To Whom It May Concern

**Re: Public Consultation on the Regulation of autologous cell and tissue products**

We appreciate the opportunity to comment on the Consultation Paper released in August 2016 regarding the regulation of autologous cell and tissue products in Australia. We are members of a research team working on an Australian Research Council-funded research project entitled "Regulating autologous stem cell therapies in Australia." The project involves an audit of current clinical and legal practices involving autologous adult stem cells (ASCs) and an empirical study exploring the attitudes of major stakeholders regarding patient access to, and regulation of, innovative therapies with ASCs. This research aims to facilitate the development of an ethical and socially sustainable regulatory environment for innovation with autologous stem cell therapies in Australia.

Our preliminary findings show that there are currently over 40 private providers in Australia that offer ASCs to patients of all ages. These businesses commonly market stem cell-based interventions directly to consumers using unsupported claims about their efficacy and safety. These marketing strategies are ethically troubling and in breach of the Australian regulation for the promotion of health services. Given our involvement in this research project, we believe that we can make a valuable contribution to the TGA’s public consultation on the regulation of autologous cell and tissue products.
Who we are

Our research team involves the following academics:

Professor Cameron Stewart is Pro Dean at Sydney Law School, a member of Sydney Health Law and an associate of the Centre for Values, Ethics and the Law in Medicine, Sydney Medical School. Professor Stewart is the leading investigator on the Australian Research Council-funded research project "Regulating autologous stem cell therapies in Australia."

Professor Ian Kerridge is an internationally recognized scholar in bioethics and the philosophy of medicine. From 2003 to 2015 he was Director of the Centre for Values, Ethics and the Law in Medicine (VELiM) at the University of Sydney. He is currently Professor of Bioethics and Medicine at VELiM and Haematologist/Bone Marrow Transplant Physician at Royal North Shore Hospital, Sydney.

Professor Catherine Waldby is Director of the Research School of Social Sciences in the College of Arts & Social Sciences and Visiting Professor at the Department of Social Science and Medicine at King’s College London. She is a Fellow of the Academy of Social Sciences in Australia, and has received national and international research grants for her work on embryonic stem cells, blood donation and biobanking.

Associate Professor Megan Munsie is a scientist who has combined her extensive technical expertise in stem cell science with an interest and understanding of the complex ethical, social and regulatory issues associated with stem cells in research and in the clinic. She is based at The University of Melbourne where heads the Education, Ethics, Law & Community Awareness Unit at the ARC funded Stem Cells Australia initiative.

Dr Wendy Lipworth is a bioethicist and health social scientist. She completed her medical degree at UNSW in 1999, and moved into academia in 2002. She is currently a Senior Research Fellow and NHMRC Career Development Fellow at the Centre for Values, Ethics and the Law in Medicine. Dr Lipworth oversees a program of research that focuses on health technology and medicines policy.

Associate Professor Tamra Lysaght’s research interests lie broadly around the ethical, sociopolitical and regulatory issues surrounding stem cell science and the clinical translation of regenerative medicines and genomics. She is currently an Assistant Professor at the Centre for Biomedical, National University of Singapore, and Principal Investigator on research projects examining the ethics and regulation of innovative cell-based therapies and translational medicine pandemic planning.

Dr Tereza Hendl is a Postdoctoral Research Fellow at the Centre for Values, Ethics and Law in Medicine (VELiM) at the University of Sydney. She completed a PhD in Philosophy at Macquarie University with a dissertation project exploring ethical aspects of sex selection for social reasons. At VELiM she works on the Australian Research Council-funded research project "Regulating autologous stem cell therapies in Australia" focusing on ethical aspects and regulation of autologous stem cell interventions.
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There is an urgent need to develop a socially and ethically responsible regulatory environment for innovation with ACSs in Australia. This regulatory framework needs to provide adequate protections for vulnerable patients who want to be part of such innovation. Recent troubling cases involving providers of ASCs demonstrates the ethically contentious practices that the lack of regulation has enabled. Examples include the tragic death of Sheila Drysdale following a scientifically unproven and clinically unjustified stem cell ‘therapy’ for dementia\(^1\) and the ‘predatory’ approach of the \[\text{MISSING URL}\], which uses coercive marketing techniques to recruit patients for expensive and clinically untested interventions with ASCs.\(^2\) We believe that Australia needs to more effectively regulate this market and to protect patients from the physical, emotional, financial and psychological harms the largely unregulated Australia industry incurs.

We strongly support Option 4 as outlined in the 2016 Consultation Paper. We support this option because it forbids direct to consumer marketing of ASCs and captures more than minimally manipulated ASCs under the TGA Biologicals Framework.

We do not support Option 1 because it essentially proposes to maintain the status quo, allowing Australian ASC providers to continue marketing clinically unproven and unjustified interventions directly to consumers. Furthermore, broadening the scope of the exclusion to dental practitioners, without additional regulatory safeguards, has the potential to facilitate an even greater number of unproven ASC products being marketed in Australia. We do not support Option 2, because while it addresses direct-to-consumer advertising, it does not attend to

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\(^2\) Please see: http://www.abc.net.au/7.30/content/2016/s4543187.htm.
issues around the degree of cell manipulation prior to transplantation. While option 3 may be viable in principle, we do not support this option due to concerns about enforcement that the TGA has pointed out.

In addition to our support for Option 4, we suggest that ASCs be excluded from regulation under the Act only when they are for homologous use. This framing was offered by the TGA in the Consultation Paper released in January 2015. We believe that the distinction between homologous and non-homologous use of ASCs is important as it reflects the different safety and risk implications of ASCs. The inclusion of non-homologous use under the Biologicals Framework would remove ambiguity from the proposed regulation and address the higher safety concerns associated with the non-homologous use of ASCs.

Furthermore, we believe that the definition of minimal manipulation, as provided in the 2016 Consultation Paper, is not sufficient, as it does not clarify which procedures involve minimal manipulation of ASCs. We prefer the definition provided in the previous Consultation Paper released in 2015, as it includes a comprehensive list of such procedures:

‘Minimal manipulation’ is defined in regulation 2 of the Therapeutic Goods Regulations 1990 (the Regulations) as a process involving any of the following actions, or any other similar action – centrifugation, trimming, cutting or milling, flushing or washing, refrigeration, freezing, freeze drying (of structural tissues only), the use of additives such as cryopreservatives, anticoagulants, antimicrobial agents, irradiation for the purpose of bioburden reduction.

We believe that this definition is more appropriate as it clearly states which procedures are acceptable under the minimal manipulation framework; any other procedures or processes should be regarded as more than minimal manipulation and thus fall under the Biologicals Framework. This definition is less ambiguous and reduces the scope for confusion and/or mis-interpretation.
Finally, we would like to raise some concerns with respect to the conceptualisation of harm in the context of autologous ASC interventions. The TGA Consultation Paper principally frames harm as physical harm in the form of possible complications from treatment. Physical harm is not the only form of harm caused by ASCs. We suggest that the TGA broadens its conceptualisation of harm to also consider the financial harms that stem from the high costs associated with ASCs, both to patients and to the communities that support them, as well as the psychological and emotional harms incurred from the exploitation of patients receiving unproven therapies that lack clinical benefit. A more inclusive and comprehensive understanding of harm is necessary to encompass the full range of possible negative impacts that patients experience from ASCs. This broader conceptualisation of harm would usefully be informed by patients as part of the TGA’s consultation process.