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24 February 2015

Biological Science Section
Office of Scientific Evaluation
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606 email: bloodandtissues@tga.gov.au

Dear Sir / Madam

Re: Regulation of Autologous Stem Cell Therapies

I am writing to you to express my concern regarding this topic.

I am a Sports Physician and Interventional Pain Physician. I have a Fellowship of the Australasian College of Sports and Exercise Medicine, I am a Fellow of the Australian Sports Medicine Federation, a Fellow of the American College of Sports Medicine, and I have a Masters in Pain Medicine (University of Newcastle) and the International Fellowship of Interventional Pain Practice.

For the last 20 years, I have been working in chronic pain with end stage patients who no-one else will see or help. I have been active in university research throughout that time as a Research Fellow, initially at ARMC (Austain and Repatriation Medical Centre) and more recently at the Centre for Health, Exercise and Sports Medicine (CHESM) at The University of Melbourne. Our practice is the only recipient in the Oceania region of the World Institute of Pain (WIP) Excellence in Pain Practice Award.

I am a past State and National President of Sports Medicine Australia. I have written multiple book chapters in Sports Medicine and Pain textbooks. I have published extensively in peer reviewed Journals. In the last 12 months, I was the first author on approximately 11 papers at International Conferences, and second author on numerous other papers.

While huge advances have been made in treating pain from the end stage joint and neural disease perspective, there are an enormous number of people we still have not helped, or only partially helped. Stem cell therapy shows potential to help the pain in these end stage disease processes but, perhaps more importantly, it shows great potential to stop the degenerative process and possibly reverse it. Clearly, there is a need for properly-run prospective case series and randomised controlled trials on this therapy. There is also a need for an industry-run code of ethics. But it is essential that regulation does not stymie innovation and the ability to run proper trials.

I wish to highlight two particular examples:

One is prolotherapy. This procedure involves injecting some form of a sclerosing agent into tissues to form scar tissue and stiffen joints to prevent pain. There have been charlatans in the past using this technique totally inappropriately. There have also been diligent clinician researchers determining where this procedure works best and this has led to two randomised controlled trials on prolotherapy for pelvic instability showing its effectiveness (Cusi et al) and our recent prospective long-term case series on over 130 patients showing 70% cure rates with this inexpensive and safe technique. Aggressive regulation of this industry would have prevented this procedure going ahead prior to the landmark studies being produced.

The second case in point is the orthopaedic joint registry. This was established with the best of intentions, initially to collect safety data on large numbers of patients over many years to compare various implants. As you are probably aware, there is a steep learning curve with any new device or procedure. Australia used to be at the forefront of orthopaedic research. An unfortunate side-effect of the registry is that device manufacturers are now avoiding the Australian market with any new technology as two inadequate outcomes during the learning curve of a new procedure are being flagged by the registry and the said new device being banned.

If we are to reduce the suffering caused by chronic pain and other degenerative musculoskeletal and neurological disorders, it is essential that we are allowed to move forward with trials of cell based therapy. An Industry code of conduct that ensures these trials are undertaken in an efficient and ethically approved way is the only means to allow this research to occur with sufficient funds and without blocking innovation.

The Melbourne Stem Cell Centre (MSCC) is currently conducting two University Ethics approved randomised controlled trials on treating knee osteoarthritis, two other ethically approved case series, and has submitted for Ethics approval a randomised controlled trial on discogenic pain. To my knowledge, there are five other Ethics submissions being processed at the present time. Knee osteoarthritis and discogenic pain alone currently cost the Australian economy billions of dollars a year and cause suffering for millions of Australians. These trials continue Australia's proud history of self-funded clinical research. A change to the regulatory environment would jeopardise these and many similar studies that are underway.

MSCC is a member of the Australian Cell Therapy Society (ACTS) and is a signatory to their Code of Practice. Industry codes of practice are a proven and effective way for industry to self-regulate emerging technologies, for the benefit of all. The IVF industry is a great example of this.

My understanding is ACTS wants to work with the TGA to further strengthen the Code of Practice and allow Australia to continue to lead the world in the area of Cellular therapies.

I thank you for your time and consideration of this matter

Yours faithfully

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