
Autologous Stem Cell ‘Therapies’ in Australia:

The Need for Regulatory Reform

Executive Summary:

This policy brief discusses ethical and legal concerns surrounding the clinical use of autologous adult stem cells (ASCs). In Australia, clinical uses of autologous stem cells are currently unregulated. While this system has enabled the introduction and expansion of autologous haematopoietic progenitor cell (HPC) transplantation for the treatment of conditions where it has been clearly demonstrated to increase remission period and overall survival, it has been open to abuse and led to the ‘selling’ of autologous cellular interventions where there is no evidence of benefit and the very real possibility of harm (to consumers, their families and the entire community). These practices are often framed as ‘innovation’; however, the interventions often fail to meet basic safety standards and lack evidence of efficacy. To encourage responsible innovation with autologous stem cells in clinical settings, we propose the following points for consideration:

1. Including autologous stem cells under the Biologicals Regulatory Framework of the Therapeutic Goods Administration;
2. Providing training for health and medical practitioners about the risks and benefits of ASCs for particular conditions;
3. Educating health consumers about the risks and benefits of accessing interventions with ASCs outside the context of clinical trials, and the differences between established clinical practice, innovation and clinical research;
4. Enforcing breaches of advertising standards through consumer protection laws;
5. Encouraging clinical research rather than ad hoc interventions;
6. Creating a register of innovative interventions to enable assessment of innovative stem cell interventions prior to their clinical use;
7. Enforcing professional standards through AHPRA (Australian Health Practitioners Regulation Agency) and the health complaints entities in each state and territory such as the Health Care Complaints Commission in New South Wales and the Office of the Health Services Commissioner in Victoria.

Introduction:

Autologous Stem Cell 'Therapies' in Australia

In Australia, the clinical use of autologous cells (cells derived from the patient's own body) is currently excluded from regulation under the Biologicals Framework (Therapeutic Goods Act). This exclusion, which encompasses autologous adult stem cells (autologous ASCs), has encouraged a booming market of private clinics offering stem cell interventions beyond the use of autologous haematopoietic stem cell transplantation for established indications, such as haematological malignancies. Autologous ASCs interventions are generally administered outside clinical trials for a fee, despite a lack of scientific evidence that demonstrates safety and efficacy of these so called 'innovative therapies'. While this market has provided profitable business opportunities, vulnerable patient populations are being exposed to exploitation and unnecessary harms, creating an urgent need to review the current regulation of autologous ASCs in Australia and develop an ethically, socially and scientifically responsible innovation framework for stem cell interventions.

1. Types of Stem Cells

Stem cells are cells that have the capacity for self-renewal and the ability to differentiate into multiple cell types. They are characterised according to their developmental potency (i.e. the breadth of their capacity to differentiate into multiple cell types) and by the source from which they are isolated (i.e. from an embryo or adult/somatic tissue). Adult/somatic stem cells can be further categorised according to their source: e.g. fetal tissues, umbilical cord blood, bone marrow, adipose tissue (fat) and the relationship between the source and 'target' application (autologous – where stem cells are taken from the patients for later re-administration to them, and allogeneic – where stem cells are taken from a donor and administered to a different 'host'). This policy brief is concerned with the clinical application of adult stem cells derived from the patient, so called autologous ASCs.

2. Established and Unproven Uses of Autologous ASCs

At present, autologous ASCs have an established role in 'blood and bone marrow' (BMT) or 'haematopoietic stem cell' transplantation (HSCT, HPT or ASCT) for a range of malignant, metabolic, immunological or genetic diseases affecting adults and children including leukaemia, lymphoma, myeloma, aplastic anaemia, immunodeficiency disorders and haemoglobinopathies

In each of these situations autologous HSCT extends survival and has become established as a standard of care. Increasing evidence from clinical trials also supports a possible role for BMT in other conditions, including multiple sclerosis, scleroderma and autoimmune diseases and there is some, limited, data to support HSCT in a small number of patients with solid cancers, such as germ cell tumours.

While there are a growing number of evidence-based uses of ASCs, autologous ASCs are also increasingly being marketed for the treatment of a wide range of conditions, including, osteoarthritis, motor neurone disease, autism, asthma, and dementia, migraine, infertility and erectile dysfunction. While there is some data to suggest possible benefit in selected patients with osteoarthritis, beyond this there is no good quality data to support autologous ASC interventions in any of these other conditions.

And even the data that exists to support the use of autologous ASC interventions in osteoarthritis is weak, deriving mainly from non-randomised, non-blinded studies involving small numbers of patients and with little standardization of inclusion and exclusion criteria or outcome measures. This means that while the accumulation of data supporting the use of autologous ASC interventions in patients with osteoarthritis justifies further research it is insufficient to justify the marketing sale and administration of autologous ASCs interventions outside of clinical trials. Furthermore, it remains unclear whether many of the autologous ASCs interventions marketed in Australia even contain stem cells.

In general terms, medical therapies are introduced and reimbursed following demonstration of efficacy and safety from Phase 3 clinical trials. Outside of HSCT, few autologous ASC interventions have been tested in Phase 3 efficacy trials (2, 3, 10) and so their use in the patient populations described above must be regarded not as evidence-based practice but as experimental innovation. Autologous ASCs are therefore currently being offered to patients as 'innovative therapies'—that is, clinical interventions that are administered without scientific evidence of efficacy and safety and outside of a formal clinical trial setting (1-3). This 'unproven' use of autologous ASCs is the focus of this Policy Brief.

This practice is troubling because patients may not be fully informed that the interventions offered to them have not been established as safe and effective, and because vulnerable and desperate patients may be willing to try a potentially harmful therapy without the usual protections of formal clinical trials. While it would seem a simple matter to condemn the marketing of autologous ASC interventions to patients where there is insufficient evidence of efficacy and the potential for significant harms, judgment on this issue is complicated by the (broadly shared) desire to also respect patient autonomy and the physician-patient relationship and to enable both clinical innovation and scientific research. Patient advocacy organisations are also placed in a difficult position with regard to regulation of this practice because they must balance the need to promote safe and effective therapies against the desire to promote all options that may help the individuals they represent. The unrestricted marketing of these unproven autologous cell therapies may also adversely impact on the efforts of the broader industry to responsibly translate promising stem cell research into clinical practice.

3. Autologous ASC Interventions in a Global and Australian Context

Private clinics selling unproven stem cell-based interventions operate around the globe, in both high and low income countries. This includes the United States, Ireland, Australia, Germany, Japan, China, India, Mexico and many more (5-9). Observers of the global stem cell industry note that it is common for stem cell providers to engage in direct-to-consumer marketing of these interventions. Evidence also suggests that this largely unregulated industry is thriving and that Australia has been increasingly becoming a destination for patients seeking treatments with stem cells (10). Thus, the ethical implications of the businesses that operate within this industry in Australia are both a national and international concern.

Currently, there are over 50 private providers in Australia that offer autologous ASCs to patients of all ages. As the market with autologous ASCs is currently unregulated, there are no reliable data that can indicate how many patients have been 'treated' by these clinics. The majority of autologous ACS interventions currently being marketed by Australian stem cell clinics incorporate adult adipose derived (fat derived) cells that are claimed to contain mesenchymal stem cells (cells that can differentiate into a variety of cell types). These are marketed for a wide range of indications, including osteoarthritis, motor neurone disease, autism, asthma, dementia and a range of cosmetic procedures, including facial rejuvenation, anti-ageing 'treatments' or hair restoration.

4. Risks and Costs of Autologous ASC Interventions

Autologous ASCs are usually administered parenterally, i.e. via intravenous injections (into a vein), intra-articular injections (into a joint) or intrathecal injections (into the spinal fluid), or subcutaneously for cosmetic procedures. These different administration routes have different safety risks profiles, with intravenous and intrathecal injections being associated with higher risk to patients. The risk of autologous ASC therapies is also a function of how it is prepared (i.e. the extent of its manipulation *ex vivo*) and its use – specifically, whether the cells administered are derived from the same type of biological source as the biological ‘target’ (homologous use) or not (non-homologous use). Homologous use is defined by the Therapeutic Goods Administration (TGA), the regulatory body for therapeutic goods in Australia, as “the repair, reconstruction, replacement, or supplementation of a recipient’s cells or tissues with a biological that performs the same basic function in the recipient as in the donor” (11). The homologous use of ASCs is associated with fewer risks for patients. Most private clinics in Australia utilize autologous ASCs for non-homologous use (i.e. cells derived from fat administered intravenously for Parkinson’s disease). Given that few autologous ASCs are prepared in accredited laboratories, and under good manufacturing standards, further raising the possibility of physical harm to patients.

There is clear evidence that unproven ASC interventions can cause considerable physical and emotional harm. Several cases have been reported internationally, including a woman who developed a tumour-like nasal tissue growth on her back eight years after an autologous cell intervention to cure her paralysis (12), a woman who developed angiomyeoloproliferative lesions following an autologous stem cell intervention for lupus nephritis (13), a man and his parents who experienced pulmonary embolism and infarct following multiple autologous stem cell interventions for cervical herniated intervertebral disc (14), and a man who developed ventricular fibrillation following an autologous ASC intervention for inherited cardiomyopathy (15).

In Australia, the unfortunate death of Sheila Drysdale in December 2013 from surgical complications of autologous ASC ‘therapy’ for dementia at a Sydney clinic has brought this issue to the fore (16). Following an inquiry into Ms Drysdale’s death, the NSW Deputy State Coroner concluded that the autologous ASC intervention was unproven and unjustified and called for regulatory measures that will ensure that medical innovation complies with “scientifically recognised clinical protocols” (17). A recent report by the ABC Radio suggests that this Australian case is far from isolated, documenting cases involving internal bleeding and irreversible joint damage following autologous ASC ‘therapies’ for osteoarthritis (18).

In addition to posing physical risks, interventions with autologous ASCs are expensive. The cost of an injection of autologous ASCs for the treatment of osteoarthritis in a joint varies from \$5,000 to \$10,000 (19-21) while the cost of anti-ageing interventions starts at \$6,000 (22), and often involve repeated administration of injections, which raises the overall cost of the so-called ‘treatment.’ Most interventions with autologous ASCs involve additional costs for consultation with health professionals, cell storage and subsequent ‘therapy.’ Some clinics offer interest free payment plans for ‘low-cost’ interventions of up to \$6,000 (23) and credit payment packages for high-cost interventions that allow patients to repay the costs of cosmetic and dental interventions up to \$70 000 over 84 months (23-25). In all cases, these costs are not reimbursed through Medicare or private insurers, with patients and their families being fully responsible for covering these significant expenses. Hence patients’ financial risk is an important consideration in framing regulation and appropriate protections.

Finally, such interventions also pose the risks associated with diverting patients from conventional medical care and expertise of qualified medical practitioner.

Regulation of Stem Cell Therapies In Australia

1. Regulation by the Therapeutic Goods Administration

The regulation of stem cell therapies and other therapeutic goods is overseen by the Therapeutic Goods Administration (TGA). The TGA's Regulatory Framework for Biologicals introduced thorough standards for stem cell therapies in 2011 (26) and provided a classification of biological products, such as human cells, according to different levels of risk associated with their use. Cells or tissues (including stem cells) administered to the same patient from whom they were extracted are, however, exempt from the regulation, provided that they are (27):

1.

collected from a patient who is under the clinical care and treatment of a medical practitioner registered under a law of a State or an internal Territory; and

2.

manufactured by that medical practitioner, or by a person or persons under the professional supervision of that medical practitioner, for therapeutic application in the treatment of a single indication and in a single course of treatment of that patient by the same medical practitioner, or by a person or persons under the professional supervision of the same medical

Autologous uses that meet these criteria are effectively not considered therapeutic goods and are excluded from any oversight by the TGA. As a consequence, any registered medical practitioner in Australia can offer autologous ASCs to patients for a single treatment outside of a clinical trial framework and charge for the privilege.

2. Regulation of Direct-to-Consumer Marketing

ASC providers commonly market interventions with autologous ASCs directly to consumers, using unsupported claims about their efficacy and safety. These marketing strategies are ethically troubling and are in breach of existing Australian regulation for the promotion of health services as outlined in the Health Practitioner Regulation National Law (the National Law, 28), advertising guidelines and the Australian Consumer Law.

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- is false, misleading or deceptive or is likely to be misleading or deceptive
 - offers a gift, discount or other inducement to attract a person to use the service or the business, unless the advertisement also states the terms of the offer
 - uses testimonials or purported testimonials about the services or business
 - directly or indirectly encourages the indiscriminate or unnecessary use of regulated health services.
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The Medical Board of Australia (MBA) is the professional body that maintains the licensure and registration of medical practitioners in Australia. The MBA has developed standards and guidelines for medical professionals, and investigates complaints that are made against licensed practitioners. *The Good Medical Practice Code of Conduct* (29) states that any information practitioners publish on their services must be factual and verifiable. Further, a practitioner must not guarantee cures, exploit patients' vulnerabilities, or raise unrealistic expectations for clinical outcomes. Finally, a practitioner must not use testimonials to advertise their services, or make unfair or inaccurate comparisons between their services and those of colleagues.

The Australian Health Practitioner Regulation Agency (AHPRA) is responsible for the implementation of the National Registration and Accreditation

Scheme across Australia and provides support to 14 discipline-focused National Boards that regulate the health professions. AHPRA has issued *Guidelines for Advertising Regulated Health Services* (30), that elaborate on the National Law. The *Guidelines* identify a series of behaviours that are incompatible with those expected of the profession, including leaving out important information, using titles that may lead a consumer into thinking that the provider is more qualified than they are, and advertising the health benefits of a service when there is no established evidence that such benefits can be attained. Failing to disclose the health risks associated with treatment, or claiming that a product is 'exclusive' or contains a 'secret ingredient' may also contravene the *National Law*.

Furthermore the *Guidelines* note that the use of before-and-after photographs in advertising has the potential to mislead and/or deceive a patient into believing that an intervention is more effective and safer than it really is and that practitioners should therefore ensure the following where images are included in advertising material:

- the images are as similar as possible in content, camera angle, background, framing and exposure,
- the images are consistent in regards to posture, clothing and make-up,
- the images are consistent in regards to lighting and contrast,
- an explanation is provided if photographs have been altered in any way, and
- the reference procedure is the only visible change that has occurred for the person being photographed.

The *Guidelines* also prohibit the use of 'testimonials,' (positive statements about the clinical aspects of a health service in advertising of health services.

Finally, the *AHPRA Guidelines* state that all advertisements for invasive procedures should include a clear visible warning that recommends patients seek a second opinion from an appropriately qualified health practitioner before undertaking the procedure. If the text of warning is in smaller print than the main text, or placed in an obscure position, the advertisement may contravene the *National Law*.

If a practitioner fails to comply with these provisions, then it is argued that they are likely to be placing their own commercial interests ahead of patients' health and well-being and so may be subject to fines or restrictions on their registration to practice.

Australian Consumer Law (31) also prohibits providers from making false or misleading statements about the quality and standard of products to the consumer and in their promotional material, including websites. All doctors who practice as private practitioners are regarded as carrying on a business and, therefore, must comply with the *Australian Consumer Law*. If a doctor fails to comply then the Australian Competition and Consumer Commission (ACCC) is able to issue infringement, substantiation and public warning notices, and may also take legal action. However, the enforcement of this regulation requires patients to register complaints. The complaint process and the assumption that patients and their families have the time, money and energy to follow through represent major limitations of this regulation.

3. Relevant Professional Regulations

Even though they are currently exempted from TGA oversight, practitioners who administer ASCs must comply with professional requirements stated in the *Health Practitioner Regulation National Law Act* (28) and Medical Board guidelines. All doctors have a professional responsibility to comply with the Medical Board of Australia's *Good Medical Practice: A Code of Conduct for Doctors in Australia 2014* (29). The provisions most relevant to stem cell providers involve:

- professional conduct in the doctor-patient relationship, including the requirement of not exploiting patients physically, emotionally, or financially;
- effective communication, including the options for managing patients' conditions and their potential benefit and harm;
- appropriate handling of adverse events, including openness and honesty in communication about adverse events and the processes for reporting complaints;
- wise use of healthcare resources, including making sure that the services provided are likely to benefit the patient;
- effective risk management, including provider's participation in systems of quality assurance and monitoring of adverse events and
- appropriate financial and commercial dealing, such as honest and transparent financial arrangements which do not exploit patients' vulnerability or lack of familiarity with medical knowledge.

Additionally, APHRA's *Recency of Practice Registration Standard 2010* (32) requires practitioners to have recent practice in the fields in which they work during the period of their registration. This means that practitioners who conduct stem cell treatments need to be able to prove to the Medical Board that they have adequate training and a demonstrated level of competence.

Each state has a specific authority to investigate complaints in order to enforce compliance with the Code. In New South Wales, complaints need to be made to the Health Care Complaints Commission. Patients in Queensland can report practitioners by making a complaint to the Office of the Health Ombudsman. In Australian Capital Territory and Victoria complaints can be lodged with Health Services Commissioner, Health and Community Services Complaints Commission in South Australia and the Northern Territory, and Health and Disability Services Complaints Office in Western Australia.

4. Other Australian and International Guidelines

In response to concerns about practices in Australia and the lack of regulation by TGA, the Australian Cell Therapy Society, a body representing those providing or interesting in autologous cell therapies, has developed a *Code of Practice* (33) to guide members in the safe and ethical clinical practice of autologous cell based interventions. Although compliance is voluntary, the Code notes that members of the Society who contravene the Code may be subject to punishment by an External Advisory Board and members of the Code Committee (although exactly what this means and how effective this self-regulation model be is unclear).

More broadly, leading peak bodies such as The International Society for Stem Cell Research (ISSCR) and the International Society for Cellular Therapies (ISCT), have outlined recommendations for the implementation of

innovative stem cell interventions (34, 35). In particular, the 2016 ISSCR *Guidelines* (36) offer a comprehensive set of requirements regarding the design, reporting and scientific review of preclinical evidence (data available before the implementation of clinical trials). The Guidelines emphasise that formal testing of innovative ASCs, including autologous ASCs, in the context of rigorous clinical trials is a matter of professional responsibility. They further accentuate the importance of transparency in innovation, advocate for the publication of all preclinical studies (including negative and inconclusive results) and that trials are only instigated when supported by strong preclinical research, as confirmed by an independent peer-review process. While the ISSCR and ISCT guidelines do not supersede Australian laws and regulations, international guidelines could inform the interpretation of the *National Law*, and provide guidance for research practice not covered by legislation.

Evidence that Current Regulations are Failing

Despite the existence of regulations guiding marketing and other aspects of professional practice, there is clear evidence that existing regulations are insufficient. As described above, patients are currently being offered unproven and unsafe procedures, with no professional consequences for unscrupulous providers. This, together with the high price of autologous ASC interventions, raises concerns regarding the potential for conflicts of interest - between the patients' best interests and the financial and professional interests of clinicians providing stem cells - to compromise patient care (1, 10, 37). This is particularly worrying given that some of the patients being targeted for ASC interventions are very close to the end of life and are likely to be financially, as well as physically and emotionally, vulnerable. More specifically, direct-to-consumer marketing of autologous ASC interventions clearly contravenes current advertising standards.

1. Unsupported Claims about Efficacy and Safety

The marketing of autologous ASCs often includes unsupported claims about their efficacy and safety. For example, according to an information package from one Sydney-based practice: "Stem cells are extremely versatile which makes this treatment an extremely valuable scientific medical procedure" (38). Another clinic operating five branches in New South Wales and Victoria claims that "Stem Cell therapy is developing into an effective and viable option for patients who want to better manage the ageing process as well as improving their general health and well-being" (39). Further, providers commonly frame autologous ASCs as "an exciting, new and innovative therapy" (22), "highly effective" (40), "extremely safe" (41), "easy to perform" (41) and "a treatment that can help patients who are suffering severe and chronic conditions gain a new hold on life" (42). One Victorian practice also claims that "stem cell therapy has a safety record demonstrated in both animals and in humans for many years" (40).

These claims illustrate the rhetoric that providers employ in their marketing materials and websites around the efficacy and safety of autologous ASCs.

The exaggerated and optimistic claims employed in autologous ASC providers' marketing materials stand in sharp contrast with lack of evidence that would substantiate them. Furthermore, the so called clinical 'evidence' offered by providers does not demonstrate efficacy or safety. While some clinics provide their own data reporting significantly high 'success' rates, with 70-90% of patients significantly improving as a result of autologous ASC 'therapy' (43-45), most practitioners do not provide published scientific data to support their claims. Rather, these claims are based on unpublished anecdotal reports purportedly collected at individual clinics. Given the unverifiable nature of providers' reports about efficacy and safety, the bold and confident claims of clinics and practitioners selling autologous ASCs are highly questionable at best.

2. The (Mis)Use of Patient Narratives by Stem Cell Providers

Several providers use patient testimonials to proclaim the transformative effects of autologous ASC 'therapies' and legitimize their interventions. For example, one provider of cellular products with four branches in Australia and one in New Zealand promotes its 'innovative therapy' with the names of high profile football players who have had the interventions (46). This practice also promotes the story of Margo Priestly, the Head of Laboratory Operations at the clinic, who underwent an autologous ASC intervention for a childhood injury, quoting her a month following her first injection enthusing that: "I've noticed a huge decrease in pain and an increase in movement already" and "It's amazing to have some movement after 12 years" (46). By selectively offering stories of patients who have framed their experiences with autologous ASC interventions in positive terms, clinics create the impression that these interventions are unequivocally successful. Many clinics also use media reports about autologous ASC technologies to boost the credibility of stem cell interventions (47-49).

The use of anecdotal stories and media reports, instead of published peer-reviewed scientific evidence, is ethically contentious (1) because they represent selected subjective views instead of verifiable data based on scientific studies with defined methodology. Furthermore, this practice is in breach of the National Law and Australian advertising guidelines that emphasise that any information published by a provider must be factual and verifiable, and prohibit the use of testimonials for the promotion of a health service (28-30, 50).

3. Other Kinds of False and Deceptive Advertising

While medical practitioners have a professional responsibility to ensure that their advertising is evidence-based, reasonable and honest, websites marketing autologous ASCs are replete with misleading and deceptive statements and visuals. Beside using misleading statistics and testimonials to exaggerate the therapeutic potential of autologous ASCs, some clinics also use 'before' and 'after' photographs which document the proclaimed positive impact of autologous ASC interventions (51-53). While the use of before and after shots does not, in principle, violate Australian regulation, the images used by clinics and the way in which the images are used arguably does breach the Australian Health Practitioner Regulation Agency Advertising Guidelines (29) as they document body parts from different angles and/or using different lighting and hence fail to offer a fair comparison. Moreover, some practitioners also breach the Guidelines by using titles like 'Stem Cell Doctor' (54) or 'Stem Cell Physician' (54, 55) – specialties not currently recognised in Australia (56).

Current Proposals for TGA Reform

The TGA regulation of autologous ASCs is currently under review – principally because of concerns about the emergence of clinics offering interventions in the absence of reliable evidence of safety and efficacy supporting their use. In 2015, the TGA conducted a public consultation on the regulation of autologous ASCs and sought public input to determine an appropriate regulatory framework for autologous stem cell interventions (11). Eighty submissions were received. In September 2016, the TGA initiated a second public consultation (57) seeking comment on four options for the regulation of on the regulation of autologous cell and tissue products (capturing autologous ASCs). It is worth noting that each option related to proposed modifications to the wording to the current exemption (27, 4q of the Excluded Goods Order) and broadened the possible exclusion to dental practitioners:

Option 1 maintains the current status quo, allowing Australian providers to continue marketing clinically unproven and unjustified autologous ASC interventions directly to consumers.

Options 2, 3 and 4 all forbid direct-to-consumer marketing of ASCs, but differ according to the degree of manipulation that is allowed before regulatory exemptions no longer apply.

Option 2 does not attend to issues around the degree of cell manipulation prior to transplantation.

The Need for a Responsible Innovation Framework for Autologous ASCs

Given the likelihood of serious and ongoing harm to patients from autologous ASCs, the most pressing issue concerns the safety and efficacy of these interventions. It is also necessary to consider how the interests of patients who receive autologous ASCs, particularly those most vulnerable to the coercive marketing of such interventions, can best be protected. Both of these issues highlight the need for a comprehensive regulatory framework that addresses, among other things, the safety and efficacy of autologous ASC interventions, marketing of ASC interventions, the misrepresentation of stem cell 'specialists' and the degree to which patients are being adequately informed about the risks, benefits and evidence-base of ASC interventions.

The current regulatory framework is clearly problematic because it fails to ensure that autologous ASCs meet the scientific and ethical standards for safe and efficient clinical practice. While the current regulatory approach enables practitioners to administer innovative autologous ASCs to patients in 'need', it also provides opportunities for commercially motivated stem cell businesses to take advantage of regulatory loopholes and capitalize on some of the most vulnerable patient groups (1, 10, 37). To stop the exploitation of patients and compromising of their health by medical professionals, a more robust regulatory framework for ASCs is needed.

Conclusion

The implementation of a robust policy for ASC interventions will create an effective, ethical and socially sustainable regulatory environment for ASC innovation in Australia. The development of such an environment is crucial for the protection of the best interests of vulnerable patient groups and for ensuring that ASC interventions comply with standards for efficacy and safety in clinical practice.

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