12 April 2019

Medical Board of Australia
G.P.O Box 9958
Melbourne VIC 3001

Dear Medical Board of Australia members,

RE: Public consultation on clearer regulation of medical practitioners who provide complementary and unconventional medicine and emerging treatments

Thank you for the opportunity to provide feedback on options for clearer regulation of medical practitioners who provide complementary and unconventional medicine and emerging treatments. As a researcher who has long been concerned about Australian and overseas medical practitioners providing unproven stem cell treatments to patients, I especially welcome the chance to comment on the need for increased regulatory oversight in this area.

There is an urgent need for greater regulation of the provision and promotion of claimed stem cell therapies. While the recent Australian Government announcement that will ultimately increase the role of the Therapeutic Goods Administration in the regulation of autologous cell and tissue products in Australia, additional oversight of medical practice in this area is required if we are to protect consumers from expensive, non-evidenced based and possibly harmful interventions.

This submission has been lodged in my capacity as a Deputy Director of The University of Melbourne's Centre for Stem Cell Systems and as head of the Engagement, Ethics & Policy Program of Stem Cells Australia, the Australian Research Council Special Research Initiative in Stem Cell Science.

My research focuses on the complex ethical, social and regulatory issues associated with stem cell research. As a member of several multi-disciplinary international research teams, we have explored community expectations in stem cell science and examined related policy considerations, particularly in relation to clinical translation of autologous cellular therapies. Over the last decade our research has been instrumental in documenting the rise in the number of Australian medical practitioners offering reputed stem cell interventions and charting how Australian patients and their carers view access to unproven stem cell treatments.

I have also contributed to international and national guidelines for stem cell research and its clinical translation, most recently developing practice standards with the Royal Australian New Zealand College of Ophthalmologists, and co-authored numerous educational resources for healthcare practitioners, educators and patients. I am Chair of the International Society for Stem Cell Research's Ethics Committee, Chair of the Australasian Society for Stem Cell Research's Policy, Ethics and Translation sub-committee and a member of advisory committees for the International Society for Cell and Gene Therapy, AusBiotech and the Australian Academy of Science.

While this submission draws on my experience as a stem cell researcher, and is informed by my professional network and shared concerns about certain 'stem cell' practices, the comments expressed are mine alone and are focused on medical practices that claim to involve human stem cells.

Yours sincerely,

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Response to Questions Raised in the Discussion Paper

1. Do you agree with the proposed term 'complementary and unconventional medicine and emerging treatments'?

I fully support the proposed term 'complementary and unconventional medicine and emerging treatments'.

This term is sufficiently broad to encompass concerning medical practices where reputed 'stem cell' therapies are made commercially available to Australian patients, despite a lack of recognised evidence that they work or are safe. Since 2011, we have seen the number of Australian medical practitioners offering these interventions steadily rise[1] with a recent audit documenting 70 clinics claiming to offer 'stem cell' interventions for a wide range of illnesses and conditions[2].

While the Discussion Paper notes that the Board views the use of stem cell therapy as an example of *emerging treatments* (p.5), it should also be noted that many of the interventions on offer in Australia may not include recognised stem cells or their derivatives. Although a small number of Australian clinics claim to use autologous bone marrow derived stem cells, by far the majority of clinics operating in Australia rely on ill-defined cellular suspension obtained from the patient's lipoaspirate[1,2]. Given the cellular products are prepared on-site in unaccredited laboratories, few of the Australian clinics perform any reputable characterisation studies to determine the composition of the cells they administer. This practice of co-opting the term 'stem cell' to describe a product, service and/or company is a well-recognised strategy employed by clinics to capitalise on public perception of the near-magical qualities of 'stem cells'[3,4]. In framing 'emerging treatments' perhaps the Board could consider broadening the description to include "expanding use of stem cell ***and other cell*** therapy" to fully capture these practices.

2. Do you agree with the proposed definition of complementary and unconventional medicine and emerging treatments – 'any assessment, diagnostic technique or procedure, diagnosis, practice, medicine, therapy or treatment that is not usually considered to be part of conventional medicine, whether used in addition to, or instead of, conventional medicine. This includes unconventional use of approved medical devices and therapies.'

I support the proposed definition as it should capture medical practices that claim to use 'stem cells'.

My only concern is whether the phrase "not usually considered to be part of conventional medicine" maybe open to interpretation as the delineation between "conventional" and "unconventional" medicine is not clear from the Discussion Paper.

In the online marketing material and in media coverage of several Australian stem cell clinics who have been in operation for many years, the expertise of the clinics and their associated medical practitioner are repeatedly stated. Consumers, the practitioners themselves and those that regulate their practice, may not see these practices as unconventional medicine or even emerging treatments.

For example, while the Medical Council of NSW imposed specific restrictions on the medical practitioner[5] responsible for the care of a woman who died of complications following 'stem cell' treatment for her advanced dementia[6], he was still allowed to continue to accept new patients for the treatment of osteoarthritis[5] despite the Australasian College of Sports and Exercise Physicians and others raising concerns about the "insufficient

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[1] Munsie M & Pera MF (2014) Regulatory loophole enables unproven autologous cell therapies to thrive in Australia. *Stem Cells and Development* 23 (Suppl 1): 34-8.

[2] Munsie M *et al*., (2017) Open for business: a comparative study of websites selling autologous stem cells in Australia and Japan. *Regenerative Medicine* 12(7) Published Online: https://doi.org/10.2217/rme-2017-0070.

[3] Caulfield T et al., (2016) Confronting stem cell hype. *Science* 352 (6387): 776-777.

[4] Sipp D et al., (2018) Clear up this stem-cell mess. *Nature* 561: 455-457.

[5] Australian Health Practitioner Regulation Agency - Register of practitioners. https://www.ahpra.gov.au/Registration/Registers-of-Practitioners.aspx?q=MED0000938042&t=GA47Z3GPuy1A09U60iSj

[6] Lysaght T *et al.*, (2017) The deadly business of an unregulated global stem cell industry. *J Med Ethics* 43(11): 744-746.

evidence to support the use of MSC therapy in the routine management of musculoskeletal injuries or degenerative conditions"[7].

Consideration will need to be given so as to ensure 'stem cell' and other unproven cell-based interventions are viewed as unconventional and/or emerging treatments by registered medical practitioners so that the proposed Guidelines are applicable.

3. Do you agree with the nature and extent of the issues identified in relation to medical practitioners who provide 'complementary and unconventional medicine and emerging treatments'?

The Discussion Paper duly documents the nature of issues and concerns that colleagues and I have raised about the provision of so-called stem cell treatments in Australia since 2012[8].

In particular, that the marketed autologous interventions are:

- advertised direct-to-consumers but lack demonstrated efficacy;
- prepared in non-accredited facilities with no oversight by the Therapeutic Goods Administration, regardless of the degree of manipulation, method of intervention and intended use;
- provided by medical practitioners who are not specialists and may not be qualified in the conditions being treated;
- offered as a 'one-off' treatment with limited follow-up care, nor links to the patient's existing healthcare team;
- expensive and offered as an 'alternative' to conventional practice (for example MSCs for osteoarthritis), and
- may pose financial, physical and/or psychological harms to consumers.

However, the extent of the marketplace in Australia for autologous interventions marketed as 'stem cells' is larger than that reported in the Discussion Paper.

In an audit conducted in 2016 we identified 70 Australian private clinics (linked to 50 companies) claiming to provide autologous stem cell therapy for conditions ranging from musculoskeletal aliments to treatments for pain, neurological, nephrological and respiratory conditions, as well as reputed anti-ageing and cosmetic purposes[2]. We also illustrated that providers of unproven stem cell interventions displayed tokens of scientific legitimacy[9], including claims that their medical practitioners were highly qualified in 'stem cell medicine', 'Stem Cell Doctors' or 'Stem Cell Specialists'; and to be involved in clinical trials to evaluate various stem cell interventions, although what was offered was not limited to participation in registered clinical trials[2].

Furthermore, following the introduction of a ban on direct-to-consumer advertising of unproven autologous cell and tissue products that came into effect on 1 July 2018[10], we have repeated our website analysis and confirmed that this is an ongoing issue.

Our preliminary findings[11] indicate that in 2019 there remains 33 companies operating across 70 Australian clinics. Although 27 companies active in 2016 closed or ceased to advertise their services, others have joined the

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[7] Australasian College of Sport and Exercise Physicians Position Statement. *The Use of Autologous Mesenchymal Stem Cells in Sport and Exercise Medicine* (2017). Available at: http://www.acsep.org.au/content/Document/ACSEP%20Stem%20Cell%20Position%20Statement%20Nov17%20Final(1).pdf

[8] Pera MF & Munsie M, (2012) Submission to the NHMRC Public Consultation - *Stem Cell Treatments: A quick guide for medical practitioners* and *Frequently Asked Questions: A resource for patients*; Munsie M & Hyun I (2014) A question of ethics: Selling autologous stem cell therapies flaunts professional standards. *Stem Cell Research* 13(3 Pt B): 647-53; Munsie M & Pera MF (2015) Submission to the Therapeutic Goods Administration's *Public Consultation on Regulation of autologous stem cell therapies*; Munsie M & Pera MF (2016) Submission to the Therapeutic Goods Administration's *Public Consultation on Regulation of autologous cell and tissue products and proposed consequential changes to the classification of biologicals*; Lysaght T *et al.*, (2017) The deadly business of an unregulated global stem cell industry. *J Med Ethics* 43(11): 744-746; Sipp D *et al.*, (2017) Marketing of unproven stem cell-based interventions: A call to action. *Science Translational Medicine* 9(397) pii: eaag0426; Bobba S *et al.* (2018) The current state of stem cell therapy for ocular disease. *Exp Eye Res* 177: 65-75.

[9] Sipp D *et al.*, (2017) Marketing of unproven stem cell-based interventions: A call to action. *Science Translational Medicine* 9(397) pii: eaag0426.

[10] TGA, 2018 *Autologous human cells and tissues products regulation*. Available at: https://www.tga.gov.au/autologous-human-cells-and-tissues-products-regulation#what

[11] Munsie M, Tanner C and Fahd S Unpublished – *2019 Review of Australian stem cell clinics' website content*.

marketplace. The majority of clinics we identified do not appear to have modified their marketing material in response to the TGA ban on advertising.

In the few companies where we observed demonstrable changes to website content, five appeared to offer the same service but removed all reference to 'stem cells' from their website content. They now claim to offer 'biological therapy', 'cell therapy' or 'Platelet Rich Plasma (PRP)', although in two instances the parent company retained 'stem cells' within their name. Our audit focused on companies that currently used the term 'stem cell', or had previously included in this term in their online marketing material. It is possible that the number of Australian clinics offering 'biologicals', including stem cells, 'stromal vascular fraction or SVF' and PRP is higher than the 70 identified in our audit.

This analysis illustrates that while the new TGA regulations may have some impact on curbing the promotion of unproven practices, the scope of the marketplace remains concerning and likely to place consumers at risk of physical, financial and psychological harms. As noted above, the Board my wish to broaden its consideration of concerning 'stem cell therapies' to include 'stem cell **and other cellular** therapies' (page 9). While it is factual there is "some evidence from early clinical trials of possible benefit for select patients with certain conditions" (as noted on page 9 of the Discussion Paper), how the cells are prepared; administered; characterised, and by whom also need to be taken into consideration.

4. Are there other concerns with the practice of 'complementary and unconventional medicine and emerging treatments' by medical practitioners that the Board has not identified?

As noted above an additional concern relates to clarification that there is a need for greater regulation around the provision of unproven 'stem cell' therapies, but unproven 'cell' or 'biological' therapies/medicines more broadly.

Some Australian clinics that previously claimed to use 'stem cells' are now promoting their interventions online as a 'biological' medicine/treatments for osteoarthritis and other issues such as nerve pain, tears to muscles and tendons, tears to ligaments and cartilage [12], or as 'cutting edge biological cell therapies' for conditions including multiple sclerosis, emphysema, chronic obstructive pulmonary disease, Alzheimer's disease and muscular dystrophy [13].

Such practices remain outside conventional medicines and should be within the scope of the Board's new Guidelines.

5. Are safeguards needed for patients who seek 'complementary and unconventional medicine and emerging treatments'?

Additional safeguards are certainly required for Australian patients seeking unproven stem cell interventions. While the recent Australian Government announcement of increased oversight by the Therapeutic Goods Administration [14] provides greater oversight of the manufacturing and administering of autologous cell and tissue products, thereby providing some safeguards for Australian patients, our recent analysis of Australian companies (detailed in the response to Question 3 above) highlights that provision of unproven interventions reputedly linked to stem cells, remains a vibrant marketplace. This is not an issue that can be solely addressed by the enforcement of TGA regulations.

In addition to greater reforms around manufacturing standards, and implementation of the greater guidance for medical practitioners that the Medical Board is contemplating in this Discussion paper, Australian patients require safeguards in the form of reliable educational resources as well as support and assistance in reporting adverse events.

As highlighted in the Discussion Paper, we believe that notifications and complaints data under-reports the occurrence of outcomes where patients are dissatisfied or harmed following the procedure. This is due to complex reasons [15]. The current complaints system - whether via AHPRA, ACCC or state-based health complaints ombudsman – assumes that the people affected have the resources, will and drive to pursue what can be a taxing process. People accessing these interventions feel they have exhausted all other options and are struggling with chronic, often painful conditions. They

[12] https://www.macquariestemcells.com/ and https://www.macquariestemcells.com/macquarie-stem-cells-treatments/

[13] https://masterderm.clinic/ and http://www.mastercell.clinic/degenerative.html

[14] TGA (2017) Media release – *Regulation of autologous cell and tissue products*. Available at: https://www.tga.gov.au/mediarelease/regulation-autologous-cell-and-tissue-products

[15] Tanner C & Munsie M (2016) The hard sell of stem cells: we need a better way to protect patients from harm. *The Conversation*. Available at https://theconversation.com/the-hard-sell-of-stem-cells-we-need-a-better-way-to-protect-patients-from-harm-65897

may have other priorities and demands on their resources. For example, the family that triggered a 7.30 Report story[16], did not wish to formally pursue a complaint and wanted to put the unfortunate experience behind them, despite wanting to protect others. While rare, other patients that I have spoken to, when they have contacted Stem Cells Australia for information about stem cell research and treatments, indicate that this family's experience was not unique.

In our recently published book, we recount an interview with a woman who describes suffering excoriating pain and not the outcome she expected following a reputed stem cell intervention at a Sydney clinic for her chronic condition[17]. Although she expressed being dissatisfied she did not mention reporting the event but rather being thankful as the doctor gave her a discounted rate as he knew she had difficulty paying, and on the proviso she would promote the treatment through her networks.

Although efforts should be made to assist patients know their rights and where to report concerning practices, we also should not be relying on consumer complaints to report and assess harm.

Furthermore, while new oversight measures will be introduced following 1 July 2019, TGA need to be fully resources to enforce their regulatory powers and investigate concerning practices. Exactly how the Medical Board anticipates disseminating the proposed Guidelines and enforcing the described standards should also be a consideration.

6. Is there other evidence and data available that could help inform the Board's proposals?

The Board should consider the complexity around the marketplace for unproven stem cell and other cellular therapies in Australia. Additional information has been incorporated into my response to Questions 1 & 3.

The Board Discussion paper appropriately notes the useful NHMRC *Quick Guide for GPs*. This is an excellent document although it is now out of date, especially with respect to how relevant regulation and practices in Australia are described. The Board should also note that the provided hyperlinks to this and the NHMRC *Frequently Asked Questions* resource are broken. It would be ideal if NHMRC could update this Guide plus the Frequently Asked Questions ahead of the release of their proposed Guidelines.

It might also be helpful to note that there are other educational resources available as well as a position statement from the Royal Australian New Zealand College of Ophthalmologists (RANZCO)[18] that may be useful to include in the revised Guidelines. Of particular note are:

- *Australian Stem Cell 2015 Handbook* and available through Stem Cells Australia and the National Stem Cell Foundation of Australia[19]. The NHMRC documents cite a previous iteration of this document - the then Australian Stem Cell Centre's *Stem Cell Therapies: Now and in the Future* – however the revised version would be preferable.
- *Stem cell treatments developed by* MSK Australia (formerly MOVE) and Stem Cells Australia[20].
- *5 things you should know about stem cells* developed by Stem Cells Australia, the Australasian College of Sports and Exercise Physicians and MSK Australia (formerly MOVE)[21].
- *Stem cell intervention for spinal cord injury* developed by Australia New Zealand Spinal Cord Injury Network[22].
- *Stem Cells for Eyesight* developed by RANZCO and Stem Cells Australia[23].

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[16] ABC 7.30 (2016) Stem cell marketer Mikael Wolfe referred to police over 'predatory' approaches to MS and cancer patients. Available at: https://www.abc.net.au/news/2016-09-21/stem-cell-marketer-referred-to-police-over/7866526.

[17] Petersen A, Munsie M, Tanner C *et al.* (2017) *Stem cell tourism and the political economy of hope*. Palgrave Macmillan, UK.

[18] Ocular Stem Cell Therapy – Joint RANZCO and Stem Cells Australian Position Statement. Available at: https://ranzco.edu/ArticleDocuments/176/Ocular%20Stem%20Cell%20Therapy.pdf.aspx?Embed=Y

[19] Munsie M *et al.* (2015) The National Stem Cell Foundation of Australia – *The Australian Stem Cell 2015 Handbook*. Available at: https://drive.google.com/file/d/0B-bysSm4lTjCMUlDSjQ3N0cyMW00RUhFamF6b09wNmlQZ25B/view

[20] *Stem Cell Treatments* https://www.msk.org.au/stem-cell-treatments/

[21] *5 Things you should know*. Available at: http://www.stemcellsaustralia.edu.au/site/DefaultSite/filesystem/documents/5thingsyoushouldknowaboutstemcells_v5.pdf

[22] *Stem cell intervention for spinal cord injury* developed by Australia New Zealand Spinal Cord Injury Network. Available at: http://www.stemcellsaustralia.edu.au/site/DefaultSite/filesystem/documents/E_StemCellBroch%20(2).pdf

[23] *Stem Cells for Eyesight*. Available at: https://ranzco.edu/ArticleDocuments/176/Ocular%20Stem%20Cell%20Therapy%20-%20Leaflet.pdf.aspx?Embed=Y

7. Is the current regulation (i.e. the Board's Good medical practice) of medical practitioners who provide complementary and unconventional medicine and emerging treatments (option one) adequate to address the issues identified and protect patients?

The current regulation of medical practitioners is inadequate as demonstrate by the growth in the number of Australian clinics and practitioners claiming to provide stem cell treatments without a strong evidence basis or links to clinical research endeavours[1,2].

8. Would guidelines for medical practitioners, issued by the Medical Board (option two) address the issues identified in this area of medicine?

The proposed guidelines will greatly help address concerning issues raised by the provision of claimed, yet unproven, stem cell treatments in Australia.

However, to be effective the standards envisaged in this Guideline, plus increased regulatory oversight by the TGA, will need to be enforced. There also needs to be ongoing efforts to raise community awareness about these concerning practices, how to report unsatisfactory medical treatment, and undertake appropriate investigations if and when complaints are made.

9. The Board seeks feedback on the draft guidelines (option two) – are there elements of the draft guidelines that should be amended? Is there additional guidance that should be included?

While it is recognised that borders around 'scope of practice' can be difficult to determine and enforce, I am concerned about the current wording of Section 2 – Knowledge and skills. For many years, we have observed medical practitioners involved in the provision of 'stem cell' treatments claim qualifications, skills and training that legitimise their business model[2,9,17]. While there is no recognised specialist medical college directly linked to 'stem cells', we have seen practitioners refer to themselves as 'Stem Cell Specialists' and claim to have undertaken extensive training, which maybe as limited as a three day workshop overseas or in-house training by another local stem cell specialist[17].

I am concerned that some practitioners will consider that they already comply with Section 2 as due to the previous business practices they may view that they "have current knowledge and skills for your practice", "have appropriate training, expertise and experience in both the treatment and condition" and have undertaken "necessary training". For too long just being enthusiastic about the potential of stem cells and using experience gained by just providing interventions (without any recognised clinical research to support them), has been sufficient justification for these practices. Looking forward Australian patients need better protection.

10. Are there other options for addressing the concerns that the Board has not identified?

Nothing in addition to what has been mentioned above.

11. Which option do you think best addresses the issues identified in relation to medical practitioners who provide complementary and unconventional medicine and emerging treatments?

I strongly support **Option 2** - *Strengthen current guidance for medical practitioners who provide complementary and unconventional medicine and emerging treatments through practice-specific guidelines that clearly articulate the Board's expectations of all medical practitioners and supplement the Board's Good medical practice: A code of conduct for doctors in Australia*.

I would urge the Board to consider how to strengthen Section 2 to ensure self-proclaimed experts, operating outside of conventional medicine and a clinical research framework, are not able to exploit patient hopes.