Society for Reproductive Biology

Biological Science Section
Office of Scientific Evaluation
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

March 2nd, 2015

Re: Regulation of Autologous Stem Cell Therapies: Therapeutic Goods Administration Discussion Paper

Dr Tony Manderson,

Please find below a statement from the Society for Reproductive Biology (SRB) in response to the TGA Discussion Paper on the Regulation of Autologous Stem Cell Therapies.

'It is the position of the Society for Reproductive Biology (SRB) that autologous stem cells are used in a therapeutic context and should therefore be considered a biological and be subject to regulation. Such regulation should protect patients against the inherent risks related to autologous stem cell acquisition, manipulation and application and guard against the presently unqualified claims of health benefits from autologous stem cell use. It should enable an environment conducive to clinical trials and the reporting of adverse events, in order to establish an evidence base upon which the risks and benefits of autologous stem cell use can be quantified for future public benefit. In our view, there is presently insufficient evidence of an arguable public health benefit from therapeutic treatments based on autologous stem cells.

SRB consider that Options 4 and 5 provide the most satisfactory level of patient protection due to the requirement for safety, restrictions on patient access, reporting of adverse health effects and blockade on advertising to the public. We acknowledge that regulation of autologous stem cells will restrict the availability of a number of treatments that are presently accessible. We caution that an unintended outcome may be that patients circumvent restrictions by seeking treatment in other countries in which standards of medical practice and patient care may result in post-operative complications that could place additional burden on Australia's healthcare system. These adverse health outcomes may be limited to the patient, or could be a more widespread public health threat, such as exposure to antibiotic-resistant infection agents. We therefore suggest that any regulations imposed are a balanced consideration of the risks and benefits with respect to individual patients and the broader public, and acknowledge that this may lead to consideration of Option 3.

Furthermore, SRB are concerned that autologous stem cells are commonly sourced from adipose tissue, a site of toxin accumulation, and that this could result in unanticipated changes in cellular behaviour following their manipulation and use. This could pose greater risk to the patient compared to cells sourced from other tissues and we therefore propose that the TGA consider stricter regulation of stem cells derived from adipose tissue compared to other tissues'.

Yours Sincerely,

Dr. Catherine Itman
Council Member, on behalf of the Society for Reproductive Biology

Secretariat: ASN Events Pty Ltd
PO Box 200, Balnarring VIC 3926, Australia
Tel: +61 3 5983 2400 · Fax: +61 3 5983 2223
Email: societyreproductivebiology@gmail.com · Web: www.srb.org.au