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Review

Curbing stem cell tourism in South Africa☆

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ABSTRACT

Stem cells have received much attention globally due in part to the immense therapeutic potential they harbor. Unfortunately, malpractice and exploitation (financial and emotional) of vulnerable patients have also drawn attention to this field as a result of the detrimental consequences experienced by some individuals that have undergone unproven stem cell therapies. South Africa has had limited exposure to stem cells and their applications and, while any exploitation is detrimental to the field of stem cells, South Africa is particularly vulnerable in this regard. The current absence of adequate legislation and the inability to enforce existing legislation, coupled to the sea of misinformation available on the Internet could lead to an increase in illegitimate stem cell practices in South Africa. Circumstances are already precarious because of a lack of understanding of concepts involved in stem cell applications. What is more, credible and easily accessible information is not available to the public. This in turn cultivates fears born out of existing superstitions, cultural beliefs, rituals and practices. Certain cultural or religious concerns could potentially hinder the effective application of stem cell therapies in South Africa and novel ways of addressing these concerns are necessary. Understanding how scientific progress and its implementation will affect each individual and, consequently, the community, will be of cardinal importance to the success of the fields of stem cell therapy and regenerative medicine in South Africa. A failure to understand the ethical, cultural or moral ramifications when new scientific concepts are introduced could hinder the efficacy and speed of bringing discoveries to the patient. Neglecting proper procedure for establishing the field would lead to long delays in gaining public support in South Africa. Understanding the dangers of stem cell tourism – where vulnerable patients are subjected to unproven stem cell therapies that have not undergone peer review or been registered with the relevant local authorities – becomes imperative so that strategies to overcome this threat can be implemented.

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1. Introduction

Interest in the field of translational stem cell (SC) research has increased rapidly in the past decade, with exciting and promising research providing hope that cures for previously incurable diseases may well be attainable in the not too distant future. Much of the excitement originates from the ability of SCs to self-renew, replicate and to differentiate into any one of the more than 200 cell types in the body.

Although SC therapy may appear to be a relatively new phenomenon, bone marrow (BM) hematopoietic SCs (HSCs) have in fact been used routinely for more than 50 years. SCs are grouped into three categories: embryonic SCs (harvested from a developing blastocyst/embryo produced by in vitro fertilization); adult SCs (harvested from various sources including BM, adipose tissue and umbilical cord blood (UCB)) and induced pluripotent stem cells (iPSCs — differentiated cells that have been reverted back to a pluripotent-like state through genetic modification). The best understood are HSCs, which have been successfully applied around the world in BM transplantation for treatments of various conditions including malignant and non-malignant hematological disorders, immune deficiencies and certain genetic disorders. However, with new discoveries of different types of SCs and many potential novel applications, interest in regenerative and translational medicine has increased.

One consequence of this interest has been a dramatic rise globally in companies and clinics that sell stem-cell-related products or services. In addition to improvement in personal health and wellbeing, the increase seen in cellular and molecular medicine creates opportunities for entrepreneurship, business development and employment. South Africa has great potential for the development of translational medicine involving SC therapies (Jackson and Pepper, in press). In light of South Africa's current burden of disease and the potential for job creation, the country certainly stands to gain substantially (individually and as an economy) from these and similar developments. A major concern for the implementation and operation of such companies and clinics would be compliance with national and international regulatory standards — with the supposed precondition that appropriate national legislation and governance exist.

However, even though SCs harbor the promise of potential cures for many previously incurable disorders, this promise is easily exploited, and many questionable SC practices occur in countries that lack governance and regulation. This has led to the phenomenon known as “stem cell tourism” (SC tourism), where patients travel abroad and are subjected to unproven stem cell therapies. These therapies have often not undergone peer review or been registered with the relevant local authorities and are generally not provided in the patients' home countries.

Bone marrow transplantation, which is a universally accepted form of stem cell therapy, has been practiced with success for several decades in South Africa. Other areas of activity in South Africa in the stem cell field include the growth of skin from small biopsies (mainly in patients with extensive burns), orthopedic and maxillofacial surgery and cosmetic surgery. Some work is being done by individual practitioners using mesenchymal stem cells for a variety of conditions. However, little to no work is being done for the wider spectrum of diseases for which stem cells have been proposed including neuromuscular disorders (multiple sclerosis, cerebral palsy etc.) and cardiac disease. Although it is likely that this situation will be reversed in the near future, these currently incurable disorders form the basis of exploitation seen globally through SC tourism.

An internationally recognized example of SC Tourism involving South Africa is the case of Stephan van Rooyen and his (now deceased) girlfriend, Laura Brown. Through their company – initially registered as Biomark – they sold untested, unproven stem cell therapies to patients suffering from various illnesses (motor neuron disease and multiple sclerosis amongst others). They marketed and sold their stem cell treatments to patients in various countries including the United States, Switzerland, Holland, Germany, Spain, India, Trinidad, Argentina, Brazil, Mexico, Turkey, Saudi Arabia, Pakistan, China and the Ukraine. After Van Rooyen and Brown's US-based company – Biomark – was shut down by the Federal District Attorney in 2003, they relocated to South Africa, changed the name of the company to Advanced Cell Therapeutics (ACT) from where they continued to sell their treatments in South Africa and abroad. The couple was charged with 51 indictments by the Federal grand jury in Atlanta (March 2006) for misconduct in offering costly (up to $26 000 for a single injection of 1.5 million stem cells) and unsound SC treatments (Keating, 2006; Rondganger, 2006). However, by the time they were charged, they were already living in South Africa. Interpol located the couple at the OR Tambo international airport in Johannesburg (2007) but they fought the extradition based on a legal technicality. Laura Brown died of undisclosed causes in 2011 in Cape Town, while the case against Van Rooyen is still ongoing. If he is to be found guilty, he could face up to 20 years in prison for committing fraud, an additional three years per misbranding of drug count, and a fine of up to $1 million per count (Black, 2007; McNabb, 2011).

It has been more than ten years since these individuals started their illegitimate practice and justice still has not been served. Their actions put even more strain on an already overloaded legal system, costing time and effort which could have been prevented with the implementation of proper legislation with national and international ramifications.

Although SCs appear to hold promise for future therapeutic applications (in addition to their current accepted applications), around the globe unscrupulous individuals have started to prematurely promote bogus “SC cures” for various – still incurable – diseases. They often portray SCs as the “holy grail” of cell therapies and have created much uncertainty and controversy in the field.

1.1. Concerns of patient exploitation by stem cell tourism

SC tourism is ethically problematic in that it offers unproven therapies that have not undergone peer review or been registered with the relevant local authorities as legitimate cures for currently incurable diseases (Master and Resnik, 2011). There exists a large discrepancy between published, peer reviewed literature and claims posted on these illegitimate clinics' websites. With SC translation into the clinic (regulated or not) happening at a rapid pace across the world, South Africans are bound to be exposed to some form of SC treatment sooner or later. They need to be able to accurately distinguish between legitimate treatments and fraudulent practices and would therefore, at the minimum, need a creditable source of information to assist them in making decisions. In light of these obstacles South Africa is vulnerable to exploitation with regard to SC tourism.

SC tourism has many facets that could lead to multiple pitfalls, each posing a unique combination of moral, legal, ethical and regulatory challenges (Strauss, 2010). Hype over false therapeutic claims, ranging from the sublime to the miraculous, is endangering the entire field of SC therapies. It is hoped that the implementation of strict regulatory frameworks – such as those established by the Food and Drug Administration (FDA) and the International Society for Stem Cell Research (ISSCR) (Strauss, 2010) – will assist in curtailing these fraudulent practices. Although the ISSCR has made a patient handbook available on their website, with information and guidance to patients on how to evaluate the safety of SC therapies, patients are mostly left to fend for themselves without the support and concern for safety from regulatory bodies.

1.2. Mechanisms for promoting stem cell tourism

While having the world at one's fingertips can be tremendously beneficial, millions of people today are bombarded with a multitude of options and opinions, leading perhaps to the single most daunting challenge of the information age: learning to distinguish fact from fiction.

The Internet and social networking have empowered many people to gain access to unrestricted information on a virtually unlimited number of topics. Many companies use the Internet and Web pages to bring their business directly to consumers through direct-to-consumer advertising. However, limited monitoring of content on the Internet often creates difficulties in verifying the accuracy and credibility of the information presented. This is especially true when it comes to the field of SCs and their current and possible future therapeutic applications and translation into modern healthcare.

Con men mainly operate by promoting their activities on the Internet and reach a much broader audience than was possible in a pre-World-Wide-Web era. They offer false hope, promises of cures and miracle healings and often advertise unsubstantiated claims on their Web pages. They play on the needs and desires of emotionally vulnerable patients to be cured and coax members of the public into signing up for unproven SC treatments provided in often precarious settings. Many unsuspecting customers have fallen prey to these illicit elements, which have the potential to discredit the legitimacy of SC research and true, current and future therapeutic applications (Lindvall and Huyn, 2009).

2. Factors that intensify stem cell tourism

2.1. Lag in regulatory oversight

Certain countries have more strict regulations (e.g. the USA with the Federal Drug Agency (FDA)) than others (e.g. China, Mexico, India, Costa Rica, Thailand etc.), with fewer opportunities for such scams in the former. Unfortunately, although the South African legislation does provide some regulatory oversight for the latest advances and discoveries concerning SCs, the lack of enforcement of this legislation leads to a large regulatory gap that could potentially be exploited by opportunistic and self-serving individuals (Pepper, 2012; Mahomed and Slabbert, 2012). There are many issues that complicate enforcement of legislation including a need for educated personnel and contentious definitions in national legislation. Even though legislation could serve as a deterrent, in itself it does not determine whether a practice is ethical or not. Furthermore, many South Africans have not heard of SCs. Those who have have mostly been exposed only in passing and have not been properly informed. This absence of regulatory oversight and the unavailability of easily accessible, reliable information regarding SCs and their applications render not only the individuals but also the country vulnerable to questionable global influences.

2.2. Lack of proper communication between scientists and the public

A substantial gap exists between scientists and medical doctors that undertake legitimate SC research and the subsequent accurate translation of such research to patients. The media often sensationalizes preliminary scientific findings, creating much hype based on half-truths — dangerous territory that is often exploited by con men. In the absence of appropriate legislation (either due to lack thereof or failure to enforce existing legislation), increasing awareness of SCs and their promise in novel therapeutic applications for a wide range of disorders will undoubtedly bring with it an escalation in illegitimate SC practices.

3. The moral and scientific dilemma

SC research has increased exponentially across the globe (Barclay, 2009). Discovering SCs in easily obtainable material such as adipose tissue and peripheral blood together with less invasive isolation techniques for obtaining these cells (such as umbilical cord blood collection) has left an open invitation to many undesirable “stem cell squatters” in the field of SC research and translational medicine.

The translational process from science to medicine is complex and slow. Proven treatments involving SCs over the past 50 years include blood malignancies and other disorders treated with adult SCs through bone marrow transplantation as well as bone-and skin grafting and certain corneal diseases or injuries, using adult SCs harvested from the particular tissue (ISSCR (International Society for Stem Cell Research), 2012).

Legitimate ethically approved clinical research is being conducted in various registered clinical trials. Although preliminary results seem positive, very few trials have, to date, successfully completed stage III, which would be required to bring the therapy or treatment to the market. The procedures necessary to accredit new treatments are tedious and painstakingly slow. Furthermore, the media generally fails to contextualize research findings into the immediate medical and scientific landscape. The vision of a cure or application needs to be tempered with a realistic view on research and regulatory time frames. The media often sensationalizes optimism without considering the context, which in turn increases the difficulty to accurately portray the currently “do-able” and future treatments to the general public.

In essence, if presented on a sliding scale we have – on the one hand – scientists doing research ethically and systematically. On the other hand are scam artists latching onto promising research by offering unproven treatments to ill, desperate but hopeful patients with a plethora of research taking place in between these two extremes. With an increase in awareness of the therapeutic potential of SCs inevitably comes a surge of illegitimate opportunists. The problem is that research needs to go through all the right channels before it can benefit patients, and this is a lengthy process. Patients often don't have the luxury of time to wait for these treatments to become commercially available or for potential therapies to go through regulation and accreditation.

Stem cell tourism increases in parallel, as desperate patients are offered the option of unproven treatments. Furthermore, patients have a right to access medical treatment and no law forbids them to undergo treatment of any nature to which they give consent. The end result is the exodus of frustrated and impatient patients, unwilling to wait for local approval of SC therapies yet willing to risk their health and livelihoods on unsubstantiated claims (Caplan and Levine, 2010). Even though nobody could prevent a desperate patient from wasting money on unproven therapies, it is the authors' opinion that the very least we can do is to provide these patients with a platform of knowledge and expertise from which to enquire about potential therapies. A single trusted source providing unbiased and accurate information regarding current available therapies, lists of risks involved with current therapies and potential risks involved in unproven therapies, could equip patients with unbiased information to aid their decision making.

Despite repeated warnings from acclaimed scientists against clinics that offer curative SC therapies for a variety of disorders, many patients ignore this advice and still opt for treatment (Lau et al., 2008). In addition, according to Sean Morrison, director of the University of Michigan Centre for Stem Cell Biology and treasurer of the ISSCR, many doctors are venturing into their own SC initiatives (Barclay, 2009). Whether they are compelled to get involved by the steadily increasing patient demand for SC treatments – only having their patients' best interest at heart – or not, is hard to decide, since many of these doctors also stand to gain commercially from the treatments.

Some doctors do however recognize the potential of SC treatments and instead of subjecting their patients to doubtful practices abroad would rather opt to treat their patients themselves, where they are more certain of the type and quality of administered SCs and the correct application thereof. This not only places them in a moral and ethical dilemma but also places a degree of risk on their licenses as practitioners.

It is important to note that not all doctors who offer SC treatments are imposters. Just the same, as Timothy Caulfield at the University of Alberta's Health Law Institute, Edmonton, Canada states, people that offer treatments should publish their data in scientific, peer-reviewed

journals (Barclay, 2009). The substantial risks involved in uncontrolled treatments necessitate verification of purported results in a controlled environment through appropriately structured clinical trials (Cyranoski, 2009). These should include assessments of safety, efficacy, harvesting, storing/culturing of cell isolates, dosing, administration procedures and ethically approved information leaflets and informed consent forms (Lindvall and Huyn, 2009). This transparency gives other researchers the opportunity to verify the claims, safety and efficacy of the treatment and to advance the field through reliable results.

3.1. Emerging stem cell clinics and treatments

The number of clinics that offer SC treatments has increased exponentially in the past four years. In 2009 there were an estimated 200 clinics in China alone and, although it is difficult to determine an exact number because of the often clandestine nature of their activities, it is thought that the current estimate well exceeds this number (Cyranoski, 2009). Clinics are found in various countries. Places such as China, Mexico, India, Costa Rica, Russia, Thailand, Germany, Hungary, Korea, the Dominican Republic, Jordan, Kazakhstan and Barbados are popular destinations, since regulations are generally less strict or non-existent (Caplan and Levine, 2010).

These clinics offer treatments and cures for still incurable disorders, including amyotrophic lateral sclerosis, spinal cord injury, stroke, multiple sclerosis, Parkinson's disease, all forms of blindness including optic nerve damage, systemic lupus erythematosis, brain injury, cerebral palsy, Down's syndrome, Alzheimer's disease, heart disease, diabetes and autism. Of the less serious treatments, cosmetic enhancement is at the top of the list with anti-aging creams, fibroblast/collagen injections (as an alternative to botox) or general “health enhancements” (Lau et al., 2008).

Of particular concern are the cell sources. According to a study carried out by Lau et al. (2008, it was found that autologous SCs were provided in nine sites, comprising 47% of their study cohort. Bone marrow comprised 37% of autologous cells used (in seven sites) while cells were also obtained from adipose tissue and blood donations. The other 53% of cells were from other sources such as fetal SCs, cord blood SCs, and embryonic SCs, peripheral blood, patient fat (adipose tissue), aborted fetuses, patient's skin, animal tissues, and human placental tissue. Treatments were provided for a wide variety of disorders ranging from neurological and cardiovascular diseases to allergies. These were generally treated by SC infusion into cerebrospinal fluid via lumbar puncture (six sites; 32%), while IV infusion was also common (Lau et al., 2008).

In addition to the obvious health and safety risks, these clinics often charge patients exorbitant amounts averaging from $15 000 to $25 000 USD for their SC treatments. Costs are often unsubstantiated and do not include patient travel or accommodation (Cyranoski, 2009).

3.2. Advocates for stem cell tourism

Advocates for SC treatments do not necessarily endorse SC tourism, but their fervor to provide treatment often clashes with opponents of SC tourism.

Those who advocate a patient's right to access all forms of treatment, potential or real, present the following arguments to support their case:

1. Patients often don't have the luxury of time. Their diseases usually progress fast and alternative SC treatments (proven or unproven) are their last option.
2. Clinical trials are costly and finding appropriate funding for trials is challenging (Barclay, 2009). In addition, clinical trials prolong the time until treatments become acceptable and therefore available to patients.
3. Advocates (some clinicians, researchers or fraudsters) propose that they have patients' best interests at heart. They work with dying patients daily and they claim, consequently, do not have time to perform studies or write articles that are subjected to peer review.
4. They claim that SC treatments have thus far yielded little or no adverse effects, failing to cite rejection of cells from allogeneic donors.
5. They disagree with the FDA with regard to classification of treatments with autologous cells. The FDA classifies all cells that are more than minimally manipulated as “drugs” that need to adhere to FDA rules and regulations pertinent to administration of a “drug”. Conversely, advocates for SC treatments maintain that a body's own cells are not drugs and should be exempt from FDA regulatory requirements. Advocates accuse the FDA of stalling developments in SC treatment since they do not stand to gain directly from emerging SC treatments and potentially stand to lose profit because of a shift in medical treatment from pharmaceutical drugs to cell therapy. A recent example is the case of the FDA against the Broomfield, Colorado, Clinic, Regenerative Sciences. On 25 July, 2012 the US district court in Washington DC ruled in favor of the FDAs injunction made in 2010 against Regenerative Sciences. They had been treating orthopaedic problems with their Regenexx product, which the FDA classifies as a drug since cells were more than minimally manipulated. However, Regenerative Science's medical director, Dr. Christopher Centeno, plans to appeal the court's decision and maintains their product is not a drug (Aldhous, 2012). In the context of this review, South African legislation has not defined the term ‘minimally manipulated’ nor given definite regulations and terms for acceptable SC treatments.
6. Advocates want to capitalize on the favorable climate for new businesses start-ups in SC treatments. They are afraid of missing the opportunity provided in the emerging market.
7. Some advocates are driven by the potential fame and recognition of potentially curing a previously incurable disease with their SC treatments. They see themselves as pioneers and argue that technology always precedes regulation.

3.3. Adversaries of stem cell tourism

Adversaries – opponents to unproven SC treatments – are cautiously optimistic about the potential promises provided by SC treatments. They do not oppose the development of SC treatments, but rather propose a safe and regulated environment in which to practice and develop new treatments.

The case against SC tourism centers on the following points:

1. New developing fields must have a balanced approach where ethical, moral and scientific principles are applied. Emphasis on scientific progress cannot override a scientist's responsibility towards the public to ensure the release of safe and reliable treatments into the market. Harmony must exist between risk and benefit that needs to be obtained through phased and structured assessment of safety, efficacy, dosing and administration of treatments. Informed consent procedures must be assessed and approved and all innovation outside of research must be demonstrable, scientific and clinical (Cyranoski, 2009).
2. Opponents object to unrealistic, incomplete and false marketing often associated with unproven SC treatments that are made available to the public. Advertisements are generally over optimistic or positive, understating potential risks involved, and have numerous unsubstantiated claims of treatment efficacy without the necessary scientific proof to back them up (Caplan and Levine, 2010; Black, 2007).
3. Adversaries object to the lack of transparency from companies providing SC treatments. At best, selective information is made available to patients and the public, creating opportunities for exploitation (Lau et al., 2008). Furthermore, little or no information is provided on experimental protocols, procedures or controls that allow for an independent analysis of the claims (Cyranoski, 2005).

4. It is imperative to subject all work to objective, peer-reviewed assessment, proper regulatory oversight and to conform to requirements from ethical councils (Lau et al., 2008). Patients are generally not followed up after treatments and there are no records kept of potential side effects. Without these measures, it is impossible to know the lasting effects of treatment, whether potential improvements are due to placebo effects or whether they are only temporary, and whether there are any side effects related to the cells administered or their route of harvesting or administration. This information is vital to the entire scientific community and could aid in developing effective, lasting treatments. With a lack of FDA-approved clinical trial data, evidence is anecdotal and controversial at best.
5. Opponents of SC tourism maintain that false claims of safety and efficacy of treatments will eventually jeopardize legitimate SC research and its clinical translation. Once public confidence in these treatments is shaken, it will be difficult to convince people otherwise.
6. Another concerning factor is the lack of understanding by providers of SC treatments of the underlying biology of many of the disorders and their proposed SC treatments (Barclay, 2009). The fate of injected cells is not well understood and could lead to serious side effects or even death.
7. Erroneous therapeutic misconceptions abound and have been turned into lucrative business models (Cyranoski, 2005). Furthermore, there are no cost regulations or structures for any of the provided treatments and patients are vulnerable to financial exploitation.

4. How to curb stem cell tourism

Legitimate SC entities could curb malpractice and corruption through transparency, peer review, clinical trials, by addressing current misconceptions with regard to SC therapy and by raising public awareness of current clinical applications and exploitations of SC treatments (Lindvall and Huyn, 2009).

This calls for better governance of genuine research and open and accurate communication from scientists to the public. Creating an overarching, global, independent regulatory body could be one way in which to curb the wealth of inaccurate information and criminal activities on the Internet. This regulatory body could serve as a platform for translating legitimate research through open communication with the global public. In turn, each country should have its own regulatory body preferably linked to the global governing body. The regulatory bodies must follow up on and monitor all therapeutic claims. They should actively raise public awareness of current SC therapies and provide an accurate and clear consumer's guide in addition to physician's or health care provider's guide to approved uses for cell therapies.

By enabling legitimate SC practices to operate under proper legislation and simultaneously increasing awareness of these legitimate practices, one could potentially reduce the appeal offered by illegitimate practices.

All doctors, scientists and suppliers of SC treatments must adhere to minimal ethical, scientific and medical standards for treating patients with any therapy. Treatment with SCs other than BM or HSCs is a recent phenomenon where minimal ethical scientific and medical standards have, for the most part, not been defined. The general consensus is to adhere to Global Best/Clinical Practice for safety, efficacy and ethical regulations. However, because many clinics fail to do so, the ISSCR has put together a task force and posted proposed minimal standards, together with a list of guidelines and clinic requirements, on its website (www.isscr.org) (ISSCR (International Society for Stem Cell Research), 2012). This includes a list of questions about the treatments offered that patients could ask the specific clinics and that ought to be answered. Through this effort, the ISSCR aims at publishing a list of clinics that it believes adhere to the minimal standards of operation as suggested by the task force (Taylor et al., 2010). The ISSCR patient handbook could also be used both by patients seeking treatment abroad and their physicians to make informed decisions about SC treatment and the necessary questions to ask the treatment providers prior to signing up for treatments (ISSCR (International Society for Stem Cell Research), 2012) (http://www.closerlookatstemcells.org).

A similar approach has been taken by the International Cellular Medicine Society (ICMS). The ICMS has realized that there is virtually no stopping patients from going abroad for so-called SC treatments and has therefore opted to encourage doctors and clinics to treat their patients on the basis of ICMS guidelines, which can be found on its website (http://www.cellmedicinesociety.org).

Caplan and Levine (Caplan and Levine, 2010) have mentioned how the neglect from mainstream medicine to act decisively on the issue of quackery has aggravated the problem, leading to whole countries purposefully gearing themselves to capitalize even more on the steady inflow of vulnerable patients from abroad. SC tourism is not a unique phenomenon, but it is potentially posing a much larger problem than medical tourism since SCs are portrayed as a "single solution miracle cure" to almost any disease.

5. Conclusion

The vibrant field of SC research and treatment consists of dramatically different stakeholders, all of whom have specific interests and agendas. For all parties involved, the stakes are high and understanding the dangers of SC tourism is imperative. It should be pointed out that the use of the word "tourism" has arisen from the propensity for patients to travel long distances to receive treatments in foreign countries. However, the principles outlined above are equally applicable to activities that may exist in one's own country.

In order to reap the greatest benefit from what SCs have to offer, it is imperative to understand the current SC milieu. It is necessary to find a balance between scientific soundness in new discoveries and medical innovations, and uncontrolled experimental treatments that abuse patient vulnerability and the regulatory vacuum. The focus should be on the creation of safe, effective, scientifically sound treatments in a controlled regulatory environment without compromising patient health care. These therapies should furthermore offer patients greater than – or at least equal – benefit to what conventional available therapies can provide. Unless the therapy provides benefit to the patient, it will be unethical and thus unacceptable to administer (Lindvall and Huyn, 2009).

Caplan and Levine (Caplan and Levine, 2010) succinctly summarize the problem:

> *Those who are drawn to SC therapies are often confused about the innovative status of these interventions, overly reliant on unsubstantiated claims about the quality of biological material being administered, or unable to readily locate balanced assessments of what medical tourism may have to offer for their particular problem. Professional societies and mainstream SC researchers have an obligation to do more.*

In light of these considerations, South Africa is especially vulnerable. Very few South Africans have access to information regarding SC treatments. In addition, no single credible authoritative voice exists to provide South Africans with relevant, reliable and accurate information with regard to current, future or potential SC treatments. There are no watchful authorities patrolling the SC arena for fraudulent practices or governing bodies dedicated to the protection and safety of potentially vulnerable patients (be it locally or influenced from abroad). Furthermore, physicians and health care providers are not kept abreast of the current state of affairs in FDA-approved SC treatments nor the legal application thereof in the South African context.

The global atmosphere around SC treatments underscores the importance of distinguishing legitimate research and therapeutic

application from potential fraudulent practices. As any virus spreads, so too will the scourges of SC tourism, in this way rendering South Africa vulnerable to elements that could taint emerging SC research and therapy in the country.

One manner in which to further legitimate SC practices in South Africa is by establishing a reliable and easily accessible source of information, accredited and supported by reputable health and governmental institutions. This information should be freely accessible to the public, provide reliable information on SC donations and therapeutic applications and in this way establish safe and appropriate avenues for regulated SC therapies that will allow patients to distinguish authentic SC therapies from fraudulent practices.

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References

Aldhous, P., 2012. Ruling Frees FDA to Crack Down on Stem Cell Clinics. New Scientist. web: http://www.newscientist.com/blogs/shortsharpscience/2012/07/ruling-frees-fda-tocrack-down.html (Date accessed: 1 August 2012).

Barclay, E., 2009. Stem cell experts raise concerns about medical tourism. The Lancet 373 (9667), 883–884.

Black, G., 2007. Alleged U.S. stem cell fraudsters shielded by South African legal logjam. Thanks to a Stalled Extradition Case, Couple Avoids Facing 51 Charges of Allegedly Illegally Distributing Costly Stem Cell Treatments. ABC News, 23 April.

Caplan, A., Levine, B., 2010. Hope, hype and help: ethically assessing the growing market in stem cell therapies. The American Journal of Bioethics 10 (5), 24–25.

Cyranoski, D., 2005. Paper chase. Nature 437, 810–811.

Cyranoski, D., 2009. Stem cell therapy faces more scrutiny in China. Nature 459 (7244), 146–147.

ISSCR (International Society for Stem Cell Research), 2012. A closer look at stem cell treatments. web: http://www.isscr.org (Date accessed: 12 May 2012).

Jackson, C., Pepper, M.S., 2013. Opportunities and barriers to establishing a cell therapy programme in South Africa. Stem Cell Research and Therapies (in press).

Keating, C., 2006. Stem-cell pair "raked in a fortune". Cape Argus: 70, 9 Aug.

Lau, D., Ogbagu, U., Taylor, B., Stafinski, T., Menon, D., Caulfield, T., 2008. Stem cell clinics online: direct-to-consumer portrayal of stem cell medicine. Cell Stem Cell 3 (6), 591–594.

Lindvall, O., Huyn, I., 2009. Medical innovation versus stem cell tourism. Science 324 (5935), 1664–1665.

Mahomed, S., Slabbert, M.N., 2012. Stem cell tourism in South Africa: the legal position. South African Journal of Bioethics and Law 5 (2), 69–73.

Master, Z., Resnik, D.B., 2011. Stem-cell tourism and scientific responsibility. EMBO Reports 12 (10), 992–995.

McNabb, D., 2011. Ex-catwalk star's shocking death in South Africa. International Extradition Lawyers. When the FBI seeks extradition… 6 September. web: http://internationalextraditionblog.com/tag/steve-van-rooyen-and-laura-brown/ (Date accessed: 25 November, 2012).

Pepper, M.S., 2012. Medicine and the law: Partial relief from the regulatory vacuum involving human tissues through enactment of chapter 8 of the National Health Act and regulations thereto. South African Medical Journal 102 (9), 736–737.

Rondganger, L., 2006. Couple in court for "miracle stem-cell cures". Independent Online (IOL News), 11 Aug.

Strauss, S., 2010. Stem cell clinic patrol. Nature Biotechnology 89 (9), 885.

Taylor, P.L., Barker, R.A., Blume, K.G., Cattaneo, E., Colman, A., Deng, H., et al., 2010. Patients beware: commercialized stem cell treatments on the web. Cell Stem Cell 7 (1), 43–49.