legitimization of novel medical research. Precise rules and regulations are integral to the ways in which clinicians make sense of their practice, but they can also be detrimental to research progress, especially to the translation into and the completion of clinical trials to establish new treatments. Clinicians reported to us that it is easier to recruit participants for safety studies than for double-blind RCTs, because patients wish to be sure that they receive stem cells and are not part of the control group. Thus, stem cell tourism has also occurred within Europe: Patients cross borders and health systems to enroll in safety or efficacy trials, in order to receive treatments with their own stem cells.

Clinical trials and protocols presuming sameness of practices across localities and cultures are only possible by approximation. In addition, there are great difficulties in conducting these trials (financially and logistically), recruiting patients and, for the researchers involved, facing the long time scale and the risks of potentially neutral outcomes. In order to manage the promise of novel therapies responsibly and with a realistic and nonpatronizing attitude, it is crucial to improve collaboration and increase our understanding of the unavoidable tension between scientific rigor, hope for cures, and the required commitments in this balancing act.

## CONCLUSION: STEM CELL EXCEPTIONALISM?

An implicit exceptionalism seems to underlie the presented criticism of stem cell tourism. If, and only if, an argument can plausibly be made that medical treatments with stem cells require more surveillance and attention from professionals and policymakers than, for example, widespread and risky tourist activities such as gambling, or beauty surgery, does it follow that the ideal of scientific knowledge production, double-blind RCTs, ought to be the normative rule to govern stem cell applications globally? The integrity of medicine as a science and trust-based day-to-day practice and its distinction from treatments outside this scientific environment are another implicit theme in this discussion. Alongside the authors of the papers here, we agree that the medical professions have only limited influence and responsibility regarding the paths of novel treatments and the fate of individual patients who want to have stem cell treatments abroad. ■

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# Stem Cell Tourism—A Challenge for Trans-National Governance

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The papers by Zarzeczny and Caulfield (2010) and by Murdoch and Scott (2010) address problematic aspects of stem cell (SC) tourism from the perspective of professional responsibility. The former authors focus on minors and suggest an approach that relates to potential child abuse by their guardians, whereas the latter recommend caution in condemning patients for seeking remedies for hopeless medical conditions. Crozier and Thomson's commentary (2010) likewise addresses the responsibility of professional organizations, suggesting they compile data that will assist

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physicians in determining appropriate action to protect minors from potentially harmful treatments. Chandler (2010) also responds in terms of professional responsibility, albeit in a different vein, suggesting there is little physicians can do for competent patients other than offer realistic advice about the pros and cons of traveling abroad for expensive, uncertain, and risky treatment. However, SC tourism raises challenges of effective regulation that are beyond the scope of doctor–patient relations.

One challenging issue is the need for measures that guarantee the safety and quality of SC bioproducts. Attention should also be paid to the ethics of the procurement of the biological material from which the SCs are extracted, including protection of the human rights of women who are the source of umbilical cord blood.

Another matter of utmost importance relates to the thin line between misinformation about the benefits of treatment, and deceptive disinformation that can amount to criminal fraud. Patients (or their parents) are not the culprits in such potentially harmful practices, and responsibility for taking remedial action lies with governments. This is not simple, since the wrongs occur outside the territorial jurisdiction of the state, so that creative forms of transnational governance need to be developed.

## A GLOBAL MARKETPLACE

Stem cell tourism is characterized by online direct-to-consumer marketing of unproven therapies (Lau et al. 2008). It is part of a larger trend toward the privatization and commercialization of conventional, complementary, and alternative medical care. Individuals play an active role in this marketplace in different ways. They act as consumers of nontherapeutic medical practices such as cosmetic surgery. They buy online personal genome tests, and in the process also pay to participate in research (Prainsack et al. 2008). As patients suffering from conditions that perplex their medical care givers, they seek out clinical trials or innovative interventions in centers over the world that might offer them some hope of relief. They also deposit their hopes in commercial cord blood banks (which contribute to the hype of SC therapy), as would-be insurance against future need.

Stem cell tourism lies on a continuum of a global market in medical tourism, together with reproductive tourism (egg donations and surrogacy for infertility treatment) and organ transplantation, both of which are known to entail human rights violations that characterize practices of trafficking in human beings, body parts, and tissue.

The market crosses national borders, and being private it can elude the governance of internationally accepted medical ethics. The private market is not conducive to the transparency and accountability that are required for oversight of research ethics in the case of clinical trials, or of patient care ethics in the case of medical innovation (Lindvall and Hyun 2009). Even if SC treatments were based on sound scientific evidence, it would be difficult to guarantee adherence to the fundamental rights of patients to full information about the risks and benefits of treatment and to the protection of confidentiality and privacy. But SC treatments involve more regulatory and ethical issues.

## SOURCES OF HUMAN CELLS

First, there is a public health interest in assuring the quality and safety of the SC bioproducts in terms of their procurement, processing, storage, and transportation (e.g., European Commission 2004: Directive 2004/23EC). Then there are questions that go to the regulatory approval and licensing of bioproducts (e.g., U.S. CFR, ch. 21). In addition, there are a priori ethical concerns surrounding the source of the SCs.

There has been much controversy around the use of human embryonic SCs (hESCs), but little attention has been given to ethical aspects of the use of SCs derived from umbilical cord blood. One website that presents SC treatment therapy as a "natural" and "holistic" treatment says "umbilical cords are readily available everywhere" and asks why they are "ignored in favor of embryonic cells." They answer: "Biotech companies want us to believe that SCs are difficult, rare, and expensive so that they can control the market" (http://www.stem-cell-treatment-now.com/Politics-and-Ethics-of-Stem-Cell-Thereapy-and-Research.html).

In a more sober tone, the possibility of replacing hESCs with SCs from umbilical cord blood might be presented as an expedient use of tissue that is normally discarded as medical "waste." However, the use of tissues for a purpose other than that for which they were removed requires informed consent (Council of Europe Convention on Human Rights and Biomedicine 1997, Art. 22).

Moreover, umbilical cord blood is not as readily available as it might seem. The process of extracting blood from the umbilical cord may increase the length and risks of postpartum hemorrhage in the third stage of labor, the delivery of the placenta, which is the leading cause of maternal death. Nonetheless, it is widely assumed that the extraction of umbilical cord blood does not pose ethical issues about harms to women, as if "the lady vanishes" (Dickenson 2007).

## SCAMS AND FRAUD

Yet another challenge lies in finding ways to redress charlatanism, quackery, and fraud. SC treatments are only one demonstration of a phenomenon of online scams that offer fraudulent health care products, ranging from counterfeit pharmaceuticals to bogus cancer cures (http://www.chcaa.org/education/online_health_scams.php). SC fraud is associated with the much-publicized scandal in 2005 of a Korean scientist who was found to have fabricated research results in relation to the extraction of SCs from cloned human embryos. A less known case involved actual criminal fraud in the offering of SC therapy.

In February 2009, the Constitutional Court of South Africa ruled that a couple of alleged SC fraudsters would be extradited to the United States. They were wanted by the FBI for the "duping of terminally ill Americans" and had been arrested by Interpol at Johannesburg airport

a year earlier (*Star* 2009). The couple was indicted in 2006 in a U.S. federal court for multiple charges of alleged criminal fraud, to wit, knowingly devising a scheme to defraud individuals suffering from incurable diseases, through placing on their website false and misleading information on SC treatment. The counts of the indictment included the commercial distribution and marketing of unlicensed biological products and of unapproved drugs, in the form of SC injections extracted from umbilical cord blood (http://www.circare.org/lex/06cr1534_indictment.pdf).

The charges of the indictment tell a story that appears to be a typical modus operandi of SC treatment fraud. Operating through a company named BioMark International, and then going by the name of Advanced Cell Therapeutics, the couple was charging patients up to $32,000 for SC interventions, all over the world. They obtained the umbilical cord blood from blood banks, and packaged the extracted SCs in misbranded vials for shipping to customers. And, they purported to treat people suffering from a wide range of serious diseases with a standard injection, using the same type and quantity of cells for all their customers, regardless of their disease.

## CONCLUSION

Levine's commentary (2010) suggests that biomedical research funding agencies, scientific societies, and disease advocacy groups concerned with the risks of SC tourism and the integrity of SC science are obligated to establish processes to collect rigorous, objective, empirical data about patients' experiences with unproven SC therapies. In a similar vein, Crozier and Thomson (2010) propose that governments collect data on SC treatments abroad to fill the informational void. But this may not be enough.

Zarzeczny and Caulfield suggest that doctors should report parents of minor patients to state authorities, in order to protect their child from harm. But Murdoch and Scott point out that patients are not to blame. Nor are the parents who act in what they consider to be the best interest of their child. The perpetrators of the crime are the medical entrepreneurs and brokers who advertise and provide the treatments (in tourism packages) through websites that employ hype and highly sophisticated disinformation and misrepresentation of the benefits and risks of treatments, so as to exploit desperate patients. Their accomplices are the practitioners who collaborate and profit from the business, as well as the blood banks that sell the cord blood. It is these that doctors should report to state authorities.

The ISSCR guidelines (ISSCR 2008) say that regulators in countries where illegitimate therapies are offered have a responsibility to take disciplinary action against the clinicians involved, and also to close fraudulent clinics. In order to do so there must be proactive cooperation with law enforcement agencies and those that are mandated to investigate international crime and cybercrime. The emerging phenomenon of cross-border medical tourism requires states to abandon the ostrich approach of territorial sovereignty and to devise new mechanisms of governance and responsibility for transnational practices that are abusive. Even the World Trade Organization recognizes the legitimacy of imposing restrictions on market access for the protection of "public morals" and "public order" (WTO 1994a, 1994b). ■

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