

## Professional Regulation: A Potentially Valuable Tool in Responding to “Stem Cell Tourism”

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### SUMMARY

The growing international market for unproven stem cell-based interventions advertised on a direct-to-consumer basis over the internet (“stem cell tourism”) is a source of concern because of the risks it presents to patients as well as their supporters, domestic health care systems, and the stem cell research field. Emerging responses such as public and health provider-focused education and national regulatory efforts are encouraging, but the market continues to grow. Physicians play a number of roles in the stem cell tourism market and, in many jurisdictions, are members of a regulated profession. In this article, we consider the use of professional regulation to address physician involvement in stem cell tourism. Although it is not without its limitations, professional regulation is a potentially valuable tool that can be employed in response to problematic types of physician involvement in the stem cell tourism market.

There is a growing international market for unproven stem cell-based interventions advertised on a direct-to-consumer basis primarily over the internet, a phenomenon often referred to as “stem cell tourism” (Ryan et al., 2010; Levine and Wolf, 2012; Regenberget al., 2009). Studies have established that clinics around the world are offering unproven stem cell-based interventions for a vast array of diseases and conditions, in the absence of robust evidence of the safety or efficacy of these procedures (Lau et al., 2008; Ogbogu et al., 2013). Engagement in this market does not always involve patients traveling out of country, and, as is discussed more below, countries such as the United States are seeing a growing market and push for use of autologous stem cell therapies (Munsie and Hyun, 2014; Bianco and Sipp, 2014).

Patients generally pay for these treatments directly, without support from public or private health insurance. Concerns associated with the stem cell tourism market are numerous and include physical risks to patients (Amariglio et al., 2009; Thirabanjasak et al., 2010; Dobkin et al., 2006; Jabr, 2012), financial exploitation of patients

and their supporters (Zarzeczny et al., 2010), and reputational risks for the field of legitimate stem cell science (Wilson, 2009). There are also financial and other implications for patients’ home health care systems when patients return from receiving treatment abroad—or merge back into publicly funded medical systems after pursuing care in the private market—and require follow-up care that may prove complex and/or expensive (Snyder et al., 2011, 2012).

These concerns have not gone unanswered. Responses include patient education efforts (ISSCR, 2008a; Master and Caulfield, 2014), guidance focused on stem cell scientists (ISSCR, 2008b; Master and Resnik, 2011), resources for clinicians (Caulfield et al., 2012), tightening of national regulation (e.g., in Germany [Stafford, 2009] and China [Cyranoski, 2009]), and stronger enforcement of existing regulatory regimes (FDA, 2011). However, recent data indicate that notwithstanding these efforts, the number of clinics and jurisdictions in which they operate continues to grow (Ogbogu et al., 2013). Perhaps this result is unsurprising given the challenges inherent in regulating and responding to online markets that tend to be very fluid, and more time is required to see the long-term effects of these efforts. However, given the potential risks involved, it seems worthwhile to simultaneously consider more direct avenues of response to stem cell tourism.

Physicians play a variety of roles in the stem cell tourism market and in many jurisdictions around the world are members of a regulated profession. Here, we propose that professional regulation may be well placed to respond to some of the key concerns associated with the challenging phenomenon of stem cell tourism.

### Physician Involvement

Physicians are involved in stem cell tourism in various capacities, which may trigger professional discipline, although some types of conduct are more direct and potentially egregious than others. For example, physicians may



provide unproven stem cell-based interventions, own and/or operate a clinic, refer patients to providers located in other jurisdictions, advertise unproven stem cell-based interventions offered elsewhere, sit as an advisor or member of a clinic’s medical board, provide information and advice to patients, provide preprocedure testing and/or follow-up, and/or, in a research capacity, share stem cell lines with providers of the unproven therapies.

There are examples from jurisdictions around the world where physicians have been sanctioned by professional regulatory bodies for providing unproven stem cell-based interventions. For example, Dr. Robert Trossel was a physician licensed in the United Kingdom who provided stem cell therapy to a number of patients suffering from multiple sclerosis at a clinic he was associated with in Rotterdam. A panel of the General Medical Council (GMC) found his fitness to practice was impaired due to his misconduct in relation to his treatment of these patients and directed his name be erased from the Medical Register (GMC, 2010). The Medical Board of California similarly disciplined a physician, Dr. Darryl See, who treated a number of patients (including a quadriplegic patient, a patient with neck pain, and a patient with spinal cord injury) with stem cells. There were various causes for discipline in that case including gross negligence, repeated negligent acts, incompetence, and false representations (MBC, 2007). In another instance, an Australian physician, Dr. Harvey Tarvydas, was sanctioned by the Medical Board of Queensland for purporting to treat a patient suffering from arachnoiditis with an experimental treatment intended to stimulate the growth of stem cells. His conduct was found to contravene the policy regarding unconventional medical practice in a number of respects including failure to obtain properly informed consent and failure to properly assess the patient (MBQ, 2010).

In other cases, physicians have been sanctioned for less direct involvement, such as advertisement or pre- or post-treatment interventions. For example, Dr. Wong Yoke Meng was a licensed physician in Singapore and owner of two clinics when he was convicted of professional misconduct for misleading advertisements suggesting he was a specialist in stem cell treatments that were recognized, effective treatments for arthritis, hypertension, diabetes, Parkinson’s disease, and cancer (SMC, 2010a). In another instance, he was convicted of professional misconduct for advertising stem cell skin therapy and stem cell therapy for facial and body rejuvenation. The services offered included escorted tours to foreign clinics as well as pre- and posttreatment care (SMC, 2010b).

Although there may be exceptions (e.g., Munro, 2005), at present it seems physicians in jurisdictions such as Canada are perhaps most likely to be involved in more peripheral capacities than as direct providers of unproven stem cell-

based interventions. In a recent series of interviews conducted by one of the authors (A.Z.) with practicing physicians and representatives from provincial Colleges of Physicians and Surgeons in Canada, the two following types of involvement emerged as most relevant, based on experience with analogous areas of medical tourism and complementary and alternative medicine: (1) information and advice to patients and/or caregivers, and (2) preprocedure testing and/or follow-up.

Indeed, a research study examining the decision-making processes of Canadian medical tourists indicates patients commonly approached their regular physicians for medical records or diagnostic tests in preparation for treatment abroad, which the physicians typically provided (Johnston et al., 2012). This study highlights broad health policy implications for patients’ home health care systems, particularly where such services are covered by a public health insurance scheme (e.g., in Canada). It also raises questions regarding whether this conduct on the part of physicians could be viewed or interpreted as support for or passive (or even direct) endorsement of the procedure at issue. Levine and Wolf (2012) present similar data on the experiences of individuals in the United States who pursued an unproven stem cell-based intervention abroad, either for themselves or for their children. They reported a range of interactions between patients and their regular physicians, including no interaction, strenuous objection, positive endorsement (or outright recommendation), and ambiguous advice (Levine and Wolf, 2012). In light of the duties physicians owe to their patients (Zarzczy and Caulfield, 2010), it is questionable whether this range of responses meets physicians’ professional obligations and relevant standards of practice.

### Role of Professional Regulation

As discussed above, in many countries, physicians are members of a regulated profession and, as such, are subject to professional discipline. Two main professional regulatory models exist: self-regulation through largely autonomous professional bodies, and direct regulation by the state. Professional self-regulation is unique in a number of respects. Professions are granted the authority to self-regulate by the state, usually by way of legislation. In other words, the state devolves its regulatory power to the profession itself, recognizing the profession has particular expertise required to effectively evaluate and ensure its members’ competence. This devolution of regulatory power is generally not unconditional, and frameworks (e.g., regarding constitution of the governing board, disciplinary processes, etc.) are typically set out in the empowering legislation. Self-regulation is generally considered to be a privilege that demands the professional body act in the public interest, to serve and protect the public (Khaliq et al., 2010).



Indeed, the obligation to protect the public is often imposed directly by the empowering legislation (e.g., *Medical Profession Act, 1981*, section 69.1) and has been characterized as a “social contract” based on the values of professionalism (Sullivan, 2000).

Canada has adopted the self-regulatory model in the form of provincial medical colleges (Colleges of Physicians and Surgeons) constituted and run by members of the medical profession. The colleges are established by provincial legislation and charged with the responsibility of licensing practitioners, developing standards of practice/ethics, and professional discipline of members. Professional regulation of physicians in the United States is complex and multilayered and varies on a state-by-state basis (Bourgeault and Grignon, 2013), and it is beyond the scope of this article to provide a comprehensive account. It is sufficient here to note that, in many cases, physicians in the United States are also subject to some degree of professional self-regulation.

In other jurisdictions, including China, Mexico, and India (countries that could be considered top clinic locations), the practice of medicine is state regulated. Under these models, the state retains more direct involvement in the regulation of the profession. In China, for example, the National Health and Family Planning Commission of the People’s Republic of China is responsible for regulating physicians in accordance with the Administrative Measures on the Clinical Application of Medical Technology. In Mexico, the Ministry of Health and the state governments, in coordination with the relevant educational authorities, have responsibility under the General Health Act for monitoring health professionals in the provision of their respective services. In India, the responsibility for professional regulation of medical practice is shared among the states and the federal government (via the Medical Council of India, through The Indian Medical Council Act), with some roles and responsibilities overlapping.

Regardless of the precise nature of the regulatory model in place in a particular jurisdiction, they all generally provide a mechanism by which physicians involved in the market for unproven stem cell-based therapies could be monitored and, perhaps, sanctioned for inappropriate conduct.

#### Benefits

One of the key reasons professional regulation could be a valuable oversight tool in this area is its focus on serving the public interest and/or protecting the public. This mandate makes professional discipline a particularly appropriate tool for responding to conduct on the part of physicians that may expose members of the public to unacceptable levels of risk.

Professional discipline also generally has a broad range of responses available to it, particularly as compared to the

judicial process in either the criminal or civil law contexts. Possible remedies typically include communication between affected parties, continuing education, fines, restrictions, and suspensions or revocations of practice permits or licenses. For example, Dr. Tarvydas (discussed above) was barred from applying for reregistration for 3 years, at which time he also would have been required to complete continuing education regarding conventional and unconventional treatment regimes (MBQ, 2010). This range of potential responses provides disciplinary bodies with considerable flexibility to tailor results to the circumstances at hand—a valuable attribute in a socially complex area like stem cell tourism.

Indeed, the fact-driven, case-by-case approach is another benefit of the professional disciplinary process. One of the difficulties associated with contemplating broad policy responses (e.g., restrictive legislation) to issues such as stem cell tourism is the speed with which the science and the market can move, given that the relevant context, information, and available data can shift fairly quickly (e.g., clinics moving to different countries, results from a clinical trial highlighting either safety or clear risks, and publication of a new case study of adverse events from a particular treatment protocol). By contrast, in a professional disciplinary action, the decision makers consider the specific facts before them, in the context of the information and evidence as it existed at the time. This approach may be especially useful for determining what was and was not acceptable conduct on the part of a physician in a particular situation. For example, in the case of Dr. Trossel (described above), the Fitness to Practice Panel heard expert evidence when considering whether Dr. Trossel’s treatment had the rigor required for a medical practitioner to embark on pioneering treatment, which the panel found it did not (GMC, 2010).

The long reach of professional regulatory bodies’ jurisdiction is another strength in this context. Patients who suffer harm as a result of a medical tourism experience may face significant hurdles in accessing traditional medical malpractice regimes via the civil litigation route, regardless of whether they seek to pursue an action in their home jurisdiction or in the jurisdiction where they received treatment (Cohen, 2010). By contrast, many professional regulatory bodies will exercise authority over their members regardless of where care is provided. For example, in the case of Dr. Trossel, the GMC determined that even where care was provided in the Netherlands, it had jurisdiction because Dr. Trossel was registered with it at the time.

#### Challenges

The application of professional regulation is, however, not without its challenges. There is considerable variation worldwide in the manner in which regulatory regimes are



structured; the content of guiding principles and codes of conduct, practice, or ethics; and the bounds of disciplinary authority, not to mention differences in political environments and the will to enforce existing regimes (e.g., [De Vries et al., 2009](#)) as well as in the financial support available to fund the regulatory bodies charged with enforcing professional regulations ([Arellano, 2012](#)). There are also differences of opinion within medical and legal professions regarding the boundaries of medical practice and acceptable contexts for use of experimental procedures such as autologous use of adult stem cells (e.g., [Chirba and Garfield, 2011](#); [ISSCR, 2013](#)). For example, the Oregon Medical Board issued an order of emergency suspension in the case of Dr. Kenneth Welker, a physician whose conduct in relation to a number of different patients was brought into question, including his provision of autologous stem cell treatments (“fat transfers”) ([OMB, 2014](#)).

Considerable debate on the issue of autologous stem cell transplants has taken place in the United States, particularly surrounding the Texas Medical Board’s approval of new rules regarding stem cell procedures using adult stem cells ([Park, 2012](#)). Similar debates have occurred in Australia, amidst recent efforts to encourage self-regulation of providers of autologous stem cell-based interventions ([Tuch and Wall, 2014](#)). It has been suggested that the sale of autologous stem cell therapies contravenes physicians’ professional and ethical duties and that preventative regulation of this area may be appropriate ([Munsie and Hyun, 2014](#)). However, perspectives regarding the appropriateness and respective merits of proactive versus reactive regulatory approaches also appear widely varied both between and within jurisdictions, which could impact the ultimate likelihood of new policy approaches in this area.

One potential concern is that jurisdictional variation in regulatory approaches and enforcement strategies could lead to forum shopping by clinics looking for the most permissive regulatory environment. For example, robust enforcement efforts in one jurisdiction could drive clinics (and thereby patients) into less regulated jurisdictions. Indeed, there is some evidence to suggest this type of jurisdiction hopping is already occurring in the stem cell tourism arena following state-level action to restrict this market (e.g., [Mendick, 2012](#); [Berfield, 2013](#)).

The complaint-driven nature of many professional discipline structures may also serve to limit their utility in this area. The degree to which individuals are aware of the option to make a complaint remains an open question, as does what motivates patients to make a formal complaint, particularly given that financial compensation is not generally available as a possible result (unlike civil litigation). The international dimension of medical tourism may further complicate the complaint process.

For example, language barriers, cultural differences in expectations regarding standards of care, and geographic separation are but a few potential hurdles for prospective complainants when dealing with a complaint process in another country. In the absence of a significant number of complaints from patients or enquiries from physicians or both, it also may be difficult to focus the attention of regulatory bodies and policymakers on this area.

A lack of clarity on the meaning of some key concepts involved in this treatment context may also contribute to ambiguity from the perspective of patients, physicians, and regulators alike. For example, while it can be ethically permissible to offer patients innovative and experimental treatments, this should generally only be done under particular circumstances, with some preclinical evidence of safety and efficacy, and after weighing risks and benefits on a case-by-case basis ([Lindvall and Hyun, 2009](#)). It is not, however, generally permissible to market unproven or experimental therapies directly to the public as a routine treatment option or on a for-profit basis (see [Munsie and Hyun, 2014](#)). Improved clarity around concepts such as medical innovation, compassionate care, and experimental treatment may go a long way toward resolving this ambiguity ([Patenaude et al., 2008](#)).

In many cases, professional regulatory bodies have a central role to play in providing this type of guidance to their members. For example, the College of Physicians and Surgeons of Ontario has a detailed practice policy regarding complementary/alternative medicine that clarifies expectations for physician conduct ([CPSO, 2011](#)). Similar guidance on the issue of stem cell tourism, perhaps as a subset of other aspects of medical tourism, may prove a useful resource. A related challenge relates to limitations in the kind of stem cell expertise that may be required for disciplinary bodies to assess whether a particular intervention is or is not appropriate given the current state of knowledge in the field. Any such limitations would not be insurmountable, however, and could be answered by consultations with relevant experts.

## Conclusions

Although there are undoubtedly hurdles and challenges that would need to be addressed, professional regulation could be an important and powerful tool in responding to some of the key concerns associated with stem cell tourism. As we have seen, it has already been deployed in several jurisdictions throughout the world. And while these actions did not necessarily result in the removal of a provider from the scene (many simply move to another jurisdiction [[Ogbogu et al., 2013](#)]), it nevertheless helps to encourage the development of a practice standard and, possibly, professional norms that may help over the long-term to dissuade clinicians from providing unproven





therapies. It may also act as a general form of deterrence from participation in other potentially concerning aspects of this market.

Ideally, there should be cooperation and sharing of information between regulatory bodies at both national and international levels on approaches to this and other analogous issues. While we recognize it may be difficult to achieve, coordinated action could work to limit the issue of jurisdiction hopping (i.e., movement of clinics and providers to less regulated jurisdictions). In addition, regulatory bodies should work closely with the international stem cell research community to ensure that policy decisions are appropriately informed by the latest scientific and clinical developments in the field.

Stem cell tourism remains a tremendously complex policy challenge. Despite years of debate and a range of policy responses, there is little evidence that the number of clinics is diminishing or that interest in this area is waning. Given the potential for harm to patients, the public, and the field of stem cell research, it seems entirely appropriate to use all available regulatory and policy tools to mitigate the risks involved.

### AUTHOR CONTRIBUTIONS

This article is the result of a workshop where the authors came together to consider the role of professional regulation in addressing physician involvement in stem cell tourism. The substance of this article, including the concept, structure, and approach, emerged from the discussion at the event and all authors contributed to and offered critical feedback on the conception of the piece and draft outline produced during the workshop. A.Z. drafted the article, with the assistance of T.C. and U.O. All authors had the opportunity to review and comment on subsequent drafts, and all authors approved the submitted manuscript.

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