“Right to Try” Should Require “Right to Know”

By Samantha Payne

Currently 37 American states have passed the “Right to Try” law, which allows terminally ill patients to seek out non-FDA approved experimental medical therapies. The law stems from the Goldwater Institute, a libertarian organization based in Arizona, and appeals to the sentiment that individuals should have access to any treatment with the potential to give them greater quality of life — no matter how experimental. However, this law can promote the dangerous practice of stem cell tourism and gives the false impression to desperate patients seeking treatment that these are viable alternative options that physicians and researchers are simply withholding from public use.

Many of us have heard the stories of celebrities travelling to other countries to seek out controversial stem cells treatments, from football star Peyton Manning to Canadian musician Gordie Howe in 2014. You can watch an informative short video about the issues of stem cell tourism — created by the Stem Cell Network (SCN) and narrated by Dr. Timothy Caufield — here. In Canada, we do not yet have a Right to Try law, but it is not illegal to seek a stem cell treatment outside of the country. Canada also has the Special Access Programme (SAP), through which patients can request access to a drug or therapy not available in Canada. This program is applicable for cases where an individual has a life-threatening condition and where conventional treatments have failed.

While stem cell therapy has tremendous potential to treat a wide range of illnesses, it is extremely important to emphasize that as of yet most stem cell therapies still require significant study before they can be made widely available. In the United States, the Right to Try law only requires that a drug or therapy has gone through a phase I clinical trial, meaning that the safety of the therapy has been tested, but there is NO DEMONSTRATED EFFICACY DATA. Human interest stories that focus on case-by-case miraculous recovery through stem cell therapies do not account for confounding factors, and do not have the proper controls in place to truly determine if any of the beneficial effects are due to that therapy.

Both autologous (such as adipose-derived stem cells) and allogenic (such as fetal-derived stem cells) are reportedly used in unproven stem cell therapies. These cells are injected into any and all patients as a cure-all for multiple conditions without supporting literature that demonstrates they are therapeutically relevant. Companies selling these treatments offer anecdotal stories as proof of efficacy, and because they control the message, risks associated with stem cell therapies are under-emphasized or implied to be outweighed by the potential benefits and do not reflect reality. In addition, these treatments are prohibitively expensive and patients must pay out of pocket. In the United States, there is also a risk of losing hospice eligibility and insurance coverage.

Thanks to continual advances in the fields of stem cell therapy and regenerative medicine, it will become increasingly important to ensure that there is an open dialogue among all Canadian stakeholders, from patients and their physicians, to researchers and policy-makers. This issue has not gone unnoticed, and researchers supported by SCN have made a number of suggestions to this effect. Dr. Amy Zarzeczny, an Assistant Professor at the Johnson Shoyama Graduate School of Public Policy, University of Regina, published an article suggesting that more professional regulation of physicians could help to deter patients from being recommended for unproven treatments and help limit the spread of misinformation. ISSCR has published a handbook for patients about stem cell therapies, as well as many other online resources that can be found at www.closerlookatstemcells.org. Social media, although sometimes found to contribute to the spread of false information, is an amazing tool that could be utilized more effectively to reach a wide audience about the risks of stem cell tourism. Lastly, Dr. Ubaka Ogbogu, an Assistant Professor in the Faculties of Law and Pharmacy & Pharmaceutical Sciences at the University of Alberta, has suggested that there is a need to push for truthful advertising laws and regulations in countries such as Canada that are targeted for stem cell tourism, in order to counter the marketing of unproven therapies.

It is part of human nature to maintain hope in the face of mounting odds and seeking out novel treatments in response to an incurable condition is something we have been doing for hundreds of years, but experimental stem cell therapies can cause irreversible harm and only provide false hope. Wherever Canadian opinions fall on the spectrum of this issue, it is important to maintain a frank and open discussion among all parties involved.

This October (2017), SCN hosted a workshop focused on how to reduce the potential harm of unproven stem cell therapies. This initiative brought together scientists, clinicians, patient advocates, public charity and media representatives, as well as leading legal, ethics and policy experts. Participants were asked to consider what factors underlie the continual demand for unproven stem cell therapies, and what information needs to be provided to physicians and patients so that they are able to make informed decisions and recommendations. By promoting an open dialogue and transparency about stem cell therapies, as well as a realistic perspective about the current state of research, we can help spread information to the public and reduce the harm of unproven stem cell treatments.

This article is just one of many covering this topic as part of SIGNAL'S second annual blog carnival on the theme "Right to Try." Please click here to read what others have to say about this important issue.