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Biological Science Section
Office of Scientific Evaluation

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Dear Sir/ Madam/ Committee

Submission regarding Regulation of Autologous Stem Cell Therapies

I write to express my clinical based viewpoint on the proposed review of regulation of autologous stem cell therapies by the TGA.

I am a Sport and Exercise Physician on the Mornington Peninsula and am the founding director of the only specialist Sports and Exercise Medicine Clinic for the region. My qualifications include MBBS from The University of Melbourne, Masters of Sports Medicine and Fellowship of the Australasian College of Sports Physicians. I also currently sit on the Board of Censors for the College of Sports Physicians, conducting and evaluating examinations for our registrars and potential registrars.

I run a clinic that prides itself on ethical high quality medical practice. My practice takes on 2-3 registrars each year, for which we receive no funding and I spend many hours tutoring, supervising

and training these young clinicians to become exceptional specialists. One of the messages I continuously reinforce to the trainees is the importance of quality medicine.

Stem cell therapy for use in musculoskeletal injury treatment is a relatively new entry into the clinical sphere. If it proves to be effective, it has potential to be an adjunct treatment in tendon and joint disease, including osteoarthritis, which has one of the largest disease burdens on our aging population.

As you are aware, there are a number of different operators offering stem cell therapy and the exact nature of the therapy offered varies between each company.

As someone who prides myself on quality medicine, I was initially very sceptical regarding these therapies, particularly those offering non isolated, non expanded cell injections. To me, the cost to the patient was prohibitive and the results uncertain at best.

I understand the TGA's concerns with regards to expanded cells, but there have been some studies from international groups indicating safety and, more excitingly, efficacy with adipose derived isolated expanded stem cells in the treatment of osteoarthritis.

Those studies are yet to be replicated or confirmed.

Early in 2014, I was offered the opportunity to be involved in research overseen by Monash and Latrobe University's ethics committees, through the Melbourne Stem Cell Centre, investigating the effect of isolated expanded cells on osteoarthritis and osteochondral lesions. Both of these trials are randomised and placebo controlled, with both functional and imaging based outcome measures.

As I have mentioned, I am a sceptic when it comes to new therapies, but the quality of the trials proposed and the quality of the laboratory set up enabled to make a decision to be involved in this research.

I do believe that this is an area that needs some form of regulation, but recent development of a code of conduct through the Australian Cell Therapy Society, to which I will be a signatory is an important first step in achieving this.

As a clinician, it is my opinion that the TGA should continue to allow the current use of stem cell therapy, including some manipulation of cells, so that quality research can continue to be performed and current ethics approved trials can be completed here in Australia, potentially allowing us to be world leaders in collating the information required to make clinical decisions. By the same token, I think the TGA can rest assured that research such as ours will report all results, whether negative or positive, openly. These results may then assist further decision making about similar therapies.

I thank you for your time in considering my opinion as part of your deliberations.

Yours sincerely

Dr Leesa Huguenin