 2005), <<http://www.info.gov.za/speeches/2005/05042013451004.htm>>.

(a) Authorisation is required from the Minister for the establishment of private stem cell banks

Private stem cell banks will need authorisation from the Minister of Health at both a more general blood products level and at a stem cell-specific level: firstly to become an ‘authorised institution’ that may acquire, use and supply blood products; secondly to specifically withdraw umbilical cord blood. The relevant sections of the Act read as follows:

54. (1) The Minister may, by notice in the *Gazette*, designate any institution other than an institution contemplated in section 63 as an authorised institution.

(2) An authorised institution may—

...

(d) acquire, use and supply blood products for any of the purposes referred to in section 56 or 64.

...

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):

...

(iv) placenta, embryonic or foetal tissue, stem cells and umbilical cord, excluding umbilical cord progenitor cells.³⁴

(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.

In order for a private stem cell bank to function, it therefore needs designation as an ‘authorised institution’ in terms of s 54, as well as authorisation to withdraw stem cells from a living person in terms of s 56.³⁵ These sections in principle make provision for the activities of private stem cell banks, subject to the Minister’s authorisation. The exercise of ministerial discretion will of course be subject to the rules of administrative justice.

(b) Regulations must make provision for private stem cell banks

The medical purposes for which umbilical cord blood-derived stem cells may be used must be prescribed in regulations, implying that, should the regulations fail to make such provision, private stem cell banking would effectively be banned:

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.

34 Section 56(2)(a)(iv) presents an ambiguity that can be grounds for an argument that s 56 is not applicable to stem cell banks: Withdrawal of ‘stem cells and umbilical cord’ requires authorisation, but removal of ‘umbilical cord progenitor cells’ does not. The latter are in fact cord blood-derived stem cells. The wording of this s 56(2)(a)(iv) should thus be clarified through amendment. Also see note 84 below.

35 It is common practice in South Africa for the stem cell bank to contract the doctor present at the birth to perform the withdrawal for a fee. This raises the question of whether every independent doctor who withdraws umbilical cord blood for stem cell banking would need ministerial authorisation.

It should be noted that the draft regulations of May 2007 effectively make provision for an *open-ended number of uses* of stem cells. Regulation 2(1)(b) makes provision for the following, subject to conditions:³⁶ to preserve, screen, test, process, store, separate, label, pack, supply, distribute *or in any other manner dispose* of stem cells; reg 2(1)(d) makes provision, also subject to conditions,³⁷ for the therapeutic use of stem cells.

(c) The Act's profit-ban is not comprehensive

The concern has been raised that the profit banning provisions of s 60 will effectively ban for-profit private stem cell banking.³⁸ We believe 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.

There is a numerus clausus of acts that are subject to the profit-ban, namely importation, export, acquisition and supply. In their normal meaning, these acts do not include all the essential services performed by private stem cell banks for their clients, such as a) purification, b) analysis and c) storage³⁹ of such stem cells. In addition, since s 60 has a penal nature,⁴⁰ 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.⁴¹ This common law rule of interpretation clearly

36 The conditions for the use of stem cells per reg 2(1) are unclear and confusing, and evidently impractical – a few examples will suffice: the labelling of stem cells is made conditional upon the prior testing of these stem cells for certain infectious agents and genetic diseases. How will stem cell units be identified prior to such testing if they cannot be labelled? In an apparent circular reference the very *testing* of stem cells (per reg 2(1)(b)) is made conditional upon the *testing* of these stem cells for certain infectious agents and genetic diseases (per reg 2(1)(c)(ii)). Regulation 2(1)(c)(ii) requires that *each* stem cell must be tested prior to storage, distribution, etc. It is clearly impractical and unnecessary to test each stem cell in a typical cord blood unit. The conditions for the use of stem cells are in clear need of complete reconceptualisation and reformulation to save them from being void for vagueness.

37 The conditions contained in reg 2(1)(d)(iii) and (iv) regarding written informed consent and voluntariness both refer to the 'donors' of stem cells, hence rendering them not applicable to private stem cell banks, since stem cells are not *donated* to private stem cell banks.

38 D Schaub, S Marrs, D Thompson, MS Pepper & DW Jordaan (comps) *Report: Bioethics Forum on Stem Cell Banking, held at the Innovation Hub, Pretoria, on 15 June 2007* (2007) 7, <<http://www.policystudies.up.ac.za>>.

39 The Regulations define 'storage' as follows: 'storage' means maintaining the product under appropriate controlled conditions until distributed.

40 See ss 60(4) and (5).

41 *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 Vooyesen* 1992 (4) SA 69 (A) 78, 81, 83.

directs that s 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 nomenclature of the acts specified in s 60.

It therefore follows that private stem cell banks will a) 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; b) 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.

(d) Conclusion on the National Health Act

In summary, chapter 8 of the National Health Act will have the following impact on the private stem cell banking industry:

- The operation of any specific private stem cell bank will be subject to ministerial discretion.
- The operation of private stem cell banks in general will be subject to the intended medical uses of the banked stem cells being provided for in regulations.
- The freedom of private stem cell banks to make profit is not prohibited, but limited to services such as purification, analysis and storage of the stem cells, since the process of acquiring the umbilical cord blood immediately after birth and supplying the umbilical cord blood-derived stem cells to the client when needed may only be charged for on a (non-profit) cost-recovery basis.

IV PRIVATE STEM CELL BANKS AND THE DRAFT REGULATIONS

In contrast to the Act that makes provision for private stem cell banks within a demarcated legal framework, we submit that the draft regulations of May 2007 effectively ban private stem cell banks at two levels:

(a) Access to stem cell banking limited to high risk families

Regulation 7 states that '[s]tem 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 regulation will clearly constitute an effective ban on private stem cell banking in South Africa.

(b) Comprehensive profit ban

In contrast with the Act's limited profit ban on specific acts, the draft regulations intend to subject private stem cell banks to a comprehensive profit ban. Regulation 3(4) states that '[a]n 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 DoH 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.⁴² 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 DoH'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 in doubt, 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:

1. *Constitution*: The SANBS is a voluntary donors' association;⁴³ there are therefore no shareholders who have invested into the setting up and running of the company, and who were willing to take the risks involved therein.
2. *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.⁴⁴ 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.
3. *Market risk*: Since the SANBS is providing an essential health service,⁴⁵ its market risk-profile is virtually zero, which contrasts with private stem

42 Workshop on the draft Regulations relating to human stem cells, organised by the DoH, Pretoria (3 October 2007).

43 <http://www.sanbs.org.za/abt_us.html>.

44 Ibid.

45 Ibid.

cell banks that are highly susceptible to fluctuations in the market. 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 under a non-profit regime. Such an argument would however be unconvincing for at least two reasons:

1. 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 Spain⁴⁶ than in South Africa,⁴⁷ which seriously impacts on the underlying risk-profile and feasibility of any private stem cell bank – whether for-profit or non-profit.
2. There is a very important and fundamental difference between the Spanish non-profit limitation and reg 3(4): While the Spanish non-profit provision only applies to the contract between the bank and its client, reg 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 2007.⁴⁸

In our submission, the most likely result of the comprehensive profit-ban as per draft reg 3(4) would be the closure of the existing for-profit banks in South Africa and not their speculative evolution into non-profit banks. Given the South African reality of three for-profit private banks and no non-profit banks, the profit-ban therefore amounts to an effective ban on private stem cell banks.

V BANNING PRIVATE STEM CELL BANKS CONSIDERED IN ABSTRACTO

While the draft regulations in their current form will ban private stem cell banking through a) limiting access to private banking to high-risk families,

46 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' *The Independent* (Ireland) (6 April 2009), <<http://www.independent.ie/health/case-studies/stem-cell-collection-the-banking-crisis-1699539.html>>.)

47 See our calculations in VII(b) 'The diversion-of-resources argument' below.

48 Cryo-Save Group NV *Acquisition of leading Spanish distributor* press release (8 July 2008), <http://www.2.cryo-save.com/cms/bib/files/929_spanishacquisitionfinal.pdf; http://www.cryo-savegroup.com/company_news.html?id_news=178>.

and b) banning profit-making by all stem cell banks, the same result could hypothetically 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 the regulations may still be amended in unforeseeable ways in order to achieve the same policy objective by other means, this article will consider the ban on private stem cell banks in abstracto, irrespective of the specific legislative means or formulation utilised to achieve this end.

VI WOULD A BAN INFRINGE ON HUMAN RIGHTS?

The ethical sphere is permeated by the values that the South African society has enshrined in its foundational political instrument – the State’s Constitution. The Constitution of the Republic of South Africa, 1996 is particularly value-orientated and also articulates its values in specific, legally enforceable human rights. There is therefore a close and essential interaction between human rights law and medical ethics – especially in the South African context.

Four constitutionally protected rights will be considered, namely a) the right to access to health care, b) the right to bodily integrity, c) children’s rights, and d) the right to freedom of economic activity.

(a) The right to access to health care

The Constitution provides for the right to access to health care services.⁴⁹ The access to health care provision has both a positive and a negative component.⁵⁰ 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’,⁵¹ the State’s negative duty is not similarly qualified.⁵² The State’s positive duty is therefore dependent on the State’s health care priorities and its health care budget,⁵³ while the State’s negative duty, on the other hand, is independent of such variables.

Let us 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

49 Section 27(1).

50 *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.

51 Section 27(2) of the Constitution. Cf *Soobramoney v Minister of Health (KwaZulu-Natal)* 1998 (1) SA 765 (CC).

52 *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).

53 The State’s positive duty will be considered in VII(b) ‘The diversion-of-resources argument’ below.

banking of her or his⁵⁴ stem cells, since she or he may in future need these cells for therapeutic purposes (the current use for autologous cells is highly 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. Second, 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 family of the newborn child covers the cost for private storage. 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.⁵⁵

The State's positive duty in the context of stem cell banking is discussed in VII(b) 'The diversion-of-resources argument' below.

(b) The right to bodily integrity

The Constitution provides for the right to bodily and psychological integrity, which includes the right to control over one's body.⁵⁶ The same interests that were identified above are also protected by this right: control over one's body denotes bodily autonomy or self-determination.⁵⁷ Since stem cells are derived from umbilical cord blood which is part of a human body – whether the mother's or the baby's – the right to control over one's body therefore entails the autonomy to decide what to do with the cells, which autonomy is protected against State intervention. Assuming the stem cells belong to the mother, the mother has this autonomy; assuming the stem cells belong to the newborn child, it is obvious that such child will not be able to exercise this autonomy herself 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 stem cells. A newborn child's and her or his next-of-kin's interests in private stem cell banking identified above are therefore also protected within the ambit of the right to bodily integrity.

The recognition of a constitutional right to bodily integrity in an open and democratic society means that paternalistic forms of intervention in people's

54 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 we will not address in this article.

55 Refer to the discussion of the current use of stem cells in II(c) 'The likelihood of using stem cells' above.

56 Section 12(2).

57 I Currie & J de Waal *The Human Rights Handbook* 5 ed (2005) 308.

autonomous health decisions must be minimised.⁵⁸ Just as a person is entitled to refuse medical treatment based on the right to bodily integrity, so too, a person is entitled to choose medical treatment or other medical interventions based on the same right.⁵⁹ A ban on private stem cell banks would limit the autonomy to choose medical interventions and therefore the autonomy to make decisions regarding one's own body. Such a ban would therefore constitute a clear infringement of the right to bodily integrity.

(c) Children's rights

The Constitution sets out specific rights of children.⁶⁰ These enumerated rights are, however, not exhaustive of children's rights.⁶¹ Of particular importance for our present purposes is the constitutional provision that a child's best interests are of paramount importance in every matter concerning the child.⁶² In South Africa, a 'child' means a person under the age of 18 years.⁶³

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. States Parties shall strive to ensure that no child is deprived of his or her right of access to such health care services.

The African Charter on the Rights and Welfare of the Child is also specifically relevant and places even greater emphasis on the best interests of the child than does the Convention on the Rights of the Child.

The general principles set out in s 7 of the Children's Act 38 of 2005 must guide all proceedings, actions and decisions by any organ of State in any matter concerning a child or children in general.⁶⁴ The 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...

58 M Bishop & S Woolman 'Freedom and Security of the Person' in S Woolman & T Roux (eds) *Constitutional Law of South Africa* 2 ed (2002) 40.

59 Cf *Castell v De Greef* 1994 (4) SA 408 (C).

60 Section 28(1).

61 *Minister of Welfare and Population Development v Fitzpatrick* 2000 (3) SA 422 (CC) 428 para 17.

62 Section 28(2).

63 Section 28(3).

64 Section 6(1)(b).

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 her or his⁶⁵ stem cells, since she or he 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 her or his family's health and lives, private stem cell banking can also indirectly be in the best interests of the child in that her or his next-of-kin may benefit. Therefore, while acknowledging both the current limited use of stem cells and the indefinable future promise thereof,⁶⁶ we submit that a ban on private stem cell banking would constitute an infringement on children's rights, in particular the 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 on both children who presently have stem cells privately banked and children who in the future would have had stem cells privately banked but for such a ban. In our 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.⁶⁷

(d) The right to freedom of economic activity

We 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. Our 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 their trade, occupation or profession freely.⁶⁸ 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 s 22 to natural persons to the exclusion of juristic

65 See note 54 above.

66 Refer to the discussion of the current use of stem cells in II(c) 'The likelihood of using stem cells' above.

67 Cf *Minister of Health v Treatment Action Campaign* 2002 (5) SA 721 (CC).

68 This is in contrast with the broader formulation of the right's predecessor, s 26(1) of the interim Constitution, 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.

persons.⁶⁹ In the absence of a Constitutional Court judgment on the matter, constitutional scholars Currie and de Waal argue that s 22 should be interpreted as applying to juristic persons as well.⁷⁰ They refer to s 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.⁷¹ They suggest that juristic persons may be regarded as citizens for the purposes of s 22 if they are incorporated in South Africa, or, with reference to an Appellate Division (now the Supreme Court of Appeal) case,⁷² if they are controlled by South African citizens. Whether private stem cell banks’ interest in pursuing their economic activities is protected by s 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,⁷³ 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 s 22. Should a restrictive interpretation of s 22 be followed that excludes juristic persons, private stem cell banks qua hypothetical applicants would have to prove that the s 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 of an occupation. An argument can therefore be made that such a ban would infringe on the s 22 rights of natural persons.

The significance of a citizen’s interest to work in a particular field, which is protected by the s 22 rights, should not be underestimated. Its importance and interrelatedness with human dignity was elaborated on by the Constitutional Court per Ngcobo J:⁷⁴

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.

69 *JR 1013 Investments v Minister of Safety and Security* 1997 (7) BCLR 925 (E); *City of Cape Town v Ad Outpost* 2000 (2) SA 733 (C) at 747F; *First National Bank of SA t/a Wesbank v Commissioner for the South African Revenue Service* 2001 (3) SA 310 (C).

70 Note 57 above, 489–90.

71 *Black v Law Society of Alberta* [1989] 1 SCR 591.

72 *Becket (TW) & Co v H Kroomer* 1912 AD 324, 334; see however *Dadoo v Krugersdorp Municipal Council* 1920 AD 530.

73 *Ferreira v Levin NO* 1996 (1) SA 984 (CC).

74 *Affordable Medicines Trust v Minister of Health* 2006 (3) SA 247 (CC) 274.

(e) Conclusion: the ban infringes on all four human rights

We 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 in our submission 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.

VII CAN THE BAN BE JUSTIFIED?

Given the infringements established above, the human rights analysis must now enter its second phase, namely the evaluation of the justifications for the infringements in terms of the Bill of Rights' limitation clause. 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.⁷⁵ Three anti-private stem cell bank arguments that enjoy prominence in South Africa will be analysed, namely the low-recall argument, the diversion-of-resources argument and the equality argument. In contrast to the first two arguments that are well-known in international literature on the subject, the latter argument is characteristically (though not necessarily exclusively) South African.

(a) The low-recall argument

As discussed above in II(c) 'The likelihood of using stem cells' above, 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 June 2007, the largest private bank in the United States – Cord Blood Registry – had released 55 samples from an inventory of 180 000 samples stored. Of these samples, 75 per cent were used for allogeneic (sibling) purposes.⁷⁶ This low incidence

⁷⁵ Section 36 of the Constitution.

⁷⁶ <http://www.cordblood.com/cord_blood_banking_with_cbr/why_cbr/most_experienced.asp>.

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’.⁷⁷

The pro-ban lobby’s argument is that, given the current low recall rate, it is unethical to profit from the private storage of stem cells – especially that of low-risk families. Underlying the argument is the policy principle that the public must be protected against exploitative practices, coupled with the perception that private stem cell banking is exploitative – a perception which is bolstered by the psychological context in which private stem cell banking contracts are typically concluded, namely during pregnancy. The position is explained by Edozien as follows:⁷⁸

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.

Let us analyse this argument: Does private stem cell banking constitute an exploitative practice? In order to answer this question, we shall first focus on the core of the argument, namely that the low incidence of recall renders private stem cell banking exploitative, after which we shall consider the broader argument that includes the special psychological context in which private stem cell banking contracts are concluded.

The core argument that the low incidence of recall renders private stem cell banking exploitative can be responded to in two ways: The first response addresses the core argument’s factual premise of a low incidence of recall: Proponents argue that it would be unrealistic to only consider the current limited therapeutic use of autologous stem cells. Stem cell research promises to revolutionise medical practice and stored stem cells have the potential to become more widely used than is currently the case, possibly increasing the frequency of recalls in the future.

The second response attacks the core argument’s reasoning: Even if the core argument’s factual premise of a low incidence of recall is accepted, this fact per se does not necessarily constitute an exploitative contract. Firstly, consensus is lacking on the disproportionate nature of the contractual obligations of a private stem cell bank and the payment received. Secondly, even if it is conceded that the performances are disproportionate, mere disproportionality of performances cannot constitute an exploitative contract; else donation as a

77 Royal College of Obstetricians and Gynaecologists, Scientific Advisory Committee *Umbilical Cord Banking, Opinion Paper 2* (2006), <<http://www.rcog.org.uk/index.asp?PageID=545> our emphasis>.

78 LC Edozien ‘Commercial banking of umbilical cord blood NHS maternity units should not encourage’ (2006) 333 *BMJ* 801.

species of contract⁷⁹ 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 the broader argument that includes the special psychological context in which private stem cell banking contracts are concluded. Without recourse to the broader argument, the core argument fails to convince.

We now consider the broader argument. Informed consent has become a cornerstone of bioethics.⁸⁰ The principle is expressed in the Universal Declaration on Bioethics and Human Rights⁸¹ as follows: ‘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’.⁸²

Given the position of authority in which health professionals are held by the public, there certainly exists a potentially exploitative situation that warrants protective measures. This potential with regard to stem cell banking is exacerbated by the future promise of stem cell therapies that may easily be blurred by current attention in popular culture. In principle, however, the situation with stem cell banking is similar to all other medical interventions provided by the private health sector: a health professional recommends a medical intervention from which she or he may profit directly or indirectly. In situations such as these, there is a statutory duty on a health professional – and a stem cell bank qua legal person – to ensure that the patient (or client) gives informed consent: s 7 of the National Health Act makes informed consent a general prerequisite for the provision of all health services, which in our submission would include stem cell banking, given the out-and-out therapeutic purpose of stem cell banking; s 55 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 specifies the specific information that must be provided, but its applicability to stem cell banks is debatable.⁸³

79 Donatio in Roman and Roman-Dutch law (Grotius, 3. 2. 1; Van Leeuwen, lib. iv. cap. xxx; Voet, 39.5.1.) as still applicable in contemporary South African law.

80 Cf *Castell v De Greef* (note 59 above); D Welz ‘The boundaries of medical-therapeutic privilege’ (1999) *SALJ* 299; FFW Van Oosten ‘Informed consent: patient rights and the doctor’s duty of disclosure in South Africa’ (1989) *M&L* 443; FFW Van Oosten ‘The so-called “therapeutic privilege” or “contra-indication”’: Its nature and role in non-disclosure cases’ (1991) *M&L* 31; FFW Van Oosten ‘*Castell v De Greef* and the doctrine of informed consent: Medical paternalism ousted in favour of patient autonomy’ (1995) *De Jure* 164.

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

82 Article 6(a).

83 Section 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 s 1 of the Act 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

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, we submit that the provisions of the Act 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.⁸⁴ 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.⁸⁵ In addition, adequate information should also include information about the procedures followed for collection, processing, testing, storing, and use of stem cells.⁸⁶

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 is conceded that such an extreme situation is potentially exploitative and 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.⁸⁷ Although we agree that informed consent should ideally be obtained as early during pregnancy as possible and that private 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 overly paternalistic and penalising the very person who is supposed to be protected through regulations.

provisions of 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 National Health Act 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 National Health Act referring to 'any law' would include the Act itself. This uncertainty can be addressed by an amendment of the Act. Also see note 36 above.

- 84 These suggested regulations are amongst recommendations made by MS Cairo, J Kurtzberg, BH Lubin & WT Shearer 'Cord blood banking for potential future transplantation' (2007) 119 *Pediatrics* 165.
- 85 These guidelines as to what constitutes adequate information are amongst recommendations made by European Group on Ethics in Science and New Technologies (note 31 above).
- 86 These guidelines as to what constitutes adequate information are amongst recommendations made by E Salvaterra, L Lecchi, S Gobbi & P Rebutta 'The ethics of cord blood banking in light of ownership, informed consent, and solidarity' (2006) 4 *Cell Preservation Technology* 91.
- 87 Drawing the line at labour and also requiring post-delivery 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; J Sugarman, V Kaalud, E Kodish et al 'Ethical issues in umbilical cord blood banking' (1997) 278 *JAMA* 938.

The emotional vulnerability of the expecting parents during pregnancy can be addressed effectively through granting parents a cooling-off period after delivery.⁸⁸ 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 should 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 medical interventions in the private health care sector; such measures will essentially address the core concerns underlying the low-recall and emotional vulnerability arguments.

The policy principle that the low-recall argument aims to promote, namely to protect the public against exploitative practices, is certainly a purpose that is aligned with our constitutional ethos. 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.⁸⁹ As discussed above, such less restrictive measures are indeed available: a) providing guidelines regarding what constitutes adequate information; b) obliging health professionals to disclose any financial interests; and c) providing for a cooling-off period post-delivery. In the light of the availability of these less restrictive means to accomplish the purpose of protecting the public against exploitation, the low-recall argument fails the Bill of Rights' limitation test and can therefore not justify the ban on private stem cell banks.

(b) The diversion-of-resources argument

The prohibition of private stem cell banks can also be argued from a social solidarity platform: it has been suggested that private banking diverts umbilical cord blood samples away from public banks, hence limiting the establishment and maintenance of public banks.⁹⁰ 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 will benefit from the ensuing therapeutic options.⁹¹

Let us analyse this argument. Firstly, the fundamental logic of the argument is flawed: if a mother who intended to bank her baby's⁹² stem cells privately is prohibited from doing so, it does not necessarily follow that she would now decide to donate it to a public bank – she might just as well decide not to

88 Cf KJ Moise Jr 'Umbilical cord stem cells' (2005) 106 *Obstet Gynecol* 1393.

89 Section 36(1)(e) of the Constitution.

90 Johnson (note 2 above).

91 C Waldby 'Umbilical cord blood: from social gift to venture capital' (2006) 1 *BioSocieties* 55.

92 See note 54 above.

donate it at all. Being prohibited from advancing her (and her family's) own interests, why would she 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.

Let us consider the statistics. We estimate the number of umbilical cord blood samples banked privately in South Africa per year to be less than 1 500. With a total of 1 999 712 live births registered with the Department of Home Affairs in South Africa in 2007,⁹³ this translates into less than 0,13 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 99,87 per cent of neonates whose umbilical cord blood is discarded. A recent study in the United Kingdom found that women in antenatal clinics had very little knowledge about cord blood banking although 86 per cent of those questioned would have been willing to donate altruistically to a public stem cell bank; 14 per cent would have elected to bank privately.⁹⁴ We 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 approximately 7 000 to 10 000 in South Africa) initially required to establish a functional public bank.

Underlying the diversion-of-resources argument is the objective 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.⁹⁵ 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,⁹⁶ 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.

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

93 <<http://www.statssa.gov.za/publications/statskeyfindings.asp?PPN=p0305&SCH=4195>>.

94 CV Fernandez, K Gordon, M van den Hof et al 'Knowledge and attitudes of pregnant women with regard to collection, testing and banking of cord blood stem cells' (2003) 168 *CMAJ* 695.

95 Section 36(1)(d) of the Constitution.

96 Section 36(1)(e) of the Constitution.

measures within its available resources to achieve the progressive realisation of access to health care.⁹⁷ 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 DoH, 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,⁹⁸ 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.

(c) 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 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 significantly to increasing the access to cell-therapy in the future; however, since the DoH’s priorities do not appear to include cell-therapy,⁹⁹ 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. The DoH’s policy decision is therefore 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 South African Constitutional Court:¹⁰⁰

97 Section 27(2).

98 MS Pepper *A model for the co-existence of public and private stem cell bank* CIPS e-brief series no 44/2007 (31 July 2007).

99 Department of Health, South Africa *Strategic Priorities for the National Health System, 2004–2009* (2004).

100 *Minister of Home Affairs v Fourie* (CCT 60/04) [2005] ZACC 19; 2006 (3) BCLR 355 (CC) para 149.

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.

A ban on private stem cell banks in South Africa would therefore not survive constitutional scrutiny if argued from an equality platform.

VIII CONCLUSION AND RECOMMENDATIONS: REGULATE RATHER THAN BAN

It must be concluded that a ban on private stem cell banks is not merely a case of proverbially using teeth where fingers can easily untie the public policy knot – it is killing the goose that potentially lays the golden eggs. In South Africa's constitutional dispensation, a ban on private stem cell banking – whether effected through the provisions contained in the draft Regulations of May 2007 or in any other way – would constitute an unjustifiable infringement on no less than four enumerated rights and would hence be unconstitutional and void.¹⁰¹ Instead of an unconstitutional ban, we have suggested that the objectives of protecting the public against exploitation and establishing a public stem cell bank can indeed be attained in a constitutionally acceptable fashion through less restrictive regulatory means. These regulatory measures are, by way of summary:

1. Adequate information must be communicated by a private stem cell bank to its prospective clients through informed consent. Over and above the information that must be communicated in terms of the Act, adequate information in the context of stem cell banking entails:
 - a. 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; and
 - b. 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 intended in point 1(b) above must be communicated in all printed and electronic media used by a private stem cell bank.

2. Health professionals must disclose to a prospective client any financial interests relevant to the stem cell bank in question.
3. Any private stem cell banking contract must be subject to a cooling-off period post-delivery.
4. Private 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.

101 Although generally sceptical about private stem cell banking, the European Group on Ethics in Science and New Technologies has come to the conclusion that a strict ban would represent an undue restriction on the freedoms of enterprise and choice of individuals. See European Group on Ethics in Science and New Technologies (note 31 above).

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, we also make the following policy recommendation:

5. The DoH must 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. The public stem cell bank must have a clear mandate to actively recruit donations.

It should be noted that it has not been the purpose of this article 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 has specifically been to conduct a human rights analysis of a ban on private stem cell banks and to make recommendations within this context. We would like to conclude with a quote from the South African Society of Obstetricians and Gynaecologists (SASOG's) Policy Statement on stem cell banking:¹⁰²

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.

102 SASOG Policy Statement on Umbilical Cord Blood Banking, <http://www.sasog.co.za/B_drcnr_PosStatements_011.asp>.