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Dr Paul Verrills

23 February 2015

Biological Science Section
Office of Scientific Evaluation
Therapeutic Goods Administration
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Dear Sirs

Re: Regulation of Autologous Stem Cell Therapies

My name is Paul Verrills and I graduated from the University of Queensland with an MBBS followed by further education providing a Graduate Diploma of Musculoskeletal Medicine (Honours) from the University of Otago, a Masters of Pain Medicine (University of Newcastle), a Fellow of the Australasian Faculty of Musculoskeletal Medicine, and a Fellow of Interventional Pain Practice (Budapest) from the World Institute of Pain.

I have been in private practice since 1988 and have worked full-time in Melbourne since 1998 specialising in musculoskeletal pain and in interventional pain practice. In the past, I have been a senior clinical lecturer for the University of Otago in the Department of Orthopaedic Surgery and Musculoskeletal Medicine. I have been the Editor of the International Spine Intervention Society medical newsletter and spent many years on the Research Committee of the International Spine Interventional Society. I was Treasurer of the Australasian Faculty of Musculoskeletal Medicine.

I am currently the President of the Neuromodulation Society of Australia and New Zealand and have been for four years, along with being a Member of the International Neuromodulation Society Board.

I have published extensively in the scientific literature and written numerous medical textbook chapters along with being an invited plenary speaker at numerous international medical congresses including the International Neuromodulation Society, International Spine Intervention Society and International Association for the Study of Pain Society along with others.

I have consulted to numerous scientific advisory boards for various medical device companies.

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The evolving practice of autologous stem cell therapies does have a number of interesting parallels to the development of neuromodulation over the last 40 years. The first spinal cord stimulator was implanted in 1967 and, since that time, the evolution of the devices and potential impact from that therapy have been extraordinary. It has taken decades for the areas to develop. However, there are now Level 1 randomised controlled trials to support the efficacy of neuromodulation in complex pain patients.

Further, I note that this is a therapy that is used to treat pain after damage has been done within the pain system and, in most cases, it has been considered that conventional medical managements have failed.

In fact, in cases of total knee and total hip replacements, there is scientifically documented evidence of significant post surgical pain syndromes in more than 20% of patients. Increasingly, these patients are now being offered neuromodulation devices to try and control their severe pain.

The medical, regulatory and legal environment within Australia, along with the highly acclaimed expertise of Australian scientists and clinicians, has allowed Australians to lead the field in research associated with these therapies and be most commonly involved in the early scientific trials to establish new trends to help patients with complex pain. Further, Australian clinicians are well recognised for their high level of integrity and ethics, and all of these studies are performed under the auspices of an Ethics approved Scientific Advisory Board.

Just as I have observed Australians leading in the field of neuromodulation, I now see the potential provided with the Therapeutic Goods (Excluded Goods) Order No 1 regulations for Australia's leading clinicians and scientists in the field of stem cell therapies being able to undertake the same cutting-edge research that puts Australia once again at the forefront of ethical medical evidence.

It certainly is of great interest to me personally, and for others following the field of severe post surgical pain, that the Melbourne Stem Cell Centre is now involved in some of the largest randomised controlled trials in the world looking at autologous mesenchymal stem cell therapies in treating knee osteoarthritis and potentially regenerating knee cartilage defects. While the early anecdotal evidence is clearly encouraging, it is critically important that studies such as these are able to be completed to enable the scientific community to draw valid conclusions about the potential efficacy of this form of therapy in treating this large patient cohort. Further, the natural conclusion of such therapies being potentially efficacious is that the rates and costs associated with major joint replacement surgery and/or post surgical pain management strategies such as neuromodulation will be greatly diminished.

In addition, I have published and presented extensively on internal disc derangement and lumbar pain associated with discogenic pain.

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The Mesoblast Company is currently undertaking studies, and the Metro Pain Group, of which I am a Co Medical Director, has recently been approved as an investigatory site for their Phase 3 trials. These trials will further impact on our knowledge base in how stem cell therapies may reduce chronic back pain.

I am also a participant in currently seeking Ethics approval in a study lead by my colleague Dr David Vivian in potentially using expanded autologous stem cells in a randomised controlled trial of discogenic pain patients.

Once again, there are potential benefits of clearly ascertaining whether mesenchymal stem cells can reduce back pain, increase productivity, reduce the need for patients going on to expensive surgical options such as fusions and artificial disc replacements which have a known outcome of more than 30% of complex neuropathic pain and the need for these outcomes being greatly diminished.

As with other Ethics approved studies, it is incumbent upon the treating clinician to work within their area of expertise and, clearly, under the auspices of AHPRA (Australian Medical Board).

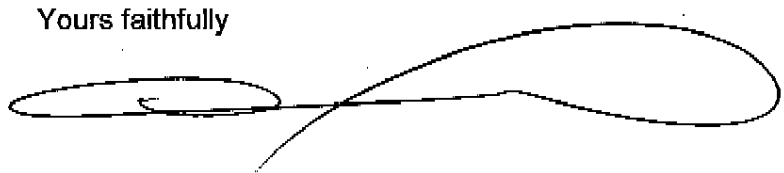
Further, I note that there is appropriate safety data in the scientific literature associated with autologous isolated mesenchymal stem cells, as per the articles by Saw et al 2013, Peeters et al 2013 and Jo et al 2014.

I believe it is incumbent upon all clinicians who undertake novel treatments such as stem cell therapies to do so under the approval of a Human Research Ethics Committee whereby appropriate safety considerations, consent and follow-up of outcomes will be undertaken, along with clear monitoring and reporting of adverse events and/or, if they occur, serious adverse events.

The current legislation has enabled Australia to undertake leading clinical trials and, to continue to do so, I would strongly advocate that you continue to allow Option 1 with the potential use of Section 7AA.

While there is great excitement in the community around the concept of stem cell therapies, it is only by the mechanisms outlined above, allowing valid scientifically achieved outcomes in an ethically appropriate setting, that will provide us with the capacity to potentially impact how medicine is practised and improve the care of our patients in the future.

Yours faithfully



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