

3 March 2015

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

Via email: bloodandtissues@tga.gov.au

Dear [REDACTED]

ASO Submission - Regulation of autologous stem cell therapies

The Australian Society of Ophthalmologists (ASO) appreciates the invitation to provide comments in response to the Therapeutics Goods Administration's discussion paper on the regulation of autologous stem cell therapies.

The Australian Society of Ophthalmologists (ASO) has for more than three decades been the peak professional body representing the medico-political interests of ophthalmologists. Through a comprehensive program of advocacy and a diverse array of educational initiatives, ASO fosters the professional development of Ophthalmologists, allied ophthalmic professionals and those involved in practice management.

ASO is committed to the provision of outstanding eye health care for all Australians and plays an active role in keeping the community informed on matters affecting eye health.

ASO supports Option 4, which requires the regulation of autologous cells under the *Therapeutic Goods Act 1989* (the Act) as Class 1 biologicals.

In the efforts to raise funds for their research, many academics have made extreme declarations that stem cells will deliver overwhelming benefits. When patients are faced with real and/or threatened vision loss, they are desperate and are extremely vulnerable to forms of false advertising particularly in the area of stem cell therapy. Unscrupulous entrepreneurs falsely promising benefits in exchange for money easily exploit these patients. With a patient's desire for a miracle it is likely that their ability to be informed of any risks will be greatly impaired.

ASO therefore believes that Option 4 properly addresses these concerns and helps to protect our patients.

We note that in many cases, cells will not be used in their original sites of origin. For example in ophthalmology, Ocata's trial Retinal Pigment Epithelium stem cells for age-

related macular degeneration patients and Stargardt's disease patients are a differentiated human embryonic stem cell. These cases will hence not fit the requirements for regulation as Class 1 biologicals, and a greater level of regulation will be required.

ASO is willing to provide further advice in regards to the issues raised above and should you require any further information, please contact the ASQ Manager, Julie Sawyer at julie@aso.asn.au

Yours sincerely



Dr Michael Steiner
ASO President