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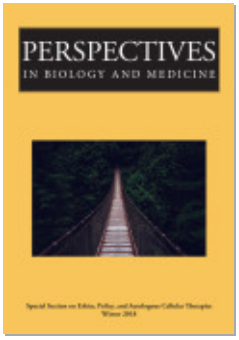

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ABSTRACT Australia has a booming market of unproven autologous stem cell–based interventions (SCBIs) for a wide range of medical conditions. Multiple SCBIs are provided in private practices outside of formal clinical trials. Some defend the provision of unproven SCBIs on grounds of patient choice. This essay interrogates this argument for patient choice and explores patients' vulnerabilities in clinical practice with autologous SCBIs. While all patients are inherently vulnerable, the regulatory framework for autologous stem cells in Australia exacerbates the problems associated with inherent vulnerabilities and generates situational and pathogenic vulnerabilities. A just state ought to implement regulatory measures that mitigate vulnerabilities and foster patients' autonomy.

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Recent years have seen the proliferation of a global industry selling stem cell–based interventions (SCBIs). SCBIs are being marketed around the globe in both low- and high-income countries, including Australia, China, India, Japan, Mexico, and the United States (Berger et al. 2016; Lau et al. 2008; Regenberg 2009; Turner and Knoepfler 2016). Per capita, Australia has one of the highest prevalence of clinics selling stem cell products per capita (Berger et al. 2016), and its drug regulator, the Therapeutic Goods Administration (TGA), has excluded autologous stem cells (ASCs), which are obtained from the patient's own body, from the regulation of biological drug products. This exemption has enabled rapid growth of a market for stem cells, with at least 70 clinics selling these products directly to patients (Munsie et al. 2017). Clinics are offering these products outside of formal clinical trials and often without sound scientific evidence of safety and efficacy (Lysaght et al. 2017; McLean, Stewart, and Kerridge 2015; Munsie et al. 2017).

Some have argued that the provision of so-called "innovative" stem cell therapies in clinical practice respects patient choice and autonomy. This argument is grounded in the premise that patients should be able to make their own health choices consistent with their preferences and interests (Salter, Zhou, and Datta 2015). However, others have countered that ASCs should not be used in clinical practice until they have been demonstrated to be safe and effective for specific medical conditions. This counterargument is based on concerns about the lack of therapeutic benefits from clinically unproven and unjustified procedures, the risks of physical, psychological, and financial harms, and the lack of regulatory oversight and rigorous controls that occurs in formal clinical research contexts (Lysaght et al. 2017; Munsie and Hyun 2014; Munsie et al. 2017 Sipp et al. 2017). Moreover, others have suggested that risky interventions with uncertain benefits increases vulnerabilities that can undermine patients' autonomy and their capacity for self-determination (Lysaght, Richards, and Anantharaman 2017).

In this essay, I build on these latter critiques to interrogate the argument for patient choice by exploring patients' vulnerabilities in clinical practice with autologous SCBIs. I argue that the weakly regulated clinical practice with ASCs in Australia exacerbates patients' vulnerabilities and undermines autonomy. Drawing on the taxonomy of vulnerability developed by Rogers, Mackenzie, and Dodds (2012), I contend that while all patients are inherently vulnerable, the regulatory framework governing ASCs exacerbates these vulnerabilities and generates situational and pathogenic vulnerabilities. Following Mackenzie (2014a), who argues that a socially just state ought to implement policies that mitigate vulnerabilities and provide protections to vulnerable patients, I argue that adequate regulatory responses should foster patient autonomy and provide patients with real treatment options.

Patient Autonomy and the Regulation of ASCs in Australia

A permissive regulatory framework for ASCs has helped to enable a market for unproven SCBIs in Australia. ASCs are excluded from the TGA's Regulatory Framework for Biologicals when they are derived and manufactured by registered medical practitioners, or by persons under their supervision, for a single course of treatment for a single indication (Trickett and Wall 2011). This exclusion has effectively allowed any registered medical practitioner in Australia to offer ASCs to patients for a single procedure in clinical practice (rather than in a research context) and to charge patients for the intervention.

A range of other laws and guidelines regulate the medical profession in Australia and have set standards for the professional conduct of practitioners. In particular, the Medical Board of Australia (MBA), the professional body that maintains the licensure and registration of medical practitioners, stipulates that the doctor-patient relationship should be grounded in effective communication, honesty, and must not be exploitative (MBA 2014). Furthermore, other Australian regulations prohibit misleading and dishonest promotion of health products (AHPRA 2014; Parliament of Australia 2010; Parliament of New South Wales 2009). Clinicians who provide autologous SCBIs are required to adhere to duties associated with the medical profession and to comply with these regulations.

The Australian regulatory framework thus gives patients the freedom to undergo clinically unproven autologous SCBIs (Trickett and Wall 2011). This framework conceptualizes patients as autonomous agents capable of making free and informed choices about their health care. This notion of patient choice is based on presumptions that patients have access to adequate information about the risks and benefits of an intervention, are able to evaluate that information, and make their own treatment decisions, even when the interventions are unproven and potentially risky. While I focus on the regulatory framework (encompassing both the TGA regulations and clinical governance), it is important to note that it assumes that practitioners are competent to prescribe appropriate interventions for patients and that they will respect patient autonomy by facilitating informed and voluntary consent.

The Australian regulatory approach is characteristic of libertarian conceptualizations of autonomy, which promote the liberty of patients to make autonomous choices in accordance with their preferences (Fenton 2006; Harris 1992, 2010; Wilkinson 2010). The application of this conceptualization involves respecting patients' choice through regulations governing access to biomedical technologies. Consonant with this approach, political scientists Salter, Zhou, and Datta (2014) maintain that regulatory frameworks for stem cells should enable autonomous patient choice. In their view, health consumers who demand SCBIs should not be protected from themselves by regulation. Instead, they argue, "such consumers require a balance between information that facilitates their ability to make ratio-

nal choices and the confidence that provider regulation is fit for their purpose" (461). On this account, patients are perceived as consumers of health services, and their "rational choice" of a particular service justifies the granting of access to the service.

The rhetoric of patient choice is echoed by associations promoting accessibility of stem cells to patients. For example, the Adult Stem Cell Foundation (2016), "a privately funded philanthropic (nonprofit) organization advising un-well people about how to gain access to Adult Stem Cell Therapy," aims to create awareness that stem cell therapy is a viable and available option for patients' consideration. Similarly, the New South Wales (NSW) Stem Cell Network (2017), a "professional community with an interest in both adult and embryonic stem cells," presents autologous SCBIs as a legitimate option being used by an increasing number of patients (Tuch and Wall 2014). While the Network representatives claim that the stem cell "industry" needs some form of regulation, mainly with respect to standards of safety, efficacy, ethics, and advertising, they promote the use of SCBIs within an "industry self-regulation" framework (196). Their approach seems to imply that patients' choices are best exercised without interference from the state, and that the market can effectively regulate the provision of autologous SCBIs.

A Critique of the Libertarian Approach to Patient Choice in Autologous ASCs

There are at least two problems with the libertarian approach to patient choice for autologous SCBIs. First, the rhetoric of patient choice as a determinant of access assumes that autologous SCBIs are clinically justified; and second, it equates autonomy with unrestricted choice.

In their advocacy for patient choice, both the Adult Stem Cell Foundation and the NSW Stem Cell Network present SCBIs as effective therapy. Thus, the claim that patients should be able to access ASCs assumes that the interventions available on the market represent medical treatments that are efficacious for particular health conditions. However, many of the SCBIs available to patients in Australia have not been reliably demonstrated to be safe and effective (Lysaght et al. 2017; McLean, Stewart, and Kerridge 2015; Petersen et al. 2017). Such reliable evidence is usually generated through formal research that has independent oversight and expert peer review (Munsie and Hyun 2014). As unproven interventions cannot be equated with known efficacious forms of treatment, justifications for providing autologous SCBIs based on patient choice in clinical contexts are weak.

Furthermore, this libertarian conceptualization of autonomy, with its emphasis on individual choice, has been subject to criticism. Critique has focused on the failure of this approach to account for social factors shaping autonomy (Lysaght,

Richards, and Anantharam 2017; Mackenzie and Stoljar 2000; Petersen et al. 2017; Rogers, Mackenzie, and Dodds 2012). Indeed, theorists of relational autonomy have developed particularly strong critiques of libertarian conceptualizations of autonomy (Donchin 2001; Mackenzie 2014b; Mackenzie and Stoljar 2000). According to these critiques, libertarian preoccupation with conceptualizing autonomy in terms of individual choice and freedom from interference is reductive, because it largely ignores the broader social environment and structural factors that shape patient decision-making. In the words of Catriona Mackenzie (2014a), "libertarian conceptions of choice fetishize individual choice but ignore the social contexts and determinants of those choices" (51). In her view, individual choices are not context-free but shaped by the social relationships and environments in which they are embedded.

From a relational perspective, the libertarian failure to account for social determinants of autonomy is concerning, as sociopolitical factors can generate a range of vulnerabilities that can limit one's capacity for self-determination and the realization of particular choices (Rogers, Mackenzie, and Dodds 2012). For Mackenzie (2014a), a focus on vulnerability also draws attention to potential or actual harm that may result from limited autonomy.

Concerns about patient autonomy and vulnerabilities are crucial in markets for clinically unproven or innovative interventions, which critics of unregulated stem cell markets have recognized. For example, Petersen and colleagues (2017) ask what choice means in an environment characterized by the absence or lack of "clinically proven treatments options available to them, or where options that are presented are perceived as equally undesirable or unaffordable" (31). Such an environment presents patients and their families with "paradoxes of choice," as they are seemingly free to choose yet their choices are limited, owing to the lack of feasible options available to them. The narrow scope of feasible choices suggests that patient autonomy can be limited, and that the availability of undesirable options can make patients vulnerable to harm.

A Relational Perspective on Vulnerability

To analyze patient vulnerabilities, I use the taxonomy of vulnerability developed by Rogers, Mackenzie, and Dodds (2012), which is grounded in a relational account of autonomy. The taxonomy distinguishes three major types of vulnerability: inherent, situational, and pathogenic.[1]

[1]Rogers, Mackenzie, and Dodd's taxonomy of vulnerability partially overlaps with a taxonomy developed by Kenneth Kipnis (2003), as he also identifies situational vulnerabilities. However, Kipnis's taxonomy explores vulnerabilities specifically in the context of clinical research, and specifically with respect to children as research participants. Rogers, Mackenzie, and Dodd's taxonomy is thus better suited for interrogating vulnerabilities in clinical practice with patients of diverse age groups.

First, inherent vulnerability is intrinsic to the human condition. In principle, all humans are inherently vulnerable, and this vulnerability arises from their physical needs or dependence on others. The extent of this vulnerability can depend on age, gender, or health status. Theorists of argue that the existence of inherent vulnerability creates moral and political obligations to protect inherently vulnerable persons vulnerability (Rogers, Mackenzie, and Dodds 2012). In particular, a socially just state ought to implement policy that mitigates or reduces inherent vulnerability (Mackenzie 2014a).

Second, situational vulnerability is context-specific and is created by the personal, sociopolitical, or economic position a person finds herself in. For example, this vulnerability can be caused by temporary unemployment, lack of affordable housing, or a disadvantaging state policy. Furthermore, inherent and situational vulnerabilities can be interconnected, for instance a person with mental impairment can be more prone to situational vulnerability, owing to the lack of employment opportunities and secure housing (Mackenzie 2014a).

Third, pathogenic vulnerability is generated by morally dysfunctional social relationships, injustice, or oppression. According to Mackenzie (2014a), the notion of pathogenic vulnerability helps explain the way some interventions designed to alleviate inherent or situational vulnerability can paradoxically increase vulnerability, for example by increasing persons' dependency on others or state institutions.

Patient Vulnerabilities in the Autologous ASC Market

All three types of patient vulnerability can be identified within the Australian market for ASCs. In my analysis, I focus on vulnerabilities involved in clinical practice with unproven ASCs—not clinically proven therapies using ASCs in blood and bone marrow and hematopoietic stem cell transplantation for a range of diseases including leukemia, lymphoma, or myeloma, that are part of standard clinical practice (McLean, Stewart, and Kerridge 2015).

Inherent Vulnerability

Inherent vulnerability arises from patients' illnesses (such as deteriorating health or pain) or poor prognosis. Patients with severe or terminal illness can be particularly vulnerable. The regulatory framework governing autologous SCBIs arguably ought to provide protections to patients and their families that would help mitigate inherent vulnerability. Mackenzie (2014a) argues that in a socially just society, the state ought to implement policy that promotes patients' resilience in the face of vulnerability. This requires regulatory measures that promote autonomy or that provide adequate material resources or social supports. In regards to clinical practice with ASCs, a just regulatory framework would only allow

for the provision of interventions that are supported with evidence of safety and efficacy (Lysaght et al. 2017; Main, Munsie, and O'Connor 2014).

Situational Vulnerability

The Australian regulatory framework has created situational vulnerabilities by allowing the provision of unproven interventions with ASCs in clinical practice. Within this context, patients undergo risky procedures without clear evidence of therapeutic benefit.

The market for autologous SCBIs makes patients vulnerable to a range of harms. These include physical harms, such as adverse health effects, psychological harms (such as from false hope), and financial harms owing to the high service fees associated with autologous SCBIs (Lysaght et al. 2017; Petersen et al. 2017). The most tragic case of harm from an autologous SCBI reported in Australia to date involved Sheila Drysdale, a 75-year-old woman who died from complications after she received "stem cell therapy" for dementia at a Sydney-based clinic (Lysaght et al. 2017). Following an inquiry into her death, the New South Wales Deputy Coroner acknowledged that the SCBI was clinically unproven and criticized the medical practitioner who administered it for not providing the Court with any relevant scientific evidence to justify the intervention (Coroners Court New South Wales 2016).

Furthermore, harms from opportunity costs arise when patients prioritize unproven SCBIs over standard treatments or discontinue standard therapy. These interventions can potentially deter patients from accessing established therapies that could treat or manage their conditions—therapies that, if not curative, could nonetheless have beneficial or palliative effects (Munsie and Pera 2014). For example, the website of an Adelaide-based clinic features a media story presenting its autologous SCBI for osteoarthritis as an "alternative to knee and joint replacement" that gives patients "a new lease on life" (Norwood Day Surgery 2017). The story includes interviews with two patients alongside the clinician who treated them. The first patient describes cancelling a knee replacement recommended by his doctors following a consultation with the stem cell provider. He reports a decrease in pain and increased mobility following the procedure, although it is unclear how much time has passed since he received treatment. The second patient reports opting for the SCBI to avoid a double knee replacement. She is filmed before and during the procedure, sharing her hopes for positive outcomes, such as that she will "have no pain" and "walk better." Her clinician is cited saying that stem cell therapy appeals to patients "as an alternative, which is much less invasive" than surgery. He states that only "4% of 120 patients so far have gone onto having a joint replacement." Similar media stories can also be found on the website of a Sydney-based clinic, showing interviews with celebrity patients who describe not wanting to take medication or undergo surgery for osteoarthritis,

with some reporting positive outcomes within three months of undergoing an autologous SCBI (Macquarie Stem Cells 2017).

However, the framing of autologous SCBIs as a better alternative to standard clinical practice is not supported with scientific evidence. Patients' positive outlook on autologous SCBIs, illustrated above, is understandable, given the positive portrayal of stem cell therapy in the media and clinics' marketing materials, and with respect to patients' personal investment, both emotional and financial, in the success of the procedure (Caulfield et al. 2016; Munsie et al. 2017; Petersen et al. 2017). However, belief in the safety and efficacy of SCBIs is not confirmed by scientific evidence that supports the use of autologous ASCs for the treatment of osteoarthritis (Little 2016). The same lack of scientific evidence supporting autologous ASCs currently applies to many other conditions. As such, opting for an unproven SCBI instead of standard therapies might harm patients by prolonging or exacerbating the illness experience.

Similar harms can arise from the discontinuation of standard therapy in favor of unproven SCBI. Australian media reported a case involving a patient who was administered ASCs for rheumatoid arthritis at a Sydney clinic (ABC Radio 2016). The patient's rheumatologist was quoted as saying that the intervention had a negative effect on the patient's health, particularly because "as part of the procedure she was obliged to stop the conventional medication" he was prescribing for her. Consequently, her illness "went generally right out of control. She had wide spread swelling, pain, stiffness [in] her hands, wrists, shoulders, feet. Every joint in her body seemed to flare up and she went backwards considerably." The doctor went on to mention that this setback had plausibly caused permanent damage to the patients' joints that would not have occurred without the procedure. Besides physical harm, the patient also experienced financial loss, as she spent AU$17,000 (approximately US$13,000) for the procedure, and the damage caused generated subsequent costs for follow-up treatment.

Situational vulnerability to harm related to autologous SCBIs can be particularly salient for desperate patients, especially for patients with conditions for which there are currently no standard therapies, such as motor neuron disease. The lack of effective therapy can worsen illness symptoms and increase patients' desperation and desire to undergo risky unproven interventions. Moreover, patients with no access to effective treatments might perceive "innovative" stem cell "therapy" as the only option available to them in Australia.

The existence of situational vulnerabilities within the Australian market for autologous SCBIs suggests that the current regulatory framework fails to provide adequate protections to vulnerable patients. Moreover, this framework exposes patients to harm by allowing the market for SCBIs to flourish with limited or no evidence of safety and efficacy. This problem was recognized in the Coroner's inquiry into the death of Sheila Drysdale described earlier (Coroners Court New South Wales 2016). The Coroner recommended that responsible author-

ities, such as the TGA and the National Health and Medical Research Council (an expert body promoting the establishment and maintenance of public health standards in Australia) consider how to best manage and regulate unproven procedures.

Pathogenic Vulnerability

Pathogenic vulnerability associated with the ASC market emanates primarily from dysfunctional patient-doctor relationships and the professional and financial conflicts of interest among clinicians providing the interventions.

The weak regulation of clinical practice with ASCs in Australia amplifies opportunities for conflicts of interest. The regulatory framework allows providers of autologous SCBIs to sell these interventions for high service fees according to market forces. While medical practitioners have professional, legal, and ethical duties to act with beneficence, or in ways that benefit patients, these obligations can conflict with their business interests (Beauchamp and Childress 2001). As practitioners are financially invested in providing ASCs, they can take advantage of the weak regulation and prioritize their interests over those of patients.

The financial interests of ASC providers are apparent in several aspects of their business practices. Foremost are the service fees charged for the interventions and the marketing practices of clinics promoting ASCs. Autologous SCBIs are expensive, and patients and their families are fully responsible for covering all treatment costs, as these expenses are not reimbursed through public health insurance, Medicare, or private insurers. For example, one injection of ASCs to treat osteoarthritis in a joint costs around AU$5,000 (approximately US$3,900), and the therapy often requires repeated injections, multiplying the total cost to patients. In additional to the treatment fees are expenses involving consultation costs and cell storage. Some clinics market interest-free repayment plans for "low-cost" cosmetic interventions of up to AU$6,000 (approximately US$4,700) and credit payment packages for high-cost interventions that allow patients to repay the costs of cosmetic and dental procedures up to AU$70,000 (approximately US$54,000) over 84 months with individually determined credit charges (Elysium Cosmetic & Medical 2013; Victorian Cosmetics Institute 2017).

The high costs of these interventions, especially in the absence of clear evidence that demonstrates therapeutic benefit, raise concerns about exploitation (Main, Munsie, and O'Connor 2014; McLean, Stewart, and Kerridge 2015; Petersen et al. 2017). As such, patients are pathogenically vulnerable to exploitation by opportunistic providers. One of the most remarkable examples of exploitation reported in Australia involved a Gold Coast–based clinic marketing unproven autologous SCBIs for auto-immune disorders, arthritis, joint pain, hepatitis B, leukemia, thymus cancer, male and female infertility, and erectile dysfunction. These interventions allegedly worth AU$100,000 (approximately US$80,000) were sold for "a limited time" at AU$44,000 (approximately US$34,000) to

patients who could provide an immediate minimum deposit of $20,000 (ABC 2016a, 2016b). According to these reports, clients were recruited by an agent via email that urged quick payments: "This has become tiresome. I'm trying to help you. I gave you a solution on a silver platter. This treatment is not available to people whom don't put their health before finances. I'm sorry," and "You will miss this opportunity if you don't take the step towards improving your health." The agent was reported to police for predatory and exploitative practices.

This case illustrates the unscrupulous marketing practices that some businesses are employing to recruit patients. These practices appeal to the desperation of patients by evoking promises of treatments, if only they are willing to make a commitment to their health and pay the requested market price. These sales tactics are part of the "political economy of hope" (Petersen and Seear 2011; Rose and Novas 2005) whereby the promise of "miraculous cures for debilitating illnesses" are sold (Moreira and Palladino 2005, 67). This rhetoric can make patients vulnerable to financial as well as emotional harms emotional harms. The current regulatory framework for ASCs in Australia has not deterred opportunistic providers from exploiting desperate patients and selling clinically unjustified and potentially unsafe SCBIs.

The business practices of some clinics also point to morally dysfunctional doctor-patient relationships that involve an abuse of power. As illustrated by the example of the Gold Coast–based clinic, the marketing style employed by predatory providers can include manipulative communication, with SCBIs being framed as miraculous therapies. At the same time, patients might be pressured in a range of ways to undertake treatments promptly—for example, by sales tactics that involve offering purportedly heavily discounted prices for treatment that are available only within short timeframes, and that suggest that treatments are likely to be more effective closer to time of injury or diagnosis. These business practices are in violation of Australian laws and guidelines governing the professional conduct of medical practitioners. This regulatory framework sanctions immoral doctor-patient relationships, such as exploitation of patients or dishonest and manipulative communication. However, the evidence of such conduct among some providers suggests that the regulation is not sufficiently enforced.

The power imbalance between doctors and their patients is also evident in providers' utilization of false marketing. Scholars have previously shown how clinics market stem cells directly to consumers and use marketing tools to spread fabricated and misleading claims about SCBIs, often overstating the benefits while minimizing the risks (Munsie et al. 2017; Petersen and Seear 2011 Sipp et al. 2017; Turner and Knoepfler 2016). These marketing practices violate the trust invested by patients in the medical profession and point to the existence of business-driven providers who are acting primarily to boost their financial profits.

Ethical and Regulatory Implications

The Australian regulatory context that has enabled clinical practice with unproven autologous SCBIs exacerbates patients' inherent vulnerability and generates situational and pathogenic vulnerabilities. These vulnerabilities negatively affect patients because they make them susceptible to risks of harm, but they also have implications for informed consent. As vulnerabilities increase, they can undermine patients' capacity for self-determination (Lysaght, Richards, and Anantharaman 2017).

The provision of false and misleading information by SCBI providers undermines informed consent. When considering SCBIs, patients may rely on the assumption that therapies are proven. However, O'Donell, Turner, and Levine (2016) argue that patients ought not be led to assume that SCBIs are safe and efficacious simply because they are on the market. Rather, they emphasize that clinicians and regulatory authorities are responsible for providing evidence that these procedures are both safe and effective in order to justify their marketing as therapies. Furthermore, patients' capacity for self-determination can be undermined as a result of their desperation and the lack of effective treatment. Patients who have few therapeutic options for their conditions might feel pressured to consent to unproven SCBIs and might lack the opportunity to weigh potential risks against the presumed benefits while being misled by providers.

In the light of these risks, policy responses cannot be reduced to an appeal for a better-facilitated informed consent process. While it is important that clinics provide honest and adequate information about medical procedures, an exclusive focus on informed consent is "empty ethics" (Corrigan 2003): it does not respond to the sociopolitical factors that exacerbate and generate patient vulnerabilities. Such a reductive approach would also place disproportionate responsibility on patients to be informed while evading clinics' responsibility for the provision of safe and effective interventions to patients.

Adequate policy responses to patient vulnerabilities prevalent in clinical practice with ASCs ought to foster patient autonomy—something that the current regulatory framework governing clinical practice with autologous ASCs in Australia does not do. A clinically unproven intervention without evidence of therapeutic benefit does not represent an actual health choice, but merely a risky procedure offering false hope.

Furthermore, effective policy responses to the prevalence of patient vulnerabilities within the market for unproven autologous SCBIs should address the roots of the problem. In particular, a just and ethical regulatory framework ought to prevent clinical practice with ASCs (outside of the contexts of research and legitimate medical innovation) before they are demonstrated to be safe and effective (Lysaght, Richards, and Anantharaman 2017; Main, Munsie, and O'Connor 2014).

Regulatory reform of ASCs in Australia is warranted. From the perspective of relational autonomy, it is crucial to implement just regulatory measures that will foster patient autonomy and mitigate patient vulnerabilities. In clinical practice, patients should only be administered autologous SCBIs proven to be safe and effective. This means that patients will not have to rely on false hope but will actually have a chance at making health choices that will benefit them.

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