

TGA CONSULTATION: REGULATION OF AUTOLOGOUS STEM CELL THERAPIES

To the Responsible Person,

I am an individual who is seeking to address the degradation of my knee and hip joints and the resulting debilitating arthritis.

Over the past four years I have extensively investigated various treatments, interventions and pain management options available to me and in doing so have monitored the research being carried out in autologous stem cell therapies. On extensive evaluation and consideration I have sought advice from the Melbourne Stem Cell Centre and have chosen to take part in their research program in this area.

The advances in research and the encouraging signs have led me to believe that there is a significant possibility of slowing down my joint degradation and reducing pain levels. I see the opportunity to potentially improve my quality of life without the need for greater levels of medication and the risks that these carry. Without question, not having the potential benefits of such therapy available would inevitably lead to a hip and knee replacement when the degradation reached a point of unmanageable pain.

I am aware of the risks associated with stem cell therapy and recognise the need to ensure any such therapies are appropriate and safe, however without allowing research such as that being carried out by the Melbourne Stem Cell Centre in conjunction with Monash and LaTrobe Universities, the chance for a significant improvement in my quality of life and the potential to delay and possibly avoid at least two major operations may be denied to me. The implantation of artificial joints in itself carries significant risk and limitations, in many ways, potentially far greater than stem cell therapy. Further, it is well acknowledged that such implantations have a limited life.

Given the nature of the therapy that I am currently undertaking, which has the approval of the Human Research Ethics committees of the respective universities, without hesitation I wish to have the right to choose to access this therapy even during the research stage.

Where issues of risk in research are considered ethically, the research is carried out within appropriate medical guidelines and practice, and the patient is well informed, as I feel fully confident with this research program, it is critical not only for those patients within the research program, but for those that follow, to have access to this therapy at trial stage.

I understand the need for government to ensure that autologous stem cell therapy is safe. However I have been very well informed as part of the research program and am aware of the nature of the therapy and risks that I may face.

Australia is one of the few countries where this research occurs and I regard myself, and others who may be considering such therapies, fortunate to have this option available under the current research regime.

I strongly suggest that the wishes of the patient be considered within this Consultation.

I am trusting that my comments as a patient weighing the risks are well considered. I seek that the existing therapy research regime is not changed in a way that denies myself and others access to the potentially significant benefits of this and similar treatments.