

2 March 2015

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Biological Science Section
Therapeutic Goods Administration
Department of Health
PO Box 100, Woden ACT 2606

RE: Public consultation on regulation of autologous stem cell therapies

Dear ██████████

Thank you for the opportunity to make a submission with regards to the regulation of autologous stem cell therapies. We will not make a formal submission but this letter serves as our expression of interest in this topic and we welcome the opportunity to participate in further discussion with regards to the regulation of autologous stem cell therapies and we would like to be an active participant in the consultative process.

From the perspective of Plastic and Reconstructive Surgery, the use of autologous stem cell is on the frontier of medical science and highly relevant to our Specialty. The current lack of sound, basic research on stem cell therapy is a significant concern for patients and from a regulatory standpoint. However, the universal restriction of stem cell therapy to clinical trial status alone would be a disservice to patients and place an unnecessary limitation on the development of the stem cell science and research.

The Australian Society of Plastic Surgery (ASPS) has long been aware of the lack of evidence-based research surrounding autologous stem cell therapies and has contributed funding, in collaboration with the Australasian Foundation for Plastic Surgery (AFPS), to support studies on the molecular mechanisms behind the activity of adipose derived stem cells in reversing radiation injury. This study is currently being conducted by Dr Ramin Shayan at the Obrien Institute in Melbourne under the supervision of Professor Wayne Morrison.

Further research and the collection of reliable data is essential. Currently, there is a striking absence of high impact basic science literature on this exponentially growing field. Randomised and double blinded trials are required, particularly to determine the efficacy or safety profile of fat grafting into former cancer bed areas and whether such practice carries an unacceptable oncological risk. Preliminary findings have shown that stem cells do produce plenty of growth factors that have been shown as either tumorigenic and prometastatic in various models. However, there is a lack of reliable research and high impact literature on which practitioners and regulatory bodies can rely.

In addition, further discussion and analysis needs to be considered for other practice areas such as cultured epithelial autografts for the treatment of burns and fat grafts for contour restoration. Further consideration needs to be given to the difference between a fat graft to treat radiation skin changes as opposed to the injection of stem cells into, for example, a joint or spinal cord to promote regeneration of particular tissues. Such distinctions will have an impact upon the regulatory framework which governs the practice of autologous stem cell therapies.

Yours sincerely



Gaye Phillips
Chief Executive
cc. Anthony Kane, President ASPS