STEM CELL TOURISM AND THE POLITICAL ECONOMY OF HOPE

ALAN PETERSEN, MEGAN MUNSIE,
CLAIRE TANNER, CASIMIR MACGREGOR,
JANE BROPHY

Health, Technology & Society

Health, Technology and Society

Series Editors

Andrew Webster
Department of Sociology
University of York
York, UK

Sally Wyatt
Royal Netherlands Academy of Arts
Amsterdam, The Netherlands

Medicine, health care, and the wider social meaning and management of health are undergoing major changes. In part this reflects developments in science and technology, which enable new forms of diagnosis, treatment and delivery of health care. It also reflects changes in the locus of care and the social management of health. Locating technical developments in wider socio-economic and political processes, each book in the series discusses and critiques recent developments in health technologies in specific areas, drawing on a range of analyses provided by the social sciences. Some have a more theoretical, some a more applied focus but all draw on recent research by the authors. The series also looks toward the medium term in anticipating the likely configurations of health in advanced industrial society and does so comparatively, through exploring the globalization and internationalization of health.

More information about this series at
http://www.springer.com/series/14875

Alan Petersen • Megan Munsie • Claire Tanner •
Casimir MacGregor • Jane Brophy

Stem Cell Tourism and the Political Economy of Hope

palgrave
macmillan

Alan Petersen
Sociology
School of Social Sciences
Monash University
Clayton, VIC, Australia

Claire Tanner
Centre for Stem Cell Systems
Department of Anatomy and Neuroscience
University of Melbourne
Parkville, VIC, Australia

Jane Brophy
Sociology
School of Social Sciences
Monash University
Clayton, VIC, Australia

Megan Munsie
Centre for Stem Cell Systems
Department of Anatomy and Neuroscience
University of Melbourne
Parkville, VIC, Australia

Casimir MacGregor
Sociology
School of Social Sciences
Monash University
Clayton, VIC, Australia

Health, Technology and Society
ISBN 978-1-137-47042-3 ISBN 978-1-137-47043-0 (eBook)
DOI 10.1057/978-1-137-47043-0

Library of Congress Control Number: 2016956384

Cover image: Fotolia.com

Printed on acid-free paper

This Palgrave Macmillan imprint is published by Springer Nature
The registered company is Macmillan Publishers Ltd. London
The registered company address is: The Campus, 4 Crinan Street, London, N1 9XW, United Kingdom

"Accessibly written and vividly illustrated with rich empirical examples, the book reframes our understanding of medical tourism and problematizes academic and policy responses to this growing phenomenon."

–Ruth Holliday, Professor in the School of Sociology and Social Policy, University of Leeds, UK

"…This terrific book is more than just an overview of the facts, it provides a unique and tremendously informed perspective on the drivers of stem cell tourism and how the policy debates can be reframed in a constructive manner."

–Timothy Caulfield, Faculty of Law and School of Public Health, University of Alberta

"Hope has been the constitutive element of stem cell research and therapy. Every year thousands of patients travel overseas to obtain stem cell therapy for a variety of conditions… this book provides an analytically suave and empirically rigorous account of the transnational landscape of stem cell therapies. Alan Petersen and his co-authors force us to rethink the accepted understanding of stem cell tourism. A must read!"

–Amit Prasad, Ph.D., Associate Professor of Sociology, University of Missouri-Columbia

"Healthcare markets are… departing from standard biomedical orthodoxies [and] Stem cell markets have crafted niches across radically divergent regulatory jurisdictions. This book makes a remarkable contribution to our understanding of these forces, helping us to understand dynamics that are actively reshaping the global biomedical landscape."

–Professor Nik Brown, Department of Sociology, University of York

Series Editors' Preface

Medicine, healthcare, and the wider social meaning and management of health are undergoing major changes. In part, this reflects developments in science and technology, which enable new forms of diagnosis, treatment, and delivery of healthcare. It also reflects changes in the locus of care and burden of responsibility for health. Today, genetics, informatics, imaging, and integrative technologies, such as nanotechnology, are redefining our understanding of the body, health, and disease; at the same time, health is no longer simply the domain of conventional medicine, nor of the clinic. The 'birth of the clinic' heralded the process through which health and illness became increasingly subject to the surveillance of medicine. Although such surveillance is more complex, sophisticated, and precise as seen in the search for 'predictive medicine', it is also more provisional, uncertain, and risk laden.

At the same time, the social management of health itself is losing its anchorage in collective social relations and shared knowledge and practice, whether at the level of the local community or through state-funded socialised medicine. This individualisation of health is both culturally driven and state sponsored, as the promotion of 'self-care' demonstrates. The very technologies that redefine health are also the means through which this individualisation can occur—through 'e-health', diagnostic tests, and the commodification of restorative tissue, such as stem cells, cloned embryos, and so on.

This Series explores these processes within and *beyond* the conventional domain of 'the clinic', and asks whether they amount to a qualitative shift in the social ordering and value of medicine and health. Locating technical developments in wider socioeconomic and political processes, each text discusses and critiques recent developments within health technologies in specific areas, drawing on a range of analyses provided by the social sciences and especially from those working in the field of science and technology studies.

The Series has already explored many of these issues, presenting novel, critical, and deeply informed research undertaken by their authors. In doing so, the books have shown how the boundaries between the three core dimensions that underpin the whole Series—health, technology, and society—are changing in fundamental ways. This latest addition to the Series examines an area which has attracted considerable debate and controversy, the arrival over recent years of what has become known as 'stem cell tourism'.

This book explores and challenges many of the assumptions on which the term 'stem cell tourism' is based, offering a nuanced and insightful analysis of how and why people seek treatment for very debilitating or terminal illnesses and disease, either in their own country or elsewhere. Based on research by the authors conducted over a number of years, the analysis is framed around the concepts of 'the political economy of hope' and the 'treatment journey', providing a detailed, qualitative exploration of patients' highly reflexive understandings of their conditions and what stem cells might offer. The authors discuss how stem cell treatment is often seen as a treatment of last resort, but within a complex and increasingly commercialised market for healthcare and its delivery. They point to the differences between countries in regard to public and private provision, considerable unevenness in terms of access to care, and, crucially, key differences in national regulatory systems relating to stem cell therapies.

The search for stem cell therapies to treat or even cure disease is part of a much wider set of developments in the area of regenerative medicine (RM). There has been some social science analysis of this field, not least through two earlier contributions to the Series (Gottweis et al. 2009; Webster 2013). RM is championed as a potential source of curative treatments for a variety of illnesses, and as a generator of economic wealth

and prosperity. Alongside this optimism, however, is a sense of concern that the translation of basic science into useful RM therapies will be laboriously slow due to a range of challenges relating to live-tissue handling and manufacturing, regulation, reimbursement, and commissioning, and to actual adoption in the clinic. This in part explains and provides the wider context through which we can understand individuals and their families trying, through their own efforts, to access therapy where they can. There is a pressing need to have an informed, social science analysis of this phenomenon that not only makes an important academic contribution but also offers insight and guidance for policymakers, and indeed patients themselves.

The authors have extensive and impressive expertise in this field and have brought this together in an exceptionally well-organised way, based on a strongly integrated conceptual framework. As Series' Editors we are delighted to mark our latest publication with a book which will attract international interest from social science scholars working across a number of disciplines. It will also be of great interest to researchers and practitioners in the stem cell field, and those who are considering the prospect of searching for treatment in the world of stem cells.

Andrew Webster and Sally Wyatt

Acknowledgements

This book was only possible through the generosity of the many individuals who so openly shared their stories and insights with us. We thank you. We would especially like to acknowledge the patients and carers who so willingly reflected on their hopes, frustrations, and experiences—which at times may have been confronting as they revisited topics that perhaps they had not thought about for some time or were painful to recall. To the many professionals, in Australia as well as in Germany and China, who shared their views about stem cell science and its clinical application, you have provided us with a unique insight into the challenge of managing hopes and expectations. We would also like to thank the organisations that provided assistance and advice in recruiting participants to this study, including the Australia–New Zealand Spinal Cord Injury Network, Cerebral Palsy Support Network, Cerebral Palsy Alliance, Motor Neurone Disease Australia and affiliated state chapters, MS Australia, Alzheimer's Australia Research Ltd., Parkinson's Victoria, Murdoch Children's Research Institute, and the Friedreich Ataxia Research Association.

We wish to thank the Australian Research Council for funding the research upon which this book is based, namely 'High Hopes, High Risk?: A Sociological Study of Stem Cell Tourism' (DP120100921). We would also like to acknowledge the funding provided by the then Australian government Department of Innovation, Industry, Science and

Research, under the National Enabling Technologies Strategy for the pilot project completed in 2010, and our colleagues Dr. Kate Seear from Monash University and Rebecca Skinner from the then Australian Stem Cell Centre, who were invaluable members of the original research team.

While all of us worked together closely in developing the outline, themes, and content for the book, we each took primary responsibility for different chapters—Alan for Chaps. 1 and 8 and jointly Chap. 2 with Claire; Megan for Chap. 3 and jointly Chap. 7 with Casimir; Claire, Casimir, and Jane led Chaps. 4, 5, and 6, respectively. Ethics approval for all interviews was obtained from Monash University's Human Research Ethics Committee. Some of the material used in the book features in other publications by this group or has been presented at various forums. Chapter 2 draws partly on material prepared for the workshop 'International Medical Travel and the Politics of Transnational Mobility in Asia', organised by the Asia Research Institute in August 2015. Chapter 3 builds upon our paper in *Health* (Petersen et al. 2015) by providing a more detailed description of the role of stakeholders, their perspectives, and the factors that have contributed to the heightened expectations in stem cell science. Chapter 4 builds on and extends our earlier work on patient experience first published in the *Sociology of Health and Illness* (Petersen et al. 2014). Chapter 5 was only possible through the support and hospitality shown to Casimir during his time in Germany. We would like to specifically acknowledge Jovan Maud, Ira Herrmann, Martin Heyer, Rita and Rainer Sobetzki, and Professor Michael Fuchs as well as thank Kate Doherty at EuroStemCell for her ongoing interest in our German research. Chapter 6 draws on research undertaken towards Jane Brophy's PhD candidature, and for this, we wish to acknowledge the generous donor of the Monash University *Science in Society* PhD scholarship, who wishes to remain anonymous, as well as the Monash University Faculty of Arts and the School of Social Sciences for providing additional funding. We would also like to thank Dr Lai Lili and the Institute of Medical Humanities at Peking University for their support during Jane's time in China.

Alan Petersen is grateful for the feedback gained from an invited presentation to a workshop on stem cell therapies organised by the US National Academy of Sciences, International Society for Stem Cell Research, and

the Institute of Medicine in Washington, DC, in November 2013. He would like to thank the Brocher Foundation and staff who supported his residence in November 2014, which provided the opportunity to develop and share his ideas. While he was at Brocher, Aditya Bharadwaj generously invited him to his conference 'Intersections: social science and bioscience perspectives on stem cell technologies', which enabled him to meet some key individuals working in the field. The World Health Organization also invited him to present findings from his work, which provided an invaluable opportunity to share ideas with those who are grappling with regulatory issues, and he would like to express his thanks to them.

The team as a whole presented the main findings at a stakeholder workshop held at the University of Melbourne in September 2015, and we wish to thank attendees for their participation and feedback and Stem Cells Australia for generously hosting the event. We thank Palgrave Macmillan, and Dominic Walker and Stephanie Carey in particular, for the support offered at all stages of the book's production and for kindly accommodating our requests for extensions. Finally, we wish to express our gratitude to our families and our institutions for their support.

The views and interpretations expressed in the book are the authors' and do not necessarily represent the views of Monash University, Stem Cells Australia, the University of Melbourne, or the funding bodies.

References

Petersen, A., Seear, K., & Munsie, M. (2014). Therapeutic journeys: The hopeful travails of stem cell tourists. *Sociology of Health and Illness*, *36*(5), 670–685.

Petersen, A., Tanner, C., & Munsie, M. (2015). Between hope and evidence: How community advisors demarcate the boundary between legitimate and illegitimate stem cell treatments. *Health*, *19*(2), 188–206.

Contents

List of Tables

1

Stem Cell Tourism in Context

In Australia, in recent years, there have been a number of news reports of patients and carers travelling overseas for stem cell treatments (e.g. Donaghey 2013; MacLennan 2014). Their journeys are part of a wider international trend, commonly referred to as stem cell tourism, whereby patients and carers of patients travel across geographical borders and jurisdictions to receive treatments that are experimental or clinically unproven, and hence, may not be available to them where they live. The stories which the articles tell are framed within a now-familiar narrative—desperate patients full of hope investing in treatments that promise much, and scientists and doctors voicing frustrations about entrepreneurial 'charlatans' or 'cowboys' operating at the margins of medicine and exploiting 'regulatory loopholes' to sell 'snake oil'. Why, authorities ask, do patients and carers embark on such treatments that are unlikely to provide benefit, are expensive, and potentially inflict great harm?

This book explores the stem cell tourism phenomenon in all its complexity, so as to cast light on the various sociocultural factors that shape patients' and carers' decisions to embark on journeys to pursue such treat-

A. Petersen et al., *Stem Cell Tourism and the Political Economy of Hope*, Health, Technology and Society,
DOI 10.1057/978-1-137-47043-0_1

ments as well as the nature of current responses to this issue. We wish to go beyond simplistic portrayals of 'the problem', how 'it' arises, who is to 'blame', and what should be 'regulated', which characterises much of the academic and media portrayal of stem cell tourism, to uncover the dynamics of a rapidly evolving treatment market. We question the current ways of understanding the stem cell tourism phenomenon including some underlying premises shaping the terms of recent discussion and the language used to frame stories such as those above, and ask, what is left out of the frame? And, how may 'stem cell tourism' be re-framed so as to offer a better appreciation of why individuals pursue these treatments and whether authorities' concerns are justified and their responses are appropriate and proportionate to the purported risks or concern over lack of demonstrated benefit.

An analysis of the stem cell tourism phenomenon, we believe, can reveal much about how new markets based on emerging technologies arise, operate, and are sustained in the context of contemporary healthcare. This is a context where national and jurisdictional borders matter much less than they did in the past and where citizens have become 'consumers' called upon to exercise 'informed choice' in decisions about health, risk, and care. We ask, what does 'informed choice' mean in this context, especially when individuals are experiencing life-threatening or life-limiting conditions and where conventional treatment options are few or non-existing? And, who are the 'choice architects' (Thaler and Sunstein 2009) who seek to steer patients' and carers' conduct along certain preferred treatment paths?

Healthcare is undergoing profound change under neoliberal policies that aim to reduce the role of government in all spheres of life and to deregulate markets. This includes efforts to wind back welfare provisions in many countries and to 'downsize' and outsource services, to casualise and 'offshore' labour, to ascribe a greater role to competitive tendering in the provision of services, and to encourage citizens to become more responsible and active in their own health, risk management, decision-making, and care, as supposed 'empowered' consumers. However, as we emphasise—despite the focus on active, empowered citizenship—in practice, individuals do not conduct themselves as ideal 'consumers' who exercise 'choice' via a rational 'weighing' up of options in the light

of perfect knowledge about these possibilities, assumed by the implicit rational actor model of economics. The consumer-centric conception of the self is one dimensional in neglecting the contexts in which individuals live their lives. Healthcare actions, including decisions about treatments, occur in a milieu of imperfect knowledge; uncertainty; emotional experiences of fear, desperation, and hope; and widely shared beliefs about matters such as whether treatments are 'risky' or 'worth the risk', 'what works' or is likely to work, and who can and should be trusted. Increasingly, citizens who explore health information and treatments are reliant upon, and are compelled to invest their hopes and trust in remote others, whose motives may be unclear and whose claims are difficult, if not impossible, to verify. In this context, one may ask, are patients' and carers' hopes and trust misplaced? And, if so, what are the likely consequences, for individuals and their families, and for science itself?

In the following chapters, we explore the role of discourses of technological promise, hope, and expectation in the stem cell tourism market, and the implications for relations of trust that are crucial for new fields of research such as stem cell science and for healthcare in general. Stem cell treatments epitomise the promises, hopes, and expectations that are attached to the consumption of new biomedical technologies, namely the potential to effectively treat conditions that were in the past viewed as intractable (Brown 2003). However, stem cell treatments are seen to hold particular promise due to their capacity to regenerate diseased and damaged tissue. Among many scientists, policymakers, and patient communities, there is considerable optimism regarding the potential for stem cell science to lead to new treatments in the not-too-distant future. This is a field with a strong 'translational ethos', namely the belief that scientific findings will travel quickly from 'bench top to bedside' (Maienschein et al. 2008). Optimism in regard to the potential for regenerative medicine has a long history, and much longer than generally recognised (Maienschein 2011). However, breakthroughs in the field of stem cell research in the 1990s and early 2000s, and associated media coverage, heightened optimism among scientists, the wider community, and national policymakers, who have been grappling with the rising number of degenerative conditions associated with ageing populations while seeking to advance economies through the development of biomedical innovations. During this

time, the field has attracted considerable investment from governments and the private sector, with research oriented to both uncovering mechanisms of stem cell differentiation ('basic research') and developing therapies for particular conditions ('applied research'). The field has also attracted controversy, especially during the early years of research involving the use of human embryonic stem cells, since this particular aspect of stem cell research involves the destruction of that which has the potential to become human life. Right-to-life groups and the Catholic Church were prominent critics of human embryonic stem cell research during its emergent phase, labelling it 'immoral' while embracing 'adult' stem cell research—where cells are obtained from a patient's or a donor's organs and tissues—as the 'ethical' alternative with little regard to the differences in biological potential or clinical validation (Smith et al. 2006). More recently, the discovery that stem cells could be created directly from cells in the body, without having to destroy an embryo, and that these induced pluripotent stem cells (iPSC) share many of the same attributes as those of embryonic stem cells, has been hailed again as the 'ethical' alternative despite the significant ethical considerations that this discovery raises (Hyun 2010; MacGregor 2013).

Meanwhile, for patients and their families, who are often desperate for new treatments, the translational pathway from research to treatment is painfully slow. Apart from bone marrow or haematopoietic (blood)-based stem cell transplants used to build a blood or immune system for the treatment of certain conditions (e.g. leukemia, lymphoma), or corneal and skin grafting, there remain few clinically proven therapies available to them in hospitals and clinics in their home country (Daley 2012). Although hundreds of novel stem cell-based interventions are being explored in clinical trials, most remain at the very early stages of investigation where the focus is on demonstrating safety in a small number of patients with strict inclusion and exclusion criteria (Li et al. 2014). As a result, even if patients would like to participate in clinical research, this option may be beyond their reach. It is in this context that providers of unproven stem cell treatments have flourished, advertising treatments 'direct to consumers' via the internet for various conditions—neurological, autoimmune, orthopaedic, cosmetic, and degenerative—marketing an array of treatments allegedly based on human stem cells but with little

or no scientific evidence to support therapeutic claims or indeed that the procedures are safe. Exactly what health risks those contemplating stem treatments could be exposed to can be difficult to ascertain and are rarely openly acknowledged on providers' websites. Rather clinics and providers are presented as 'experienced', 'renowned', and 'acclaimed' specialists practicing 'state-of-the-art' medicine (Connolly et al. 2014). However, given that the treatments can be highly invasive, involving the injection of living cells into the patient's veins, the fluid around the brain and spinal cord or even directly into their heart or brain, it is not surprising complications have been reported. For example, patients with spinal cord injury were discovered to have developed meningitis—an inflammation of the membranes surrounding the brain and spinal cord—following the use of contaminated cells in China (Dobkin et al. 2006). Other patients have been reported to develop a blockage in the lungs (pulmonary embolism), heartbeat irregularities, and the formation of tumours following stem cell treatments (Jung et al. 2013; Pytel et al. 2010; Amariglio et al. 2009; Barclay 2009; Thirabanjasak et al. 2010; Dlouhy et al. 2014). There have also been reports of deaths as a consequence of the highly invasive techniques used by the clinics to administer the cells (Cyranoski 2010; Tuffs 2010; Pepper 2012). Although such reports are rare, they highlight the uncertainty about these procedures and the real possibility that the intervention could actually harm rather than help. In the chapters, we examine how the hopes and expectations attached to stem cell treatments are engendered, and how relations of trust that underpin decisions to pursue such treatments are established and sustained.

As our research has revealed, among those seeking stem cell treatments the language of hope is pervasive and, we argue, has been extensively used by those advertising new treatments. In the chapters, we explore how discourses of hope emerge, circulate, and are sustained and shape actions and how they contribute to the generation of expectations regarding treatments. The concept of the 'political economy of hope' originally used in relation to oncology treatment (DelVecchio Good et al. 1990; DelVecchio Good 2007), and subsequently in the context of patient activism in regard to genetic research (Rose and Novas 2005), we believe, usefully captures the entangling of individual aspirations and actions with wider sociocultural and politico-economic processes, including efforts to

bring new treatments to market, and consequently provides a framework for our analysis. The political economy of hope is sustained by the actions of many constituencies, including scientists, clinicians, patients, the biotech industry, and governments that have some stake in the future promised by stem cell science. However, as we shall see, these different parties have very different investments in this future and different conceptions of when and how research will find practical application.

In this chapter we discuss the details of the research upon which this book draws and introduce the chapters that follow. To begin, however, we locate 'stem cell tourism' within the wider landscape of health and medical travel and global healthcare.

Stem Cell Tourism in the Context of the Health and Medical Travel Industry

Stem cell tourism is part of a growing and highly diverse global health and medical travel industry, including specialties such as spa and wellness tourism, cosmetic and dental tourism, organ transplant tourism, and reproductive tourism. This sector comprises, apart from the doctors, hospitals and clinics themselves, and supporting staff, various advisory, insurance, marketing, and conference and events management services, interpreter and 'concierge' services (e.g. arranging accommodation and pickup from airport), and travel agencies. The health and medical travel industry even has its own publication, *The International Medical Travel Journal*, established in 2007. There are now education and training courses in health and medical tourism, underlining the professionalisation of the sector (IMTJ 2015a). According to one estimate, the global medical tourism market was valued at $US10.5 billion in 2012 and was predicted to grow to $US32.5 billion by 2019, or a mean annual growth rate of approximately 18 per cent (BioSpectrum Asia 2013). It is an industry that many governments have been keen to nurture as a significant value-adding component of 'the bioeconomy' (Petersen and Krisjansen 2015: 30).

The origins of 'stem cell tourism' as a concept and niche market within this global health and medical travel industry are obscure. In Australia, the first news article on 'stem cell tourism' appeared in July 2009 in *The Weekend Australian*:

> A burgeoning international stem cell tourism industry is luring vulnerable people into embarking on stem cell therapy that has not been subjected to any of the usual stringent safety protocols, including clinical trials, that apply to potential new medical treatments. The internet is filled with websites offering purported stem cell treatments for conditions that conventional medicine as yet has no cure for. (Davies 2009)

However, the term 'stem cell tourism' was used earlier. A 2006 news article in the Hong Kong–based *South China Morning Post* reported that a Bangkok hospital was undertaking stem cell therapies using cells from the patient's own blood (Montlake 2006). As the article noted:

> The procedure uses stem cells grown from samples of the patient's blood, which are processed at a laboratory in Israel and flown back to Bangkok. The cells are then injected into the patient's heart. It is an experimental technique that is only performed in a few countries, and is usually offered to patients with severe heart failure, whose only alternative is a transplant.

Reflecting the sensitivities surrounding the use of human embryos in stem cell research and treatments at the time, this article notes that the hospital offering this treatment 'doesn't use embryonic cells, which generate the most controversy from campaigners who say embryos are human life' (Montlake 2006).

In the following year, 2007, *The Scotsman*, reported that a patient who had lost his sight 24 years previously, due to a rare hereditary condition, was seeking a stem cell treatment (described as a '"revolutionary" therapy') in the Netherlands. It noted: '[S]pecialists in the UK are concerned about premature applications of this technology, and warn that "stem-cell tourism"—the practice of going abroad for treatments not yet permitted in this country—could not only raise false hope in desperately vulnerable people, but also put them at serious risk of further complications.' The article also noted that the clinician provider, who had clinics in London and in Holland was 'currently under investigation by the General Medical Council in Britain and the Dutch health authorities, for prescribing stem-cell treatments which are unproven and unvalidated' (*The Scotsman* 2007).

It is difficult to estimate the overall number of patients who have travelled to receive medical treatment of any kind, let alone the proportion of these who undertake specifically stem cell treatment, due to a lack of

verifiable data at the country level and inconsistencies in defining medical travel. Currently, there are no national registries of medical travellers, or a universal requirement to obtain a 'medical treatment' visa from the country where they seek treatment, nor a mandate for travellers to disclose that they have sought treatment upon returning home. Hence there is no mechanism for recording data on medical travellers that would provide a picture of the growth and character of the market. Market researchers provide various estimates of medical travel, broken down by the country of destination and the type of treatment, but these estimates vary between companies and should be viewed with caution. *Patients Beyond Borders*, which provides consumer information on health and medical travel, estimated in 2014 that approximately 11 million patients travel across borders, spending an average of $US3,500 to 55,000 per visit, including all medical costs, transport, inpatient stay, and accommodation; 1.2 million Americans alone were estimated to travel abroad for medical care in 2014 (Patients Beyond Borders 2015a). In the UK, The International Passenger Survey undertaken for the Office of National Statistics estimated that 200,000 UK patients would travel abroad for medical treatment in 2015 (IMTJ 2015b). However, this figure is considered conservative and unreliable, as the Survey is drawn from a small sample size, based on asking people about the purpose of their travel of which medical reasons are a minute proportion; the Survey does not differentiate between those who do and those who do not view their trip as primarily for leisure (IMTJ 2015b). While 'stem cell tourism' can be considered to be an integral element of a burgeoning global health and medical travel market, its contribution to total patient traffic is unknown and, given the definitional and technical challenges in collecting such data, it is probably unknowable. In terms of *qualitative* criteria, however, stem cell tourism has some characteristics that distinguish this form of medical travel.

First, while the term 'tourism', which implies some recreational activity (usually in some purportedly exotic location) accompanying treatment, may apply to some forms of health and medical travel—perhaps most notably cosmetic tourism and spa and wellness tourism—this is generally not the case with stem cell tourism. As we shall see, those patients who embark on such treatments typically are those suffering severe,

life-threatening or life-limiting conditions and have generally exhausted conventional treatment options where they live. By the accounts of at least some who elect to travel (Chap. 2), they are not seeking a recreational experience, and providers who advertise stem cell treatments via the internet generally do not address patients as consumers in search of such an experience—although we have documented some instances where this has occurred (Chaps. 5 and 6). Hence, the term 'tourism' is a misnomer in regards to this form of medical travel. We use the term 'stem cell tourism' in this book not because it is unproblematic but because it is widely used in the media, and among scientists, clinicians, and those who seek to govern the field, as a shorthand description of what is in reality a complex phenomenon.

Second, unlike many if not most varieties of health and medical travel, stem cell tourism involves the use of interventions that are not considered by the mainstream medical community to be *clinically proven*. That is, the stem cell 'treatments' being offered by these 'stem cell' clinics are yet to be fully evaluated in clinical trials to show if they work or are even safe. It is generally expected that a novel treatment, whether using stem cells or any other approach, will be supported by evidence collected in clinical trials and gain regulatory approval, before it is made widely available to the public and eligible for funding through national health and medical benefits schemes or private health insurance. Within biomedicine at least, the 'gold standard' of evidence is the randomised double-blind control trial (Timmermans and Berg 2003) or better still a systematic review summarising the evidence from all the trials of a certain minimum quality standard that have been undertaken in the field (Cochrane 2015). We discuss later the question of 'evidence' and how advisors and patients view this concept (Chaps. 2 and 3), as well as how Australian providers view regulatory oversight (Chap. 7). However, for now, we wish to simply state that this is the standard of evidence guiding those who offer advice to patients and carers in regard to treatments and that informs authorities' judgements about treatment safety and efficacy. While medical and scientific communities delineate between proven 'treatments' and 'interventions' that have yet to be shown to provide benefit, and include all unproven approaches whether they are being assessed within the clinical trial framework or sold with little in the way of recognised evidence, in this book

we have elected to use the term 'treatment' to refer to clinically unproven interventions as this is how patients see the services they contemplate.

Third, the idea that stem cell treatments necessarily involve travel, generally outside a patient's or carer's home country, to a destination with more lax regulations is challenged by the rapid rise of autologous treatments involving the use of the patient's own cells—generally adipose tissue obtained from liposuction (often referred to as 'stromal vascular fraction' (Taylor-Weiner and Zivin 2015))—that may *not* involve travel across state or other jurisdictional borders. The provision of these treatments, which has increased in a number of countries (e.g. the USA, Canada, and Australia) in recent years, are undertaken as a consequence of regulatory ambiguity, adventitious regulatory exemptions, and/or government backed initiatives to foster a local 'stem cell' industry (Bianco and Sipp 2014; Munsie and Pera 2014; Turner 2015). As we will explore in detail (see Chap. 7), the breadth of the regulatory exemption in Australia provides a particularly broad pathway to market for a growing number of private operators. While Australia, like many other jurisdictions, has a risk-based regulatory framework, where the highest level of scrutiny is reserved for the interventions that pose the most risk to the health of the patient—for example, where the biological properties of the cells have been substantially altered—relatively recent legislative changes effectively mean that the use of the patient's own cells broadly exempts a clinic or doctor from having to comply with Australian manufacturing standards no matter how the cells are prepared, stored, or given back to the patients (Lysaght et al. 2013; McLean et al. 2014)

Finally, our research suggests that stem cell travellers tend *not* to use the services of health and medical tourism facilitators that have emerged in recent years to help locate providers of treatments, advise on treatments, and assist with travel arrangements, accommodation, and recuperation. The rise of such companies, which advertise their services via the internet, reflects growing consumerism in health and an emphasis on offering 'personalised' facilitation services to consumers whom, it is assumed, are to be too busy and/or potentially too overwhelmed by options to make a properly 'informed choice' from the mass of information on the different types and costs of medical travel in the healthcare marketplace. Much like a house buyer may use an estate agent or buyer's advocate to assist

in navigating the complexity of the property market, health and medical tourism facilitators claim to offer a unique, professional, 'personalised' service, to ensure that patients connect with providers who can offer the most appropriate care and 'value for money', and are 'trustworthy'. As one such company states on its website, 'Our mission is to help connect patients like you locate the highest-quality, most affordable care, and to provide information and advice that helps give you the confidence to make the best choice among your many options' (Patients Beyond Borders 2015b).

It is not known how many travellers use health and medical tourism facilitation and advisory services, but their sizeable number would suggest that there is a strong market for them. On their websites, companies list many conditions for which treatments can be negotiated at clinics and hospitals around the world but often lack transparency about the relationship (financial and otherwise) between the facilitator and the provider/s. Some include stem cell therapies, for example, for stroke rehabilitation (Medical Tourism Corporation 2015), but it is not known how many patients seek providers via this means. The company Treatment Abroad lists a number of stem cell clinics in different countries (Germany, India, Spain, Switzerland, Turkey, Thailand) offering treatments for various conditions, and its 'Search' function reveals 1110 results for each of 'stem cell treatment' and 'stem cell therapy' (Treatment Abroad 2015). We endeavoured to make contact with some medical tourism facilitators to gain their views on those seeking stem cell treatments, but none responded. However, no individuals we interviewed mentioned using such services—although we did not explicitly explore this; rather, they came to learn about providers via other means, especially the recommendations of other patients or carers; that is, informal networks. For some, social media, especially Facebook, was mentioned as a source for recommendations. We explore these avenues of contact in Chap. 2.

In short, stem cell tourism can be considered to be a niche market within a wider, global health and medical travel industry with some distinctive aspects. However, as we wish to emphasise here and in the following chapters, any characterisation of 'stem cell tourism' will inevitably provide but a 'snapshot' and simplification of what is a complex, constantly changing phenomenon. We make no claim to offer a definitive

coverage of our topic. Our perspective is sociological, which offers many illuminating insights and distinctive ways of understanding the stem cell tourism phenomenon. However, we believe that to do justice to the topic, one needs to acknowledge the dynamic character of 'healthcare' and of related technological developments and forms of citizenship and sociality—defined by increasingly porous borders, where patients and providers are highly mobile, where technologies and information about them and their application and their regulation are constantly evolving and converging, and where treatments are either unregulated or regulated in ways that support providers to flourish. This context has shaped the opportunities for certain practices, including medical travel, and for sustaining the hopes and expectations that attach to promising technologies such as stem cell treatments.

The Rise of Global Healthcare

'Healthcare' can be conceived narrowly, in terms of a field of action oriented to the restoration or maintenance of health or the related procedures, institutions, and expertise employed—generally within a delimited geopolitical domain—or broadly in terms of the historically specific forms of governance that characterise its interactions and define and circumscribe the sphere of action (Osborne 1997). It involves forms of governance premised on certain specified or assumed relations between different actors (including public and private sector, professional, and lay citizens) and entities, and related knowledge, expertise, and practice. Within the context of the welfare state, 'healthcare' traditionally has been seen to comprise fairly stable and, to a large extent, predictable patterns of interaction between and within discrete institutions such as hospitals, clinics, pharmacies, universities, and other research entities, on the one hand, and particular accredited experts and lay citizenry, on the other, mostly within some geographically defined terrain. However, beginning towards the end of the 1970s, under the growing influence of neoliberal theory, and related policies and programs (Harvey 2005), and technological developments, 'healthcare' has undergone profound, rapid change.

During this period, there has been growing questioning of the significance of 'the state', conceived as a centralised top-down force operating

within a defined geographical region ('the nation state'), with writers such as Nikolas Rose and Peter Miller (1992) drawing attention to the operations of power 'beyond the state', which acknowledges forms of governance involving 'the conduct of conduct' (Gordon 1991: 48), as in expert prescriptions concerning 'correct' health, eating practices, ways of living, and so on. Rule has come to rely more on subtle techniques of self-governance rather than on coercion, although the latter is still significant. Power, it is recognised, is dispersed and capillary-like and can be 'bottom up' as well as horizontal and 'top down' (Foucault 1977). Thus, while the nation state continues to play a role in governance, other, more de-centred expressions of power, and the forms of resistance to which such power gives rise, are evident. The rise of the internet and, more recently, social media, both reflects and enables this dispersion of power. We discuss later in some detail the significance of the development of these technological platforms for health and medical travel in general, and 'stem cell tourism' in particular (Chap. 8).

Under neoliberal policies and related technological developments, 'healthcare' is no longer constrained by geography, and is somewhat less constrained by national policies and regulations than in the past. At the same time, associated practices and actors have become highly mobile. Institutions are rapidly and constantly changing, and relationships that were relatively stable within the context of the welfare state, such as those between the health professional and patient, are being redefined and re-enacted. For example, tele-health is enabling diagnosis and treatment to occur at a distance, via the use of new telecommunications technologies and robotics. Processes of competitive tendering and the outsourcing of services is now common across many healthcare systems around the world. At the same time, there is a growing number of private providers marketing a vast array of new treatments—some oriented to existing health conditions and some to enhancement—which are advertised directly to consumers via the internet. Health and healthcare have been commodified and advertised like other commodities, namely for what they promise. This includes treatments for cosmetic purposes, surrogacy services, a host of 'anti-ageing' treatments, and stem cell treatments. Further, individuals are called upon to adopt an entrepreneurial approach to their health by becoming more self-sufficient and 'resilient' and fending for themselves in the healthcare

marketplace. They are encouraged to 'shop around' and select products and services from those providers who offer the 'best' options. For those frustrated with conventional treatment and medical advice—a common experience of patients and carers (see Petersen et al. 2014)—treatments available in another country or jurisdiction may be appealing. Consumerism in health has been greatly facilitated by the rise of the internet and new technologies of communication, including direct-to-consumer advertising and, increasingly, social media. Such media has enabled citizens to become both producers and consumers ('prosumers'), and to contribute to developing their own resources and communities (Chap. 2). This is reflected in the rise of patient activism, community fundraising for treatments, and patient-driven research. Sociologists have used the term 'biological citizenship' to capture this active dimension of citizens' endeavours to shape health-related research agenda—endeavours that have manifested in areas such as cancer research, genetics research, and, more recently, stem cell research (Petryna 2002; Rose and Novas 2005).

The emergent global healthcare has been created by policies that aim to reduce the role of the state in the economy and in social life more generally and to provide greater scope for the operations of 'the market'. Under the influence of the ideas of Milton Friedman and his followers, politicians of both the Right and Left have sought to 'free' private enterprise from purportedly stifling regulation, to reduce the role of governments in social provision, and to engender 'market freedoms and market ethics' (Harvey 2005: 183). The growing global provision of new tests and treatments has been a boon for the biotechnology and pharmaceutical industries in their relentless pursuit of new markets that has become critical with the expiry of many patents for 'blockbuster' drugs (Petersen and Krisjansen 2015). The opening of markets has also facilitated the outsourcing of clinical trials to the private sector (Fisher 2009), and the development of an international pharmaceuticals industry that benefits both from access to and exploitation of new experimental subjects as a new clinical labour (Petryna 2006; Cooper and Waldby 2014). At the same time, for at least some scientists and practitioners, moving from the public health system to the private sector evidently seems appealing, given the promise of considerable profits and a degree of autonomy and self-direction not offered by public institutions. Entrepreneurialism has

become a guiding doctrine in many countries around the world, shaping practices of healthcare and self-care as it has other areas of economic and social life.

National governments, on the other hand, are keen to develop their 'bioeconomies' as the 'new engines of growth' and as hotbeds for biotech industries that can address the degenerative conditions of ageing populations, and increasingly market particular regions or zones for their purported economic and healthcare advantages (Petersen and Krisjansen 2015). It is within this landscape that medical tourism has flourished, with governments seeking to emphasise their competitive advantages in the global market of medical technologies. However, it is not just mature developed economies that are seeking to capitalise on the perceived market of health and medical travellers. Emerging economies, likewise, have actively sought to encourage an inbound movement of patients through explicit policies or regulatory tolerance, as can be seen in China, a formally communist country, which has enabled health and medical practices to flourish in certain parts of the country (Chap. 6). Countries have begun to compete for patients, and have sought to highlight the unique benefits they offer, in terms of quality of service, use of 'state-of-the-art' technologies, and cost-effectiveness. For example, in recent years, the Victorian Government in Australia has been keen to promote Melbourne, the centre for Australia's biotech industry, as a medical tourism hub, capitalising on Australia's reputation as a developer of medical technologies and as possessing an advanced healthcare system (West 2014). For countries seeking to gain a competitive edge, controlling public representations of the quality of their services and cost-effectiveness, is of crucial significance.

All economies are subject to cycles of boom and bust, and this is especially so for bio-based economies, which rely on optimism to realise value, even if no products or devices are delivered in the short-to-medium term (Petersen and Krisjansen 2015). In some countries, especially poorer countries such as India, this may be challenging as various factors such as inadequate infrastructure, poor standards of cleanliness, and the harassment of foreigners, may offer an impediment to growth prospects, leading other countries such as Thailand, Malaysia, and Singapore to gain advantage (Deccan Herald 2015). Further, contrary to common stereotypes,

medical travel is not necessarily from the rich developed West to poorer developing countries. Within Asia, for instance, there is much inter-country travel, often from middle income to lower income—and hence, cheaper—countries. Indonesia is a major source country for medical tourists for Malaysia, for example, and medical institutions market cardiology and orthopaedics to Indonesia and the Gulf states (BusinessWire 2015). Finally, it should be acknowledged that companies as well as people are mobile, often moving to jurisdictions that have a more permissive regulatory environment. In the field of reproductive tourism, for example, In Vitro Fertilisation (IVF) providers, along with human gametes (öocytes and sperm), knowledge and patients may travel across multiple borders in efforts to negotiate and benefit from regulatory, national/ethnic, and financial contexts (Knoll 2012). As we found in the field of stem cell tourism, too, providers are increasingly mobile, and in some cases, they cross borders where this is more congenial to their operations (see Chap. 6).

In short, contemporary healthcare is characterised by globalisation, commodification, marketisation, mobility, and constant change, under relentless pressures of competition and the drive for profit and the influence of discourses of hope, self-care, personal empowerment, and freedom of choice that are strongly attached to the personal consumption of technologies. It is in this context that a growing number of technological innovators and providers have emerged, using the language of promise and hope to promote and sell new treatments. Patients have mobilised, building communities of the like-minded and similarly placed that advocate for the development of or access to new treatments, raise funds to support patients' endeavours to undertake treatments, and develop their own research programs and patient-based resources and forums. This patient activism is expressive of a new form of citizenship—one that is active, entrepreneurial, optimistic, and oriented to the consumption of technologies that are seen to offer much but for which evidence of any kind is often lacking. The stem cell tourism phenomenon is a manifestation of this citizenship and its emphasis on individual choice and rights—including 'right to try' when no other options exist (Chap. 7). Further, growing responsibilisation in healthcare, whereby individuals are held accountable for decisions, means that individuals are liable to be blamed when their decisions prove to be 'wrong' (Chap. 2).

In the context of 'stem cell tourism', such citizenship occurs against a background of regulatory uncertainty. While regulators in some jurisdictions have specifically taken steps to curb the sale of unproven stem cell treatments such as in Germany in response to the X-Cell Center controversy (Chap. 5), authorities in other countries are yet to address ambiguity around how and by whom such medical interventions should be overseen, if at all (Chap. 7). In the absence of harmonised global regulations, the response to the phenomenon of 'stem cell tourism' has largely been limited to countering the claims promulgated in online 'direct-to-consumer' advertising. Driven principally by the scientific community, these efforts have been based on the assumption that by arming the 'consumer' with more information, they will rationally 'weigh up' all options to reach an 'informed' decision. However, as we will go on to argue, 'stem cell tourism' and efforts to address it need to be re-framed to encourage appreciation of the complexities involved. The factors shaping human action, the evidence base for interventions, the character of citizen communications in an increasingly digitalised environment, and the context of contemporary healthcare must all be taken into consideration (Chap. 8). Before we introduce our research and discuss how it can assist in the re-framing of 'stem cell tourism', some comments on the background to our study and how it evolved are in order. What have been our aims, guiding questions, and methods? Why have we asked the questions that we have? What are the strengths and limitations of our methods? And, what have we learnt during our work—both the challenges and limitations of undertaking this kind of research?

Exploring the Sociocultural Dynamics of Stem Cell Tourism

In our research, we have examined the complex, sociocultural dynamics of 'stem cell tourism', paying particular attention to the various factors that shape or potentially shape patients' and carers' views and expectations of stem cell treatments. While we have focused on Australians' views and experiences, from the outset we have been cognisant that our work is likely to have wider significance and consequently we have sought

to keep abreast of international developments and literature in this field. Our interest in this topic was initially sparked by the responses of a number of scientists whom we interviewed in 2008 in relation to their participation in a stem cell awareness event held at Monash University in September of that year. During the interviews, these scientists raised concerns about patients travelling overseas for unproven stem cell treatments and the dangers this posed both to individuals' welfare and to stem cell science itself—a field that was still emerging and, as mentioned, had already attracted controversy regarding the use of human embryos in research. We can see now that these concerns reflected a growing consensus within science and policy communities in Australia and overseas about the dangers posed by the stem cell tourism phenomenon to stem cell science itself.

Our research commenced in 2009, with a small study, funded by the Australian Commonwealth Government, which explored 16 Australian patients' and carers' perspectives on stem cell travel (Seear et al. 2010; Petersen et al. 2014), along with a qualitative analysis of websites advertising stem cell treatments (Petersen and Seear 2011). This work highlighted a range of factors shaping patients' and carers' treatment decisions, and the significance of 'hope', both in patients' and carers' accounts of their treatments and in providers' online advertisements, which rely heavily on patients' testimonials. It also highlighted that participants' expectations were more modest than was widely assumed: they frequently indicated that they embarked on treatment without any expectation that the benefits would be significant, but hoped for small yet personally important shifts in their condition. Further, patients felt that treatments had been denied them in Australia, and that, given the nature of their condition, which was often serious and, in some cases, life threatening (e.g. spinal cord injury, cerebral palsy, motor neurone disease) and the limited options presented by their doctors, time was crucial and they effectively had no choice but to travel.

While this initial study was small, the findings were intriguing and engendered considerable interest among colleagues since the stem cell tourism phenomenon was beginning to attract media coverage and gain serious traction in science and policy communities. Consequently, this led to an application for funds to the Australian Research Council

(2012–2015) to investigate this phenomenon further, which allowed us to explore the views of those who had travelled overseas for stem cell treatment and those who had contemplated undertaking treatment, allowing us to offer some generalisations about the decision to travel abroad and the treatment journey and its aftermath. We were especially interested in examining how individuals constructed benefit and risk and how, if at all, this differed from expert constructions. Do patients and carers hold conceptions of risk that predispose them to minimise potential harms resulting from treatments? Our research commenced soon after the launch of Stem Cells Australia, an Australian Research Council Special Research Initiative (2011–2018), which enabled us to both further develop cross-disciplinary links and capitalise on the momentum and networks established through that initiative, including contacts with patients, scientists, clinicians, community advocacy groups and regulators. This proved particularly useful in framing the science and the attempts to address the phenomenon, given the complexity and rate of change in the science that underpins the field of regenerative medicine.

Capturing Expectations and Experiences

Central to our research were qualitative interviews conducted with 100 individuals who shared their personal experiences of stem cell treatments (specifically patients and carers, and representatives of clinics offering treatment), or were involved in responding to 'stem cell tourism' (scientists, researchers, clinicians, representatives of patient groups and regulators). To protect their privacy all individuals we interviewed were assigned pseudonyms. We also employed a content analysis of print news media and social media on the topic of 'stem cell tourism'; a discourse analysis of advertisements and other information available to patients and carers, and observations made at clinics and hospitals in China.

To explore the perspectives of Australian patients and carers, semi-structured interviews were conducted via the telephone. Usually this involved speaking to the individual patients or carers by themselves, but on three occasions the interviews were undertaken with both the patient and their carer being present. We spoke to two relatively distinct groups

of individuals. The first included 24 Australian patients and carers who had undertaken treatments, all overseas with the exception of one who had undertaken stem cell treatment *only* in Australia. (A second patient receiving treatment in Australia also undertook treatment in Thailand.) For convenience, in the presentation of our findings, we have identified this group as 'travellers'. The overseas travellers had visited clinics in various countries, including China, India, Thailand, Israel, Germany, Panama, Mexico, and the USA. The second group included 27 Australian patients and carers who, at the time of the interview, had contemplated embarking on a stem cell treatment but had *not* done so. In our findings, we refer to this group as 'non-travellers'. One individual was interviewed on two different occasions, first, as a non-traveller and, later, as a traveller, and we have given them two different pseudonyms to preserve their privacy (See Tables 1 and 2, Appendix). The interviews, conducted between 2012 and 2014, explored patients' experiences of treatments, including the events leading up to individuals' decisions to undertake or not undertake treatments at the time of the interview, sources of information, and the factors shaping decisions about treatments and destinations. These revealed a series of typical critical junctures, described in Chaps. 2 and 4.

To help us contextualise these experiences, we also interviewed 20 Australian stakeholders in the field of stem cell science—scientists, clinician-researchers, and representatives of patient groups—whom patients and carers consulted in the course of deciding whether or not to embark on a stem cell treatment, to gain their views (Chap. 3). Five of these were scientists from a range of research centres (hereafter 'researcher'); four were doctors, all of whom also undertook some stem cell related research ('clinician-researcher'); and 11 were representatives of support groups for people suffering a range of conditions ('patient support'). None of the participants were involved in the provision of unproven stem cell treatments. During the interviews we asked participants to reflect on the most recent enquiry they had received; how they responded to the enquiry; how the advice was received; how they felt about being asked for assistance; and their views on unproven stem cell treatments being offered abroad. We also provided them with the opportunity to raise any other matters they considered relevant. While no one described themselves as an 'advisor', each of the three groups had distinct

roles and expertise that shaped their interactions with patients and carers and the context in which they received enquires.

In addition, we undertook interviews with providers, scientists, clinicians, and regulators in two countries where Australians travelled for stem cell treatment, namely Germany (Chap. 5) and China (Chap. 6), to develop our understanding of their practices and how these were justified and sustained. We asked, what enables these providers to operate, even where authorities purportedly seek to tightly regulate their operations, and why may they fail (as in China); further, how can jurisdictions successfully and creatively respond (as happened in the case of the X-Cell Center (hereafter X-Cell) in Germany)? To gain insight into the context shaping the provision of treatments in China, in 2014 we re-interviewed seven Australian patients and carers who travelled to China for treatment, or contemplated going (to focus more specifically on their engagement with China), and four representatives of clinics that offer stem cell treatments, as well as four other local stakeholders and policy makers. To learn about the factors shaping the rise and fall of X-Cell, in 2014 we also interviewed 15 German and European Union stakeholders—namely stem cell scientists, clinicians, lawyers, state regulators, federal regulators, and EU-level regulators—who were involved or had an interest in the X-Cell controversy, and 'stem cell tourism' more broadly. These findings are complemented with data from interviews with several Australians who underwent treatment at X-Cell.

As our enquiries progressed, we became aware of the growing market of autologous stem cell treatments emerging 'onshore', in Australia, and so in 2014 we also interviewed six providers who offered these treatments, to gain some insight into the practices sustaining this sub-market (Chap. 7). As we have noted, the arrival of local autologous providers forced us to reconsider our assumption that patients and carers necessarily need to travel abroad for stem cell treatments. In undertaking these interviews, we considered: How do these providers of autologous stem cell treatments justify their operations? Are they simply 'charlatans' exploiting regulatory 'loopholes', as some commentators suggest, or can they be considered to be biotech pioneers, charting new frontiers, encouraged by a favourable regulatory environment?

Through the course of our research, we also examined the various other sources of information available to patients and carers, such as direct-to-consumer advertising and news media reporting on stem cell treatments, along with social media communications. We examined in detail the case of a patient whose plight to undertake a stem cell treatment in Russia was the focus of an Australian television program (Chap. 8).

Outline of Remaining Chapters

Chapter 2 examines the paradoxes of 'choice' that characterise global healthcare, focusing on the experiences of Australians who have either undertaken or contemplated undertaking a clinically unproven stem cell treatment overseas. The chapter focuses on critical junctures that typify treatment journeys, highlighting the dilemmas confronting those with few or no options for treatment in Australia. For patients and carers, the decision about whether or not to travel overseas for a treatment otherwise unavailable to them in their own country is not straightforward. For most, 'doing nothing is no option' and yet those searching the internet and other sources will be confronted with diverse information and advice. Neoliberal healthcare is defined by the rhetoric of choice, and yet individuals in search of treatment options will be confronted with considerable uncertainty and imperfect knowledge. We argue, in light of these paradoxes, that the promised 'choice' in global healthcare is largely illusory and calls for an investment of trust in those whose claims are difficult, if not impossible to verify. Acknowledging these paradoxes, we conclude, is a necessary first step in developing forms of governance for unproven treatments that are attentive to the context of contemporary healthcare.

Chapter 3 explores the challenge of managing community expectations, particularly from the perspective of those who are regularly consulted by patients or their families and carers for advice about whether 'stem cells' have anything to offer them. Dubbed 'accidental' advisors—as they were usually consulted outside a formal role in the patient's healthcare team—many described how they assumed a non-directive role as they sought to balance hopes by providing a realistic portrayal of available

evidence. Highly critical of the operators selling unproven treatments and fostering 'false hope', the analysis of their views and recollections offers a unique window into examining the working of the politics of hope and the realities of healthcare in the age of medical travel.

Chapter 4 examines the journeys of patients and carers who have travelled to different destination countries to receive an unproven stem cell treatment. Travellers' accounts of travelling abroad for treatment underline the complexity of the phenomenon of stem cell tourism. In the chapter, we consider key stages of people's journeys: travel to the destination country; first impressions and experiences of the clinic and care; the treatment regimes people underwent, and people's experiences and reflections upon returning home. Each step demonstrates the profound practical challenges that travellers face in undertaking their journeys as well as the more abstract challenges they pose with respect to the management of competing risks, claims, and models of healthcare, and the significance of hope and trust in travellers' negotiation of them. We consider the significance of shifting dynamics of trust and distrust, expectation and hope, and fear and uncertainty as inherent aspects of people's journeys. In so doing, we demonstrate the importance of moving beyond narratives of empowerment and exploitation that dominate responses to stem cell tourism to advance understanding of the stem cell tourism phenomenon.

Chapter 5 provides an account of the rise and fall of one of the most infamous stem cell treatment clinics—X-Cell in Germany. The chapter describes the German and European regulation that enabled X-Cell to operate. It also examines how scientific uncertainty was used by X-Cell to exploit patients' and carers' hopes. The chapter draws attention to how X-Cell and the regulators sought to balance risk within this context of scientific uncertainty and how German regulators became mediators of trust in order to restore regulatory order and shut down X-Cell. The chapter demonstrates how within the economy of hope, uncertainty can be used to promote and expand the market for unproven stem cell treatments, and how regulators have a key role to play in establishing and maintaining trust to protect the public and establish certainty.

Chapter 6 shifts attention to China, which has become a major destination for those seeking stem cell treatments. It describes the context in which the treatment market developed and assesses the impact of

recent regulatory measures, which are starting to see unsanctioned clinics move underground or offshore. Despite China being perceived by some Australian patients as an unlikely destination to travel for innovative healthcare, others evidently view it as an attractive option. Why might this be so? This chapter examines the views of representatives of clinics in China, which reveal how they use marketing to influence patients' expectations and experiences in order to increase China's attractiveness as a destination. As we explain, China also represents an attractive destination for foreign doctors and entrepreneurs, who attach their own hopes and expectations to the promise of stem cells.

Chapter 7 examines the significance of 'hope' in the creation of the Australian market for unproven autologous stem cell treatments; that is, those using cells from the patient's own body. The chapter draws attention to how the Australian-based market provides a potentially different patient experience than that offered at overseas clinics. In fleshing out the creation of the Australian market, we examine the hopes and concerns of patients and providers of stem cell treatments and the different views of patients, providers, and stakeholders in regard to the future regulation of this market. The chapter concludes by highlighting the significance of the political economy of hope in creating the conditions that will enable the development of a future dynamic and legitimate market for stem cell treatments.

Chapter 8 offers a summary of the preceding chapters and concludes with some reflections on the adequacy of authorities' responses to the stem cell tourism phenomenon thus far. It raises some questions and offers some suggestions for further thinking and action in relation to the issues arising from our work. The chapter argues for a re-framing of 'stem cell tourism' so as to offer a better appreciation of why individuals pursue stem cell treatments and whether authorities' concerns are both justified and proportionate to the possible risks and high costs, or lack of purported benefit. We argue that the current dominant emphasis on tempering 'consumer demand', through authorities' efforts to offer more or better information to individuals, is not only limited in terms of curtailing the market and protecting patients from harm but may also be counterproductive. As we conclude, those who develop policies and strategies in relation to 'stem cell tourism' need to pay much greater attention to

how early treatment markets operate in contemporary global healthcare and to the emergent forms of citizenship and sociability enabled or facilitated by the internet and social media.

References

Amariglio, N., Hirshberg, A., Scheltthauer, B. W., Cohen, Y., et al. (2009). Donor-derived brain tumor following neural stem cell transplantation in an ataxia telangiectasia patient. *PLoS Medicine, 6*(2), 221–230.

Barclay, E. (2009). Stem-cell experts raise concerns about medical tourism. *The Lancet (World Report), 373*(9667), 883–884.

Bianco, P., & Sipp, D. (2014). Regulation: Sell help not hope. *Nature, 510*(7505), 336–337.

BioSpectrum Asia. (2013, October 3). Medical tourism market to reach $32.5 bn globally in 2019: Report. *Academic OneFile*. http://go.galegroup.com/ps/i.do?id=GALE%7CA347329322&v=2.1&u=monash&it=r&p=AONE&sw=w&asid=a2ed676eb3e9b03b1b89622fa5ee2abb. Accessed 20 Feb 2016.

Brown, N. (2003). Hope against hype: Accountability in biopasts, presents and futures. *Science Studies, 16*(2), 3–21.

BusinessWire. (2015, July 15). Research and markets: Malaysia medical tourist arrivals and spending forecast to 2020. *BusinessWire*. http://www.businesswire.com/news/home/20150715005956/en/Research-Markets-Malaysia-Medical-Tourist-Arrivals-Spending#.VfYsrmSqpHw. Accessed 20 Feb 2016.

Cochrane. (2015). When and how to update systematic reviews. http://www.cochrane.org/MR000023/METHOD_when-and-how-to-update--systematic-reviews. Accessed 20 Feb 2016.

Connolly, R., O'Brien, T., & Flaherty, G. (2014). Stem cell tourism—a web-based analysis of clinical services available to international travellers. *Travel Medicine and Infectious Disease, 12*, 695–701.

Cooper, M., & Waldby, C. (2014). *Clinical labor: Tissue donors and research subjects in the global bioeconomy*. Durham: Duke University Press.

Cyranoski, D. (2010). Korean deaths spark inquiry. *Nature, 468*(7323), 485.

Daley, G. (2012). The promise and perils of stem cell therapeutics. *Cell Stem Cell, 10*(6), 740–749.

Davies, J-A. (2009, July 11). Forlorn Aussies flock to take risky stem cell therapy. *The Weekend Australian*, p. 3.

Deccan Herald. (2015, August 28). Touting, harassing foreigners, lack of infrastructure hit India's medical tourism. *Deccan Times*. http://www.deccanherald.com/content/497749/touting-harassing-foreignerslack-infrastructurehit.html. Accessed 20 Feb 2016.

DelVecchio Good, M.-J. (2007). The medical imaginary and the biotechnical embrace: Subjective experiences of clinical scientists and patients. In J. Biehl, B. Good, & A. Kleinman (Eds.), *Subjectivity: Ethnographic investigations* (pp. 362–380). Berkeley: University of California Press.

DelVecchio Good, M.-J., Good, B. J., Schaffer, C., & Lind, S. E. (1990). American oncology and the discourse on hope. *Culture, Medicine and Psychiatry, 14*, 59–79.

Dlouhy, B. J., Awe, O., Rao, R. C., Kirby, P. A., et al. (2014). Autograft-derived spinal cord mass following olfactory mucosal cell transplantation in a spinal cord injury patient. *Journal of Neurosurgery: Spine, 21*(4), 618–622.

Dobkin, B. H., Curt, A., & Guest, J. (2006). Cellular transplants in China: Observational study from the largest human experiment in chronic spinal cord injury. *Neurorehabilitation and Neural Repair, 20*(1), 5–13.

Donaghey, K. (2013, October 12). Sunshine Coast mum flies to Beijing for unproven stem cell treatment for autistic daughter. *The Courier Mail*. http://www.couriermail.com.au/news/queensland/sunshine-coast-mum-flies-to--beijing-for-unproven-stem-cell-treatment-for-autistic-daughter/story-fnihsrf2-1226738607476. Accessed 20 Feb 2016.

Fisher, J. A. (2009). *Medical research for hire: The political economy of pharmaceutical clinical trials*. New Brunswick/London: Rutgers University Press.

Foucault, M. (1977). *Discipline and punish: The birth of the prison* (trans: Sherian, A.). London: Penguin Books.

Gordon, C. (1991). Governmental rationality: An introduction. In G. Burchell, C. Gordon, & P. Miller (Eds.), *The Foucault effect: Studies in governmentality*. Hemel Hempstead: Harvester Wheatsheaf.

Harvey, D. (2005). *A brief history of neoliberalism*. Oxford: Oxford University Press.

Hyun, I. (2010). The bioethics of stem cell research and therapy. *Journal of Clinical Investigation, 120*(1), 71–75.

IMTJ International Medical Travel Journal. (2015a). Education and training for medical travel, health tourism and spa tourism. http://www.imtj.com/education/. Accessed 17 Aug 2015.

IMTJ International Medical Travel Journal. (2015b). The latest "fact" about medical tourism. http://www.imtj.com/articles/2015/internet-facts-on-medical-tourism-40205/. Accessed 17 Aug 2015.

Jung, J. W., Kwon, M., Choi, J. C., Shin, J. W., et al. (2013). Familial occurrence of pulmonary embolism after intravenous, adipose tissue-derived stem cell therapy. *Yonsei Medical Journal, 54*(5), 1293–1296.

Knoll, E.-M. (2012). Reproducing Hungarians: Reflections on fuzzy boundaries in reproductive border crossing. In M. Knecht, M. Klotz, & S. Beck (Eds.), *Reproductive technologies as global form: Ethnographies of knowledge, practices and transnational encounters* (pp. 255–282). Frankfurt/New York: Campus Verlag.

Li, M. D., Atkins, H., & Bubela, T. (2014). The global landscape of stem cell clinical trials. *Regenerative Medicine, 9*(1), 27–39.

Lysaght, T., Kerridge, I., Sipp, D., Porter, G., et al. (2013). Global bionetworks and challenges in regulating autologous adult stem cells. *Cell Stem Cell, 13*, 647.

MacGregor, C. (2013). *Science and controversy: An historical ethnography of stem cells, bioethics and politics in Australia*. Unpublished PhD thesis, Macquarie University, Sydney.

MacLennan, L. (2014, October 18). Overseas MS treatment sought by hundreds of Australians despite risks and cost. *ABC News*. http://www.abc.net.au/news/2014-10-18/australians-seek-ms-treatment-overseas-despite-risks/5823790. Accessed 20 Feb 2016.

Maienschein, J., Sunderland, M., Ankeny, R. A., & Robert, J. S. (2008). The ethos and ethics of translational research. *The American Journal of Bioethics, 8*(3), 43–51.

Maienschein, J. (2011). Regenerative medicine's historical roots in regeneration, transplantation, and translation. *Developmental Biology, 358*(2), 278–284.

McLean, A., Stewart, C., & Kerridge, I. (2014). The emergence and popularisation of autologous somatic cellular therapies in Australia: Therapeutic innovation or regulatory failure? *Journal of Law and Medicine, 22*(1), 65–89.

Medical Tourism Corporation. (2015). Medical. http://www.medicaltourismco.com/medical-procedure/. Accessed 20 Feb 2016.

Montlake, S. (2006, May 26). Stem-cell tourism. *South China Morning Post*. http://www.scmp.com/article/550313/stem-cell-tourism. Accessed 20 Feb 2016.

Munsie, M., & Pera, M. (2014). Regulatory loophole enables unproven autologous cell therapies to thrive in Australia. *Stem Cells and Development, 23*(S1), 34–38.

Osborne, T. (1997). Of health and statecraft. In A. Petersen & R. Bunton (Eds.), *Foucault, health and medicine* (pp. 173–188). London/New York: Routledge.

Patients Beyond Borders. (2015a). Medial tourism statistics and facts. *Patients Beyond Borders*. http://www.patientsbeyondborders.com/medical-tourism-statistics-facts. Accessed 20 Feb 2016.

Patients Beyond Borders. (2015b). About Patients Beyond Borders. http://www.patientsbeyondborders.com/about. Accessed 20 Feb 2016.

Pepper, J. (2012, January 26). Croydon man died in long haul op, inquest hears. *Croydon Guardian*. http://www.croydonguardian.co.uk/news/9491936.Paraplegic_man_died_in_long_haul_op__inquest_hears/. Accessed 3 Mar 2016.

Petersen, A., & Krisjansen, I. (2015). Assembling "the bioeconomy": Exploiting the power of the promissory life sciences. *Journal of Sociology, 51*(1), 28–46.

Petersen, A., & Seear, K. (2011). Technologies of hope: Techniques of the online advertising of stem cell treatments. *New Genetics and Society, 30*(4), 329–346.

Petersen, A., Seear, K., & Munsie, M. (2014). Therapeutic journeys: The hopeful travails of stem cell tourists. *Sociology of Health and Illness, 36*(5), 670–685.

Petryna, A. (2002). *Life exposed: Biological citizens after Chernobyl*. Princeton: Princeton University Press.

Petryna, A. (2006). Globalizing human subjects research. In A. Petryna, A. Lakoff, & A. Kleinman (Eds.), *Global pharmaceuticals: Ethics, markets, practices*. Durham/London: Duke University Press.

Pytel, P., Husain, A., Moskowitz, I., Raman, J., et al. (2010). Ventricular fibrillation following autologous intramyocardial cell therapy for inherited cardiomyopathy. *Cardiovascular Pathology, 19*(2), 33–36.

Rose, N., & Miller, P. (1992). Political power beyond the state: Problematics of government. *The British Journal of Sociology, 43*(2): 173–205.

Rose, N., & Novas, C. (2005). Biological citizenship. In A. Ong & S. J. Collier (Eds.), *Global assemblages: Technology, politics and ethics as anthropological problems* (pp. 439–463). Oxford: Blackwell.

Seear, K., Petersen, A., Munsie, M., & Skinner, R. (2010). *Hopeful journeys: Experiences of stem cell treatment offered outside Australia*. Clayton: Monash University.

Smith, S., Neaves, W., & Teitelbaum, S. (2006). Adult stem cell treatments for diseases. *Science, 313*(5786), 439.

Taylor-Weiner, H., & Zivin, J. G. (2015). Medicine's Wild West—Unlicensed stem-cell clinics in the United States. *The New England Journal of Medicine, 373,* 985–987.

Thaler, R. H., & Sunstein, C. R. (2009). *Nudge: Improving decisions about health, wealth and happiness*. London: Penguin.

The Scotsman. (2007, February 2). A leap in the dark? http://www.scotsman.com/news/a-leap-in-the-dark-1-681313. Accessed 2 Feb 2016.

Thirabanjasak, D., Tantiwongse, K., & Thorner, P. S. (2010). Angiomyeloproliferative lesions following autologous stem cell therapy. *Journal of the American Society of Nephrology, 21*(2), 1218–1222.

Timmermans, S., & Berg, M. (2003). *The gold standard: The challenge of evidence-based medicine and standarization in health care*. Philadelphia: Temple University Press.

Treatment Abroad. (2015). Stem cell clinics offering treatment abroad. http://www.treatmentabroad.com/hospitals-clinics/stem-cell-clinics. Accessed 2 Feb 2016.

Tuffs, A. (2010). Stem cell treatment in Germany is under scrutiny after child's death. *British Medical Journal, 341*(7780), 960–961.

Turner, L. (2015). US stem cell clinics, patient safety, and the FDA. *Trends in Molecular Medicine, 21*(5), 271–273.

West, K. (2014, February 7). High-tech healthcare on offer in growing Australian medical tourism market. *ABC News*. http://www.abc.net.au/news/2014-02-06/an-aust-medical-tourism-kesha-west/5243868. Accessed 20 Feb 2016.

2

'Choice', Hope, and Stem Cell Treatments

> *Oh well, I mean, to us it's like there's no other choice. Do you know what I mean? No, we don't want to go. We don't want to get on the plane. We don't want to go and do it but there is no other choice.* (Eloise, mother of a child with autism who elected to travel to Mexico for a stem cell treatment)

As perhaps the most visible aspect of an increasingly global healthcare market, medical tourism would seem to epitomise the 'consumer choice' of free-market capitalism and everything that is seen to entail—namely, self-determination via freedom to decide treatments and travel, freedom of mobility, and the consumption of products and services that are 'personalised'. In societies governed by neoliberal philosophies and policies, 'freedom of choice' has strong appeal, suggesting the absence of personal constraint or self-control over one's circumstances and destiny. But what does 'choice' mean for patients and their carers in contexts where there are few or no clinically proven treatment options available to them, or where options that are presented are perceived as equally undesirable or unaffordable?

This chapter explores the paradoxes of 'choice' in the global market of clinically unproven treatments, pointing to their profound personal

A. Petersen et al., *Stem Cell Tourism and the Political Economy of Hope*, Health, Technology and Society,
DOI 10.1057/978-1-137-47043-0_2

and sociopolitical implications. Focusing on typical critical junctures in the treatment journeys of patients and carers of patients (partners or children), this chapter discusses the nature of these paradoxes and how they arise from the context in which citizens are compelled to choose and yet are confronted with various constraints—biophysical (associated with the condition itself), medical (the lack of locally available treatment options), ideological (belief in the promises of new technologies), financial (family resources), and informational (about the efficacy and safety of new clinically unproven treatments and the trustworthiness of those who market them). We argue, in light of these paradoxes, that the promised 'choice' in neoliberal global healthcare is largely illusory and calls for an investment of trust in those whose claims are difficult, if not impossible to verify. We conclude that revealing the paradoxes of 'choice' and their implications is a necessary first step in developing forms of governance for unproven treatments that are attentive to the conditions of contemporary healthcare. However, before embarking on the details of our argument, we should first elaborate on 'choice' and its paradoxes.

'Choice' and Its Paradoxes in Global Healthcare

As explained in Chap. 1, the discourse of choice looms large in contemporary healthcare, as it does in many other spheres of social and economic life. Terms such as 'freedom to choose', 'freedom of choice', 'informed choice', and 'empowerment through choice' permeate government policy statements and programs (Nordgren 2010). In the healthcare field, one can find examples of the deployment of the language of choice, in policies pertaining to the development and introduction of new technologies (e.g. genetic tests) into clinics and hospitals, in the online advertising materials of those selling the numerous medical products and services available in the healthcare marketplace, and in web-based patient forums organised around disease-specific conditions. The allure of 'choice' is significant and provides the explicit or implicit rationale for numerous initiatives. However, as Annemarie Mol (2008) has argued, 'continuing to emphasise patient choice will not bring about the improvements hoped for' in healthcare. Indeed, the logic of choice, which assumes autonomous

action by an idealised individual actor (an assumed white Western educated male), may come into direct conflict with the logic of care, which includes a complex array of social practices and interventions (including 'cure') (2008: 1–15). When it comes to stem cell interventions, we suggest that what is promised by the discourse of choice, namely, the power to decide on a course of action or select from various clearly defined options with known outcomes, cannot be delivered.

As Rose (1999) observes, choice and freedom are integral to the analytics of power in contemporary societies: individuals are *obliged* to be choosers, with 'freedom' being defined by the capacity to choose, and further, in exercising such 'choice', individuals as responsible citizens are called upon to align their personal actions with wider social goals. In short, 'choice', the implied domain of unconstrained, self-directed action, is subject to intense governance, with citizens expected to express their agency ('empowerment') in prescribed ways towards predefined ends. Evidence of this can be found in various policy arenas where 'choice architects' (Thaler and Sunstein 2009) have developed mechanisms for making 'choices easy' for citizens through paternalistic means. The philosophy of 'libertarian paternalism', that has gained salience in many policy communities in recent years, suggests that individuals should remain 'free to choose', but 'nudged' in directions that will make their lives better, easier and healthier, and thus, ultimately contribute to the fulfilment of wider economic and social objectives. This 'nudging' includes the use of technologies and changes in the physical environment, the use of feedback mechanisms to remind users of when things are 'going wrong' or about to go wrong, the use of incentives of various kinds (e.g. often economic-based) to guide behaviours, and the employment of default options in health insurance and superannuation schemes to ensure that personal actions are in accordance with what are assumed to be citizens' 'best interests' (Thaler and Sunstein 2009: 5–6, 11–12, 96–100).

In the sphere of health promotion and public health, 'nudging' may entail prescriptions regarding 'healthy' diets and 'correct' levels of exercise, safe sexual practices, and so on, as well as associated rewards (e.g. discounts on health insurance) and punishments for those adopting 'unhealthy' practices; for example, taxes on 'fatty' foods and cigarettes. The assumption is that by 'making healthy choices easy' or 'unhealthy

choices difficult' individuals will play their part in creating 'healthier', more productive, economically efficient societies. Similarly, in the healthcare arena, choice architects seek to guide behaviours in predetermined ways, to use tests, treatments, and services that are deemed to be in accordance with the broader social and economic good. For example, state-subsidised medicines (in Australia, via the Pharmaceutical Benefits Scheme) cover only certain prescribed medicines deemed to be safe and effective and to produce optimal health outcomes and fulfil economic objectives (PBS 2015). Citizens may purchase non-subsidised medicines, but the costs will be fully borne by the individual. Similarly, citizens may undertake clinically unproven treatments, but carry the burden of risks, both financial and physical.

The emergence of global healthcare, whereby the nation state and geography play a less significant role than in the past, presents a unique set of challenges for state-based choice architects who seek to steer citizens' conduct along 'healthy', risk-averse consumption paths. In this context, the 'health consumer' has been 'responsibilised' in ways that may lead citizens to undertake actions that are contrary to those suggested or approved by authorised state-based experts and agencies. The term responsibilisation has been used by scholars to convey 'the process whereby subjects are rendered individually responsible for a task which previously would have been the duty of another—usually a state agency—or would not have been recognized as a responsibility at all' (O'Malley 2009). This responsibilisation manifests in many spheres of social life, but is perhaps most evident in fields where state agencies previously had almost exclusive or primary responsibility, such as healthcare. While in many countries, citizens continue to look to the state to provide for basic healthcare, including hospital care and expert advice on health and risk, responsibilisation in a neoliberal context implies greater attention to self-care and increased reliance on market-based mechanisms and solutions; for example, the use of public-private partnerships and competitive tendering or the 'outsourcing' or downsizing of services.

A number of trends in policies and technologies have converged to engender responsibilisation in healthcare, especially as it shapes patients' decisions involving medical travel and the consumption of experimental treatments such as stem cell treatments. These include the globalisation of

markets enabled by deregulatory policies (e.g. international trade agreements) and the associated competitive pressures (seen in the marketing of nations or regions as medical tourism 'hubs') (Chap. 1); the advent of the internet and social media; increasing healthcare costs in developed economies combined with the provision of relatively cheap healthcare in emerging economies; efforts by insurers in some jurisdictions to promote cross-border medical travel to reduce their costs (particularly evident in the USA); the growing commodification of the body and health; and the emergence of new markets oriented to the perceived relatively wealthy 'baby boomer' population. This trend can be seen, for example, in the marketing and use of self-monitoring devices and bodily enhancements (e.g. cosmetic treatments), attention to risk factors (e.g. diets, levels of exercise), efforts to increase risk literacy (Gigerenzer 2014), and the growing incidence of 'health anxiety' (Petersen 2015). It is in this healthcare context that health and medical tourism has flourished, with a new array of non-state actors endeavouring to steer 'consumers' along potentially profitable paths by exploiting the optimism surrounding biomedical technologies and packaging treatments and services via the language of personalisation and choice.

These actors include those who manufacture, provide, and market alleged medical products and services directly to consumers via the internet. New, user-generated social media profoundly challenge the established notion of 'the expert', with patients increasingly becoming experts of their own conditions and establishing their own disease-specific communities bound by commonalities of experience and sentiments of hope. Patients may advocate for or even sponsor research ('patient-driven' research; e.g. PatientsLikeMe), engage in fundraising (e.g. GoFundMe), and gain access to treatments not available to them in their home country irrespective of authorities' claims about their physical and financial risks (Petersen et al. 2015a). Further, marketers address citizens as 'informed consumers' capable of exercising autonomous 'choice' in the market of medical treatments and services.

Online advertising conveys unlimited options for health, bodily enhancement, and reproduction—that is, a significant level of control over life itself—for those with sufficient resources and 'will power'. Such advertising, which employs techniques enabled or facilitated by new

media to promote products and services directly to consumers, are integral to what is now an increasingly interconnected global healthcare marketplace. This marketplace is one where patients and providers are highly mobile and seemingly unconstrained by time and place, using technologies and services that were, until relatively recently, unimaginable to the majority of citizens. These include treatments that promise to regenerate diseased and disabled bodies and reconstruct or enhance already healthy bodies, as well as surrogacy services for those unable to conceive.

The use of the language of choice and personalisation can be readily found in the marketing materials of stem cell treatment providers. As outlined in Chap. 1, currently, stem cell treatment options that are *clinically proven* (i.e. part of routine care usually shown to be safe and effective according to biomedicine's 'gold standard' evidence of the randomised control trial) are few, being limited to the use of bone marrow or haematopoietic (blood) stem cell transplants to build a blood or immune system for the treatment of certain conditions (e.g. leukaemia, lymphoma), and corneal and skin grafting (Daley 2012). Nevertheless, numerous providers throughout the world have advertised stem cell treatments directly to consumers via the internet for a range of chronic conditions, including multiple sclerosis, cerebral palsy, macular degeneration, spinal cord injury, and Alzheimer's disease. Advertisements offer little or no readily verifiable evidence, instead making their appeal via the language of hope and choice, and relying heavily on the use of patient testimonials that directly address consumers as individuals with specific needs (Lau et al. 2008; Petersen and Seear 2011). Like all advertisements, they use often-subtle, well-established techniques of persuasion to attract 'consumers'—crucially, patients' stories of successful treatments that speak directly to readers, and also strong visual imagery conveying clinical competency, cleanliness, and efficiency, often along with links explaining procedures, expertise, news and events, and 'contact' details so that providers may get back to those contemplating treatments. In short, such advertisements seek to engender confidence and trust by conveying competence, professionalism, and attention to users' personal needs. While for some, these advertisements evidently have strong appeal, as we show, making reference to individuals' accounts of their treatment decisions, the practices of 'choice' are more complex and ambiguous than is generally supposed,

being shaped by various factors, raising significant questions for authorities who seek to achieve a balance between advancing translation of promising technology and regulating the risks of novel interventions.

Critical Junctures in Decision-Making

The interviews with Australian patients and carers, which are the focus of this chapter (and Chap. 4), explored patients' experiences of treatments, including the events leading up to individuals' decisions to undertake or not undertake treatments at the time of the interview, sources of information, and the factors shaping decisions about treatments and destinations. As noted (Chap. 1), those who had travelled overseas to receive treatments visited clinics in various countries, including China, India, Thailand, Israel, Germany, Panama, Mexico and the USA; however, two travelled interstate in Australia to receive autologous stem cell treatments, one of whom also received treatment in Thailand. In this chapter, we discuss patients' and carers' accounts of their experiences at critical junctures of their decision-making, highlighting how the discourse of choice is manifest in the expression and experience of the path to treatment or non-treatment.

Individuals generally presented themselves as having undertaken treatment decisions that were well considered in light of the information available to them at the time, in some cases, using the language of choice. Like other communities that navigate a range of intermediaries to address their health needs, they endeavoured to learn about their options through online research for information and advice from other sources (Wathen et al. 2008) and, in the main, can be said to have adopted what may be described as an optimistic outlook. Confirming the findings of our earlier work, references to 'hope' were common in stories of treatment decisions (Petersen et al. 2014). Of course, our sample, being self-selected, likely reflects the views of those who are especially active and optimistic in regard to exploring treatment options. Some mentioned that they were interested in participating because they saw it as an opportunity to increase awareness of the plight of those suffering their condition or of the benefits of stem cell treatments. We know relatively little about those patients and carers who are less active and/or are pessimistic or who had poor outcomes

from treatment, apart from one young man who reported complications post-treatment. Several patients and carers reported disappointment and/or frustration with the lack of improvement post-treatment. We also noted some negative comments from patients during joint media appearances. It may be that some do not continue to explore options due to physical, mental, financial, or other reasons. Some individuals had decided *not* to proceed with a stem cell treatment, with a number expressing scepticism about such treatments or adopting a 'wait and see' approach. However, for virtually all, 'doing nothing' was not an option. Thus, even the 'non-travellers' continued to explore options, as we discuss below.

In any event, as individuals' accounts revealed, treatment decisions were rarely arrived at via a rational 'weighing up' of various options or undertaking a risk-benefit analysis at a fixed point in time—the ideal 'informed choice' described or implied in the expert literature—but rather were evidently shaped by a complex interplay of various factors over an often-extensive period of time. These factors included the accumulation of knowledge of treatment options in Australia and overseas, gained through a combination of online research, personal contact with providers (generally by email or travelling to their clinic or hospital) and/or third-person accounts; the reactions and circumstances of family, friends, and other personally significant individuals (e.g. trusted doctors); the character of one's illness or disability and previous encounters with healthcare; practical considerations like work commitments, and financial ability to pay for the treatment and travel. For many, chance encounters (e.g. with other patients) or those orchestrated by treatment providers and/or actively pursued by patients/carers via online networks, and/or impressionistic information or 'gut feeling' were among the factors cited as playing a role in decisions. Some claimed to not want to know about the details of the treatment they were undertaking, but rather simply trusted that this would benefit them. For all, decisions were informed by the perceived technological options and the belief that new biomedical technologies *could* improve lives. This strong attachment of individual hopes to purportedly promising technologies, we suggest, helps account for why patients and carers may travel overseas for treatments that are deemed by authorities to be 'experimental' or 'clinically unproven', and hence, potentially of no benefit or 'risky'.

The following paragraphs identify some recurring themes in patients' and carers' accounts of how and when they arrived at their decisions, what we describe as 'critical junctures' or key decision points on the path to treatment or non-treatment. While the reported timing and confluence of events that defined these junctures varied for individuals, sometimes considerably, each juncture can be seen to have been shaped by a distinctive architecture of 'choice' that shaped the perceived options. We begin with the immediate aftermath of what is experienced as the most critical point for most patients; namely, diagnosis.

The Immediate Aftermath of Diagnosis

> Like basically, when you get the diagnosis here, it's kind of like, 'Oh, here's the diagnosis. Speech therapy. OT [occupational therapy]', and that's it. And it kind of gives you, there's no, that's all. It's like they've given you, that's all your choices are. That's all that you can do and you have to just leave it at that, basically. And I was like, 'Well no, there's got to be something.'
>
> (Eloise, mother of a child with autism who elected to travel to Mexico)

By their accounts, patients and carers tended to embark on the search for information, about the condition itself and about treatment options, very soon after diagnosis, and often in the absence of definitive expert advice. Ivan, a father-carer of a child with cerebral palsy, articulated a commonly expressed view; namely, that 'no one gave us any real direction so we sort of had to do all the research ourselves'. Research can be long and tortuous, spanning in some cases a period of years, and take individuals and their families down numerous avenues, and sometimes 'blind alleys'. Their post-diagnostic experience is thus in many respects similar to that of other patients, such as those suffering genetic conditions, long reported in the literature (e.g. Bury 1982; Charmaz 2000; Petersen 2006). However, the rise of the internet and social media, along with the burgeoning number of online resources, has radically changed the architecture of 'choice'. During their investigations, patients and carers encounter an array of online resources, found primarily via search engines such as Google, and information provided by disease-specific patient communities, individual patients and their families, as well as

information offered by providers on their websites. A number mentioned the importance of Facebook for sharing information, and YouTube videos and blogs for finding relevant sources. Through these avenues, and invariably after being advised of their limited options by their treating doctors after diagnosis, individuals soon came to the realisation that their options for proven treatment in Australia were limited or non-existent.

The nature of the condition and the prognosis constrain options and the potential and urgency to pursue those that are available. Individuals who embark on a stem cell treatment are in most cases struggling with severe, life-limiting conditions (e.g. spinal cord injury, motor neurone disease, multiple sclerosis, cerebral palsy), some terminal and, for many, time is of the essence. As one patient, Greg, with a progress degenerative neurological disease affecting movement, explained in relation to his decision to pursue stem cell treatment in China: 'If you're in a condition like mine or cancer … you will try these sorts of things. If you haven't got a condition like that you tend to be more sceptical.' As he reasoned, stem cell treatment 'seemed to have more going for it' than 'the whole range of things out there' and, as they were financially able to undertake treatment, 'Well, why not try it now while I can?'. At least in one case, an element of pragmatism played a role in the decision to undertake stem cell treatment. Parents of a child with cerebral palsy, Ivan (above) and Vlasta, said they had explored and tried various therapies and hoped that stem cell therapy would offer something different—a 'sort of more attractive way of try and give him a little boost'—thereby obviating the need for intensive, time-consuming daily therapy. As they explained, 'We're very busy people and running [a] business, and we have very little time to ourselves'. This pragmatism also appeared to be a factor in their decision to take their child for treatment in Germany and China, as we shall see later.

In their search for options, some individuals experimented with diets and complementary and alternative therapies. Two interviewees—a patient with multiple sclerosis and a mother-carer of a child with autism—mentioned that their research had uncovered the role of nutrition, which had led them to exclude gluten and dairy from their diet, which they felt had resulted in improvements in health. In the latter case, as in a number of others, stem cell treatment was seen as *additional* to rather than supplanting complementary and alternative therapies—as one of an array of options that was seen as worth exploring. For some participants, clinics that were

offering treatment 'packages', which included a range of therapies beyond biomedicine (i.e. acupuncture, massage, traditional Chinese medicine) in addition to stem cells, were particularly attractive and influenced their decision of where to travel.

The Perception of 'No Choice'

The lack of stem cell treatment options in Australia was often cited as being crucial in the decision to travel overseas. Many individuals commented or implied that stem cell treatment *should* have been available to them in Australia and, since it was not, they felt that they had 'no choice' but to seek treatment overseas. One carer, Donna, whose partner suffered a rare neurological condition, when asked about the benefits for people travelling overseas for stem cell treatments, responded: 'Well you can't get it here so you don't really have a choice. If you want to try it … well you don't have a choice'. A patient who had spinal cord injury, Axel, expressed similar sentiments when explaining the treatment challenges confronting those in his community: 'If there's no treatment available in Australia now and there won't be for a long time … we've got no choice but to go overseas to get treatment in the future.' Indeed, some described feeling 'desperate' about their situation, underlining the anguish that they experienced. As we explain, this sense of abandonment, loss of hope and/or desperation does not always lead to the decision to pursue treatment; however, for virtually all, this perceived hopelessness and limited options or 'no choice' in Australia defined the context within which decisions were made.

Experiences of Doctors

Confirming our earlier research, individuals often recounted feeling abandoned by their doctors and being offered 'no hope' (Petersen et al. 2014). However, among patients and carers, a range of responses from doctors was noted, ranging from indifference and equivocation to support. For example, Philip, a parent-carer, whose child was diagnosed with autism and suffered problems with his motor skills following birth, said their doctor commented: 'Well, it's not practiced in Australia and I can't comment. I wouldn't say go and I wouldn't say not.' However, one doctor

'we had seen a few years back' told him and his wife: 'Look, he said, it's not, not done here but, from all of my reading, it would really help a child like [my child] because it will help the brain to regenerate and, and to make new pathways, and that's what [he] needs to, to go further with his development.' Those who advise on stem cell treatments have been found to be reluctant to be directive in their communications with patients and carers, preferring rather to 'manage hope', despite the concerns of many about the risks of unproven treatments (Petersen et al. 2015b), as we discuss in the next chapter (Chap. 3).

The Significance of Other Patients' Personal Stories

In coming to their decisions, our individuals especially valued other patients' personal stories of treatments, as found on Facebook pages or on providers' webpages or gained via personal contact. A number indicated that they generally valued these views above those of their doctors. As Greg, a patient suffering a progressive degenerative disease (mentioned earlier), said, he learnt about stem cell treatments from his carpet cleaner who suffered a similar condition. Although this person had not undertaken a stem cell treatment himself—Greg suggested that he was likely unable to afford the expensive treatment given his relatively young age—he sent Greg a link to a site in China which he then investigated and travelled to for his treatment. When asked how he came to decide on the particular clinic to attend, he said that 'I wasn't really aware of others', which suggests that Greg relied solely on the informal advice that he had received.

Such stories, which often included optimistic narratives about treatments or providers as well as accounts of dissatisfaction with their Australian doctors and other health professionals, would seem to have played a crucial role in many treatment decisions. This was the case for Stephen who travelled to Germany for treatment soon after leaving rehabilitation for spinal cord injury. He described his experience of care in Australia and subsequent lack of confidence in medical professionals:

> Obviously they allocate you a doctor when you have a spinal cord injury, whoever looks after your fracture, whoever it may be. I didn't see that

> doctor once. Yeah, so I didn't even see the person that was supposed to have looked after me or took interest in me from day dot. So I didn't really have respect for anyone because there was no-one that was really looking after me.

Another factor influencing Stephen's decision to travel was the professionalism of the provider's website, which included anecdotal reports of recovery of bladder and other functions ('that's the clincher for sure'). Bruce, also with a spinal cord injury who had travelled twice to Germany for treatment and was planning a third trip, described the profound importance of speaking to other patients about their experiences in deciding if and where to travel for treatment:

> [I said to the clinic] 'Well I want a list of your patients that you've done stem cell surgery on. I want to know and I want to talk to them … face-to-face.' … So we got a whole handful [of contacts] and some it didn't work for, and some it did…. The guy we got most excited about was a C3, 4 and 5 incomplete [quadriplegic]. He now runs in half marathons [and we spoke via] phone and email. Phone and email. I was prepared to fly him over at one stage but by that stage we'd already decided [to travel].

David, who cared for his wife who had Parkinson's disease, said his wife had made contact with another patient through Parkinson's conferences who had been in touch with a clinic in China and was 'very impressed with their replies'. He said he 'then started to contact the clinic with emails, etc., and actually I was quite impressed with the way I'd get immediate replies and the … standard of English that was … portrayed in the emails. And I thought, "Well this sounds … pretty good"'. After reading material on the clinic's website and discovering that the doctor had published a number of articles in medical journals they decided to proceed with treatment. The couple were planning to take a cruise which finished in Hong Kong and they reasoned that, as it was 'only a two-and-a-half-hour flight to Beijing', 'we'll take the opportunity'.

As these accounts reveal, chance encounters and third-party recommendations may be crucial in orienting patients towards undertaking a stem cell treatment in a particular country, underlining the social negotiation of

decisions that tend to be seen as 'purely personal'. Further, they highlight the significance of sentiments of trust—typically, as in these cases, in other patients who offer information or advice and in the material presented on providers' websites. Individuals' comments, such as those of Stephen, above, suggested that that they tended not to invest this same level of trust in their Australian doctors. For example, Nicole, a mother-carer of a child with cerebral palsy who had considered travelling to Mexico for a stem cell treatment but decided against it, commented, 'I absolutely respect the doctors' opinions but I'm also inclined to put a lot of weight on what some parents say'. She added that other parents and they know their children better than doctors, and that 'we can pick something three weeks before the doctor can confirm it…. We know exactly what's going on with our child.' This implicit investment of trust in third parties, especially other patients, was apparent in many individuals' accounts.

They often said that learning about other patients' positive experiences of treatments gave them hope and confidence to pursue their own treatment. For example, Donna (referred to earlier), whose husband had a rare neurological condition, commented:

> I phoned a very close friend of ours who had a brain tumour removed and she went on to have a stem cell therapy and six weeks later she was absolutely amazing and [she] told me about it and I phoned the hospital and they said, no, they only did it for brain tumours, they didn't do it across the board. And then I had another friend who had myeloma and he just had stem cell therapy and she just came out of it wonderfully—eighty percent better than she was. There's no guarantee that…it won't come back, but she is just wonderful and she has just had twelve months of hell and you kind of hear these stories and you think it's worth trying.

This particular patient decided to seek treatment in Germany rather than Asia, which they had considered—a decision she said had been influenced by a chance meeting with a patient at her husband's chiropractic clinic who claimed to have had success with stem cell treatment there. As noted, such chance meetings were commonly reported. This particular exchange also illustrates that the decision to pursue a stem cell treatment can be based on the experience of others with completely unrelated medical conditions.

Community Support and Fund-Raising

An ability to pay for treatment, often enabled by community support, was a crucial factor in travel decisions. As Donna noted, treatments can be expensive and 'although we're not rich … we were able to do it'. She and her partner had paid $AU26,000 in total, including two tickets for the airfare. Many travellers, consequently, had to raise funds, often through community efforts. One individual, Jackie (partner of Philip, above, and the carer of a child with autism) was assisted in her travels to China for treatment through community fundraising efforts. As Jackie noted, 'a lot of people … were quite interested and most people really didn't know much about it [the treatment]. Everyone was supportive and we did fundraising to get [child's name] there.' They mentioned that they had raised $AU45,000 from community fundraising and that they 'had a walk and 700 turned up' as well as 'an auction night' which 'raised another $AU15,000'. Support was also offered by the local newspaper which gave front-page attention to the case. Overall costs of treatment varied, depending on the condition, the clinic, the number of treatments, and whether patients were accompanied by carers; accommodation costs were additional if in-patient stays were not sold as part of the treatment package. Such fundraising, which we also found in our earlier work, underlines the often high level of community approval and assistance for such treatment (Petersen et al. 2014: 677), and has the potential to further engender positive outlooks and carries the risk of shame for the patient and their family if the treatment does not provide the expected benefits.

The Experiences of 'Non-Travellers'

> I think, at some point, especially early on, you're ready to grab at anything that can help you. And sometimes you can be blinded by the light I suppose, of the hopeful light at the end of the tunnel and not look at everything.
>
> (Sean, who researched stem cell treatments for a spinal cord injury)

The 'non-travellers' expressed similar frustrations to the 'travellers' in regard to stem cell treatments not being available in Australia and, like

the latter, actively sought to inform themselves about options via the internet and other sources. Many maintained contact with a clinic, but some were turned off by requests for money in early communications or a lack of information. Other facts cited as shaping decisions not to proceed with stem cell treatment included lack of family support; the financial cost; 'uncertainty about where to go for treatment'; and which stem cell therapy was best for their condition. Some patients and/or carers were simply waiting for development of the science or evidence from clinical trials on stem cell therapies. Whilst the costs for a small few were prohibitive, none of our participants described their decision not to pursue treatment as solely due to their inability to raise funds. Rather, for people who had decided not to travel, considerations of cost invariably occurred alongside concerns over the lack of evidence of effectiveness, and the potential of harm, that was most often articulated as the unknown risks experimental treatments potentially posed in reducing what 'quality of life' they had. The notion that one should 'do all you can for your health' to improve your 'quality of life' irrespective of cost was nonetheless a strong theme woven through both travellers and non-travellers accounts of their decision-making processes. As Gwen, a young woman with multiple sclerosis explained:

> I'm happy to take some money from my future to put into my present for my conceivable better future and quality of life…. The expectation and positive outcome [of stem cell treatments] would be a quality of life, of everyday life. The relief of symptoms and just a basic quality of … overall life. It's not the quantity of life that you learn to realise that when you do get a condition. It's definitely the quality.

Significantly, decisions about whether or not to travel all pivoted on whether treatments were conceived as either potentially reducing or improving 'quality of life', with cost featuring as a prohibitive factor only when participants were not convinced of either the evidence of benefits or risk of harm. As Janine, who researched stem cell treatments for optic nerve damage and reduced vision, explained:

> I mean your health, first and foremost, your health is the most important but, you know, the financial implications … I mean that's a huge, that's a

> lot of money … you wouldn't get a lot of change out of $AU30,000…. The reason that it's holding me back is because I don't want to do anything that's going to make things worse.

Concerns about what providers were actually offering were also expressed. When explaining his reasons for not travelling overseas for stem cell treatment after fourteen years of research on the issue, Axel, the aforementioned patient with spinal cord injury, replied:

> I don't think it was open and transparent. You couldn't really tell what was actually being done to you and what they were actually applying to you. You wouldn't even know what stem cells they are really. And, and the evidence wasn't there. I'm not saying you need a working base evidence to make a decision 'cause anecdotal can be quite persuasive sometimes. And, ... really for me I don't think we're there for a full evidence-based opportunity yet…. So really I haven't seen the evidence yet, enough evidence to persuade me to make a decision to go. It's a big decision.

He acknowledged the difficulties of assessing treatments being offered in other countries with one's own country's standards of evidence. As he noted, 'Just 'cause it's not the same way a lot of countries in the world do it doesn't mean that no-one's really got onto it. 'Cause in China, you know, India, they do things differently. Doesn't mean they do it wrong; they just do it differently, you know.' This individual went on to explain that, for him, there were both 'risks for me going but also risks for me doing nothing and sitting on my bum'. He elaborated on his dilemma: the potential impact on his family of a failed treatment that would make his situation worse, and of having to return to the use of ventilator, which he was on for six months after his injury, as well as the cost and creating unrealistic expectations for his wife and children.

It is evident from some of the accounts that patients and carers had often undertaken considerable research, some showing familiarity with scientific terms and developments in the field of stem cell science (for example, citing 'success' rates for particular treatments)—which may explain their hesitation in seeking treatment. One especially sceptical participant, a carer of a boy with paraplegia, Alistair, referred to their

experience with a 'charlatan' in the USA and offered to send us correspondence they had had with them and their website details. He commented:

> My experience is worthy of being aired on the *60 Minutes* television program in my opinion. This would really convince people not to pursue these totally useless stem cell cures overseas.

Like Alistair, most participants who had decided not to travel for treatment had had their suspicions raised after contacting providers at some point. For Louise, whose partner had been diagnosed with motor neurone disease three months earlier, there were a number of 'huge alarm bells'. These included feeling 'intimidated' by one provider into skyping with him and not contacting other medical facilities he was citing to legitimate his own practice, and the speed at which some providers reached out to them after sending a request for information. As Louise commented, 'it does go back to money being part of that whole alarm bell ringing stuff'.

For many non-travellers, the decision not to travel, or to wait for clinical evidence of efficacy before doing so, was informed by the broader journey of illness post-diagnosis, where conceptualisations and understandings of what 'quality of life' meant to them and/or their loved ones had changed. As Louise, above, whose husband was recently diagnosed with motor neurone disease, explained:

> I'm thinking, 'What quality of life? He's not going to have a quality of life. He's got motor neurone disease. We're going to do anything we can to get him back to where he was.' And then, as you go along, you realise he does have quality of life. Okay, he can't walk, he can't run, you know, but, you know, apart from that…. You go from looking at what isn't there any longer to what is still there and you want to preserve that…. Well ultimately it comes down to quality of life and does that quality of life mean rushing around all over the world and creating more stress in your life? You know. Or does it mean just accepting that we can just sit and have a cup of tea, and potter in the garden, and that's quality of life for us, you know? So it comes down to that in the end, really.

Significantly, for all our participants, any re-orientation of what 'quality of life' meant was a difficult process and did not equate to 'giving up

hope' or being complacent about the search and investment in the possibility of future treatment options, including stem cell treatments. As Louise explained:

> We're going to see another neurologist who I feel has got passion and is up with the latest developments because, even though it might not happen in my husband's lifetime, we're still hoping that there'll be something that can give him at least some better quality of life. You know, if there's no real breakthroughs while he's still around, we just want to be on top of whatever is the latest, whether it be drug therapy or stem cell treatment. Whatever is available we want to be able to have access to it.

Not Wanting to Know Details of Treatment

While many patients and carers had evidently arrived at their treatment decision following considerable research, and in some cases, using technical terms that conveyed some understanding of what the stem cell treatment entailed, others claimed to *not* want to know the particulars of their treatment—instead adopting a stance of 'blissful ignorance'. One such case was Jenny, a sufferer of multiple sclerosis, who seemed to have gained some appreciation of what was involved in her treatment. When asked to elaborate on the details of her treatment, which she said entailed taking cells from her body and then taking her 'immune system down to zero', she explained:

> So, you have your chemo, it drags you down to zero then they give you this other BEAM [chemotherapy]… I'm not quite sure exactly how that [worked], …'cause I'll be perfectly honest: I didn't look it up step-by-step because, if I knew exactly what they were gonna do to me, I would chicken out… There was plenty of opportunities for me to view what procedures was gonna happen to me but I chose not to because I felt that I would approach each thing that was thrown at me with a clear head as best I could, and go, 'Well, I've chosen this road.'

While Jenny articulated her 'blissful ignorance' about the details of their treatment as a choice, and means of avoiding its fearful aspects, the comments of some other patients and carers suggest that they adopted a

similar stance in relation to the details of their treatment. Some travellers wished not to know the details, such as the provenance or manner of storage of the cells, or the safety of procedures. These patients and carers were evidently prepared to simply trust that procedures would do no harm, be of low or no risk, or simply leave them out of pocket. Some, such as Jenny, used a lay rationality of risk, as when asked whether she understood whether there was a risk of death: 'Yeah, 0.04 per cent, so it's more risk going to your letterbox, going to the local shop.' It is interesting to note here how the biophysical risk involved in treatment was downplayed by making reference to the risk associated with a mundane matter like a stroll to collect mail or a visit to the local shop—for Jenny, one of such small magnitude that it was evidently worth taking. Some of our participants also, counterintuitively, cited the few high profile cases of harm and death that have been caused by experimental stem cell treatments as evidence of the low risk associated with stem cell treatments. As Ivan, a parent with a child with cerebral palsy who accompanied his child to Germany and China, explained:

> One thing that I find very frustrating is, yes, there has been a child that died in Germany and they keep talking about this one, as far as you're aware, I mean how many actual instances of death related to stem cell therapy have you actually heard of? I mean we've only heard of two and everyone keeps talking about those two…. So there's a disconnect there between [advice that says] this is hugely risky and then the numbers in terms of the statistics of people that are actually being obviously critically hurt.

Our findings indicate that for travellers and non-travellers, the question of what constitutes 'evidence', 'risk' and 'harm' and their relative importance and significance in decision-making is open to interpretation and contestation according to the familial, medical and social context. This suggests that for those concerned with conveying information about the efficacy and safety of experimental treatments, the power of uncertainty and the protective value of 'blind-spots' for people in their decisions to undertake treatment and in their accounts of their experiences of treatment should not be underestimated. That many travellers do undertake,

and are encouraged by providers to undertake repeated treatments to purportedly maximise results is also significant in this context. For carers, and especially parents deciding whether their children should receive treatment, the perceived harms and risks of their loved one's illness/condition are primary considerations, with decisions to pursue treatment experienced as expressions of extreme love and care. As Donna, who accompanied her husband to Germany for treatment after he had been diagnosed with a degenerative neurological condition, explained, 'I would have gone to the ends of the earth to do anything for him'. Such subjective positioning, which involves both enormous sacrifices and investment in hope that the treatments will improve their loved one's quality of life, are potentially impossible to reconcile with interpretations that their actions expose their loved ones to extreme harm or risk. As parents Ivan and Vlasta explained, 'Having hope [in stem cell treatments] allows…us to give more love to our child'. Significantly, no individuals recounted undertaking a detailed 'weighing up' of the financial and physical benefits and risks of treatment—the kind of cost-benefit analysis implied by the concept of 'informed choice'. Instead, travellers and potential travellers must navigate the profound uncertainty that characterises the stem cell treatment market—about what is offered, about the benefits and risks of treatments, and about the competence, motives and trustworthiness of those who offer them. For many travellers, 'not knowing' in this context was an option embraced as part of their journeys and is a subject to which we return in Chap. 4.

Country of Destination

As with the decisions about the treatment itself, those concerning the country of destination are rarely based on a 'rational' consideration of the various 'pros' and 'cons' of all the options presented to them for the patient's condition at a fixed point in time. Impressionistic information, national/cultural stereotypes, and third-person accounts and hearsay evidently played a role in decisions. Again, in line with our earlier research (Petersen et al. 2014), convenience, English language proficiency, and confidence and trust in the providers played a role in decisions. Accounts

suggested that these decisions were partly shaped by existing biases in favour of or against particular countries or regions, which may be reinforced or sometimes challenged by early communications with providers, such as about what the treatment entailed.

A combination of factors was often evident in decisions to travel or not to travel to a particular country. For example, Stephen, who had a spinal cord injury, chose Germany above India for treatment which he had also considered, citing a range of factors in his decision, revealing the influence of national stereotypes, concerns about the quality of treatment, and pragmatic considerations. When asked, 'what was important to you in weighing up … a decision whether or not to travel?' he responded: 'Pretty much I think Germany 'cause obviously the Germans that do stuff there are obviously pretty adept at what they do. It was, you know, the European country where we were going looked … professional.' Stephen also said that he decided against India because 'you had to go for like three months which for me I had three kids as well. And so it put me off … a bit, and that it was embryonic stem cells, so I was like … didn't really know where they came from or whatever they may be.'

Regardless of their decision about the destination, individuals typically reasoned that what the preferred country offered was better than what was available or presented to them in Australia. Personal contact and providers' demonstration of receptiveness and empathy for the patient's or carer's concerns were commonly cited factors shaping decisions. For example, Jenny, above, said that she:

> Got in contact with [name of person] and also my partner had done research on the internet, and we found that [place in India] was a legitimate place to go. They answered all of our questions. I could ring them up. I could ring the neurologist on my phone and speak to him direct. Like, in Australia, you can't do that. There's just no way. So I would ring him and constantly question him, and ... it was a protocol that I needed to go through for my transplant. So they were doing exact same treatment but in a different country.

Vlasta and Ivan informed us that their first preference was to use autologous stem cells as they had heard that 'if the stem cells are not your own, that the body's immune system just kills them the moment they go in', and

that 'we were never going to consider going anywhere other than Europe or … America, or somewhere with medical facilities'. They first visited Germany for treatment and felt that their child had had 'quite significant improvements' which, while not matching their 'hope for a miracle', had encouraged them to continue stem cell treatment. However, after the closure of the German clinic in question, they considered other countries and decided on China after Ivan visited China for a work-related event which made them realise 'how much China had changed over the last five, ten years'. His account reveals how stereotypes of China as a 'third world country' had influenced his earlier views:

> And I always expected China to be, you know, guys with hats running around, pulling those little, what do you call them? Like in Bali and … you know, I … expected it to be a third world country. When I saw the facilities and the money, and the technology, I said, 'Look, you know, this is pretty safe'.

The parents had also made enquiries though a local cerebral palsy support group who put them in touch with a family who had travelled to China for stem cell treatment for their child who was also suffering cerebral palsy. After meeting the family and hearing positive stories—about their child's improvement and that 'it was a safe place to be in, and doctors were very careful'—they undertook further research and decided to travel to China the year after their visit to Germany.

In this case, as in others, the establishment of confidence and trust was crucial in the decision to travel—here, evidently achieved by the providers' demonstration of concern for the child and apparent thoroughness in the treatment regime, which inspired a sense of safety. As Vlasta explained, the doctors 'were very careful' in that 'before they would consider any treatment, they would double check and triple check…. They wouldn't even trust the parent with information….So, that sort of made us feel safe to be in their hands.' Ivan added, 'They even performed an MRI [magnetic resonance imaging scan] before we started any treatments just to see what state our [child's] brain is in.' An MRI was also contemplated by their Australian neurologist, but that would have entailed a general anaesthetic, whereas in China they 'just gave him a mild sedative', which the parents saw as 'non-invasive'.

In this particular case, practical considerations again played a role in the treatment decision. As Ivan noted, 'It was quick and easy whereas in [capital city in Australia] … it would have had to be planned ahead, general anaesthetic, recovery, this, that….' The couple said they returned to China six months later for a second infusion of stem cells from umbilical cord blood after having noted 'a lot of little improvements'. They said that they were at a 'crossroad', commenting that they were 'sitting back and trying to work out exactly what we want, what we should be doing, and now we're considering all the different stem cells and all the different things that are available.' They asked us whether we could suggest someone to assist them in answering their questions. Evidently recognising the biased nature of online information available to them, they commented that they were a 'bit over' searching the internet and felt that 'the main world-wide suppliers of stem cell products are monopolising … the search engines and their … rankings, and there's too much of them popping up instead of the sort of more medical and forum-based information.'

Conclusion

Our analysis highlights the complex, paradoxical character of 'choice' in relation to treatments marketed internationally that are experimental yet seem to offer patients and carers that which they believe they have been denied in Australia; namely, 'hope'. Neoliberal healthcare promises 'empowerment through choice' via the consumption of what appears to be a vast and growing array of technological options. However, for those with severe, life-threatening and life-limiting conditions, the *clinically proven* treatment options are often restricted or non-existent. However, responsibilisation in health implies that individuals *should*, as a duty of citizenship, explore all options, including those advertised as being available outside their home country. As we noted, many individuals felt that they had 'no choice' but to travel abroad for stem cell treatment. It is in this context of limited conventional treatment options in Australia that many patients decide to embark on treatments that are seen as promising and offering 'hope'.

Individuals' accounts of their decisions regarding stem cell treatments overseas revealed the interplay of a complex array of factors shaping thinking and actions over time, including accumulated knowledge of treatments, chance encounters, third person recommendations, and engagement with the providers themselves. Rather than decisions being arrived at via a 'rational' 'weighing up' of options and known benefits and risks at a fixed point in time, as portrayed by the ideal of 'informed choice', they were made in a context of uncertainty and imperfect knowledge. It is in this context that patients and carers are likely to be receptive to positive stories about treatments and to invest their trust in those who are seen to offer so much. While, as noted, some may resist the imperative to pursue treatments, none escape the paradox of 'choice'; namely, the compulsion to decide between, on the one hand, 'no option' and, on the other, the prospect of undertaking treatments that are promising but offer no guarantee of a much better future.

This paradox brings into question some fundamental assumptions about individual rational action and agency that underlie existing regulatory responses to the provision of unproven treatments; namely, the ethical principles of respect for autonomy and 'informed choice' in regard to treatment options. The rise of global healthcare and the rise of active patienthood, along with new non-state-based actors who operate outside national regulatory borders, have meant that authorities have struggled to respond adequately to the provision of clinically unproven treatments such as stem cell treatments. Increasingly, providers, like patients, are mobile and can travel to exploit regulatory loopholes and grey areas, and gain leverage from the economy of hope surrounding new biomedical technologies, and yet be unaccountable for their claims and when patients suffer harm.

While we have no simple solutions to the socioethical and regulatory dilemmas posed by the paradoxes of 'choice', we suggest that an approach that acknowledges these paradoxes is a necessary initial step in developing forms of governance for unproven treatments that are attentive to the context of contemporary healthcare (Chap. 8). When 'doing nothing is no option', citizens need to be confident that 'doing something' will not lead them to undertake treatments that will in all likelihood be of little value and potentially inflict great harm. In the following chapter,

we consider how those charged with the responsibility of advising people about whether or not to travel for stem cell treatments negotiate these paradoxes in their communication with travellers and potential travellers. In so doing, we explore how those stakeholders on the other side of the 'bench and bedside' navigate the socioethical and regulatory dilemmas posed by the paradoxes of 'choice' through managing hope whilst also policing the boundaries of what constitutes evidence, science and non-science in the context of stem cells and global healthcare.

References

Bury, M. (1982). Chronic illness as biographical disruption. *Sociology of Health and Illness, 4*(2), 167–182.

Charmaz, K. (2000). Experiencing chronic illness. In G. L. Albrecht, R. Fitzpatrick, & S. C. Scrimshaw (Eds.), *Handbook of social studies in health and medicine* (pp. 277–292). London: Sage.

Daley, G. (2012). The promise and perils of stem cell therapeutics. *Cell Stem Cell, 10*(6), 740–749.

Gigerenzer, G. (2014). *Risk savvy: How to make good decisions*. London: Allen Lane.

Lau, D., Ogbogu, U., Taylor, B., Stafinski, T., et al. (2008). Stem cell clinics online: The direct-to-consumer portrayal of stem cell medicine. *Cell Stem Cell, 3*(6), 591–594.

Mol, A. (2008). *The logic of care: Health and the problem of patient choice*. Abingdon/New York: Routledge.

Nordgren, L. (2010). Mostly empty words: What the discourse of "choice" in healthcare does. *Journal of Health, Organisation and Management, 24*(2), 109–126.

O'Malley, P. (2009). Responsibilization. In A. Wakefield & J. Flemming (Eds.), *The Sage dictionary of policing* (p. 276). London/Thousand Oaks: Sage.

Petersen, A. (2006). The best experts: The narratives of those who have a genetic condition. *Social Science and Medicine, 63*, 32–42.

Petersen, A. (2015). *Hope in health: The socio-politics of optimism*. Basingstoke/New York: Palgrave Macmillan.

Petersen, A., & Seear, K. (2011). Technologies of hope: Techniques of the online advertising of stem cell treatments. *New Genetics and Society, 30*(4), 329–346.

Petersen, A., Seear, K., & Munsie, M. (2014). Therapeutic journeys: The hopeful travails of stem cell tourists. *Sociology of Health and Illness, 36*(5), 670–685.

Petersen, A., MacGregor, C., & Munsie, M. (2015a). Stem cell miracles or Russian roulette?: Patients' use of digital media to campaign for access to clinically unproven treatments. *Health, Risk and Society, 17*(7–8), 592–604.

Petersen, A., Tanner, C., & Munsie, M. (2015b). Between hope and evidence: How community advisors demarcate the boundary between legitimate and illegitimate stem cell treatments. *Health, 19*(2), 188–206.

Pharmaceutical Benefits Scheme. (2015). About the PBS. Australian Government Department of Health. http://m.pbs.gov.au/about-the-pbs.html. Accessed 26 Feb 2016.

Rose, N. (1999). *Powers of freedom: Reframing political thought*. Cambridge: Cambridge University Press.

Thaler, R. H., & Sunstein, C. R. (2009). *Nudge: Improving decisions about health, wealth and happiness*. London: Penguin.

Wathen, N., Wyatt, S., & Harris, R. (Eds.). (2008). *Mediating health information: The go-betweens in a changing socio-technical landscape*. Basingstoke: Palgrave Macmillan.

3

Managing Hope

> *Hope is something that we hold dear and we encourage patients to have hope that there will be a breakthrough or there will be cure.… And to have hopes dashed can be very difficult for families, friends to, to cope with.* (Michael, representative from Australian patient advocacy group, interviewed in 2012)

For many, medical research is synonymous with hope. Scientific advances are viewed as a pathway to a future free of the limitations imposed by disease, illness, ageing, or injury. Stem cell research in particular has been the focus for such hopes, offering a possible healthcare revolution where faulty or absent cells and organs could be replaced or regenerated, thereby restoring health and saving lives. Such hopes are held not only by those seeking a means to alleviate their suffering, or that of their loved ones, but also by the scientists and doctors who hope to be able to harness the potential of stem cells and bring new treatment options to the clinic.

The challenge of managing community expectation, and the need to keep such hopes in check with the actual progress of stem cell science, has long been recognised (Daley et al. 2003; Hyun et al. 2008). While numerous national and international organisations have attempted to address

A. Petersen et al., *Stem Cell Tourism and the Political Economy of Hope*, Health, Technology and Society,
DOI 10.1057/978-1-137-47043-0_3

this issue, most educational strategies have focused on providing the 'decision makers' with more, and some have argued possibly inadequate, information that is posted on websites or in dedicated handbooks that can be downloaded and read at leisure (Master et al. 2014) (See Table 3, Appendix). Although such resources can be useful for those contemplating a stem cell treatment, perhaps stoking scepticism about overly optimistic claims made by providers, written information is unlikely to be enough. What many want is someone to speak to about the 'evidence' they have discovered during their online research. But to whom can they turn?

Conventionally it has been medical practitioners, usually the local family doctor or maybe a specialist that they have been referred to, that patients would consult about their health options including experimental treatments. However, as we and others have observed, many patients considering stem cell treatment describe being thwarted in their attempts to engage their doctors due to a perceived lack of knowledge about this emerging area of medical research, or due to their doctor holding a position that firmly dismisses the option without having the opportunity to fully discuss with their patient why that might be so (Levine and Wolf 2012; Petersen et al. 2014). In the absence of what they view as adequate support, patients and their loved ones are then left on their own to seek advice from those in the community seen to be knowledgeable in stem cell research, such as a scientist mentioned in a newspaper article, or someone from a patient support group for the condition that they are researching. However, for these 'accidental' advisors—who are mostly not trained health professionals nor directly involved in the patient's care—responding to such enquiries can be a significant challenge. They can feel an obligation to respond to the often very personal, moving, and sometimes desperate enquiries despite what they may view as their inadequate training in the area of patient care. They may be concerned about the exaggerated claims of 'curative' treatment by the clinics and see the need to uphold scientific principles and evidence-based medical practice, yet also worry about not 'dashing' the hopes people place in stem cells and what they could mean in terms of new treatments. How these 'accidental' advisors view their role and those who approach them provides a fascinating opportunity to explore the 'management of hope' in the age of global healthcare and will be the focus of this chapter. To start, we will place the role of the 'accidental' advisors in context by discussing what

stem cell research may mean to Australians and what attempts have been made to bridge the expectations gap between what treatments are available now and what might be possible in the future.

Heightened Expectations

Numerous surveys conducted over the last decade in Australia have placed stem cell research as an area of biotechnology that is perceived as being the most likely to 'improve' our way of life with the least 'risk' (Ipsos Social Research 2013). While public expectation has remained high over this period, with over 90 per cent of those surveyed aware and supportive of 'stem cell' research, less than half felt that they knew enough about what was involved to explain the concept to a friend. To some extent, this heightened familiarity and acceptance in the Australian population can be attributed to the highly politicised debate that played out in Australia during early 2000s around whether it was acceptable, or indeed necessary, to use human embryos to isolate stem cells for medical research.

As was the case in many other jurisdictions around the globe following the discovery of human embryonic stem cells by American research in 1998, the public discourse in Australia focused on the source of stem cells (Lysaght and Kerridge 2012). Those opposed to the use of human embryos to obtain stem cells argued that such destructive research—as the human embryo is destroyed in the process of creating the stem cells—was 'unethical' and unnecessary when 'adult' stem cells appeared to offer an alternative. Countering this view, proponents for embryonic stem cell research emphasised that the embryos used for stem cell research would otherwise be discarded, as they were no longer required for infertility treatment. Some added that unlike adult stem cells that usually had a restricted ability to grow, embryonic stem cells could be rapidly expanded in the laboratory and could be coaxed to form any cell of the body making them an ideal source of possible replacement cells for currently incurable diseases and illnesses. This consequentialism theoretic, that 'the end justifies the means', was particularly prominent in Australia as contentious legislation was debated in federal and state parliaments. Among the arguments to allow permissive legislation was recognition that Australian

scientists were leaders in stem cell research, a position that needed to be protected. Australian researchers had already made discoveries about blood or haematopoietic stem cells that fundamentally changed how leukaemia and similar diseases were treated around the world. They had also made significant contributions to scientific understanding about other types of stem cells, including the second report of human embryonic stem cells (Trounson and Harvey 2008).

Although legislation to allow the use of human embryos in research was eventually passed in 2002 following a rare conscience vote in the federal parliament, the public debate had a significant impact on community expectation. Having heard about stem cell research and the prospect of life-saving discoveries, many Australians were now highly tuned to this area of medical research. Their interest was further tweaked in 2002 when the Australian Government awarded $AU100 million to form the Australian Stem Cell Centre (ASCC), a ten-year national initiative to nurture adult and embryonic stem cell research towards clinical therapies. In addition to being charged to accelerate Australian stem cell and regenerative medicine research, the ASCC also became the touchstone for community enquiries.

By 2007, the ASCC was routinely receiving over 400 enquires each year from patients and their carers, particularly in relation to experimental stem cell treatments being offered abroad. Indeed, anecdotal reports of patients contemplating and then deciding to travel long distances for reputed stem cell treatments was not restricted to Australia but rather was becoming a global concern. As noted (Chap. 1), the first news reports on 'stem cell tourism' began to appear around this time. In response to the 'stem cell tourism' phenomenon, organisations such as the International Society for Stem Cell Research (ISSCR) saw the need to set standards to delineate 'medical hucksters' selling unproven treatment, from 'responsible' efforts to develop new evidence-based treatments (Nelson 2008; Hyun et al. 2008). Encouraged by the ISSCR, the ASCC in conjunction with leading Australian patient advocacy groups, developed a patient handbook incorporating ISSCR's warnings but tailored to the local climate—*The Australian Stem Cell Centre Information Handbook: Stem Cell Therapies: Now and in the Future* (ASCC 2009; Nature Editorial 2010). While the provision of information via the ASCC Handbook (since

updated several times, most recently in 2015, and now known as *The Australian Stem Cell Handbook*) was seen as a helpful contribution to temper heightened community expectation in stem cell science, it was also recognised that the decision to travel or not was complex and not well documented nor understood.

It was around this time that our research collaboration was also formed. We recognised, that by linking scientists at the ASCC who were responding to patient enquires on a daily basis, with sociologists keen to understand the sociocultural dynamics of stem cell tourism, we would be in a unique position to examine this issue and the policy implications. In addition to wanting to capture the journey of Australian patients who sought treatment, we were eager to explore the experience of the 'accidental' advisor and how they responded to enquiries. In order to do so, we approached Australian researchers whom we knew were routinely contacted by the broader community due to their prominent public profile and asked them whether they would be willing to participate in our study ('researcher' and 'clinican-researcher'). We also invited representatives from leading Australian patient support groups for neurological conditions, congenital conditions, and acquired injuries, who routinely field enquires on a wide range of topics, including experimental treatments, to participate ('patient support'). While none of the 20 professionals we interviewed described themselves as 'advisors', each group had distinct roles and expertise that shaped their interactions and the context in which they received enquires (Chap. 1). Common to all was the heavy reliance on the use of scientific 'evidence' to draw a boundary between legitimate and illegitimate treatments (Petersen et al. 2015). As we will now discuss, this was particularly evident with respect to how the clinics and doctors offering treatments overseas were viewed.

Fringe Science

No matter their background, all of the advisors we spoke to expressed strong concerns about the providers and their motivations. Doctors and clinics offering this treatment were seen to be located at the margins of 'real' science with a lack of sound evidence to substantiate the claims

made about the nature, benefit, and safety of their proposed treatments. They also expressed concern about the lack of appropriate regulatory oversight of these practices. The following quote from Susan, a researcher, was a typical response—calling for transparency and full evaluation of possible interventions prior to making such treatments widely available:

> I have real concerns that this is preying on people at a point in time where they're very emotionally vulnerable, and offering them completely untested and unproven technologies, often without even telling them what they are doing, what cells they're injecting. I see very little scientific evidence that these treatments work and I also have great concerns that in many of the countries offering this to people that the development of the said technologies has not been monitored by a regulator, has not gone through standard clinical trials, and therefore has the very real risk not just of failing but of causing harm.

Echoing this point, Kerryn who worked in patient support commented:

> [T]here is actually very little evidence to suggest these stem cell treatments work and, until there is a proper, rigorous evidence behind this, it's something we would never recommend as an organisation, that's for sure.

While others also referred to the providers' questionable agenda and used disparaging terms such as 'dubious operators' offering 'snake oil' with 'unbridled enthusiasm for the miracle of stem cells which obviously is just unfounded', many also noted that the marketing of a 'miraculous' remedy without evidence is not restricted to stem cells. As Charles, a researcher, explained:

> People take all kinds of remedies for which there's no scientific basis. Stem cells isn't unique in this respect. When people are desperate, they fall victim to all sorts of chicanery. And it may be natural remedies, it may be all sorts of strange things … It [stem cell treatments] is just yet another manifestation of people wanting to believe in snake oil.

There is little doubt that 'stem cells' are a powerful marketing tool. As highlighted earlier, there is a heightened awareness in the community about the perceived benefits offered by this science but little deep understanding

about how these can be achieved. When asked whether those contemplating treatment were aware of what the treatment actually involved, Teresa, who worked for a patient support group, acknowledged that few may go beyond recognising the term:

> It [the term stem cell] gets thrown around, so … well carelessly or … it's not carelessly, really … it's quite a deliberate use of, of the jargon to, I suspect to bring an air of scientific-ness, for lack of a better word, to some of these less evidence-based therapies. But the language is so common in the media and on the web forums and things that I think a lot of people have heard it flitting around but have never actually investigated it to any depth, to realize what that might mean.

The overseas clinics were also viewed through cultural stereotypes, where the offshore providers were seen as offering 'dodgy stem cell treatments' in developing countries with different, that is lesser, ethical and regulatory standards (a theme we examine in greater detail in Chap. 6). As Donald, a clinician-researcher, explains when discussing the 'one-size fits all' stem cell practices abroad:

> But in those countries you can come with whatever disease, it's like a miracle thing and then you receive treatment and you're cured. From a medical perspective it's quite strange. Because [in Australia] first you have a diagnosis, then you design a therapy according to that diagnosis, and there you just come and everybody gets the same therapy and it works for everything. I think that's a typical Asian thing as well, with the wonder drug, curing everything.

However, others noted that being from a developing country was seen as an advantage by some people they spoke to. Rather than being backward, certain developing countries were seen as being on the vanguard of this and other technological developments that was not as restricted by bureaucracy—a sentiment passionately expressed by one treatment provider in China discussed in Chap. 6 who has explicitly moved from a Western country to take advantage of the perceived lack of bureaucracy. When discussing the frustration that some people express about the lack of treatments available to them in Australia, Damian, who works for a patient support group, commented:

> They say that the environment [in Australia is] too regulated … and also that doctors are set in their ways. And there's … a funny thing; it used to be the clever country but I think that Australians don't think that we're that clever. Straight away we think that Indians, because I think of this IT boom and you know like the, the third world nations emerging as, you know, clever and developing, and stuff—China and India, and Brazil, and stuff—they are including medicine in that as well. And they think that these Indians are onto something that, or these Chinese are onto something that Australia's just too slow which is why it's so costly to buy commodities that are so cheap to make. The same with care as well, medical care.

This perception of Australia being 'behind the times' was a familiar sentiment—and echoed findings from our earlier, smaller study (Petersen et al. 2014). However, as we will explore later in Chap. 7, the provision of stem cell treatments is now big business in Australia where a growing number of doctors are justifying the use of the patient's own cells—autologous therapies—as a legitimate form of medical innovation despite the lack of evidence to substantiate their claims (Munsie and Pera 2014; McLean et al. 2014). The fact that, for Australians, the treatments are now available 'at home', albeit only relatively recently, provides an aura of legitimacy to stem cell treatments, further complicating how these treatments are viewed by patients, doctors, and advisors.

Concerned About the High Cost of Hope

What was clear, however, was that all advisors questioned the motivation of overseas providers and questioned the high financial costs of these treatments, describing the clinics and those involved as being motivated 'just for money' and not interested in developing the science. When asked about various overseas clinics, Keith, a researcher, noted:

> [I]t's money-driven. Many of them are out to make a dollar and they don't really care about clinical outcomes. They're riding on the wave of promise. They ride on the wave of patient vulnerability. And they can make a dollar out of that—no doubt about it.

Many also raised the unknown but 'very real' costs that these yet to be proven treatments may pose to patient health, noting that possible risks differ depending on what type of stem cells are used and how the cells are prepared. As Charles, a researcher, elaborates, it is only through clinical research that the risks can be fully revealed:

> Yeah, there's a fair range of risk. Anytime you harvest cells there's a risk associated with the procedure of harvesting them, depending on where they're coming from. Anytime you manipulate cells outside of the body [you] risk contaminating them with pathogens. So there are very specific conditions under which these things should be done. If the cells are grown outside of the body for any length of time, there's the possibility they might accumulate genetic change; genetic change which might allow uncontrolled growth in the formation of a cancer. And, even if it's not a cancerous growth, if the cells grow inappropriately and they're put back in a patient, an inappropriate growth can have negative physiological properties. For instance, if … it was found from human experimentation that, if you graft skeletal muscle into the heart, it can cause arrhythmia in the heart muscle. You can get tumour formation. You can get simple growth and impingement on vital structures via the graft. So there's a whole range of negative outcomes that we have to concern ourselves when we're doing proper safety investigation.

Such risks weren't only seen as having dire health consequences for the individual, depending on the source of the cells, but also the potential to negatively impact the field of stem cell science and regenerative medicine, as Keith, a researcher, goes onto explain:

> Well … I guess the biggest problem is sometimes someone will get a treatment that really causes them damage and you will have heard this comment from everybody you've interviewed. That's the biggest, scary thing. Because, while it is terrible for the patient involved, it's also terrible for the whole field because it sets it back. As soon as there's a negative, as soon as there's a detrimental effect of stem cells, quite rightly the regulators will come in and say, 'Stop! What's causing all this?' And it'll set the field back years. So there's a massive risk in people going to these unregulated clinics. They're being ripped off. They get treatments that may have no logic at all. And

> they run the risk of damaging themselves, losing money and, and the negative effect on the whole, total field. I mean medicine's not based on magic.

While concerns were raised about the effect poor outcomes and related 'bad' publicity might have on the long-term development of the legitimate translation of clinical research, several advisors also commented that the stem cell community itself had substantially over-hyped the field, raising expectations that cannot be met. Murray, a researcher, noted, when commenting on the broader impact of claims of 'miraculous cures':

> I think that the reputation of the stem cell community is … more damaged, has been more damaged by the hype of … the stem cell community itself, in terms of getting public support … [S]aying that cures or treatments are, you know, five years away or 10 years away, I think people [scientists and doctors involved in basic research] will say a number like that and have no idea how long it takes, actually, to get something into a clinical trial and through the clinical trials process … it's basically a kind of a sales pitch out of ignorance. And that could have a bigger effect I think because it hypes it up too much.

As we now explore, such hype raises patient's hopes, a point frequently made by the advisors and the source of the most challenging issue for them, namely how they seek to manage such hopes.

Managers of Hope

Hope and the power it holds for patients and their loved ones was a strong recurring theme expressed by our advisors. It was often expressed that such hopes and the need to 'explore all options' including unproven stem cell treatment were understandable particularly for conditions where conventional medical care has little to offer. As Rohan, a clinician-researcher, commented:

> You've got MS … or you've got something and you're dying, I mean, or you're going to be in a wheelchair for the rest of your life, you would wish to explore all options. And not everyone is going to accept just because

> medical, people who are allegedly knowledgeable tell them it isn't going to work. I mean they don't want to lose hope, and that's an important aspect.

Interestingly, similar hopes are also expressed by providers who are offering unproven autologous stem cell treatments in Australia (Chap. 7). Many advisors acknowledged their own hopes for stem cell research but frequently expressed that real benefits are unlikely to be delivered until sometime into the future. While noting 'stem cells do epitomise hope for a lot' of people, Kerryn, who works for a patient support group, answered a rhetorical question about whether stem cell research is promising with:

> Yes, I do, but it's a long way from delivering. And I think it's … only fair to let our community know that there is hope, that it's what I'd call 'realistic hope'.

The opportunity to frankly discuss stem cell research with those who hope to benefit from it was one that some of the advisors especially embraced. For example, Dale, a clinician-researcher, commented:

> I feel very privileged that I … can bridge the gap between clinical and science, … to actually see patients keeps you honest because, at the end of the day, you have to be truthful and you have to also be realistic. And so yeah, I feel very privileged that I can sit down with people and … give them hope as well as trying to be realistic that there's, that it's still going to take time, and there's many unknown questions.

Such attempts to nurture 'realistic' hope were contrasted with the 'false' hope that was being raised, particularly in media coverage of stem cell science. When asked whether he had concerns about the promotion of unproven treatments, Shaun, a clinician-researcher, noted that,

> [I]t's way, way premature and very naughty and bad of these people to be indicating that there are treatments available. It gives people false hope and that is just not there yet. And unfortunately the media doesn't help.

The challenge of maintaining hope in future medical research but discouraging the pursuit of unproven treatment was often raised in relation

to the condition the patient was suffering from. For example, Barbara, a representative of a patient support group, expressed uncertainty about how she would respond placed in a situation where stem cell treatment appeared the only 'hope':

> I just don't know what I would do in, in their position. People dealing with these horrendous situations do really survive on small amounts of hope so, even if there's a very small percentage, that something, that even a small part of it might, might benefit, they'll, they'll pursue that. And I, I don't know if I can say that that's wrong to do that, even, you know, despite my enormous concerns.

Exactly how to effectively engage with those making enquiries was often mentioned. However, as Rohan, a clinician-researcher, acknowledged, 'some people will do their homework', and may decide to go anyway. When reflecting on a recent conversation, Teresa, who works in patient support, noted that while the patient mentioned that she had 'read all the literature' and 'looked at all the research' and acknowledged that 'it probably won't work', she still felt she had to 'do something':

> There's … on one level, a knowledge that there's risks. There's a knowledge that there's not good evidence to support it working. There's, you know, all those things but there's … this other … more emotive thing going on where a sense of hope or a sense not even always of hope but the need for agency. And, certainly, one of … the things along with hope that's more common across different types of diseases, I suspect agency is one … Just the need for people to feel like they're doing and controlling something.

The need to do something can often mean that warnings about risks of unproven treatment are ignored. As highlighted by Jeanette, who worked for a patient support group, the motivation to act now can be particularly acute for parents:

> So, you know, they're … clutching at straws 'cause they want their child to live and survive, and be happy, and healthy. So whatever information they see, no matter who it comes from, whether it comes from the dodgiest person of, you know, Timbuktu, they're going to … go, 'Oh I want that

> treatment!' So I don't think they process the information. You know, I think that goes out the window. Do you know what I mean?

As Michael, another representative of a patient support group, eloquently explains, maintaining hope, particularly in conditions with a dramatically reduced life expectancy, is an important consideration and one that is taken very seriously:

> Generally we talk about the risk of false hope because, in [this particular neurological disorder] hope is something that we hold dear and we encourage patients to have hope that there will be a breakthrough or there will be cure … And to have hopes dashed can be very difficult for families, friends to, to cope with … So … we talk about, you know, in terms of hope, it, it's not this unfilled yearning for a cure because hope for a cure between now and someone's average life expectancy, yeah, with this, is not going to happen, you know. Even if there was a breakthrough in the lab today, it'll be 10 years before a treatment hits … the floor. And, in 10 years, we will have gone through, you know, three or four generations of people [with this disease]. So it's more about having hope that interventions, service delivery, the love of carers and family will help you live better for longer and, you know, I'd have … to say, as a healthy person, I have that same hope! You know, it's … not as if your hopes for … the future are going to be any different; it's just that they're complicated by the fact that you've got [this disease].

However, chasing such hopes can be a costly endeavour. As discussed in Chap. 2, many of the Australians we have spoken to have paid between $AU10,000 to 60,000 for treatment as well as having to fundraise for additional expenses for their travel and accommodation, plus that of their carers (Petersen et al. 2014). For advisors, the high costs of pursuing unproven stem cell treatment is a point of concern as patients and their families divert precious financial resources away from support that could actually improve their day-to-day care now, or may be required sometime in the future. For example, Michael, above, went on to comment:

> The one thing I hate to see is families wasting money on things that aren't going to work and then not having the opportunity to do things that will

> actually be meaningful within the family or for the family. You know, carers left with little or no funds post-death. The inability to afford to take the family out for dinner because you've blown it all on a trip to China. I find that … very disappointing. And, I suppose the passing up of quality of life for an attempted cure that we know is not going to work. You know it's just, that, I feel very disappointed for people and very sorry for people when that … occurs.

Others expressed an even stronger reaction and while they wanted to support patient autonomy they could barely suppress their frustration at what they view as the highly exploitative practices of these overseas clinics. Teresa, who worked for a patient support group, commented:

> I guess sometimes I just want to shake them and say, 'For goodness sake, stop wasting your money on hope and just, you know, put some more practical strategies in place that are more likely to achieve something!' But again that's not my role here and I really work very hard to function as a facilitator of information and a facilitator of autonomous decision making. So I … try and keep a very clear line between roles.

The delicate nature of this balance was particularly clear with many advisors acknowledging that they rarely dismiss a treatment completely out of hand no matter their personal reservations. Anita, who worked for a patient support group, noted, when recounting how she responds to enquiries from those with terminal degenerative neurological illness, that it is crucial to foster hope in medical research and future discoveries:

> They're desperate for something that's going to make a difference. So I feel, if we actually say, 'This is not going to work. This is rubbish sort of treatment', then they will lose hope in terms of what's available … it's essential that people maintain hope and the belief that eventually, you know, this condition will be overcome. I sound very evangelical but I don't mean to … I think, if we can, you know, give them, be positive and enthusiastic about what we're doing, and look a lot of that also I think our stem cell scientists are fabulous and they're very inclusive. And so we, they're happy to talk to patients and their families about what they do. So we … kind of really try and connect the scientists with them so they actually really, they understand and they know what's going on.

Others, such as Dale, a clinician-researcher, emphasised that it is important when responding to enquiries that it is clearly acknowledged that progressing stem cell research from the laboratory into the clinic will take time:

> Hope is an important thing and you can't take that away. And, and just indicate, you know, that there are a number of hurdles still to cross but that the, the field is … moving so fast and, and, you know, there is, there is distinct possibilities of having studies here in Australia which would obviously be much easier and safer than, that trekking over to another country.

It was also commented that access to experimental stem cell therapies was viewed differently to the research and development of new drugs. When reflecting about conversations with patients who are following the development of other areas of medical research, Michael, above, recalls how the failure of a new drug, even where huge hopes have been invested in its success, may be met with disappointment and a comment such as 'okay, this one didn't work but gees there's 10 more; maybe one of those'll work'—thereby shifting hope to the next candidate. However, as illustrated by the following quote from Michael who provides patient support, when it comes to stem cell treatments, the situation is more acute:

> Usually the … problem with the journey, if they go through a stem cell treatment is the fact that it's cost them a lot of money and so the … hope that fails because nothing changes is then magnified by the fact that they've effectively poured this money down the drain … spending $AU50,000 or $AU100,000 and running off, and having stem cells injected in your head and it doesn't work. And I think … false hope rarely benefits the person in … the long-term. Hope for the bigger picture does. And, you know, really … the hope for the bigger picture is about research in stem cells, not in about treatments … of stem cells that might currently be available.

'Accidental' Advisors

Although those consulted by patients and carers do not refer to themselves as 'advisors', they often described how they felt an obligation to assist those contemplating possible treatments abroad make a more 'informed'

choice. While they recognised that such decisions may be better discussed with the patient's general practitioner or medical specialist, as the following quote from Keith, a researcher (mentioned earlier), illustrates, for many patients this does not appear to be an option and instead they turn to the 'accidental' advisors in the community:

> So we advise patients that, firstly, they should operate through their Australian clinicians, their doctors, and make the doctor fully aware of what the potential treatments are 'cause only the doctor can really understand that particular patient's condition. And the answer to that is mostly the doctors will say to them, 'Well we don't know. We can't advise you'. So then it becomes a personal decision and we advise them that the treatments are unproven … But, you know, you can't tell them not to go. I never say, 'Don't go!' I say, 'It's your decision but know these are unknowns. Treatment is unproven.'

Except where clinician-researchers were consulted by their actual patients (as opposed to enquiries from the general public), the advisors viewed their role not as providers of medical advice but one of providing 'the facts as unbiasedly as possible' and where they could consciously be 'objective' and take 'an un-emotive stance' to assist those contemplating treatment make an 'informed' decision. This is illustrated in the following quotes from Anita, who provides patient support, and researcher Susan, respectively:

> I suppose we see our role is to inform and provide them with all the options … The crunch to me is, if people choose to do that, that's okay, as long as they make a completely informed decision. I never say to a patient … 'don't go'… I just say, 'These are the facts. I don't believe that it's a proven therapy … I can appreciate your desire but, personally, … I would recommend you spend the money on, on your current life in some other way.'

All groups saw responding to patient or carer enquiries as an extension of their professional responsibilities. While some, notably the scientists who had limited experience and expertise in patient care, mentioned that after the initial response they may refer the person to another Australian organisation or individual with more relevant experience, all appeared to be comfortable in responding. As Christina, who works for a patient support group, asserted:

> I'm very comfortable with providing that information to people because I know … the desperation that they're experiencing once they've got to that point. I know that there's such a huge lack of information, at least officially, in this country about this situation. And I think … that there's one tiny service that we can provide to people because otherwise they're going to be on the internet, and they're going to be perhaps making incorrect assumptions about what they're reading. And, and there's so much misleading information on there anyway so it's hard for anyone to decipher what's correct and what's not.

Advisors drew strength and confidence in their ability to respond based on their own knowledge of the disease and/or by having access to leading experts. However, as Michael, who worked for a patient support group, commented, even then providing such advice can be personally challenging:

> Look, to be honest, I don't have any problems with delivering that sort of information. Me personally I believe in telling the truth. This organisation does not dance around the fact that [degenerative neurological disease] is going to kill people. You know, like it is a fact, it is a truth, let's not walk away from that. Let's make that clear and then let's say, 'Well, but we can do these other things.' I suppose I feel comfortable in making those statements because I regularly attend international meetings where research on stem cells and other scientific experimentation and development are taking place. We've got a very good network around the world of … people who report these things so that information gets shared quickly. If someone's coming in to talk about that sort of thing and I know beforehand, I … do some research on the net with trusted websites and, if they come in and say they want to talk about that, I ask them to go and have a cup of coffee so I can … pull out the information that I need to make sure that I've got right up-to-date. And if people mention a particular thing, I can go on-line straight away with them there and say, 'Well, have you seen this? Have you seen that?' I don't lack any … confidence in doing that. Whether you like doing it is a different issue. You know, you don't like taking away peoples' hopes and dreams but I think we have a responsibility as a professional organisation working in a hard health area to always be telling the truth and being accurate. It's no good dancing around the edges.

The responsibility to manage hope was also echoed by Barbara, the representative of the patient support group (mentioned earlier), who when asked about how she felt in providing information to a recent patient considering treatment in India, responded:

> It's a bit of an awkward one because you don't want to, you don't want to be too critical, especially given how enthusiastic he was that, if you're too critical of it, they'll just switch off straight away. And I think there is potential for it to be useful in the future but I wouldn't be confident, you know, I wouldn't consider it myself and so it's … kind of … an awkward one to convey without quashing their enthusiasm.

To aid them in these difficult discussions, the advisors relied on scientific evidence to highlight the unknowns and risks that the patients may be exposed too. For example, Shaun, a clinician-researcher commented:

> Well, it's very hard, because if you come across all strong and say look, this is all rubbish, then they get their back up, so you've got to take them through it and say, look, let's have a look at the evidence of these trials … I try and point to the bona fide peer reviewed literature and say, you know, just point out that as yet there are no studies showing definitive efficacy from using these treatments, and I point out all the complications and questions that are unanswered.

Several advisors also commented that there was a need to provide training to general practitioners so that they can better support their patients. For example, when asked what else could be done to try to address the issue of Australians travelling abroad for unproven treatment, Damian, who worked for a patient support group, suggested that while it might be difficult to incorporate into ongoing education for doctors it would be extremely influential:

> If we can sneak in some information [about stem cell research] into the GP's continuing [education programs] … then they'll be able to disseminate that information to patients and appear more knowledgeable. I think that, because, at the end of the day, you know, people will listen to their doctors but, if the doctor seems particularly inept about it, they're [the patients] very quick at shutting him down or shutting her down.

Since 2012, the Australian National Health and Medical Research Council—Australia's leading expert body promoting the development and maintenance of public and individual health standards—has prepared an information booklet for general practitioners as well as a question and answer fact sheet for those in the community contemplating treatment (NHMRC 2013). Drawn from the existing *Australian Stem Cell Handbook*, clear advice is for patients to 'think twice' about stem cell therapy claimed as 'quick fix', 'scientific breakthrough', or 'miracle cure' and encourages patients and their carers to discuss any information they 'uncover in your research' with their Australian general and specialist medical practitioner/s warning:

> If it sounds too good to be true—such as a claim that the treatment can cure a disease or treat a variety of conditions—it usually is. It is also important to seek information from a source other than the clinic that is offering the treatment.

Regardless of whether this intervention, together with strongly worded position statements by professional medical bodies like the Australian Rheumatology Association and the Australian College of Sports Physicians (ARA 2015; Osbourne et al. 2016), enable Australian doctors to more adequately address patient enquiries, it is highly likely that Australians will continue to turn to 'accidental' advisors. Such conversations are extremely influential as the following quote from Louise, carer of her husband who is suffering from a degenerative neurological condition, illustrates. Having initially considered travelling to China to a clinic which provided 'a four-week program which had traditional Chinese medicine thrown in as well as stem cell treatment', the couple eventually decided not to travel after discussing options with a representative of the local patient advocacy group:

> I thought, 'Here's a person I can really talk to in, in this minefield.' I felt an instant connection to be able to talk to [patient advocacy group representative]. He said all the right things in terms of someone who's in this situation. He, he knew how to handle it beautifully. But, when he said that [the treatment was unproven], I was sort of quite devastated because there was this hope and it was being, you know, 'Don't, don't take that hope away from me.' That was that feeling.

As Louise's quote reveals, accessing reliable information and finding the 'right person' to talk to about the healthcare 'minefield'—in which stem cells may be portrayed as the only hope—is undoubtedly an ongoing challenge and for some down to 'luck'.

Conclusion

It has long been recognised that stem cell science engenders enormous excitement and hope—especially for those to whom conventional medicine appears to have little to offer—and that such hopes need to be kept in check with the actual progress of the science (Braude 2005; Hyun et al. 2008; Taylor et al. 2010). However, current strategies to manage hopes can often be limited to providing the 'decision makers' with more and possibly inadequate information (Master et al. 2014) rather than recognising and proactively managing hopes invested in a therapy and the emotional and/or spiritual distress that many patients with intractable medical conditions face following diagnosis (Hyun 2013). As outlined in Chap. 2, many patients and their carers do attempt to 'do their research' before they decide to embark on a journey to pursue stem cell treatments, but they are often thwarted in their attempts to engage with their local medical professionals who may not have the experience, knowledge, or time to offer assistance (Zarzeczny and Caulfield 2010; Levine and Wolf 2012; Petersen et al. 2014). So patients and their loved ones turn to others in the community, such as scientists and representatives from patient advocacy groups for advice.

These 'accidental' advisors, by virtue of their position and not their formal training, are then faced with the challenge of assisting patients navigate between 'regimes of truth' and 'regimes of hope' (Brown 2015; Moreira and Palladino 2005), with uncertain and potentially harmful consequences. As we have outlined in this chapter, our research reveals that community advisors clearly position themselves as decision facilitators between worlds of science and non-science where they engage in a form of boundary-work using the concept of evidence to demarcate the borders (Petersen et al. 2015). For example, providers of unproven treatments are clearly located at the margins of 'real' science, or indeed, in

some cases, well beyond the fringe, consciously exploiting public misunderstandings about the current status of stem cell science and regulatory 'grey areas' in order to promote their own self-interest, that is their business of selling treatments. Others perhaps are simply overly enthusiastic about the promise of stem cell science and regenerative medicine, prematurely—but not necessarily maliciously—treating patients with the hope that it might provide some benefit.

As supporters of evidence-based medicine, the group of stakeholders we spoke to saw themselves firmly located within the boundary of 'good' science. However, they also acknowledged that there were many unknowns, uncertainties, and unresolved issues inherent in medical research, and especially in the emerging regenerative medicine and stem cell research fields, and that these have been overshadowed by overly enthusiastic portrayals in media and online. As previously noted 'by rousing public excitement for the promise of stem cell technologies, stem cell supporters may have inadvertently contributed to the creation of a market for offshore treatment, enabling the very charlatans they now criticize' (Murdoch and Scott 2010). Whether such enthusiasm is the product of genuine excitement about the possibility of the science, or the need to justify the significance of the field to funding bodies, investors, policy makers, and regulators, or a deliberate commercial decision to drive a new 'industry', these overtly positive portrayals have significantly contributed to heightening community expectation and remain a substantial challenge.

In an age of medical travel, where access to an alternative treatment choice is but a click of a mouse away, our analysis reveals that the boundary between science and non-science needs to be re-conceptualised—especially for the development of stem cell treatments (Petersen et al. 2015). The stakes are high not only for patients and carers, who hope for better lives now, and who may see stem cell 'breakthroughs' as the only means to achieve this, but also for the broader field of stem cell science. Hype must be tempered with the reality of scientific progress (Brown 2003; Daley 2012). Instead of allowing 'stem cells' to be presented as 'magic' or a 'miracle cure' capable of righting all injury or disease, a more nuanced approach is required. While some have called for educational materials to better describe the process of clinical translation (i.e. clinical trials) as opposed to the untested treatments being sold in commercial

clinics (Master et al. 2013), the differing concepts of 'evidence' also need to be acknowledged. For many in the community, patient testimonials may appear as convincing and far more accessible than data from clinical studies. While several groups have attempted to meet this challenge and developed tailored online resources (see Table 3, Appendix), it remains unclear as to the extent to which the broader community, and even health professionals and researchers, are aware of these decision-making aids. Furthermore, there has been limited analysis on whether these educational initiatives adequately meet the needs for those who want to do their 'homework' regarding stem cell options.

While educational approaches assume a rational actor model and risk overlooking the 'context in which identity is formed and hope assumes meaning' (Petersen et al. 2014), it would appear that 'accidental' advisors play an important part in countering the 'hype' narrative. As Louise's comment revealed, her experience in speaking to a representative from a patient support group enabled her to form an 'instant connection' and assisted her and her husband to navigate the information 'minefield' while maintaining hope. Although ultimately deciding not to travel, Louise and her husband's journey also implies that she believes she was fortunate to find 'the right person' to speak to and that perhaps this was by chance. In the next chapter we describe the journeys of those who chose a different path and decided to travel abroad for stem cell treatment.

References

Australian Rheumatology Association. (2015). ARA position statement on stem cell therapies. https://rheumatology.org.au/downloads/ARA%20Position%20Statement%20042014.pdf. Accessed 26 Feb 2016.

Australian Stem Cell Centre. (2009). *Stem cell therapies, now and in the future: The Australian Stem Cell Centre patient handbook*. Melbourne: ASCC.

Braude, P., Minger, S. L., & Warwick, R. M. (2005). Stem cell therapy: Hope or hype? Safety and quality must be assured before this treatment can really benefit patients. *British Medical Journal, 330*(7501), 1159–1160.

Brown, N. (2003). Hope against hype: Accountability in biopasts, presents and futures. *Science Studies, 16*(2), 3–21.

Brown, N. (2015). Metrics of hope: Disciplining affect in oncology. *Health: An Interdisciplinary Journal for the Social Study of Health Illness and Medicine, 19*(2), 119–136.

Daley, G. (2012). The promise and perils of stem cell therapeutics. *Cell Stem Cell, 10*(6), 740–749.

Daley, G. Q., Goodell, M. A., Snyder E. Y. (2003). Realistic prospects for stem cell therapeutics. *Hematology American Society of Hematology Education Program*, 398–418.

Hyun, I. (2013). Therapeutic hope, spiritual distress, and the problem of stem cell tourism. *Cell Stem Cell, 12*, 505–507.

Hyun, I., Lindvall, O., Ahrlund-Richter, L., Cattaneo, E., et al. (2008). New ISSCR guidelines underscore major principles for responsible translational stem cell research. *Cell Stem Cell, 3*, 607–609.

Ipsos Social Research. (2013). Community attitudes towards emerging technology issues – biotechnology. http://www.industry.gov.au/industry/IndustrySectors/nanotechnology/Publications/Pages/Public-Attitude-Research.aspx. Accessed 26 Feb 2016.

Levine, A. D., & Wolf, L. E. (2012). The roles and responsibilities of physicians in patients' decisions about unproven stem cell therapies. *Journal of Law & Medical Ethics, 40*, 122–134.

Lysaght, T., & Kerridge, I. (2012). Rhetoric, power and legitimacy: A critical analysis of public policy disputes surrounding stem cell research in Australia (2005–2006). *Public Understanding of Science, 21*(2), 195–210.

Master, Z., Zarzecny, A., Rachul, C., & Caulfield, T. (2013). What's missing? Discussing stem cell translational research in educational information on stem cell "tourism". *Journal of Law, Medicine and Ethics, 41*(1), 254–268.

Master, Z., Robertson, K., Frederick, D., Rachul, C., et al. (2014). Stem cell tourism and public education: The missing elements. *Cell Stem Cell, 15*, 267–270.

McLean, A., Stewart, C., & Kerridge, I. (2014). The emergence and popularisation of autologous somatic cellular therapies in Australia: Therapeutic innovation or regulatory failure? *Journal of Law and Medicine, 22*(1), 65–89.

Moreira, T., & Palladino, P. (2005). Between truth and hope: On Parkinson's disease, neurotransplantation and the production of the 'self'. *History of the Human Sciences, 18*(3), 55–82.

Munsie, M., & Pera, M. (2014). Regulatory loophole enables unproven autologous cell therapies to thrive in Australia. *Stem Cells and Development, 23*(S1), 34–38.

Murdoch, C., & Scott, C. (2010). Stem cell tourism and the power of hope. *The American Journal of Bioethics, 10*(5), 16–23.

National Health and Medical Research Council. (2013). *Stem cell treatments—A quick guide for medical practitioners and stem cell treatments—Frequently asked questions*. https://www.nhmrc.gov.au/guidelines-publications/rm001. Accessed 26 Feb 2016.

Nature Editorial. (2010). Regulators must step up stem cell oversight. *Nature Medicine, 16*, 492.

Nelson, B. (2008, June 5). Stem cell researchers face down stem cell tourism. *Nature Reports Stem Cells*. http://www.nature.com/stemcells/2008/0806/080605/full/stemcells.2008.89.html. Accessed 9 Mar 2016.

Osbourne, H., Anderson, L., Burt, P., Young, M., et al. (2016). Australasian College of Sports Physicians—Position statement: The place of mesenchymal stem/stromal cell therapies in sport and exercise medicine. *British Journal of Sports Medicine, 50*, 1237–1244.

Petersen, A., Seear, K., & Munsie, M. (2014). Therapeutic journeys: The hopeful travails of stem cell tourists. *Sociology of Health and Illness, 36*(5), 670–685.

Petersen, A., Tanner, C., & Munsie, M. (2015). Between hope and evidence: How community advisors demarcate the boundary between legitimate and illegitimate stem cell treatments. *Health, 19*(2), 188–206.

Taylor, P. L., Barker, R. A., Blume, K. G., Cattaneo, E., et al. (2010). Patients beware: Commercialized stem cell treatments on the web. *Cell Stem Cell, 7*(1), 43–49.

Trounson, A., & Harvey, R. P. (2008). A critical time for stem cell research in Australia. *Cell Stem Cell, 2*(2), 118–122.

Zarzeczny, A., & Caulfield, T. (2010). Stem cell tourism and doctor's duties to minors—A view from Canada. *American Journal of Bioethics, 10*, 3–15.

4

Hopeful Journeys of Stem Cell Tourists

> *I wouldn't knock anyone going. You know, some people, a lot of people call them desperate. I like to call them pioneers myself because they're true people that are … You know, they might be making a mistake but at least they're having a go.*
> (Axel, a patient with spinal cord injury)

Narratives surrounding stem cell 'tourism' and 'tourists' are dominated by stereotypes. From the perspective of those stakeholders operating within conventional scientific paradigms, like the 'accidental' advisors discussed in the previous chapter, prevailing stereotypes of vulnerable victims and exploitative 'cowboys' are typically drawn upon in descriptions and understandings of the phenomenon. Such stereotypes indeed exist among both those operating within and those seeking treatments outside those paradigms, with travellers and providers alike alternatively characterised as brave pioneers and/or impassioned mavericks, placing their bodies and reputations on the line in order to improve their quality of life or that of others in critical need. We argue that these stereotypes, along with the narratives of empowerment and exploitation in which they typically feature, do little to advance understanding

A. Petersen et al., *Stem Cell Tourism and the Political Economy of Hope*, Health, Technology and Society,
DOI 10.1057/978-1-137-47043-0_4

of the phenomenon of stem cell tourism and the lived experiences of 'stem cell tourists'.

In the preceding chapters and those that follow, we show how contextualising stem cell tourism within a broader political economy of hope and global healthcare is important in garnering greater insight into the complex and multi-layered mechanisms and sociocultural dynamics underpinning the market. The varied journeys that people undertake to receive stem cell treatments, their significant financial and emotional investments in experimental treatments far from home while acutely unwell, and the affective force of their experiences, all attest to the profound complexity of this healthcare phenomenon. In recent years there have been several sociological studies that have considered patient experience and provider perspectives in clinics in India (Prasad 2015; Patra and Sleeboom-Faulkner 2011; Bharadwaj 2013) and China (Song 2010), respectively. With the exception of this valuable work, relatively little in-depth qualitative research has considered the experiences of those who have travelled, and, aside from our own, none has examined patients' perspectives based on travel to diverse destination countries (Petersen et al. 2014; Tanner and Munsie 2014). This chapter seeks to address this critical gap and contribute to the emerging body of work that considers patients' experiences by taking as its central focus the journeys of people who have travelled to different countries to receive treatment. Given the significant role that family members/carers play in supporting and facilitating these journeys, this is as much a story about their experiences as it is about the patients who travel for treatment.

The chapter is divided into key stages of people's journeys: travel to the destination country; first impressions and experiences of the clinic and care; the treatment regimes people underwent, and people's experiences and reflections upon returning home, including the response of family, community, and healthcare providers in Australia, and travellers' reflections in the light of the treatment received and perceived benefits or harm (if any). Each step demonstrates the profound practical challenges that travellers face in undertaking these journeys as well as the more abstract challenges they pose with respect to the management of competing risks, claims, and models of healthcare, and the significance of hope and trust in travellers' negotiation of them. We consider the significance of shifting dynamics of trust and distrust, expectation and hope, fear, uncertainty,

and investment as inherent characteristics of people's journeys. As the following discussion demonstrates, these dynamics are highly variable and co-exist in often seemingly contradictory and complex ways in people's journeys. We have chosen to adopt an approach that draws heavily on participants' accounts in this chapter, as we believe that quoting our participants at length offers a valuable opportunity to present unique insight into people's experiences through their own words. This is also a method that, as our following analysis makes clear, also assists us to move beyond reductive stereotypes and narratives of empowerment and exploitation that inhibit understandings of the experiences of travellers, especially their navigation and management of the profound challenges and investments these journeys entail. The following section begins at the literal starting point of people's journeys overseas for treatment: their experiences of preparing for and travelling to destination countries for treatment.

Difficult Leaps of Faith: Journeys to the Clinic

As discussed in Chap. 2, a range of factors may influence people's decisions to travel for treatment, including the severity of illness and/or condition, experience of diagnosis and medical care in Australia, response to provider websites and by providers after initial contact, and communication with others who had travelled. Travellers and non-travellers alike express their frustration with being forced to travel overseas for treatment. This relates to the great expense and risks involved in long-haul flights to destination countries while acutely unwell or with reduced mobility. Invariably, multiple tickets are needed so carers and/or families are able to travel together, with some travellers having no choice but to travel business class due to the nature of their illness and condition (e.g. people with severe spinal cord injuries or those travelling with ventilators and other equipment). Many individuals describe the practical challenges and associated stresses involved in preparing to fly with their condition and/or illness, which include the need for assistance for walking (e.g. wheelchairs at each airport and flight interchange), and concern over health risks. In her account, below, Simone, who travelled to India with her partner who had a C4 spinal cord injury, describes the complex range of considerations, practical challenges, and health risks she had to navigate

to undertake the trip, which didn't end with the flight itself as her partner contracted a life-threatening respiratory infection after arriving in India:

> 'Oh God, how do I get [him] onto a plane?' No-one could answer that question for me so I had to track down all these people again and ask them questions. I guess he was like the manager of the spinal ward. I'm just trying to remember but he actually said that he took a patient overseas to travel and just made me more aware of what I'd need to do. Because having him on a plane and what to look out for … So that was the only help we got. But … we were really cutting it fine. James had only just gotten off the ventilator by six weeks and we had him on a plane … obviously we had to be vaccinated for certain things and I could, no-one in the hospital would actually see James about his vaccination so I had to get him into the wheelchair and take him across the road. Well actually I went to three different doctors' surgeries in, down the area where the hospital was … which was just ridiculous that he was surrounded by doctors, but no-one would give him anything. And also too we had a bit of a problem because [of the medication] James was on, he had two blood clots in arm … So, you know, and he was on warfarin and had to have blood checked every three days … I mean James had two beers on the flight which, much to my disgrace, I was nearly having a heart attack about thinking, he's going to just cark it on me having a beer. But he didn't, clearly. But, you know, I was really highly, highly stressed … Just even down to the moment of us turning up at the airport. They wanted to put James, [laughs] it's kind of funny when I look back on it, it's not but I mean I've got to laugh at it. They wanted to put James in the back of a taxi and I was like, 'Physically, how is that going to happen?' you know. So we were lucky enough that we had this male nurse that flew over with us. So he did the whole trip and, believe me, the trip enough was hard enough work like flying and … But anyway, so, we ended up calling an ambulance and, in the end, we had to lay him flat. And it was such a blunder.

Like Simone, other carers undertook a major role in preparing for trips and yet they often had little support or guidance, and few resources. For parents caring for children, the flight and distance posed unique challenges, especially for those parents left behind. For some parents who were able to generate funds via borrowing money or fundraising, travelling as a family was prioritised over the burden of additional financial costs, as

Russell, who travelled to the USA for treatment for his child's cerebral palsy, explained:

> We were fortunate. We did a lot of fundraising so that really helped. In fact, we raised about half the cost. Initially, it was just going to be myself and [the child] going over but then we kind of decided, well, no, we would travel together as a family, so it doubled the cost in that respect. But it's something we had to do as a family. My wife … didn't want to sort of let go and let me go and her child go, which I can understand entirely. So we ended up getting a home loan and all up, with the trip, the medical sides of things, we were close to about $AU40,000.

For parents whose domestic or paid work responsibilities or finances prevented them from travelling, staying behind was especially difficult, particularly with respect to not being able to participate in the care work required for a long flight to a foreign country with a young child. As Eloise recounted, reflecting on the tremendous emotional toll of having to stay behind to look after her other children while her child, with autism, travelled with her husband to the USA and was then taken over the border to Mexico for treatment (twice with a third trip planned):

> Well my main thing was how on earth is he going to sit in a plane for 14 hours? You know, that was a huge … Like how are they going to control him? Like he's a kid. Like he was, child alone, autism or not, you're talking about he was what, three, four. Who, what kid … That was my big concern. That was huge. Okay, then obviously the flying to another country, like the flight itself. 'Oh I hope it's safe. I hope everything goes well, blah, blah, blah.' So then there was that. Then, 'Oh my God, when they go to Mexico, oh God, I hope they're taking my child across the border to …' There was every, every worry that could possibly, I mean I had panic attacks … I'm on medication basically because of my anxiety and just the stress of everything. My body couldn't cope itself so it's a huge, it's not something that … I can't even explain. Yeah, major worry. Huge, huge worry. That's why, if anybody had any thought that that could be done in their own country, oh my God. It would be like … just, because you'd be worried as it is for the treatment let alone going to another country. Let alone that, you know. And organising flights, and making sure accommodation is organised. Making sure it's suitable for a child. Or how are they going to

> cross the border to Mexico? What are they going to come across? Da, da, da, da, da. Whereas in your own country it's a lot easier to sort of control the situation in your own country or know what's happening. Or, if something happens, okay, well, let's just go there. In another country you can't. You're on the other side of the world, basically. So it's huge, huge, huge. Like I'm stressing about the [next] one. Even though we've done it twice. But they still, they've got to go on a plane. They've got to go … so yeah.

Like Eloise, almost all our participants described the trips themselves as arduous, costly, and stress-inducing, regardless of whether they were staying in the home country or travelling with their loved ones. Providers allowed some of our participants only a short timeframe to prepare for their travel, which compounded the associated financial, emotional, and practical burdens. This was the case for Simone, cited above, who had been advised by their provider to travel to the clinic as soon as possible after the injury to maximise the possible benefits of treatment:

> She said, 'The sooner you get over here the better because, you know, there's damage that's done.' And she said, 'And scar tissue wouldn't have formed over completely' … She then said 'that there'd be no guarantee that [just] better to get him over here' and we'd go on our first trip for three months. Yeah, honestly, I just don't know how I did it. I did it by myself too, so I learnt all that needed to be done for James's care. Everything down to his bowel movement, all of it. Changing his catheter. Like it was just, it was a journey and a half.

Donna, who travelled to Germany with her husband who had been diagnosed with a rare degenerative neurological illness, was also given a short timeframe to prepare for reasons relating to the clinic's schedule. She explained how this increased the financial costs and stresses for her and her partner:

> We just made up our minds and well we kind of knew, well we knew it was going to be $10,000 to start with at the clinic, before we started and the rest was however we got there and I must say they didn't give us a lot of time. They rang us on the Friday and said they wanted us there by the next Thursday so we couldn't use our Flybuys [frequent flyer points] because

> they didn't give us enough time. So I phoned them and said 'I can't manage to do it that quickly and can it be another week?' And they phoned back and said 'No', that he was on that program. They were very nice about it. So we just had to take the best airfare we could, which we had to pay for instead of using our points. It still didn't, I guess we had, we went away with such hope that it would give Gary perhaps a more comfortable life than where he was going at that stage.

For travellers, the trip to the clinic invariably poses financial, emotional, and practical challenges. Some challenges are a 'normal' part of international travel but were especially difficult due to the condition of travellers (e.g. accessing vaccinations, managing children's coping and behaviours in-flight). Others are more difficult to foresee prior to travelling and have to be managed as they arise (e.g. how to travel from the airport to the clinic with a spinal cord injury) and others require significant resources and assistance to manage and prepare for pre-flight, particularly with respect to healthcare and risks (e.g. ventilators, blood thinning agents, wheelchairs). For those who have made the decision to travel, these challenges are rarely considered 'deal-breakers' or sway their decision to travel, but are experienced as obstacles to overcome in order to receive and maximise the potential benefits of treatment. For those whose providers place them under the pressure of tight time constraints, this is sometimes compounded by factors such as the need to manage health risks soon after the injury (e.g. for people with spinal cord injuries) and the expense of travel. Eloise's experience, above, reflects the sense of frustration and perceived injustice frequently expressed by travellers who understand they have 'no choice' but to undertake such expensive and arduous international trips for treatment (Chap. 2). The following section considers people's experiences after undertaking these flights and arriving at the destination country and clinic.

At the Clinic

Individuals reported a diverse range of impressions and experiences of healthcare facilities and of care; however, these tended to be vary according to the kinds of clinics visited and treatments undertaken. For those

who travelled to clinics offering one-off or short-term treatment regimes, most described being very impressed with the professionalism, efficiency, and support received, which for some extended to the facilitation of luggage collection, accommodation, and transit to and from the clinic. Those travellers who had travelled to Germany and to Panama for treatment, recounted their positive impressions, including the standards of hygiene and cleanliness of facilities. For Natalie, whose child suffered cerebral palsy, the standards in Panama were likened to those in Australia:

> There was a concierge who [the clinic] put us in contact with so he arranged everything as far as our accommodation. He arranged to pick us up from the airport and they met us at the airport waiting lounge, then went and got our luggage organised, all that stuff for us. Took us through customs. So we didn't have to worry about doing any of that sort of stuff. They took us to a hotel. We checked in there and then every day we got picked up from the clinic. The clinic sent a driver to pick us up, take us to the clinic and then take us back to our accommodation. The clinic was really good. It was really clean, really what I would have expected from a clinic in Australia. The staff were lovely and no language barriers whatsoever. And the whole process was about five minutes a day. We'd sit there, wait for our turn, go in. They'd put a cannula in [child's name]'s hand. Inject stem cells into a cannula, which was just one needle so it didn't have very long at all. And then we'd be back out and dropped back to our accommodation.

Lara, who travelled to Germany for treatment for her multiple sclerosis, had a similar experience:

> Oh it was just so clean and they just knew what they were doing. I could just tell reading the thing what people said and the doctor who rang or the guy who rang to organise going over there, he was just brilliant.

For those travelling to other countries, which included China and India, individuals recounted a greater diversity of experiences of facilities and care. In particular, their long-term stay in clinics (typically four weeks to three months) invariably shaped their experiences and the demands and rewards of treatment journeys. For example, some told 'horrific' stories of unsanitary conditions, including rats, poor care, unsatisfactory

equipment required for day-to-day care, especially for spinal cord injury patients, and being billed for ongoing equipment and supplementary medicines such as vitamins, syringes, and IV drips, in addition to the high cost of the stem cell treatment/s. Other challenges that were raised included cultural differences, for example, language barriers and differences in food. Safety, pollution, temperature, distance from home, lack of support to navigate cultural differences, and the boredom of day-to-day living in the confines of a clinic, were also featured in people's accounts as negative aspects of their experiences. The experiences of Kimberly, who travelled to China for the treatment of her child who suffered nerve paralysis, is illustrative:

> It's very hard to source food. Communication's very difficult and it's very hard to source sort of decent food or food that you were, you know, western food, you know. Just the extent of it. You're away from your family. You're away from school. [We went] to a very poor part of the country. At night with cannon balls going off and gunshots, [because] there was a massive military base. Like there was jets flying past and it was quite disturbing. Well it was because you just didn't know. I mean the doctors at the thing were fine. It was just a shame that you just don't have any help from, to help you get food or, you know, their food's so different. We had to live within the hospital environment, [it was] 10 degrees while we were there … First up was getting away from the family. That's probably the hardest thing. Probably that was [for my child] too, like you use the skype and that but being in such a remote area that you couldn't, there was nothing to do other than sit in your room and it was so cold. And I mean to get anywhere was an issue and … yeah. There was nine million people in the place where we were staying … It was a very poor part of China, … very industrial. With lots of smog. We in Australia think there's a smog problem; you want to get over there.

Significantly, many of the factors that individuals cited as posing challenges for them were also those that were deemed to be valuable. For example, the value and support of living for an extended period of time in a community of international visitors with diverse illnesses and conditions invested in the hope of stem cell treatments, and being immersed in cultures with vastly different ideological approaches to illness, health and

care provided the context for experiences that, for many, were extremely positive and, for some, were life-altering. These were benefits that participants had not considered prior to travelling. For example, Greg, who travelled to China with his carer Suzanne for treatment, commented:

> I felt really good there. It was an interesting experience. There were kids with autism, people with strokes, and there were a couple of young teenagers who had what I have but not hereditary. Some other thing. And, I suppose I was able to walk reasonably well and I smiled a lot, and laughed a lot … They had a common room with a kitchen and stuff, and TV, and whatever. And it was like a little United Nations. There were people from France, United States, Venezuela, Argentina, Brazil, Egypt, Poland, France, Scotland, Algeria and Kenya I think … They actually put our flags on the doors so it looked like a little UN … Actually that part was really enjoyable. You know, I thought, 'Well okay, woe is me,' but then there were two brothers from Egypt about 17 and 14, and they had this genetic eye problem. They could only see if they held the print up really, really close, and they were there for some eye treatment with stem cells. And I thought, 'Well, you know, at least I've had, you know, I worked for 37 years,' and these guys they were quite bright, very bright, but they had this problem.

Similarly, Simone, who travelled to India so her partner could gain treatment for his quadriplegia, noted:

> Then about six o'clock it was, it was always a given: everyone that was there as a patient, we'd all meet up out the front and all the carers, and we'd just watch the world go by. It was safe, we had a security guard there and, you know, it was all good … And most people that were the carers were a lot of foreigners so a lot of people used to get some beers and play some music, and we did everything we could to entertain ourselves, and we really did. We had some quite huge parties actually … James's actually going back. He's going back in February. I'm not going with him. There's no way I'm putting myself through that again because it's just too much hard work for me, you know. But I think, in terms of the environment that's there, it's unbelievable. Like you do, you learn so much and, and yeah it honestly it, it's like I said to you, just what I said before: James was certainly the happiest I've ever seen him, I mean obviously post-injury, when he was there … The support network that you have there is, is just unbelievable. And I have to say even I enjoyed the support.

For many of our participants, particularly those who undertook long-term treatment in clinics, their journeys came to carry far greater significance beyond the treatments they originally were travelling to receive. The benefits of living day-to-day in unique communities comprising travellers from around the world, who suffered from diverse and debilitating conditions yet invested in the hope that the treatments they were undertaking might work, were a welcome surprise to many of our participants. The sense of collective care and support, in combination with intensive treatment regimes, were conditions that in and of themselves were productive of improved wellbeing for many of the people we spoke to. As Simone noted in regard to her partner, in spite of their very minimal health gains derived from the 'treatment', and none that could be attributed to the stem cells in isolation, it was during his visit to the clinic that, surrounded by an 'unbelievable support network', he was the 'happiest' he had been post-injury, which influenced his decision to return for more treatment.

Treatment

As described above, the treatments offered by clinics around the world vary significantly in length of stay, and types of stem cells administered and the means of administering them. For many, these factors shape where people decide to travel, within the broader context of treatment options available internationally influencing people's experiences of the treatment they undertook. For example, for some, long-term treatments were considered highly undesirable, with efficiency prioritised and valued as an important part of the treatment process. As Lara, a patient with multiple sclerosis who travelled to Germany (referred to earlier), explains:

> Over there (Asia) you had to be there for six weeks or something and they put stem cells into you like every day they'd put so many in. And I said, 'Oh that's just … there's no way. No way!' And I had it, and I had the stem cells: it probably took five seconds. Injected into my spine and that was it.

For others, the prospect of long-term stem cell therapy, which invariably was accompanied by other intensive forms of therapy, was a valuable part

of their experiences. Most participants who had stayed in facilities for four weeks or more described intense, regimented regimes of care involving scheduled day-to-day physiotherapy and occupational therapy. Stem cells were often administered in various ways over the course of their stay, including daily injections into adipose tissue, intravenously several times a week, and via lumbar punctures once a week. Most participants were keen to emphasise the lack of invasiveness of procedures, even when they involved lumbar punctures. Parents, however, commonly spoke of the challenges associated with different aspects for treatment. For example, Kimberly, whose child suffered nerve paralysis (referred to earlier), described the challenges associated with acupuncture treatment that was a central part of her child's treatment regime:

> I think the treatment was fine; it was only the acupuncture that was probably more terrible than any of it involved. Feverish and they … use a much larger needle. And [the child] could have up to 15 needles in [their] face.

As with our earlier study (Petersen et al. 2014), individuals exhibited little knowledge about the source of the cells used in their treatment and how they were stored and processed, instead relying largely on what providers had told them. As Audrey, a patient who travelled to Germany for treatment for her multiple sclerosis, explained:

> They took three … punctures from the back of my hip and they had this big bag of what they said was bone marrow. And they said, 'What we'll be doing is we'll be taking this to a machine where they will extract the stem cells from this.' And so, when I went back the next time, they showed me they had six vials and they said, 'There's three million stem cells in here, so that will be injected back into your …' They hooked me up to a drip and they said, 'We'll get the saline going through and then we'll put the Manitol in,' which was supposed to open up the blood-brain barrier. 'And then we will be injecting the stem cells into the saline and that will go into your blood.' So that's what they were supposed to have done … You know, I don't have a great deal of understanding of medical stuff so I was taking it all at face value.

As we noted in Chap. 1, cellular transplants are not without physical risks, with cases of harm following and apparently linked to stem cell

treatment being documented in the scientific literature. Perhaps due to some awareness of cases of serious harm, the moment when stem cells were first administered was for some a key event in their journeys, and involved having already passed a 'point of no return', as Lara, above, informed us:

> They just said, you know, 'You realise you're entering into da, da, da, and this usually works but, if it doesn't …' [They] just told me, you know, that it could have terrible, adverse effects … But I just didn't take any notice of it because I was going to do it anyway … I was there with my husband and he heard it all as well. And I just looked at him and I said, 'Well that's it: I'm still doing it.' And yeah, but it was a pretty daunting experience, I will, I've got to admit. There's a couple of things in the whole thing that I remember and that was one of them. Because I just thought it was like sort of straight ahead and da, da, da. No, no, nothing [could go wrong]. But they don't tell you until you get there … I was there and I thought, 'I've come this far.' … It was too late to say, 'I wanna go home!'

As Lara's account reflects, after 'com[ing] this far', the 'choice' not to receive stem cells after travelling for treatment was not an option for her. Instead, the risk of 'terrible, adverse effects' and the uncertainty she was suddenly presented with upon arrival to begin treatment she had already committed to translated to a frightening and daunting experience.

Reflections: Home Again

Most of our participants assessed that travelling for stem cell treatments was 'worth it', and reported positive outcomes from the treatments but found it hard to specify exactly what changes and improvements had been made. Many spoke in general terms about their improvement; for example, that they had 'more energy', felt 'great', or 'just feeling better'. As noted in our previous work, when people undertake stem cell treatments along with other therapies it can be difficult to determine what has contributed to experiences of improvements (Petersen et al. 2014). While this was acknowledged by many of our participants they were nonetheless keen to attribute any perceived improvement to the stem cells. Many recounted miraculous stories of recovery that they bore witness to or

heard about while at clinics. Donna, whose partner had died prior to the interview, described the significance of a one-off 'miracle' that happened after she and her husband returned from Germany, which she attributed entirely to the stem cells:

> When we got back, a couple of weeks after we got back, [my husband] and I were having a drink at 5.30–6 o'clock, and I used to just get everything for [him] at that stage, because he was getting very very tired. And he got up and went into the kitchen, and I said, 'What are you doing, I'll …', and I realised he was getting a drink, which he never did, and I said, 'I'll do that', and he said, 'I didn't even know I wanted one', as clear as that. Well, we were over the moon. We laughed, we cried. We phoned up our friends and family. And he never spoke another word after that. Not another word. He couldn't speak before he went to Germany, he just couldn't make words.

Others reflected on how in spite of the huge cost it was worth undertaking the trip due to perceived improvements. For example, in commenting on her child's improved motor skills, Eloise explained:

> So, you know, it's definitely not a cheap thing. It's very, very expensive. But I just knew if I could get the money somehow, I was going to do it. I don't care how much, you know, obviously we're struggling now very badly but what do you? I mean, the mortgage is through the roof but, you know, that's what you do when … like I didn't even, you know, you struggle now but that's fine because [my child] improved so much. So it was worth it.

For others, even without any perceived improvement the journey was worth it as not actively pursuing stem cell treatments as an option would have been a significant failure. As Russell, the father and carer of a boy treated for cerebral palsy (referred to earlier), commented:

> I would say no, I don't think [my child] has, there has been any improvement from it. But, at the same time, I wouldn't say it's a failure … It sounds probably more like semantics but had we not tried, I think that would have passively been more of a failure, I think … I think if it had worked, if it had been beneficial to [my child], I mean either way, really, I think but, if it had been beneficial then yes, it would be worth every cent and even more, you

> know. You, you pay, I guess, as a parent you want the best for your child and you want the child to be the best that he or she can be. For I guess for the price of a small family car it's … I mean it's a big deal but it's not that great a deal, you know.

Our participants uniformly reported that there was either no or very little follow-up by providers after treatment, and any follow-up was typically very general, for example, a brief one-page questionnaire. This was also the case for Jackie, the mother and carer who travelled to China for the treatment of her child's autism, who reported significant improvement in her child's condition:

> They just ask us for an evaluation after one month after treatment, three months, six months and 12 months. Yeah. They want us just to fill in an evaluation. And its basically things like: has [child's] communication improved? Has [child's] gross motor improved? [Child's] fine motor? It's quite broad. And then you get room at the bottom to add, you can tick on a scale there: 'slightly improved' up to, you know, 'hugely improved' or whatever they've got it worded as. And then [there's] a bit at the bottom where you can write your own comments for each section. Yeah, so they, they just sort of are asking things like that. So it's more a broad sort of a tick and sort of checklist.

While miraculous narratives of benefit and significant improvement abound in both direct-to-consumer online marketing of clinics, and anecdotally via word of mouth among patient groups, participants themselves were careful to moderate their hopes and expectations of treatment. As Stephen, a patient who travelled to Germany for the treatment of their spinal cord injury, explained:

> I never thought that I was going to go over there and get stem cells and be able to walk down the road again or whatever it may be. I was just hoping that I might be able to get some sort of like movement or, yeah, bladder, my bladder might have been better. Or just stuff like that, really.

Jackie, whose case was examined above, expressed similar sentiments:

> Like, we were hoping for some improvement. We were hoping that it would help just to click those sounds together so that he could even say one syllable words, you know, like 'cat' and 'dog'. And we were hoping that any speech would have been better than what he had and, and that somehow this would help that co-ordination to happen … You don't like to get your hopes up too high.

Here the uncertainty surrounding potential benefits is negotiated by patients in part by minimising their hopes in the face of grandiose claims of success, like those found on provider websites, and discussed among patients informally. This stance of qualified optimism is a means by which individuals reclaim agency, by countering the assumption that travellers are simply 'dupes' of mercenary, dodgy operators, while allowing them the prospect of looking forward to an improved 'quality of life'. Significantly, for most of our participants, just the search for an improved 'quality of life' is experienced as worthwhile. As Russell, above, who travelled to the USA for treatment for his child, reflects:

> I'd do it again in a heartbeat. Sort of knowing if we hadn't done it and it was still, available, and if this came to us now, yes, I would still go. It's even the, I guess the unsuccessfulness of the treatment hasn't … put me off in that respect. I don't feel bitter and twisted in any shape or form from it. I think I would feel more bitter and twisted had I known about it and not done it, and not gone.

Here we see emerge another dimension to the paradox of choice that we discussed in Chap. 2; namely, the notable lack of regret that characterises these stories and the belief that *undertaking* a treatment is in itself beneficial, irrespective of the outcomes, since it denotes having *done something*.

Conclusion

Axel's words that introduced this chapter spoke of his admiration for the 'pioneers' who travel overseas for treatments who are 'at least … having a go' in spite of the associated risk and uncertainty. In people's narratives about their journeys overseas for stem cell treatments, the powerful

neoliberal imperative that individuals should 'do all they can for their health', and draw upon all their resources and agency to do so, is an unquestioned good. In many senses, these stem cell travellers can be seen to acting like ideal neoliberal citizens (or pioneers), who seek to exhaust all the avenues available to them in pursuit of their health (Harris et al. 2010). One of the implications of this is that people's stories about their journeys, rather than being about regret in regards to their decision to travel, and the adversity and challenges that they faced (i.e. associated with the flight, living in a foreign country, the clinic, the cost, uncertainty of outcomes and risk associated with the treatment itself), rather are stories of success, empowerment, and agency irrespective of the outcomes of 'treatment'. This means that for some, the very risks and uncertainties that regulators rely upon to dissuade people from travelling in fact function as plot-points in heroic and necessary quests to improve their quality of life, however small the benefits or great the cost.

As our discussion throughout our various chapters makes clear, in the political economy of hope what narratives are told, who tells them and how they are interpreted are critical factors that shape the dynamics of the stem cell market in significant ways. The experiences of stem cell 'tourists' are commonly presented in media stories, as emotive and highly compelling quests that are undertaken against all the odds by strong and determined citizens who are defiantly refusing to be passive, helpless, or hopeless. Yet they may, alternatively, be interpreted as journeys characterised by desperation, potential exploitation, and compounded suffering, especially by those stem cell scientists and clinicians who are working within a conventional paradigm of Western science and medicine (Chap. 3). As our findings make clear, neither of these constructions satisfactorily account for the range or complexity of the lived experiences of people who travel overseas for stem cell treatments.

With the rise of online direct-to-consumer advertising, networking, and social media, the power of the patient voice has taken on new significance (as we discuss in the context of China in Chap. 6, and further in Chap. 8). Given the power and potency of narratives of patient experience, we argue that it is important to consider how and in what ways new and different stories about these journeys can be told: what other narratives might be told about the people who travel for stem cell treatments,

about stem cells and about the journeys themselves? What is left out of accounts that dominate media representations? What other narratives can be told that move beyond characterisations of travellers as either pitied victims or celebrated beacons of hope, and journeys as either pioneering quests or dangerous and futile misadventures? More broadly, how might narratives of hope in stem cell science be re-framed so as to acknowledge the uncertainty that characterises the field without jeopardising future investment in promising research?

The next chapter turns attention away from the perspectives of people who received stem cell treatments to those that provided them and the regulators that shut them down, through an account of the rise and fall of one of the most infamous international stem cell tourism clinics—X-Cell in Germany. In so doing, we reveal the ways in which 'hope' may be exploited in the marketing of unproven treatments.

References

Bharadwaj, A. (2013). Experimental subjectification: The pursuit of human embryonic stem cells in India. *Ethnos, 76*(1), 84–107.

Harris, R., Wathen, N., & Wyatt, S. (Eds.). (2010). *Configuring health consumers: Health work and the imperative of personal responsibility*. Basingstoke: Palgrave Macmillan.

Patra, P., & Sleeboom-Faulkner, M. (2011). Recruiter-patients as ambiguous symbols of health: Bionetworking and stem cell therapy in India. *New Genetics and Society, 30*(2), 155–166.

Petersen, A., Seear, K., & Munsie, M. (2014). Therapeutic journeys: The hopeful travails of stem cell tourists. *Sociology of Health and Illness, 36*(5), 670–685.

Prasad, A. (2015). Ambivalent journeys of hope: Embryonic stem cell therapy in a clinic in India. *Health, 19*(2), 137–153.

Song, P. (2010). Biotech pilgrims and the transnational quest for stem cell cures. *Medical Anthropology: Cross-Cultural Studies in Health and Illness, 29*(4), 384–402.

Tanner, C., & Munsie, M. (2014). Seeing the full picture: The hidden cost of the stem cell and regenerative medicine revolution. In A. Pebay (Ed.), *Regenerative biology of the eye: Stem cell biology and regenerative medicine* (pp. 291–304). New York: Humana Press/Springer.

5

Exploiting Stem Cell Hopes in Germany

This chapter focuses on the controversy surrounding the provision of stem cell treatments by one German clinic, namely the X-Cell Center—once a leading European destination for patients and carers, but now a potent symbol of all that can go wrong with unproven stem cell treatments and its regulation. X-Cell was established in early 2007, and during its five years of operation, it was a successful clinic as it was able use the internet to tap into the hopes and expectations surrounding stem cells, especially their therapeutic potential for currently incurable conditions.

According to its website at the time, X-Cell offered treatment for conditions including diabetes, stroke, spinal cord injuries, multiple sclerosis, cardiovascular disease, Parkinson's disease, and Alzheimer's disease, among others, attracting many thousands of mostly overseas patients. All 'treatments' involved taking a small amount of bone marrow from the patient (autologous cell therapies), then preparing the 'stem cells' for administration on-site by placing the bone marrow aspirate in a centrifuge to reduce it to a stem cell concentrate. The cells were given back to the patient via an intravenous drip, injections into muscles, or even

A. Petersen et al., *Stem Cell Tourism and the Political Economy of Hope*, Health, Technology and Society,
DOI 10.1057/978-1-137-47043-0_5

injected directly into the brain depending on the condition. Although haematopoietic or blood stem cell transplants, which rely on the stem cells in bone marrow (the same cells X-Cell claimed to isolate and use) are a routine treatment for disorders of the blood and the immune system such as lymphoma and acute myeloid leukaemia, there remains little scientific evidence to support the use of these stem cells in broader therapeutic applications (Copelan 2006; Daley 2012). Despite the limited scientific justification, the X-Cell website featured stories proclaiming 'miracle' treatments, such as the success of a former patient who was cured of diabetes, and appeared to downplay the risks associated with their treatment, stating that they only use 'ethically inoffensive adult stem cells for treatment and research' (X-Cell Center 2008).

While many in the stem cell research community, within Germany and elsewhere, voiced concerns about X-Cell's operations, the risks that these unproven treatments posed to patients, and the regulatory loophole in which X-Cell operated, it was not until the death of an 18-month-old Romanian boy in 2010 that German regulators took a stance which eventually led to the closure of the X-Cell Center. In this chapter we will explore the events surrounding this controversy and examine the context in which this clinic operated, namely one of scientific and regulatory uncertainty, and argue that this uncertainty was a key factor in fostering X-Cell's success in selling 'hope'. We will also examine how German regulators responded to this situation, highlighting the challenge and importance for regulatory bodies at all governmental levels (regional, federal, and supra-national) to enforce their legal responsibilities and obligations to ensure patients have access to safe and effective therapies in a timely manner.

The chapter will firstly describe the German and European Union regulatory context that enabled unproven stem cell therapies to be undertaken and allowed X-Cell to become a leading destination for those seeking treatment. Secondly, it describes the clinic itself and how this facilitated the exploitation of hope. Thirdly, it examines how X-Cell and regulators viewed 'risk'. And, finally, it discusses how regulators acted as 'mediators of trust' and sought to restore regulatory order by eventually closing X-Cell's operations in Germany.

Regulating Cell Therapies in Germany

The European Union (EU) has been at the forefront of establishing an effective framework for dealing with emerging biomedical technologies including cell therapies. Specifically, new regulations (Regulation EC No 1394/2007) were introduced in 2007 to ensure that treatments involving cell therapy were subject to appropriate authorisation, supervision, and controls through the auspices of the European Medicines Agency (EMA) in order to reduce and manage risks associated with the emergence of cell therapies and applicable to all EU member states (EMA 2013). By placing the protection of patients at the centre of all regulation, the EMA sought to specifically capture cell therapies that involved more than minimal manipulation or used in a different way to their normal bodily function, as the following EMA (2013) statement illustrates:

> Cell therapies are defined as medicinal products when there is more than minimal manipulation of any cell type destined for clinical application or where the intended use of the cells is different to their normal function in the body. Any use of such cell-based medicines is subject to authorisation and controls, including their manufacture. Permitting manufacturers to avoid compliance with quality standards, for example by inappropriate reclassification of the treatment beyond the mandate of competent authorities for control of medicines, could risk exposing patients to cross-contamination and inadequate characterisation of the cell preparations, resulting in short and long-term risks for individual patients.

Furthermore, the 2007 EU legislation defined cell therapies as Advanced Therapy Medicinal Products (ATMPs)—medicines for humans that: (i) use cells or tissue that have been *manipulated* to change their biological characteristics; or (ii) use cells or tissues in a manner where they are not performing the *same essential functions* in the body. The latter criterion is also referred to as *non-homologous* use and is best explained as a situation in which the intended therapeutic benefit would require the cell or tissue to have a different physiological function than that it usually has. For example, the use of donated bone marrow to re-establish a patient's

depleted bone marrow is an example of homologous use; while the use of bone marrow to restore function to a patient with Parkinson's disease where certain nerves are absent in the brain would be an example of *non-homologous* use. However, as we will go on to explain, the interpretation of these definitions has led to regulatory ambiguity in Germany and elsewhere around the globe (see Chap. 7).

Timing, Exemptions, and Terminology Ambiguity

As a regulatory authority for all EU member states, the EMA had the right to exercise oversight on medicinal products, including those involving stem cells. However, effective enforcement in Germany proved to be particularly challenging. The new 2007 regulation (which directly applied in all EU member states) itself provided a transition period for ATMPs already on the European market to obtain authorisation by the EMA. But ATMPs, which were individually produced on a non-routine basis for a specific patient, were excluded from the scope of the regulation—this is what is often called 'hospital exemption'. The exemptions, and issues associated with implementation of new regulations in combination provided a 'loophole' for those seeking to sell unproven treatments and to obstruct the action of regulators.

In Germany, as in many other jurisdictions around the globe, doctors are allowed to treat patients while a therapy is still being developed or undergoing certification through 'compassionate use' programmes. While access to compassionate use programmes have been used for many years to provide a 'one off' treatment for those with few options (particularly in relation to cancer and palliative care), such programmes have recently gained notoriety through a discourse that asserts it is the patient's 'right-to-try' emerging treatments. A recent prominent case involved the Stamina Foundation in Italy, whereby patients lobbied for—and for a short period of time gained access to—an unproven stem cell treatment, demonstrating how an argument for the compassionate use of a treatment may override scientific evidence for its efficacy (MacGregor et al. 2015).

Across the EU, the 'hospital exemption' meant that medicinal products, including those derived or containing stem cells, could be made available to an individual patient in a European hospital under the

exclusive professional responsibility of a clinician. Under German regulation, the 'hospital exemption' is defined within the German Medicinal Products Act 2005 (the Drug Law) and its various amendments, stating that certain ATMPs are exempted provided approval is obtained from the relevant federal authority (Medicinal Products Act, 2012). While conditions to receive such an approval in Germany may differ from other jurisdictions, approval remains dependent on some level of manufacturing transparency and evaluation.

Although introduced in 2007, the EU regulation encompassing ATMP across Europe started to apply from December 30, 2008, and included a transition period until December 30, 2011 to allow compliance with this regulation for gene therapy and somatic cell therapy medicinal products (Schnitger 2014). This meant that there was a period of 36 months in which companies could formally seek authorisation from the EMA and the relevant local authority. This transition period thereby contributed to a lack of clarity regarding whether a stem cell-based product had to be regulated under the EU regulation or the German Drug Law.

In addition, the interpretation of the 'non-homologous use' definitional aspect (the use of cells for purposes other than their biological function) in relation to ATMPs was contentious, leading some providers to argue that their stem cell therapy was a medical 'treatment', not an ATMP, and therefore, outside the remit of both the EMA and the German regulations. Combined, these ambiguities and uncertainties contributed to an environment that allowed X-Cell to flourish.

Enter X-Cell

When contemplating where to establish their stem cell clinic, the entrepreneurs behind X-Cell did not necessarily consider Germany to be their first choice. However, following the introduction by the Dutch government of a moratorium banning all unproven stem cell treatments and requiring all clinics providing stem cell-based treatments to have a licence, the backers looked across the border. By establishing X-Cell in Germany, they were able to take advantage of regulatory uncertainty

that existed in German and European law at the time, as well as capitalise on the hopes and expectations surrounding stem cells, particularly those 'ethically inoffensive' stem cells derived from the patient. From 2007 to 2011, X-Cell treated many thousands of people. Jakob, a lawyer who at one time examined X-Cell's operations, suggested that this numbered over 13,000 people, almost exclusively foreigners, over a two-year period, at its zenith. In this section, we wish to describe the presentation of X-Cell and how it created a sense of trust with patients and regulators, despite scientific and legal uncertainty. A key factor in X-Cell's initial success was the physical setting of its operations.

By renting floors in Catholic Hospitals, such as the Dominikus Hospital in Düsseldorf and the Eduardus Hospital in Cologne, the clinic conveyed the impression of offering contemporary and quality medical care. As Anja, a German regulator, commented after visiting the site for the first time:

> It was a very stylish clinic … there was some great orange paintings on the wall and it was stylish. I was a little bit surprised because normally, when I go to something like … [laboratories] or one of the wholesalers, they're not that perfectly styled.

Jakob, the aforementioned lawyer, described his experience when visiting the Düsseldorf clinic:

> They had rented … a whole floor of, of the hospital, renovated it with marble tiles and dark wood panels … on the reception. They, they had receptionists that looked like models, that were fluent in every imaginable language. They had a perfect presentation in the internet and they used a shuttle service to pick patients and their relatives up at the airport here in Düssseldorf, and drive them right over to the hospital.

The experience of going to X-Cell for treatment was sold as a form of 'medical tourism', with patients being met at the airport or train station by a representative, accompanied to the clinic and offered transfers to and from the patient's hotel. Treatment at X-Cell was presented as a premium service, with the autologous stem cell treatments for almost any

condition priced from €EUR3,000 to 10,000 upwards. Undoubtedly, one of the biggest selling points for X-Cell was 'Brand Germany'—capitalising on the country's international reputation for exacting manufacturing standards and high medical care. All of our German participants indicated that 'Brand Germany' was one of the key reasons X-Cell became an early hub for stem cell tourism. As one state level policy maker said about X-Cell treatments: 'it has the quality of "Made in Germany" … that was really … troubling us'. As Stephen, a patient with spinal cord injury, said, going to Germany meant that they felt 'reassured about what was happening as opposed to being in a [developing country]'.

We would suggest that the perception of legitimacy was a key aspect in the success of X-Cell. However, another factor explaining the clinic's success was its ability to develop a niche service oriented to those hopeful citizens who had exhausted conventional treatment options. As Jakob, a lawyer, observed:

> [T]he people are willing to risk the money and the health of their relatives, their own health because they are in such a miserable medical condition and every doctor they had visited in the past said, 'Well I can't do anything for you anymore'. 'You won't get better anymore', or, 'You are supposed to die in half a year.' … I think that that's human. Everyone would do that because no one wants to … watch this … child die or … live miserable without any hope that it'll get better.

Australian patients and carers, however, were not uncritical about the clinic and its operations. Some former patients recounted their suspicions about the motives of X-Cell and the legitimacy of its treatments and operations. In recalling her experience of treatment at X-Cell where she undertook treatment for spinal cord injury, Catherine recounted:

> I went into the room. The thing that did get me a little bit suspicious when I got there was they took my money straight away, which I think's a little bit odd but, then again, I can understand that people are coming from overseas … and then, basically, they did the procedure the following day.

Another former Australian patient, Audrey, who undertook treatment for multiple sclerosis, commented:

> When I was hooked up to the drip, before they injected the stem cells in, the manager of the place, a great, huge guy came out and he said, 'Oh we haven't got a receipt for the money', so I had to make sure the money had gone into their account before they would put the stem cells in. On my return [to Australia] … my neurologist sent me to a haematologist and got my bloods checked, and he said there's no evidence whatsoever to say that I have had a stem cell transplant.

The marketing techniques utilised by X-Cell extended to the employment of staff with diverse language skills. While they may have been able to enhance the experience for patients by addressing communication difficulties, questions have been raised about whether they effectively translated sufficient information about the procedure and associated risks. As Jakob, the aforementioned lawyer, noted:

> They hired people that are able to speak in the native language of the patients and their relatives in Eastern European, Arabian or the Turkish language, or whatever … there were hints in the investigation that these people minimised the risk and … told the people of even higher success rates than X-Cell Center itself stated in the internet. They, of course, were clever. They said, 'Well, there is a possibility of such-and-such percentage that you get healed or that it's getting better.' They, didn't state that, they didn't guarantee a healing. So, of course, the lawyer who's representing the parents of the boy from Romania that died he accused them of fraud, saying they, they guaranteed a healing. Well, in the internet they didn't and the medical doctor said, 'I didn't.' He says, 'Well, but the guy who worked as translator'.

Such descriptions depict a situation some commentators critical of the commercial provision of unproven treatments describe as 'false' hope (as explored in Chap. 3). While the selling of hope may result from a combination of various factors, such as patient demands, financial exploitation, legal and administrative mandates, and media hype (see Chap. 4), hope is often 'based on unrealistic set of expectations, encouraged

through incomplete or faulty information or by a patient's unwillingness to acknowledge the limits of medicine' (Rettig et al. 2007: 286). For those we spoke to in Germany (and similar to that reported in Chap. 3), managing patients' hope in stem cell treatments can be confronting. As Knut, a stem cell scientist from Berlin, explained, you do not want to deny the patient the right to seek out treatment:

> I cannot take away the responsibility and the right of a single patient to seek treatment wherever they want … there is no way to really go in and say, 'You are not allowed to spend this X, Y amount of money on this and this treatment', right. So I can only go in and educate the patient, and say, 'According to what we consider a scientific, solid evidence, this is not approved therapy.' However, to go in and say, 'This doesn't work on scientific terms. We only know that this is going to be very difficult', right. How can you really prove it doesn't work? Right? It is hard to prove that something works. It's even hard to prove that something doesn't work, right. So I think we have to be very, very careful saying that, you know, this doesn't work, that doesn't work. We can only always try to educate the patient and say, 'These are our rules'.

So who does set and enforce the rules? What conspired in Germany to enable X-Cell to continue to operate despite concerns being raised by those within the stem cell community? In the next section we will examine the role and ultimate actions of the regulators to close X-Cell and the circumstances in which this occurred.

Recognising and Responding to Risk

Risks do not 'arise from the presence of particular precise danger embodied in a concrete individual or group. It is the effect of a combination of abstract *factors*' (Castel 1991: 287). In the case of X-Cell, while the factors can in hindsight now be clearly articulated, defining and responding to the risks of the treatments being administered at the clinic took many years and a tragedy to solidify.

As we explained earlier, the use of stem cell transplantation (from bone marrow or peripheral blood) to re-establish haematopoiesis (the

generation of blood) in the course of treating malignant haematological diseases has a long history and is considered a clinically proven stem cell treatment. By using a similar source of stem cells to that routinely used in medical care (albeit for different applications), X-Cell was able to distance itself from other more 'experimental' stem cell therapies and cast an aura of safety around their provision despite a lack of scientific evidence. Bernhardt, a federal regulator, noted:

> X-Cell said, 'Okay, bone marrow is going on. It's a safe substance to be administered', and they claimed, 'Well we know that in bone marrow there are stem cells not only for haematopoiesis but they are absolutely versatile. They can cure anything.' And that was their … claim without any scientific proof but they advertised it very smartly and so they got a lot of patients for that.

Another German regulator involved in monitoring X-Cell's activities went on to explain that from their point of view there was nothing wrong with X-Cell's manufacturing protocol, noting that the clinic had a manufacturing licence and complied with the legislation. Rather, the problem was how the clinic *used* the product. Carsten, a stem cell policy advisor suggested that attempts to close X-Cell were initially stymied 'because of the legal situation in Germany … if you don't hurt anyone, you can offer treatments although it's not really clear if they do something good for people'.

So what level of risk or possibility of harm is required to instigate regulatory action? A precautionary approach to drug development has been an essential part of German law since the Contergan controversy in the early 1960s. Contergan was an over-the-counter tranquilliser and sleeping pill that contained thalidomide and widely marketed to help alleviate the symptoms of morning sickness and was taken by many expectant mothers (Tuffs 2007). During the late 1950s and early 1960s, approximately 5000 babies were born with deformities and birth defects in West Germany. In 1961, some scientists discovered a link between the deformities and thalidomide. It was only when health officials threatened to ban the drug that the company acted and took it off the market. However, unlike the Contergan controversy, initially X-Cell sought to

argue with German authorities that they only provided a medical practice with little risk (similar to the arguments of Australian providers which we explore in Chap. 7).

It was not until the criticism became more public, following reports of a ten-year-old boy from Azerbaijan suffering severe internal bleeding in the brain after he was given treatment that involved injecting stem cells into the brain, and the death of another child, that regulators appeared to move. Hanna, a German patient advisor, explains her frustration in gaining the attention of regulators:

> It took us … unfortunately, more than two years because we … started to talk with … the highest authority in Germany right from the beginning and they were not motivated at all because they … basically said … 'in two years' time, there's a new regulation. Everything is involved. No problem.' And then we said, 'Yeah, but there are more patients going' … but then the first kid was severely hurt, their position changed. And, when the second kid then died, then, of course, [clicks fingers] just like that [X-Cell was closed down] …

The treatments being offered by X-Cell were exposed by several severe adverse reactions and a death. This situation meant that regulators sought to work out who was the relevant authority to deal with the issue—was it a problem of medical practice (the mode of application into the brain of the child) requiring the intervention of the medical association or was it a problem with the quality or safety of the medical product, requiring regulation?

Anja, a state regulator, explained, one of their main issues with X-Cell was how they used their therapies, especially the lack of scientific evidence to support the use of stem cell therapy to treat certain conditions:

> The way they prepared these stem cell solutions I think this was very easy and this was not critical for us. The problem was what they did with the solutions. They put the solution anywhere … There was no evidence why they put it in the brain of this child, for example.

Bernhardt, a federal regulator, recounts their discussions with X-Cell and their disagreement over the risks associated with the stem cell therapy:

> In conversation with the company and with the lawyer of this company … we told them that there is a negative risk-benefit ratio. We said they did not present us any data concerning the benefit, but we have seen a lot of adverse reactions. And then … they told us that they presented their data and this was more or less the report. They asked the patient weeks after the treatment whether they feel better now, whether they can confirm that they really benefit from this treatment. And they told us that they do not need pre-clinical data because they have the evidence for the successful treatment.

Among regulators, a persistent concern was the possibility that X-Cell and its ongoing operations could harm the future of stem cell science and any chance of developing legitimate stem cell therapies in Germany. As Andreas, a former paediatrician, and now federal regulator, explained:

> We had a discussion with the stem cell [science] section … and they told us, 'Please stop this company because they will throw a dark light on our … scientific work, and they will hinder our successes.' And then we told them, 'How could we do this? We need good arguments to really stop this company and this is a problem within itself because they also are starting with new treatments and they, of course, they are convinced that their treatment is really beneficial, and this is the good one', yeah … And this, this company did the bad one. This was very obvious. But now to make the differentiation between the good and the bad treatment, this is really difficult also from a scientific point of view. And this was really, for us a really interesting and very important case to really, to improve our knowledge and to come to better decisions.

Ingrid, a regulator with expertise in monitoring the effects of medical drugs, echoed this need to foster 'good' but block out 'bad' practices as the goal of regulators:

> On the one hand, cell therapies are a very promising field and we are sure that there's a lot of potential in this field. And we do not want to … hinder the development of good, new therapies. That's one thing. But, on the other hand, this may be … doctors who advertise, [but] … do not have yet any scientific proof or that … our goal is that … those who develop therapies would really develop that in a scientific way and, and do good

> pre-clinical and clinical studies, and then, at the end, come to us with an application for approval or marketing authorisation. That's, our goal and that's what we are striving for. But unfortunately there may be some colleagues, some doctors who claim they know it better and they have already the … holy grail, and they can sell it for a lot of money. But that's our problem.

The X-Cell controversy presented regulators with a challenge in how best to manage risk. Providers presented treatments as having minimal risk, which meant they could sell treatments to patients hopeful of some improvement or cure to their illness. When the level of risk became 'too high', regulators were able to step in, in order to help stop the marketing of these potentially harmful unproven stem cell treatments. But the question arose, what constitutes 'risk' and when does this become unacceptably high? In the ensuing debates, different actors used 'risk' in different ways to advance their objectives, either to exploit hope, or to 'protect' 'the public', with regulators in this context performing a key role as 'mediators of trust'.

Regulators as 'Mediators of Trust'

In this section we examine how German regulators acted as 'mediators of trust' (borrowing a term used by Brown and Calnan 2010) to protect the public by closing down X-Cell, and how this trust was important for maintaining the integrity of the regulatory system and its ability to prevent any future harm from similar unproven treatments and providers. Möllering (2006) has stated that in conditions where risk, uncertainty, and harm become prominent, trust becomes a necessary process of constructing knowledge to bridge over this risk. Trust is generally understood sociologically in two senses: first, a generalised confidence in the belief in the systems, that is, systems-trust; and second, as a communicative process whereby trust becomes a 'solution for specific problems of risk' (Luhmann 1988: 95). As regulators enforcing biological and medicinal product frameworks are often engaged in 'faceless' work behind the scenes, the X-Cell controversy forced regulators into a communicative process of

'facework' (Giddens 1991) to directly engage with clinicians, the public, the media, and other state, local and EU officials. The German regulators were engaged in various conflicts with X-Cell and the medical profession and faced public pressure to do something, given the adverse reactions of former patients and the death of the Romanian child. However, a core issue was to determine who had the authority to act to close down X-Cell, as at the time this was unclear. As Max, a federal regulator, pointed out, 'the field you are talking about … is in the zone between medical practice, between experimental therapy, development of medicinal products and then approval of medicinal products. So this is not so easy'. Therefore, a key aspect of the X-Cell controversy was about establishing who had the authority within Germany to protect the public and uphold the values of the *Bundesland* (Federal state).

A core unresolved and unanswered issue remains; namely, how was X-Cell able to operate and flourish for so many years? Why didn't the German Medical Association react to X-Cell's activities and why didn't they at least state clearly that they considered X-Cell's business unethical? These questions cannot be answered in this chapter, but they are central issues that need to be answered. The approach taken by the German Medical Association was not uniform across Germany. For example, in September 2009 the General Medical Council of the North Rhine issued an official warning against commercial unproven stem cell treatments (AEKNO 2016). Due to the lack of action by the German Medical Association, and the timing ambiguity associated with the transition to EU regulations, product regulators sought innovative approaches to shutting down X-Cell. As Martine, a federal regulator, recalls:

> Well it didn't stop it itself but we had to say fix it by … an official order … saying that they need an authorisation to do Section 4b of the German drug law from the [Paul Ehrlich] Institute. And a separate [product] authorisation for each indication. And they didn't apply for any of them at the end of the transition period when Section 4b was introduced into German drug law. And that was a time I think in early 2011. So when we fixed that by an official order, that was the point when the local authority could say, 'Okay, you do not have the [product] authorisations you need. Now close your business!'

Therefore, a critical element for regulators was to demonstrate that the regulatory systems could be trusted and enforce the law to create certainty where uncertainty had previously prevailed. However, in 2011, the establishment of compliance between German and EU ATMP regulation re-drew the boundary around what should be considered a medicinal product. As Gunter, a lawyer and federal regulator, explains, the new ATMP regulation, which aligned German law with EU laws, created new interpretations of what a medicinal product was in Germany:

> Especially the ATMP regulation … had a … new approach where the drug law started regulating products that weren't considered as products before and where physicians usually say, 'We don't … practise with products. These are therapies.' It's a practice. It's a … doctor's practice.

This new law created great frustration among scientists and clinicians alike due to the complicated nature of trying to regulate non-homologous stem cell treatments, especially when there was ambiguity regarding whether it should be regarded as a medical practice or a medicinal product and where regulations have the potential to impose new barriers for existing *proven* medical practice. As Knut explained:

> One of the problems … of X-Cell was … you take [the] cell population out of the person, leave it in the operating theatre and give it back into the patient. That was what X-Cell was doing. And this is very tricky to regulate … There's always the question: is that now homologous or does the cell which you take out in the primary place fulfil the same function in the secondary place where you're putting it or does it do anything different? ... But there are a lot of [existing] procedures out there which are approved, which work, which are good procedures which are based on … that idea to take cells and put them right back. Yes, so one wished one could have closed down X-Cell by saying, you know, 'You're, you're just, you're putting stem cells or you're putting cells back from one place in the body into another. You … have no proof that it works so … we stop that.' If you would do that, you … [would introduce] a process of regulation and approval for all these different procedures which we were doing already for 20, 30, 40, 50 years which … work. So you open a box of worms.

These comments convey the complexity of regulating stem cell therapies and instituting trust to resolve uncertainty surrounding unproven stem cell treatments. As another federal regulator, Martine, explains, regulators placed their trust in the new ATMP regulation and took a hard stance on unproven stem cell treatment:

> A very important element of this whole legislation is the definition of advanced therapy medicinal products which are regulated I say more intensively than the … normal medicinal products. And one aspect is that … new therapies are prepared in a special way and manipulated … so that you need to have a closer look because of this manufacture. And the other criterion is that the stem cells are used for another purpose than … the normal physiologic function [non-homologous]. And the argument of X-Cell was, of course, yeah, 'This is bone marrow and the cells in bone marrow. Everybody knows that … it's not different from the physiologic function.' But we follow the very strict view that the indication for bone marrow is rescue of haematopoiesis and that's the normal function for us. And everything else for us is a criterion for considering this as an ATMP, which gives us … more options for intervention … And, of course, we get a lot of criticism for this and a lot of colleagues who develop more stem cell therapies argue against that and, and say, 'Oh you are stupid! You don't know what … stem cells are capable of.' We know that but … we have our reasons for our position … The X-Cell case was very important for being so harsh on this.

The X-Cell controversy evidently helped to demonstrate that the new ATMP regulation was strong enough to deal with emergent issues, such as the marketing of unproven stem cell treatments, and to create a sense of trust in the German system of technology governance. As Martine reflects:

> I think the current legislation is adequate … because there's a higher level of awareness now after this X-Cell, but you never have any kind of regulation which hinders … criminal [activity]. Criminals … look for a gap and any criminal will find … a gap, and then you have to adjust perhaps the law. At the moment, we feel that … the awareness is so high that, with the laws we have at the moment … [we will be able to] avoid such things like X-Cell [happening again].

The future of regulating medicinal products used for advanced therapies within Germany will continue to face many challenges, yet one of the major positives in helping to restore trust in German regulation in the wake of the shutting down X-Cell was the establishment of stronger support and coordination between EU and German regulators. Reflecting on the X-Cell controversy, Sasha, an EU regulator, commented:

> I think it brought to very wide attention the risks of stem cell treatments quite nicely. Not nicely to the patient who died, but to the knowledge of the community that these are not random treatments that can be given to anyone by anyone.

Indeed, as Sasha went on to explain, despite the X-Cell controversy and trust fostered in the regulations, unproven stem cell treatments can still be offered under the hospital exemption—albeit under certain strict conditions and approvals:

> I have heard that, under the hospital exemption, still we are having a lot of treatments and even stem cell tourism taking place in … Europe.

While regulators were able to finally act and close down X-Cell, thereby protecting patients and establishing a degree of trust and legitimacy in the new transnational regulatory framework, practices of questionable scientific merit continue to be provided in Europe. Indeed, not long after the closure of X-Cell, individuals involved in the clinic opened another stem cell treatment clinic called Cells4health in Beirut, Lebanon (Mendick 2012). This clinic appears to offer similar unregulated treatments to those previously offered by X-Cell, and again charging many thousands of dollars to vulnerable patients. This clinic is an international operation—it takes autologous cells from the patient's bone marrow in the clinic in Beirut and then sends them to the UK's Precious Cells laboratory for processing—then sends the stem cells back to Lebanon where they are injected into the patient. It would appear in this case that despite the lack of credible evidence to support the serial activities by clinics such as X-Cell, patient demand in the face of regulatory ambiguity or vacuum have allowed this concerning and potentially risky intervention to continue.

Conclusion

The X-Cell controversy and the German experience of inbound stem cell tourists illuminates how the exploitation of 'hope' and of scientific and regulatory uncertainty may serve in the rise of the stem cell treatment market. In this context of uncertainty and high hopes, X-Cell was able to use 'Brand Germany' as a marketing strategy to engender trust in the 'safety' of its autologous stem cell treatments. However, following the publicity around the death of a child, regulators eventually were able to use patient harm as grounds to justify the closure of X-Cell. In short, as competing claims-makers in regard to stem cell treatments, regulators were able to position themselves as 'mediators of trust' in order to counteract the uncertainties associated with clinical practices.

The German experience demonstrates that there is no easy solution to the complexities raised by the provision of clinically unproven stem cell treatments. For scientists, stem cell technologies, like other experimental treatments, need time to develop and prove their efficacy before they are made widely available, and certainly before they are sold and marketed to the public—trust between regulators, clinicians, and the public is crucial in this regard. Yet, as we have pointed out in previous chapters, those contemplating undertaking stem cell treatments often cite a lack of trust in state and medical institutions to take an interest in their well-being, and in some cases, they indicate that they would rather invest trust in unknown others who offer treatments of uncertain benefits.

Our next chapter turns to the case of 'selling hope' in China—one of the main destinations for people travelling for stem cell treatments in recent years. It explores the views of those involved in the sale of unproven treatments, to reveal how providers may seek to engender trust and shape the clinical experience—in this case, in a country that does not have a regulatory infrastructure comparable to Germany, or arguably the level of legitimacy conveyed by 'Brand Germany'.

References

Ärztekammer Nordrhein [AEKNO]. (2016). Comment regarding the commercial application of adult stem cells. https://www.aekno.de/page.asp?pageID=7460. Accessed 26 Feb 2016.

Brown, P., & Calnan, M. (2010). Braving a faceless new world? Conceptualising trust in the pharmaceutical industry and its products. *Health, 16*(1), 57–75.

Castel, R. (1991). From dangerousness to risk. In G. Burchell, C. Gordan, & P. Miller (Eds.), *The Foucault effect: Studies in governmentality* (pp. 281–298). Hemel Hempstead: Harvester Wheatsheaf.

Copelan, E. A. (2006). Hematopoietic stem-cell transplantation. *New England Journal of Medicine, 354*(17), 1813–1826.

Daley, G. (2012). The promise and perils of stem cell therapeutics. *Cell Stem Cell, 10*(6), 740–749.

European Medicines Agency. (2013, April 22). Stem cell therapy treatments. http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2013/04/news_detail_001769.jsp&mid=WC0b01ac058004d5c1. Accessed 4 July 2015.

Giddens, A. (1991). *Modernity and self-identity: Self and society in the late modern age*. Cambridge: Polity.

Luhmann, N. (1988). Familiarity, confidence, trust: Problems and alternatives. In D. Gambetta (Ed.), *Trust: Making and breaking cooperative relations* (pp. 94–108). Oxford: Basil Blackwell.

MacGregor, C., Petersen, A., & Munsie, M. (2015, December 13). Patient access to unproven stem cell treatments: A human rights issue? *Eurostemcell*. http://www.eurostemcell.org/commentanalysis/patient-access-unproven-stem-cell-treatments-human-rights-issue. Accessed 4 Mar 2016.

Medicinal Products Act - The Drug Law. (2012). Arzneimittelgesetz – AMG. Bundesministerium der Justiz und für Verbraucherschutz/juris GmbH. Federal Republic of Germany. http://www.gesetze-im-internet.de/englisch_amg/. Accessed 9 Mar 2016.

Mendick, R. (2012, April 7). Stem cell doctor forced to close his clinic after child's death is back in business. *The Telegraph*. http://www.telegraph.co.uk/news/health/news/9192216/Stem-cell-doctor-forced-to-close-his-clinic-after-childs-death-is-back-in-business.html. Accessed 4 Apr 2016.

Möllering, G. (2006). *Trust: Reason, routine, reflexivity*. Oxford: Elsevier.
Rettig, R. A., Jacobson, P. D., Farquhar, C., & Aubry, W. M. (2007). *False hope: Bone marrow transplantation for breast cancer*. Oxford: Oxford University Press.
Schnitger, A. (2014). *The hospital exemption: A regulatory option for unauthorised advanced therapy medicinal products*. Unpublished master's thesis, University of Bonn.
Tuffs, A. (2007). Thalidomide—The drama continues. *British Medical Journal, 335*, 1125.
X-Cell Center. (2008). The miracles from Dusseldorf and Cologne. http://web.archive.org/web/20080512193510/http://www.xcell-center.com/news190a.html?id=17. Accessed 12 May 2008.

6

Selling Hope in China

> *A lot of the patients, historically, are patients who are in bad shape, so you know, I mean, you're selling hope … There are more questions than answers.*
> (Douglas, a Western doctor and representative of a clinic selling stem cell treatments in Beijing)

In the shadow of a large public hospital in Beijing is a small private clinic in a compound that caters to wealthy local and international patients, who come from abroad to undergo stem cell treatments for a wide variety of conditions. In early 2014, this clinic was one of a handful of clinics advertising on the internet in order to attract patients to China despite a ban prohibiting such practices. The ban had been in place since 2012 while the Chinese government deliberated over a regulatory solution that could curb the availability of unproven stem cell treatments, while at the same time nurture the innovation and clinical translation of stem cell science.

Upon visiting Douglas's clinic, you might feel as though you are at any modern, private clinic in the world. The focal point of the foyer is a fish tank surrounded by an elaborately lush garden display, tended to by multiple service staff. A small number of medical staff and families pass in

A. Petersen et al., *Stem Cell Tourism and the Political Economy of Hope*, Health, Technology and Society,
DOI 10.1057/978-1-137-47043-0_6

and out of the adjoining coffee shop. In the corridors that lead away from the foyer, open doors give glimpses into large rooms full of rehabilitation equipment. Occasionally, patients are wheeled through on gurneys by medical support staff, accompanied by nurses and family members or carers speaking a variety of languages, including English, Mandarin, and Arabic. The sterility and technological modernity within the clinic is in stark contrast to the surrounding suburb. Winding alleyways are filled with local businesses that cater to the needs of families caring for their loved ones in the large, adjacent public hospital. Provisions beyond prepaid medical services and medications are not supplied, as is the case in most public hospitals in China. The smells of noodles, steamed buns, and other basic meals waft out of single-room brick restaurants, while other small shops sell bedding and blankets, small plastic tubs for cleaning and bathing, and myriad other goods for families to help make their relatives' time in hospital more comfortable. Laundry services make use of hanging space between low tree branches and old brick walls. Yet, back inside the clinic, sparkling tiles, immaculate uniforms, and comfortable furniture convey modernity and a sense of order for those visiting from abroad. Glossy brochures in the foyer explain that the hospital 'is constantly striving to find the healthcare of tomorrow, and make it available today'. Their website asks prospective patients to consider 'the promise of hope, life is waiting'. Across Beijing, another rival clinic's brochures bear the motto 'every life, every family, every hope'.

The question of whether hope is being fostered or exploited in the context of stem cell tourism is highly contentious, and invariably provokes strong responses from a diverse range of stakeholders. Previous chapters have explored the critical significance of hope in shaping the stem cell tourism market through consideration of the perspectives of Australian citizens who have travelled for stem cell treatment, or considered doing so, those charged with the responsibility of advising people about whether or not to travel, as well as regulatory authorities in the case of Germany. In this chapter we examine the context, practices, and processes that have led to the growth of the market for stem cell treatments sold to foreign patients in China, predominantly along its more developed eastern and southern seaboards. In so doing, our examination of hope moves beyond consumers or potential consumers of unproven stem cell treatments to

consider the hopes of the many other people and institutions that have sought to take advantage of the opportunities that China has provided.

As the market for treatments burgeoned in the 2000s, China attracted the label of the 'Wild East' of stem cells, with connotations of lawlessness and danger (Dennis 2002; Chen 2009; Song 2011; Zhang 2014). However, far from being random and chaotic, the stem cell treatment 'industry' in China operates in a complex, sophisticated, and constantly evolving landscape, in part driven by national hopes for economic development and prestige in the field of stem cell science. Yet, as this chapter argues, China is also an attractive destination for foreign doctors and entrepreneurs who want to capitalise on the opportunity to work in a permissive environment, also motivated by their own hopes and expectations surrounding stem cell technologies. We begin by examining 'Brand China', and the challenges treatment providers face in selling China as a destination for the latest in innovative and safe stem cell therapy. We then look at the context in which the market has developed and how treatment providers work to make China an attractive destination, as well as shape the expectations and experiences of those who undergo treatments in their clinics. We then move on to a discussion of the ways that treatment providers transform hope into a commodity, particularly using positive stories from past patients, used to attract new patients to their clinics. In particular, our analysis of the stem cell treatment market in China pivots on the moral and ethical complexities associated with the notion of 'selling hope' as a treatment in itself.

Brand China

In Chap. 5, various stakeholders commented that 'Brand Germany' came with an association of high medical and manufacturing standards, and this contributed to the aura of legitimacy around X-Cell's unproven treatments. In contrast, China may not necessarily be the first destination that comes to mind for patients contemplating where to access the latest in cutting-edge healthcare. To explore this further, this section illustrates some of the expectations Australians hold about treatments in China. In Chap. 2, Ivan and Vlasta, who care for their child with

cerebral palsy, explained that they 'were never going to go anywhere other than Europe' until regulatory changes left them with no choice. It was not until they had the opportunity to visit China for business that they became open to exploring non-European destinations. Ivan described his expectations of it being a third world country, but upon seeing the 'facilities and the money, and the technology', he and Vlasta concluded that it would be safe to seek medical treatment there. In this instance, having an opportunity to visit changed their minds about the level of modernity to be found in contemporary China. However, this experience was not the same for others who had also previously travelled there. Sean, who was considering stem cell treatment for spinal cord injury, held a negative view of the standard of facilities available in China, generalised from his experience of travel in the country. As he explained,

> My wife found a program that was being run at the time in Germany … And we thought, 'Oh, okay, that sounds a little bit more promising than India or China.' There was no way I wanted to go to any of those places. Completely scared off. But something in Germany suddenly sounded, 'Oh okay, it's in Europe, it's got to be, have some legitimacy and, and it's got to be good.' … I had travelled to China so I knew what China was like and there was no way I wanted to go there.

For those with little personal experience of China, the unfamiliar gave rise to a range of preconceptions and assumptions about the state of healthcare in China. Again, in Chap. 2, we heard Ivan's surprise at arriving in China to find that it wasn't populated by 'guys with hats running around' pulling rickshaws. However, Felix, an Australian who was exploring treatment for multiple sclerosis, saw China as part of a region capable of offering world-class facilities, due to its proximity to Thailand and reports from friends who had travelled there for medical treatments:

> The only thing that would have influenced [my perception of China] would have been things like, you know, friends of mine who've gone to Thailand and stuff for dental treatment and they get the absolute state of the art treatment at a fraction of the cost compared to here, and that sort of thing. I thought, well, you know, they probably know what they're doing.

Felix decided not to travel after the information the clinic sent him was insufficient and they were 'either unwilling or unable' to answer more specific questions; however, he did not express any reservations about what he might encounter at a clinic in China had he chosen to travel. For Australians at least, it would seem that 'Brand China' lacks a coherent narrative regarding innovation and safety in healthcare.

These varying preconceptions and experiences are an apt reflection of the current regional and institutional variations within the Chinese healthcare system. In marketing China as a destination for stem cell treatments, one of the key tasks facing treatment providers is bringing some clarity and familiarity to an unfamiliar and constantly changing treatment landscape. The next section charts the context and development of the market for stem cell treatments in China, before leading into a discussion of how providers of treatments in China work to make such an unfamiliar destination attractive to people considering travelling for stem cell treatments.

Creating the Chinese Market

The historical development of the healthcare system in China gives context as to why China became a leading destination for people seeking stem cell treatments. After Mao Zedong came to power following the revolution led by the Chinese Communist Party in 1949, a number of policies underpinned by a strong commitment to public health led to a rapid growth in health infrastructure (Liu et al. 1994; Yang 2006). Since 1978, as China's policy of *gaige kaifeng* (reform and opening) under Deng Xiaoping pursued a national shift towards a free-market system, healthcare funding was increasingly abandoned to market mechanisms, doctors' salaries remained low, and hospitals were encouraged to survive on a fee-for-service basis rather than government funding (Blumenthal and Hsiao 2005, 2015; Lin 2012). Hospitals that were able to survive in the marketplace were able to dramatically upgrade the quality of their facilities and equipment; however, this situation also led to a scenario termed 'public identity, private behaviour' (Zhao 2005), whereby illegal practices did not necessarily attract regulatory attention as long as

they brought in much-needed revenue for doctors and hospitals. Well-known methods of generating extra income include the over-prescription of medication and the gifting of *hongbao* (red packets filled with money) from patients to doctors for a variety of reasons, such as to circumvent a surgery waiting list or to encourage the medical professional to perform to a high standard (Bloom 2001; Yang 2006).

In the 1980s and 1990s, Asian nations sought to rapidly develop life sciences and technology as a route to economic development (Ong 2010: 30). Japan, Singapore, and South Korea, all pursued national agendas in stem cell research (Sleeboom-Faulkner 2010a; Thompson 2010). In China, stem cell research and tissue engineering were designated national priorities as part of a broader programme of innovation that also focused on 'IT, bio-technology and advanced agricultural technology, advanced materials technology, advanced manufacturing and automation technology, energy technology as well as resource and environment technology' (Ministry of Science and Technology 2006). As in other Asian nations, stem cell technologies became bound up with regional and national hopes and expectations for economic and social development. At times, such high hopes for rapid development led to individuals being caught engaging in unethical practices. For example, a scandal rocked South Korea when it was discovered that one of their nationally and internationally celebrated scientists, Dr. Hwang Woo-Suk, fabricated his stem cell research and employed coercive practices to collect öocytes from research participants (Gottweiss and Kim 2010; Thompson 2010: 103). In the context of this regional competition, the commercialisation of unproven stem cell treatments started in the 1990s and proliferated during the 2000s in China (Chen 2009; Ryan et al. 2010; Levine and Wolf 2012).

To support rapid development in the life sciences in China, the government invested heavily in scientific and medical infrastructure (initially borrowing technology from Western countries) and implemented policies that attracted Chinese scientists back from overseas positions to contribute to Chinese stem cell research with generous salaries and good working conditions (McMahon et al. 2010). While clear but legally unenforceable guidelines about acceptable practices in stem cell research had been in place since 2003 (Cheng et al. 2006), an underfunded

healthcare system that already engendered entrepreneurial practices and inadequate infrastructure to monitor and inspect hospitals and clinics meant the regulations often went unenforced, were subject to the discretion of individual institutions, and failed to halt the growth of the market for stem cell treatments (Giles 2006; Sipp 2009; BIONET 2010). As well as a desire to be regionally competitive, the growth of the market for stem cell treatments in China has been shaped by regulatory changes in other countries. In particular, China has been able to capitalise on the closure of clinics abroad, such as X-Cell in Germany (Chap. 5), in the same way that other countries have capitalised on changes occurring elsewhere. As we explained in Chap. 5, X-Cell itself was partially a product of regulatory changes in the Netherlands that prompted a Dutch entrepreneur to move to another jurisdiction. Vlasta and Ivan's decision to take their child to China was prompted when Germany was no longer an option for treatment.

While stem cell treatments appear to have been available to foreign patients since the 1990s, predominantly in state and military hospitals, it was not until 2006 that China attracted the attention of the international media as a destination for stem cell tourism when Dr. Huang Hongyun at the Beijing Xishan Institute for Neuroregeneration and Functional Recovery sought to share what he considered strong evidence for the efficacy of his treatments using foetal cells derived from aborted foetuses (Enserink 2006). According to Dr. Huang, over a thousand patients had already travelled to his clinic from all over the world to undergo stem cell treatments for neurological conditions and spinal cord injury. However, his claims were rejected by the international medical community as anecdotal and inconclusive (Zhang 2014). Despite such criticism, the market continued to grow during the 2000s. Private clinics also appeared, and biotechnology companies began to rent out wards in public hospitals to set up affiliated clinics. By 2012, it was estimated that over 200 clinics were offering treatments to foreign patients (Martin 2012), offering a range of treatments using a variety of cell types, including foetal, cord blood, embryonic, and adult, both autologous and allogeneic, and a number of different delivery methods, such as intrathecal (injection into the fluid around the spinal cord via lumbar puncture), intravenous (into the blood), and through surgical implantation into the brain (Lau

et al. 2008). Other studies provide further insight into this treatment landscape from various perspectives, including accounts of the political economy of stem cells in the Chinese context, analyses of forms of governance and novel models of clinical translation, and ethnographies of individual clinics (see Chen 2009; McMahon et al. 2010; Sleeboom-Faulkner 2010b, 2013; Song 2010, 2011; Ogbogu et al. 2013; Zhang 2014; Salter et al. 2014).

Regulating the Market

Clinics operating in public and private hospitals are nominally subject to the regulatory oversight of both the State Food and Drug Administration and the National Health and Family Planning Commission (formerly the Ministry of Health before it changed in March 2013), whereas clinics in military hospitals are regulated by the military wing of the Chinese Communist Party, the People's Liberation Army. However, given the practice of distinguishing between 'public identity' and 'private behaviour', noted above, the mechanisms and realities of regulatory oversight remain opaque. At the beginning of this research, the clinics we were hoping to visit included a variety of public, private, military, and biotechnology company-affiliated ones. However, as the 2012 ban on charging fees for unproven stem cell treatments stretched on longer than anticipated, while the government faced similar difficulties in deciding how to regulate stem cells to those faced in other jurisdictions, most of the clinics in the public and military hospitals had removed their websites. As we embarked on our research in China, the clinics continuing to have the strongest presence on the internet, aside from the biotechnology companies that could facilitate treatment in partner clinics in other countries, were the small private ones (which one clinic representative explained was because they were small and were not causing problems for the government). While this suggests a degree of effectiveness in top-down regulatory action, it is unknown to what extent this actually resulted in a reduction in the availability of stem cell treatments in China at the time, or whether some clinics just reduced their public profile.

As noted in Chap. 1, it is also difficult to track the number of people who may have undergone stem cell treatments in general, let alone China, given that patients are often travelling outside of conventional medical pathways and are under no obligation to disclose whether they are travelling for medical treatment. By 2014, various estimates put the numbers of people travelling to China for stem cell treatment between over 300,000 to over 600,000—the latter provided by one Chinese-based biotechnology company (Salter et al. 2014). Such disparities in estimates are a source of contention as clinics often point to the number of patients treated as a form of advertising and a marker of legitimacy, with the implication that their treatments must work if they can attract that many patients without incurring the kind of regulatory backlash described in Chap. 5. Likewise, the price of treatments is difficult to pinpoint. Treatments in China often start at $US20,000 to 30,000, with some patients including additional, non-stem-cell–based therapies at further expense (such as physiotherapy and traditional Chinese medicine), and some may return for multiple or ongoing treatments. Some models of medical innovation allow for the charging of fees; therefore, the debate over whether these treatments constitute medical innovation or the commercial sale of experimental or unproven treatments is also hotly contested (Lindvall and Hyun 2009). As this study and others have found, some clinics exclusively sell treatments without engaging in basic or clinical research, whereas other clinics and biotechnology companies use the money generated from commercial treatments to fund concurrent research activities. For example, while a clinic may have a trial registered on the USA-based ClinicalTrials.gov database run by the National Institutes of Health, they may also be offering that treatment for other conditions not being investigated in the trial as a clinically unproven treatment on a commercial basis as a way of funding the trial (Salter et al. 2014). However, the extent to which this distinction is made clear to prospective patients is unknown.

As countries the world over grappled with the complexities of how to regulate such a rapidly changing field of scientific and medical innovation, the regulatory approach the Chinese government took to commercial stem cell treatments was guided by a logic that prioritised pragmatic considerations and rapid advancements in research and clinical translation.

However, as international attention grew, increased scrutiny and criticism had the potential to threaten the reputation of the large amount of stem cell research conducted in China (McMahon et al. 2010: 42–3). In 2009, new regulations were introduced in order to curb the growth of clinics that sold commercial treatments in contravention to national guidelines. China's Ministry of Health (MoH) and State Food and Drug Administration (SFDA) jointly released national guidelines requiring clinics to seek MoH approval for 'risky, ethically complex or unverified' treatments (Sipp 2009). After these made little impact, the MoH and SFDA instituted a ban in 2012 on the commercial sale of unproven treatments and on charging fees for participation in approved clinical trials, and a notice posted on the MoH website emphasised that existing trials must not deviate from approved protocols (Tam 2012). Further regulations were introduced in March 2013 that distinguished between clinical trials and commercial stem cell treatments, with a ban on charging fees during the clinical trial phase (Zhang 2014: 173). As noted above, while a number of public and military hospitals ceased or suspended the sale of stem cell treatments, some private clinics and biotechnology company-affiliated clinics continued to market and facilitate treatments for foreign patients. New laws introduced in August 2015 focused on restricting which hospitals would have permission to conduct research and clinical trials, and have been touted as the legal basis that will allow the government to take enforcement action in instances of non-compliance. There is also a stronger emphasis on product safety, reinforcement of informed consent, and long-term follow-up of participants (Shan 2015). Nonetheless, as enforcement continues to be a problem, it is not clear whether these laws will have the intended impact.

To return to the popular cultural depiction of the 'Wild East', the question remains: how is it that China became such an attractive destination for international visitors beyond the simple availability of treatments? While perhaps not unique to China, the clinics that have succeeded in attracting foreign patients have a number of practices and processes in common. The remainder of this chapter explores these via three key themes that emerged in the data: how providers help patients access the unfamiliar, and shape the treatment experience; how hope becomes a commodity used to sell treatments; and the role that foreign doctors and entrepreneurs have played in the market for commercial

stem cell treatments in China. For providers of treatments, framing their treatments as a commodified form of 'hope' has certain commercial advantages. However, it comes with associated moral and ethical conflicts, spoken about by some treatment providers below, that complicate the narrative of exploitation that 'selling hope' suggests.

Destination China: Making the Unfamiliar Accessible

The previous sections demonstrated the uncertainty about what 'Brand China' represents, the variety of facilities in which treatments are available, and the degree to which they may or may not be subject to regulatory oversight. The difficulty faced by outsiders in trying to evaluate the quality and safety of the healthcare setting in which treatments are being offered is apparent in the following quote from Natalie, who took her child to Panama for treatment for cerebral palsy.

> We went and spoke to a [specialist in Australia] and he said China has some really fabulous healthcare and some really bad healthcare … [If] we got recommended to go to China, I would be OK with that, but because we were pretty well doing this on our own, it made it a little bit difficult, because no doctor could recommend anywhere in China. All they said was 'yes, they've got really good stem cell clinics and they've got some really bad ones too' and no one would offer that information as to how you sort out the good from the bad, if that makes sense … They didn't necessarily support us giving [our child] stem cells, but they were supportive of the healthcare system in Panama and said 'yes, it's not dodgy, it's a good healthcare system', as opposed to China, where they said 'yeah, it's good if you get the right place'.

This quote underscores how, among the wide range of considerations that shape the decision-making process, including which types of cells and treatments are on offer in which countries, broader perceptions about national healthcare systems can also influence choice of destination. While the doctor with whom Natalie spoke was against her pursuing stem cell

treatments in general, he gave a positive impression of the healthcare facilities available in Panama. For Natalie, one of her key concerns was linguistic and cultural barriers, and she felt that this would be less of a problem in Panama than in China. Clinics devise a number of strategies to overcome such preconceptions and try to make the unfamiliar and foreign more accessible. This section documents some of these strategies, such as the use of 'clinic concierges' and past patients to build personal relationships and lessen the language barrier, and some of the ways they try to shape experiences of treatment within the clinic beyond medical care.

Clinic Concierges and Past Patients as Ambassadors

As noted in Chap. 1, the use of medical tourism agencies in facilitating connections between prospective patients and clinics seems less of a feature in comparison to other forms of medical travel (see Snyder et al. 2011), with clinics tending to favour in-house direct-to-consumer marketing and personalised communication. However, while this tended to be the case for the Australian travellers, this may vary in other jurisdictions. One example of this this was given by Douglas, a Western doctor speaking on behalf of his clinic in relation to recruiting patients from the Middle East:

> If you're an agent in Abu Dhabi and you sent us a patient and the patient was keen for a 300,000 RMB [approximately $US47,000] round of treatment, um, you might expect to get ten to twenty percent … I don't think anyone's in an exclusive relationship, so there's a little bit of a bidding war … And then, to the embassies, you know, this is a world capital and all the embassies in the Middle East are here, so its not unnatural that their relationships, certain people in the embassies are happy to refer us patients and happy to ask for a gratuity, expect a gratuity, or they'll send them somewhere else.

Douglas suggests this is commonplace when recruiting from certain countries; however, the use of medical tourism agencies or other such commercial facilitators did not appear to be a common route to treatment for our Australian patients. While there are organisations such as

the Adult Stem Cell Foundation that direct those who are interested to a partner clinic in Shanghai (as well as clinics in Australia, to be discussed in Chap. 7, and other countries around the world), Australian patients more often spoke about personal interactions that led them to particular clinics (Chap. 2). Personalising interactions between clinics and prospective patients was one way of establishing familiarity and trust. Many clinics in China employ staff who perform various concierge services, such as the day-to-day communication that facilitates contact between prospective patients and medical staff, providing assistance with preparations and travel plans, as well as ensuring patients' needs are met during their stay. While they are known by various titles such as 'patient representatives', 'patient care managers', and 'sales representatives', this chapter will refer to them as 'clinic concierges' in order to distinguish them from other clinic representatives whom we discuss. The people who perform these roles have a wide variety of backgrounds. For one European clinic concierge encountered during this research, the job enabled him to spend some time living in a foreign country while he felt he was helping people navigate the difficult task of undergoing medical treatment in a foreign environment. According to an Australian patient, the American clinic concierge he got to know during his time in the Chinese clinic had previously undergone stem cell treatment at that clinic and decided to stay and take on the role after experiencing a positive outcome.

As the language barrier represents a deterrent for some prospective patients, clinic concierges are able to address such concerns with proficiency in a number of languages and promote their clinic in a way that is accessible and attractive to a foreign audience. As Douglas explained, at his clinic:

> We've got an excellent guy here now, excellent Chinese and Arabic and English, and he's basically working with another editor on the English site to [ensure the websites' content] stay in sync. Each of those two sites are gonna be optimised and we're gonna have one for the Western world and one for the Arabic world, and social networking and forums and all that kind of stuff.

In Chap. 2, we noted that it was not uncommon for our Australian patients and/or carers to recount interactions with someone who had

previously travelled when they were asked how they came to choose the particular clinic they did. Liang, a Chinese representative of a clinic in Beijing spoke about the role of patient networks in facilitating discussion and publicity of clinics that treat specific conditions, and the implicit importance of maintaining a good reputation in such groups:

> The patients suffering from one kind of disease, it's not the flu, it won't be gone in a week, it will be with them for years. So they have their own circle, they have their own websites … they always keep their eyes open for any new possible effective treatment. So once the patient is treated in our centre with or without a good outcome, they will know.

One such person, who was happy with the treatment her child had received at a clinic in China, and maintained an ongoing relationship with the clinic with a view to ongoing treatment, was Vlasta who spoke about her willingness to share her story with people who were looking into that particular clinic. This phenomenon has been observed in other studies of stem cell tourism, where people who have felt that their treatment was successful and, for a variety of reasons ranging from gratitude to a sense of duty, go on to play an active role in recruiting new patients for the clinic they visited (Patra and Sleeboom-Faulkner 2011). For Vlasta, it was her own experience of the frustrations involved in finding information about treatments that motivated her:

> I know it's very hard to get information and it is a big dilemma and it's hard for people to decide whether to go or not to go, and I wish I had more time to, I could maybe sit on the internet and maybe answer a query of a person who is looking and unsure. Unfortunately I'm too busy and I haven't really put anything on the internet myself, but yeah, whenever I can help I'm happy to help … So basically everyone I spoke to I always said, yeah if you want to give me as a referral to another parent who wants to ask a few questions, I'm happy to have a quick conversation.

The ways in which past patients interact with those seeking information or advice in researching particular clinics may range from the kinds of ad hoc and informal encounters Vlasta describes, to more sustained and

public communication, as in the case of Australian patient Kristy Cruise, who actively encourages others to travel to a clinic in Moscow following her positive experiences of undergoing an autologous haematopoietic stem cell transplant to treat her multiple sclerosis (see Chap. 8). As a quote from Anthony, a Western executive at a biotechnology company in China, suggests, the formality of these relationships vary and is not always clear or transparent. He recalled past patients or brokers may have been reimbursed for speaking publicly about their treatments.

> There were some people that were given partner status, um, and I think their costs were reimbursed, 'cos a lot of those people had costs like telephone calls, they were flying around, they were speaking at Rotary clubs [community-based meeting venues], they were arranging conferences. Sometimes with the assistance of [our online marketing] team, sometimes on their own. Sometimes people became extremely passionate.

While Anthony claims that these practices only occurred in the past in his clinic, the arrangements Douglas described above were framed as current and ongoing, suggesting a variety of formal and informal practices (involving reimbursement or otherwise) designed to attract new patients to clinics. As part of this picture, past patient testimonials are exceptionally valuable. However, the degree to which past patients may be willing to share their experiences is likely influenced by their experience of undergoing treatment in the clinic. The next section explores some of the ways that clinics shape the patient experience beyond the purely medical sphere.

Shaping the Treatment Experience

Patients' lack of familiarity with China and its culture and languages sometimes offers a major potential impediment to their willingness to travel there. Natalie, who took her child to Panama for treatment for cerebral palsy, said that they would have considered China, but that they 'didn't want to get caught up in some sort of language barrier when we're dealing with our child's health. We don't know the system, we don't know

how the country works, we don't understand them well enough'. As we heard from Kimberly in Chap. 4, language and culture barriers presented significant challenges that negatively impacted on her experience of taking her child to China for four weeks of treatment for nerve paralysis. For those who decide to travel, a factor that profoundly shapes their experiences of treatment itself is how comfortable they feel in the Chinese clinical environment beyond the medical treatments, a factor well-recognised by providers. For patients and carers, the presence of foreign doctors, or Chinese doctors who have trained or worked overseas and achieved strong English-language proficiency plays a significant role. In the clinics visited by Australian patients and carers, medical staff possessed varying degrees of English proficiency, and at times clinic concierges or interpreters were called upon to assist during medical consultations. Aside from addressing language barriers where possible, clinics attempt to bring the physical surroundings in line with expectations of international patients. In contrast to the lush and relatively peaceful private clinic described at the beginning of the chapter, Vlasta's child underwent treatment in a clinic in a rented public hospital ward, affiliated with a biotechnology company:

> It was a huge public hospital, and within the hospital they had one floor, and on that floor there was twenty ward rooms, [a] separate section with separate nurses that just looked after international patients, and there was a separate kitchen, separate sitting area, so the whole section of the hospital was … Look, conditions were pretty poor but they were considerably better than conditions with the local public hospital where local patients stayed.

In clinics in public hospitals where the clinical environment cannot be as easily tailored to non-Chinese clientele as in private hospitals, some attempts are made to help patients negotiate the unfamiliar cultural context. One example was given by Suzanne, who was accompanying her husband Greg, as he underwent treatment for his degenerative neurological condition, also in a biotechnology-affiliated ward in a public hospital. She described the information pack provided in his room that explained the role of Chinese nursing staff in the hospital system, which was of particular interest to her as she was a nurse herself.

> [T]hey had information in the room that gave a breakdown of things and they explained what nurses did—nurses did the treatment and gave injections, not like nurses in other countries where they make beds and help wash patients, [they said] "we don't wash patients", so the family go in and care for them. So they don't do any of that and so I was Greg's carer, and he didn't really need a carer but I was there for him, so the nurses don't do that, they see that that's the family's responsibility. They're there to give treatments.

In some instances, the standard of care from nursing staff surpassed patients' and carers' expectations. Greg was very happy with his standard of care as there was a far higher nurse-to-patient ratio than he experienced in Australian hospitals. Vlasta, however, described her frustration over cultural differences. In one example she gave, she was not allowed to open the window of her child's hospital room during one treatment stay, which led to disagreements with the staff ('apparently they thought for some reason if someone arrives there, they would decide to commit suicide there, I don't know why someone would pay so much money and travel there to commit suicide!'). In another story, she was not allowed to accompany her child while he was being sedated prior to his treatment via lumbar puncture (which involved stem cells, in this case derived from bone marrow and cord blood, being injected into the cerebrospinal fluid around his spine), which contributed to her child's distress.

Another cultural difference for Australian patients is that Chinese hospitals do not generally provide food for in-patients—a frustration recounted by Kimberly in Chap. 4—as this is also considered the duty of the family. As a result, some patients and carers spoke about clinic concierges arranging shopping trips to international supermarkets where they could source familiar food to cook in a communal area in the clinic, or assisting in ordering familiar fast food where available. For some, this was an added inconvenience; for others, it enhanced their experience. Greg's health enabled him to venture out for meals and to go shopping, facilitated by the clinic, which he described as a positive addition to his time in the clinic, because he enjoyed the challenge as well as the novelty of visiting local Chinese supermarkets filled with a diverse and exotic range of produce.

Clinics also make an effort to create a sense of community within the clinic to overcome the sense of isolation associated with receiving treatment in a foreign country, as has been observed in previous studies, such as in India (Prasad 2015)—also exemplified by Simone's description of her and her husband's time at a clinic in India in Chap. 4, as he underwent treatment for quadriplegia. As Greg described in Chap. 2, the clinic he was at looked like a 'little UN' with patients' flags of their country of origin on their doors—'France, United States, Venezuela, Brazil, Egypt, Poland, France, Scotland, Algeria and Kenya'. He also described the shared communal area where they cooked their meals and socialised. Fostering this sense of community is an important way of shaping the treatment experience, where patients are often required to stay for a number of weeks, with recreational opportunities being dependent on their health. Douglas described his clinic's intention to begin throwing parties every few weeks to 'break up the monotony'. For patients that are physically able to participate, some clinics assist with tourist activities as well, although the extent to which this is commonplace is not known. Greg described that in between procedures, clinic concierges would arrange various activities for them, such as going into the city and on river cruises. Following his treatment, Greg and his wife were also able to add some sightseeing onto their trip, arranged with the assistance of a clinic concierge:

> We were in [the hospital in southern China] for four weeks. Now, our visa was for four weeks. We wanted to extend by one week to go to Beijing and see the wall and go to Xi'an and all those things, and the hospital was great. We went with my liaison person to the immigration in town, which is quite daunting, and they wrote a letter saying I had to stay for more treatment, which was a white lie, and it was so easy to get due to their help.

While Greg did not believe he experienced any physical change from the treatment itself, he spoke fondly about the environment within the clinic, and the help he received from the clinic concierge. The potentially therapeutic effect derived from a sense of community and shared experiences is not lost on treatment providers, as exemplified by Douglas's comment above about throwing parties, and the situation Greg describes

seems to be a common scenario in such clinics all over the world. In his ethnography of a stem cell clinic in India, Amit Prasad also described the amount of communal activity and camaraderie fostered by clinic staff, noting that they 'joke and banter with patients, and the patients often respond similarly' (2015: 146). All of these practices contribute to a positive experience beyond just medical treatment. While they are not unique to clinics in China, these ways of managing the patient experience might contribute to past patients' willingness to speak positively about the non-treatment aspects of the clinics, further helping combat the sense of unfamiliarity and uncertainty about what to expect from undergoing medical treatment in China in those contemplating it as a destination for stem cell travel.

Commodifying Hope

The online presence of a clinic, often being one of the first points of call for prospective patients, is arguably a critical tool in 'selling hope' to potential travellers. As previous chapters have noted, internet-based direct-to-consumer advertising is a universal feature of stem cell clinics the world over. For Chinese clinics, their online presence is an opportunity to combat the possible perceptions of poor quality and cultural or linguistic barriers. As Douglas explained, they devote significant resources to directing prospective patients to their website as a way of attracting people to his clinic:

> The model we use is Google adverts, Bing adverts. Pretty sophisticated … [We used] the Google 'pay tracking' business, and then they began selling the mechanisms to end up on page one … It's very insidious! And it's quite expensive. It's easy for us to spend $US30,000 a month on Google campaigns … for marginal numbers of cases with semi-exotic diseases or injuries … And then there's search engine optimisation, which is yet another way of working your website to the top by ciphering out what Google's current formula is so it picks you, so either way you pay; you pay an optimiser or you pay Google directly.

Many companies use search engine optimisation to increase their rank in a list of search results, which includes strategies such as 'pay per click' campaigns to artificially increase the apparent popularity of a site, or obtaining de-identified data to develop targeted advertising (Kritzinger and Weideman 2013; Turow 2011: 101). Appearing at the top of a list of search results may give the impression of popularity and authority. While this is not unique to China, and people draw on many different sources of information and forms of evidence in making their choice, the above quote demonstrates that clinics see value in managing their online presence in such a way, shaping the type of information people are brought into contact with through internet-based searches. This was commented on by Vlasta and Ivan in Chap. 2, who were beginning to tire of searching online when they became aware that the main suppliers of stem cell treatments worldwide were 'monopolising' such search strategies.

In attracting people to their websites, one of the key resources clinics rely on to sell hope is the success stories of past patients (Lau et al. 2008; Petersen and Seear 2011). As has been noted in previous chapters, these testimonials—often emotive stories of regaining the ability to touch a loved one or return to a treasured hobby—serve to present a picture of a successful treatment outcome that prospective patients can connect with (Petersen and Seear 2011). Over the course of our research, clinics have often updated their websites to convey an increasingly professional look. However, despite increased scrutiny of these marketing practices, a study comparing the claims made on 18 websites of providers of stem cell treatments from all over the world between 2008 and 2013 found that while clinics have tended to include more detail of treatments and outcomes, they continue to be overly positive about potential outcomes (Ogbogu et al. 2013).

It has long been recognised in social studies of health that telling stories about experiences of illness and seeking treatment, either about oneself or a loved one, can be a powerful way for people to regain a sense of control over the sense of disruption to their life caused by the advent of an accident or illness (Kleinman 1988; Bury 1982). Patients and carers who have travelled to access stem cell treatments may derive therapeutic value from sharing their stories, particularly if they feel there has been a successful outcome. However, in the practice of 'selling hope', such stories have also

become a commodity in and of themselves. As Costa et al. (2012) argued in relation to 'survivor narratives' in the psychiatric system in the USA,

> [L]anguage such as 'resilience' and 'recovery', as told through client accounts, is a means by which mental health service systems have been able to absorb resistance accounts, sanitize them, and carry them forward in ways that are useful for them, without disrupting their dominant practices. (Costa et al. 2012: 87)

As discussed in Chap. 4, patients and carers who have pursued stem cell treatments describe a diverse range of emotional and physical journeys, and treatment experiences and outcomes. Yet, to draw on Costa et al.'s argument, in creating the patient testimonials that feature on clinic websites, negative experiences are marginalised, positive ones are sanitised, and stories of successful treatments become a powerful tool in selling hope and treatments to prospective patients. As Liang explained, when patients are completing their treatment at his clinic, they are asked by staff whether their story can be used on the clinic's website.

> Before [patients] are discharged, our service staff will talk to them, [and say], 'based on your treatment we would like to do an interview with you. Would you like to have your name present on the website?' … Of course, you know, we only publish some good cases. There are some cases without good outcome, and we just leave it there.

The use of patient stories (specifically the 'good' ones) as a marketing strategy, which excludes anything other than stories of success and hope, is unremarkable. However, the reliance on patient stories as one of the key ways of attracting new patients comes with certain challenges, and the temptation to play a role in shaping them is evident in speaking with clinic representatives. The practice of clinics encouraging patients to blog during and after their treatment had been documented previously (Ryan et al. 2010). Some patients who feel their treatment has been a success understandably wish to share their stories, exemplified by Vlasta who was willing to speak to those considering treatment at the clinic with which she maintained a relationship. However, Anthony's quote in the previous section regarding the possibility of past patients being reimbursed when shar-

ing their stories in the public domain implies a degree of tension in how these commodified narratives are established, coordinated, and controlled. Anthony also spoke about a process that could be seen as sanitising, which he framed as making sure patients only pass on the 'right' information:

> A lot of times, people that had a positive experience or felt that it was beneficial to them would come to us [and] say, 'oh, you know, can I tell other people?' So we'd [respond] … 'here is the standardised information that you should pass on to another person, right? It's the same stuff that you received, you know, don't doctor it, don't change it if you wish to facilitate it.' Anything that they wrote was their own personal experience, there was no coaching, there was no manipulation. And if they wanted to get on Facebook to tell other people about it, et cetera, we kind of ran an oversight role.

The apparent contradiction in claiming that there is no coaching or manipulation, yet that they run an 'oversight role' suggests a concern with managing the commodity that narratives of hope represent, and that providers are in an uneasy situation where they are both facilitators of such narratives yet do not retain ownership of them. Anthony described one way they attempt to manage negative experiences retrospectively, as he went on to explain:

> I'm sure there are some that believe that, you know, they were totally misrepresented, probably there are some that were totally converted … Some people come back and question the results et cetera, and, you know, we always like to go back to the beginning and say, you know, we kind of outlined your condition, what we initially thought would happen, and I guess they pretty much found they were on the mark.

The work that is done to engender a positive view towards stem cell treatments, particularly the use of patient narratives, can set up high hopes and expectations in those seeking a successful treatment. As Anthony describes, for providers this can make it difficult to turn patients away who are hopeful that their treatments will also provide them with an improvement or cure:

> You know, it's a very complex psychological thing that people have no alternative and you tell them 'no', I mean they've been rejected by people saying

> 'no, the stem cells will not work' and the hospitals are saying 'no, we cannot treat you', and yet they insist. They want to come. Then are you in a position where you've rejected somebody based on what? You know. [They say], 'no, I want to come, I've made my own decision.' It's very complex.

While there is heated debate about the ethics of 'selling hope', Anthony's quote suggests this is also a 'complex psychological thing' for those who have chosen to work in the market for commercial stem cell treatments. They too grapple with their own hopes, expectations, and motivations that are as diverse as the patients who travel. The following section gives some insight into these people, and the complexities they face in positioning themselves as 'purveyors' of hope.

Purveyors of Hope

This chapter has principally focused so far on patients travelling to pursue treatments that are unavailable at home; however, China is an attractive destination to more than just the patient community. As in other clinics around the world, there are also many non-local doctors, businesspeople, and entrepreneurs with a stake in the stem cell treatment market who have their own hopes and expectations, drawn in by the 'biotechnical embrace' (DelVecchio Good 2007; Prasad 2015) offered by the promise of stem cells, and who have gone to China to explore the opportunities that a freer regulatory environment provides. This mixture of nationalities of medical staff was commented on by Jackie, whose husband Philip accompanied their son to China as he underwent treatment for autism in a biotechnology company-affiliated clinic in a public hospital:

> I know one of the consultants that I did speak to at one stage was an English guy. And then somebody else that Philip saw, I think he was of Chinese descent but he'd grown up in America, and then was back there working, so I think they have quite a range of nationalities … When Philip was there he said there were some Chinese doctors, but there were many from all over the world, there were Americans, there were English, there were some European doctors.

The people encountered during this research expressed a variety of reasons for why they had chosen to work in China. One clinic representative, Liang, is Chinese and holds a PhD in biochemistry from a top Asian university. He speaks English fluently after spending a number of years working in the biotechnology industry outside of China. Liang explained that he had returned to China at the invitation of the Chinese doctor and founder of the company he was representing, who required someone to manage the public engagement side of the company. While he acknowledged that the treatments his clinic was offering were not considered evidence-based, his belief was that they fell within the remit of a doctor's duty to help patients who otherwise had few options in evidence-based medicine. As a Western doctor and clinic representative, Douglas described his desire to move to China in response to his frustrations of trying to advance the state of stem cell treatments in his home country, which he felt was dominated by excessive bureaucracy that hampered innovation.

> I watched that system in [my home country] harden and set up into what had become now a system dominated by insurance companies and hospitals, which has managed to get the government to cram that system down everybody's throat by law … which sets that system up as something finished or defined, by implication, absolute and 'this is medicine'. Well, not necessarily! I mean, it's the least effective model of medicine in the West, and the most expensive.

Drawing on the argument that the most rapid advancements in medicine have historically happened in extraordinary circumstances, such as battlefields, he argued that China provides a similarly 'free' environment to experiment and rapidly forge a new path.

> With having a certain disillusionment with the West, and a certain level of optimism about a system that's still developing, is that it hasn't set up yet and there is the possibility of, if you're willing to work in the shades of grey and get your hands dirty, there's the opportunity to build something that maybe has some of the better qualities of both. Something that's more pragmatic and not as bound up in bureaucracy and bad habits.

While Douglas acknowledged that his position may be considered morally and ethically problematic by some, he is open about the fact that he is 'selling hope'. Yet, for him, the funding brought in by the commercial treatments allows him to pursue a trial in another area of medicine, which he hopes will result in evidence-based treatments for cartilage regeneration in the near future—a potentially lucrative area given the wide number of potential applications to conditions related to ageing, which guarantees a market:

> I'm interested in nudging this other [clinical trial] forward, because rather than treating marginal numbers of marginal cases with marginal responses, cases that we're mainly treating with hope, um, just being able to focus on cartilage regeneration alone, there's plenty of business to be had there, but it's moving things up to a level that I'm much more comfortable throwing my energy into, which is evidence-based medicine.

Douglas exemplifies how treatment providers are also driven by their own hopes and expectations attached to new medical technologies. Yet, while positioning himself as a purveyor of hope, he also battles contradictions over the moral and ethical implications that come with it. He justifies his choices by pointing out that people are often required to make complex ethical choices and he hoped that his actions would bring about future benefits, both in helping patients, but also financial benefit to himself. As he went on to explain:

> I have a kind of divided sense of things right now, because on the one hand, being a good … Catholic boy, a doctor and a [former government employee], there's all these arbitrary codes we cling to and oaths, but I mean, … what's that thing about great minds being able to hold contradictory arguments? I mean, life's full of that stuff, and so coming from the West, is this last free country, is this frontier, something to feel guilty about? Or is it the opportunity that I really asked for? Because I asked for it. I wanted something that hadn't set up yet, and I'm driving things forward in a way that I think is meaningful, and it could make oodles of money. So I have to say that I think I've been provided with an excellent and meaningful opportunity.

As our analysis suggests, the sale of commercial stem cell treatments is not a straightforward or simple transaction between purveyor and customer. It involves a complex, and at times contradictory, set of justifications and negotiations of ethical boundaries. While the lure of the financial is ever-present, and increasingly an imperative in medical innovation the world over driven by public–private partnerships, the picture is not as simple as implied by the 'snake oil' salesman characterisation often invoked by critics. Those involved in the provision of stem cell treatments also share some of the frustrations articulated by patients in relation to bureaucratic hurdles and the slow rate of progress in basic science and clinical translation. As captured by the quote from Douglas at the beginning of the chapter about having 'more questions than answers', there remain a great many uncertainties involved in what their stem cell products and treatments can actually deliver, making it an ethically complex and uncertain transaction for the providers as well as patients.

'Cleaning Up' the Market: Regulations, Detours, and New Destinations

In August 2015, the Chinese government moved to crack down on clinics that did not meet the requirements of new regulations (Shan 2015). While it remains to be seen whether they will have the same success as Germany in this regard, in response to the changing regulatory environment since 2009, many clinics have already modified their practices as a result of regulatory pressure—some moving underground, and others moving offshore.

Attempts to Regulate

China has implemented increasingly restrictive regulations, as described above, although enforcement continues to be a problem. Regulatory weaknesses, combined with government investment in stem cell research and clinical translation, underpinned by national hopes for rapid advancements in stem cell technologies, led to a huge growth in the market for

commercial, unproven treatments over the last 20 years. The government's dream of catching up and overtaking international competitors, particularly in the field of science and technology, persists under President Xi Jinping. In a 2014 joint address to the 17th General Assembly of the Chinese Academy of Sciences and the 12th General Assembly of the Chinese Academy of Engineering, he insisted:

> The boundaries between research into basic and applied sciences, technological development and industrialization in the traditional sense are becoming increasingly blurred. The chain of scientific and technological innovation has become more flexible, technology upgrading and conversion have become quicker, and industry upgrading continues to speed up … In the face of the new trends of scientific and technological innovation, the world's major countries are seeking to make new scientific and technological breakthroughs and gain competitive edges in future economic as well as scientific and technological development. We cannot afford to lag behind in this important race. We must catch up and then try to surpass others. (Xi 2014: 131–2)

However, in recognition of the need to engender international trust in the image of state-funded research activities intended to attract international investment, collaboration, and prestige, the new regulations have emphasised more explicit parameters for what might be considered 'legitimate' trials and make it clearer which institutions have government permission to perform clinical trials for stem cell treatments. As explained by a representative of the National Health and Family Planning Commission in an article in the China Daily:

> Only eligible hospitals can perform the practice as a clinical trial for research purpose and it must not be charged or advertised. Anyone caught breaking the rules will be punished according to the new regulation.
>
> (Zhang Lingming, quoted in Shan 2015)

As commentators have noted, the reference to punishment is vague, and the impact remains to be seen (Cyranoski 2015). At the time of writing in late 2016, many clinics that sold treatments prior to the 2015 laws continue to do so. Furthermore, despite apparent attempts to limit

patients travelling to illegal clinics, China is developing an official medical tourism infrastructure in relation to approved stem cell treatments. For example, the 'Shanghai Medical Tourism Products & Promotion Platform' is advertising stem cell treatments in certain partner hospitals, with implied government approval. Their website advertises a wide variety of treatments still considered clinically unproven—such as autologous bone marrow cells to treat spinal cord injury and multiple sclerosis, neural cells to treat cerebral palsy and Parkinson's disease, and umbilical cord blood derived cells to treat diabetes (Shanghai Medical Tourism Products & Promotion Platform 2016). While the number of foreign patients may be relatively small in comparison to the local population undergoing treatments, foreign patients' choice of China as a destination holds geopolitical significance, as they have the capacity to draw attention to developments in Chinese scientific endeavours (Song 2010: 395). However, while the government's centrally planned funding and decision-making may see a rise in people travelling to China to participate in registered clinical trials that meet international standards (Hyun et al. 2008), it could also force those clinics that offer stem cell treatments outside of the clinical trial framework to move further underground or offshore.

Detours and New Destinations

This brings us back to the story of Vlasta, Ivan, and their child, who started out in Germany, but then travelled to China for treatment with a Chinese biotechnology company. In response to mounting regulatory pressure in China, the company began a partnership with a hospital in Thailand in 2009, as well as exploring partnerships with other clinics and hospitals around the world. While Thailand also has a number of stem cell clinics, also operating in an unclear regulatory environment, it has only featured as a destination in a small number of studies into stem cell tourism, and does not yet seem to rival other major destinations (Salter et al. 2014). Following the 2012 Chinese government ban on the sale of unproven treatments, the already established link with a clinic in Thailand enabled this company to stop offering treatments in China to

comply with local regulations, while continuing to take patients at clinics in other countries. When the company closed their treatment centres in China, Vlasta, Ivan, and their child followed the company to Thailand, and they had already been for one treatment, with others planned. The company still provides stem cells from their source in China, and Chinese doctors travel in order to administer treatments in Thailand alongside local medical and support staff. Jackie, whose husband had also previously taken their child to China with this company and was planning to go to Thailand in the future, explained her understanding of the arrangement:

> They said that they would still be using the same stem cells from the same [cord blood] donor bank that they use in China … They must transport them over. And they said a lot of the doctors in the Bangkok centre [travel across] from their Chinese centres.

According to what Vlasta was told by her clinic concierge, the move to Thailand was initially a temporary solution to what was expected to be a short-term ban on the sale of treatments in China. However, lengthy debates within the government over how best to regulate the market and which agency should be responsible for enforcement stretched on for the years preceding the 2015 laws, leading the company to strengthen their partnership with the Thai hospital.

Yet, Thailand as a destination is also not an obvious choice for some. Natalie, who took her child to Panama and did not consider China due to concerns about a language and culture barrier, was also sceptical about Thailand as a destination.

> We actually had someone send us through some information about going to Thailand which I just laughed at because, in my opinion, and it might be completely wrong but just for the way my mind is set up, I don't want to go to Thailand—it sounds dodgy. It sounds like something you would see on *60 Minutes* [an Australian television current-affairs program]. [My child] will come back, you know, with horns growing out of his head or something! So I'm not going to go somewhere like Thailand.

Nonetheless, patients who are keen to pursue stem cell treatments at times feel compelled to make pragmatic decisions about their choice of destination as the global regulatory and treatment landscape shifts. As China

moves to 'clean up' and shape the domestic market through top-down regulatory mechanisms, there may be a further offshoring of Chinese companies and clinics as they push into new markets. Furthermore, as this chapter has demonstrated, providers employ a range of strategies that can make previously dismissed destinations more attractive.

Conclusion

There is little uniformity to the healthcare standards and practices in China, with the healthcare system representing a patchwork of standards in quality, hygiene, and regulatory oversight, and is therefore understandably difficult for people considering stem cell treatment to assess as a prospective destination. Australians' preconceptions about China are informed by a wide range of cultural and social reference points; for some travel it is undertaken despite their trepidations, for others images of modernity provide them with reassurance. Treatment providers within the stem cell industry in China have responded to the challenges posed by this context in a number of ways so as to attract international custom to their clinics. The market for stem cell treatments was able to grow as a result of funding and governance strategies that encouraged innovation in stem cell research and clinical translation. However, providers of treatments also engage in various forms of marketing and manipulation of patient expectations and experiences to increase China's attractiveness as a destination. Nonetheless, it is not just a matter of Chinese entrepreneurs exploiting lax regulations and 'desperate' patients keen to travel anywhere to access treatment. Foreign doctors and entrepreneurs have also sought to capitalise on working in a permissive environment, placing themselves in the morally, ethically, and, at times, contradictory position of being 'purveyors of hope'. In an effort to place China at the forefront of the next revolution in healthcare, the government embarked on a strategy to lure Chinese scientists back home, and encourage foreign entrepreneurs to invest, and whether by design or happenstance, this has resulted in China taking one of the largest shares in the global market for stem cell treatments.

Yet China's future as a destination for stem cell treatments is not necessarily secure. The question remains: will China stay open for business, or will regulatory pressure see clinics close, and patients once again forced to explore new destinations for stem cell treatments? Will treatments be fast-tracked in patients' home countries, making the decision to travel abroad redundant? As we shall now see in Chap. 7, in Australia, a recent change in regulations means that stem cell treatments can now be accessed locally—fundamentally changing how Australian citizens may view the need to leave their shores at all.

References

BIONET. (2010). Ethical governance of biological and biomedical research: Chinese–European co-operation. BIONET. http://www.lse.ac.uk/researchAndExpertise/units/BIONET/. Accessed 26 Feb 2016.

Blumenthal, D., & Hsiao, W. (2005). Privatization and its discontents: The evolving Chinese health care system. *New England Journal of Medicine, 353*, 1165–1170.

Blumenthal, D., & Hsiao, W. (2015). Lessons from the East: China's rapidly evolving health care system. *The New England Journal of Medicine, 372*, 1281–1285.

Brown, N. (2005). Shifting tenses: Reconnecting regimes of truth and hope. *Configurations, 13*(3), 331–355.

Bury, M. (1982). Chronic illness as biographical disruption. *Sociology of Health and Illness, 4*(2), 167–182.

Chen, H. (2009). Stem cell governance in China: From bench to bedside. *New Genetics and Society, 28*(3), 267–282.

Cheng, L., Qiu, R., Deng, H., Zhang, Y., et al. (2006). Ethics: China already has clear stem-cell guidelines. *Nature, 440*(7087), 992.

Costa, L., Voronka, J., Landry, D., Reid, J., et al. (2012). Recovering our stories: A small act of resistance. *Studies in Social Justice, 6*(1), 85–101.

Cyranoski, D. (2015, August 26). China announces stem-cell rules. *Nature News*. http://www.nature.com/news/china-announces-stem-cell-rules-1.18252. Accessed 26 Feb 2016.

Dennis, C. (2002). China: Stem cells rise in the East. *Nature, 419*, 334–336.

DelVecchio Good, M.-J. (2007). The medical imaginary and the biotechnical embrace: Subjective experiences of clinical scientists and patients. In J. Biehl,

B. Good, & A. Kleinman (Eds.), *Subjectivity: Ethnographic investigations* (pp. 362–380). Berkeley: University of California Press.

Enserink, M. (2006). Selling the stem cell dream. *Science, 313*, 161.

Giles, J. (2006, March 2). Rules tighten for stem-cell studies. *Nature News*. http://www.nature.com/nature/journal/v440/n7080/full/440009a.html. Accessed 26 Feb 2016.

Gottweiss, H., & Kim, B. (2010). Explaining Hwang-Gate: South Korean identity politics between bionationalism and globalization. *Science, Technology & Human Values, 35*(4), 501–524.

Greenhalgh, S. (2009). The Chinese biopolitical: Facing the twenty-first century. *New Genetics and Society, 28*(3), 205–222.

Hyun, I., Lindvall, O., Ahrlund-Richter, L., Cattaneo, E., et al. (2008). New ISSCR guidelines underscore major principles for responsible translational stem cell research. *Cell Stem Cell, 3*, 607–609.

Kleinman, A. (1988). *The illness narratives: Suffering, healing, & the human condition*. New York: Basic Books.

Kritzinger, W. T., & Weideman, M. (2013). Search engine optimization and pay-per-click marketing strategies. *Journal of Organizational Computing and Electronic Commerce, 23*(3), 273–286.

Lau, D., Ogbogu, U., Taylor, B., Stafinski, T., et al. (2008). Stem cell clinics online: The direct-to-consumer portrayal of stem cell medicine. *Cell Stem Cell, 3*(6), 591–594.

Levine, A. D., & Wolf, L. E. (2012). The roles and responsibilities of physicians in patients' decisions about unproven stem cell therapies. *Journal of Law & Medical Ethics, 40*, 122–134.

Lin, V. (2012). Transformations in the healthcare system in China. *Current Sociology, 60*(4), 427–440.

Lindvall, O., & Hyun, I. (2009). Medical innovation versus stem cell tourism. *Science, 324*, 1664–1665.

Liu, G., Liu, X., & Meng, Q. (1994). Privatization of the medical market in socialist China: A historical approach. *Health Policy, 27*, 157–174.

Martin, D. (2012). Perilous voyages: Travel abroad for organ transplants and stem cell treatments. In J. Hodges, L. Turner, & A. Kimball (Eds.), *Risks and challenges in medical tourism: Understanding the global market for health services* (pp. 138–166). Santa Barbara: Praeger.

McMahon, D., Thorsteindóttir, H., Singer, P., & Daar, A. (2010). Cultivating regenerative medicine innovation in China. *Regenerative Medicine, 5*(1), 35–44.

Ministry of Science and Technology. (2006). National high-tech R&D program (863 program). http://www.most.gov.cn/eng/programmes1/200610/t20061009_36225.htm. Accessed 5 Feb 2016.

Ogbogu, U., Rachul, C., & Caulfield, T. (2013). Reassessing direct-to-consumer portrayals of unproven stem cell therapies: Is it getting better? *Regenerative Medicine, 8*(3), 361–369.

Ong, A. (2010). Introduction. In A. Ong & N. C. Chen (Eds.), *Asian biotech: Ethics and communities of fate* (pp. 1–54). London/Durham: Duke University Press.

Patra, P., & Sleeboom-Faulkner, M. (2011). Recruiter-patients as ambiguous symbols of health: Bionetworking and stem cell therapy in India. *New Genetics and Society, 30*(2), 155–166.

Petersen, A., & Seear, K. (2011). Technologies of hope: Techniques of the online advertising of stem cell treatments. *New Genetics and Society, 30*(4), 329–346.

Prasad, A. (2015). Ambivalent journeys of hope: Embryonic stem cell therapy in a clinic in India. *Health, 19*(2), 137–153.

Ryan, K., Sanders, A., Wang, D., & Levine, A. (2010). Tracking the rise of stem cell tourism. *Regenerative Medicine, 5*(1), 27–33.

Salter, B., Zhou, Y., & Datta, S. (2014). Health consumers and stem cell therapy innovation: Markets, models and regulation. *Regenerative Medicine, 9*(3), 353–366.

Shan, J. (2015, August 21). Health authority announces step to rein in 'wild' stem cell treatment. *China Daily*. http://www.chinadaily.com.cn/china/2015-08/21/content_21662613.htm. Accessed 26 Feb 2016.

Shanghai Medical Tourism Products & Promotion Platform. (2016). Stem cells. http://www.shmtppp.com/procedures/stem-cells/introduction/. Accessed 5 Feb 2016.

Sipp, D. (2009, September 23). The rocky road to regulation. *Nature Reports Stem Cells*. http://www.nature.com/stemcells/2009/0909/090923/full/stemcells.2009.125.html. Accessed 26 Feb 2016.

Sleeboom-Faulkner, M. (2010a). Embryo controversies and governing stem cell research in Japan: How to regulate regenerative futures. In A. Ong & N. C. Chen (Eds.), *Asian biotech: Ethics and communities of fate* (pp. 215–238). London/Durham: Duke University Press.

Sleeboom-Faulkner, M. (2010b). Boundary making and 'good' stem cell research (SCR) in mainland China: Including bioethics, excluding debate. *East Asian Science Technology and Society, 4*(1), 31–51.

Sleeboom-Faulkner, M. (2013). Competitive adaptation: Biobanking and bioethical governance in China Medical City. *East Asian Science Technology and Society, 7*(1), 125–143.

Snyder, J., Crooks, V., Adams, K., Kingsbury, P., et al. (2011). The 'patient's physician one-step removed': The evolving roles of medical tourism facilitators. *Journal of Medical Ethics, 37*, 530–534.

Song, P. (2010). Biotech pilgrims and the transnational quest for stem cell cures. *Medical Anthropology: Cross-Cultural Studies in Health and Illness, 29*(4), 384–402.

Song, P. (2011). The proliferation of stem cell therapies in post-Mao China: Problematizing ethical regulation. *New Genetics and Society, 30*(2), 141–153.

Tam, F. (2012, January 11). Halt to rogue stem-cell therapy. *South China Morning Post*. http://www.scmp.com/article/989799/halt-rogue-stem-cell-therapy. Accessed 26 Feb 20.

Taylor-Weiner, H., & Zivin, J. G. (2015). Medicine's Wild West—Unlicensed stem-cell clinics in the United States. *The New England Journal of Medicine, 373*, 985–7.

Thompson, C. (2010). Asian regeneration? Nationalism and internationalism in stem cell research in South Korea and Singapore. In A. Ong & N. C. Chen (Eds.), *Asian biotech: Ethics and communities of fate* (pp. 95–117). London/Durham: Duke University Press.

Turow, J. (2011). *The daily you: How the new advertising industry is defining your identity and self-worth*. New Haven/London: Yale University Press.

Xi, J. (2014). Transition to innovation-driven growth (Address to the 17th General Assembly of the Members of the Chinese Academy of Sciences and the 12th General Assembly of the Members of the Chinese Academy of Engineering, June 9). In J. Xi (Ed.), *The governance of China* (pp. 131–142). Beijing: Foreign Language Press Co Ltd.

Yang, J. (2006). The privatization of professional knowledge in the public health care sector in China. *Health Sociology Review, 15*(1), 16–28.

Zhang, J. Y. (2014). Does China offer a new paradigm for doing science? In D. Kerr (Ed.), *China's many dreams: Comparative perspectives on China's search for national rejuvenation* (pp. 156–179). Basingstoke: Palgrave Macmillan.

Zhao, H. (2005). Governing the healthcare market: Regulatory challenges and options in the transitional China. Unpublished MA thesis, La Trobe University, Melbourne.

7

Hope 'at Home': Stem Cell Treatments in Australia

> *Why would you spend up to $US100,000 to go to Russia when you can have a much safer procedure done here for a fraction of the cost?* (Australian-based Adult Stem Cell Foundation Facebook post June 22, 2014)

In one simple statement this quote encapsulates a new development in the stem cell treatment market in Australia—as well as in a number of other countries. No longer do patients need to travel abroad for treatment; a potentially better option is available 'at home'. While this Facebook post and other promotional material imply that the Adult Stem Cell Foundation was seeking to promote a new treatment 'pioneered' by a local doctor, there remains little in the way of external verification as to whether the procedure was safe or even beneficial. Indeed, many of the same criticisms levelled at providers in China, Germany, and other 'stem cell tourism' destinations, are applicable to the emerging market in Australia. However, for an increasing number of Australians, the mere fact that treatment is available 'at home', in a country with a high level of universal medical care, lends a sense of legitimacy. The fact that it is cheaper, uses one's own cells to heal—with connotations of being more

A. Petersen et al., *Stem Cell Tourism and the Political Economy of Hope*, Health, Technology and Society,
DOI 10.1057/978-1-137-47043-0_7

'natural' and 'safe'—and is endorsed by a charity, makes the option potentially more acceptable to many contemplating their options.

Over the last decade there has been an exponential growth in the commercial stem cell industry in Australia. From one specialist clinic selling 'autologous' stem cell therapies using the patient's own cells in 2011, it is now possible to find several 'stem cell' clinics in any major city offering a wide range of solutions to alleviate pain and suffering or counter the effects of ageing (Munsie and Pera 2014). While some clinics rely on cells isolated from the patient's bone marrow or blood, of increasing popularity in the last five years has been the use of cells obtained from liposuction of body fat. The majority of Australian clinics claim to focus on the treatment of arthritis and sports injuries by injecting the cells back into the affected joint, yet a growing number offer treatment for crippling injuries and illnesses such as stroke, dementia, multiple sclerosis, vision loss, motor neurone disease, and autism where the cells are re-suspended (placed in fluid) and injected directly into the patient's vein or, in the case of one clinic, into the cerebrospinal fluid via a lumbar puncture. Usually offered as a same-day medical procedure in private clinics outside a hospital setting, such practices are at present effectively unregulated. The risks—both physical and financial—that this places patients and, indeed, the fledgling stem cell and regenerative medicine sector in has led to calls for restraint and greater regulatory oversight from academics, patient groups, and professional bodies (Munsie and Pera 2014; McLean et al. 2015). While the government regulator, the Therapeutic Goods Administration (TGA), has canvassed possible changes that could provide better safeguards, there is yet to be any substantive movement to address these practices (TGA 2015). Provided a patient can find $AU10,000–20,000 to fund such a treatment, it is possible to find a doctor and simply book in. Although Australia is not the only country facing the challenge of an emerging domestic market for unproven stem cell treatments (Connolly et al. 2014; Bianco and Sipp 2014; Taylor-Weiner et al. 2015), the relatively recent emergence and breadth of the practice provides a striking example of an adaptation in the sector, fundamentally challenging the notion that stem cell tourism only occurs in jurisdictions with limited or lax regulatory oversight of therapeutics.

In this chapter, we seek to explore the specific circumstances that have allowed the creation of the Australian market of stem cell treatment and, in particular, the politics of hope underpinning this development. We examine the patient experience, and how this compares to those who pursue treatment overseas, as well as the experience of those who provide unproven stem cell treatments. Finally, we examine contested views expressed during a recent public consultation undertaken by the TGA where providers, their patients and supporters argued that such treatments heralded a new era of innovative medicine best overseen by self-regulation, while their detractors accused them of cashing in on hopes invested in stem cell science, thus exposing patients and the sector to unacceptable risks. But first let us outline the Australian regulatory context that has enabled the market to be created.

The Rise of Unproven Stem Cell Therapies in Australia

As mentioned in Chap. 3, there is broad community support in Australia for stem cell science and high hopes for clinical benefit. Indeed, Australian researchers have been lauded for their substantial stem cell research discoveries for many decades (Trounson and Harvey 2008). For many in the community, the restorative capacity of stem cells is already familiar. Almost everyone knows someone with leukaemia or another blood disorder who has been 'cured' following a blood stem cell transplant by either a transplant from a matched donor (allogeneic transplants) or receiving their own cells back—referred to as autologous treatment. Such treatments do not usually involve having to coax or manipulate the blood stem cells in the laboratory but simply rely on the cells making their way back to the bone marrow via the circulation where they lodge and start making red blood cells, white blood cells, and platelets, thereby restoring the patient's normal blood and immune system function.

The question of whether scientists can harness the regenerative potential of other types of stem cells—isolated from fat, placental, and other tissues, donated IVF embryos, or made in the laboratory from the

patient's own body cells—remains a focus of substantial research initiatives around the globe (Daley 2012). Depending on the source of stem cells and the intended therapeutic use, additional 'manufacturing' steps may be required to collect, select, and purify the cells. Indeed many novel 'stem cell' approaches being developed rely on creating specific replacement cells, such as heart cells, nerves, or pancreatic cells, rather than injecting just 'stem cells'. However, considerations such as where the cells are obtained from and how they are collected, grown in the laboratory, stored, and, ultimately, given to the patient have the potential to expose the patient to the risk. Such risks include the risk of viral or bacterial infection through contamination—common to the manufacturing of any therapeutic product—as well as the possibility of inherently changing the biological properties of the cells or simply putting a type of cell 'where it does not belong' (Snyder 2011). While many jurisdictions have instigated some regulatory measures to address potential risks associated with therapeutics, their implementation, especially when it comes to autologous-based therapies, has proved challenging (Lysaght et al. 2013).

In Australia, the legislation that sets out requirements for the import, export, manufacture, and supply of therapeutic goods, the Therapeutic Goods Act (henceforth 'the Act'), was amended in 2011 to reflect the new era of therapeutics manufactured from biological sources, which had until this time been largely unregulated (Trickett and Wall 2011). The TGA made the decision to exempt (under the accompanying Therapeutic Goods (Excluded Goods) Order No. 1 of 2011, henceforth 'Excluded Goods Order') some established medical procedures from having to comply with new legislative requirements—such as the aforementioned autologous and allogeneic blood stem cells; the use of fresh organs for transplantation, and the use of sperm, eggs, and embryos for infertility treatment—as these practices were viewed to be sufficiently overseen by existing review and accreditation processes (TGA 2013). However, also included with the Excluded Goods Order was a broad exclusion around the use of autologous cells and tissue. In effect, only cells from donated sources were viewed as 'therapeutic goods' and expected to meet the requirements under the Act (McLean et al. 2014). Provided the autologous cells or tissues are used for the treatment of the patient from whom they are taken, and that they are used under the supervision of a medical

practitioner registered in Australia who is caring for that patient, for a single indication in a single course of treatment, such practices were deemed outside the remit of the Act and the TGA. While there remained a requirement for the medical practitioner to adhere to professional standards, this 'medical practice exception' has enabled clinicians to market their 'stem cell treatments' without preclinical 'proof of principle' experiments, manufacturing oversight and safeguards, or any requirement to evaluate the safety and efficacy of proposed autologous therapies in clinical trials, irrespective of the degree of manipulation or how the cells are transferred to the patient (Munsie and Pera 2014; McLean et al. 2015). Such a blanket exemption appears out of step with other jurisdictions. For example, the Food and Drug Administration (FDA) in the USA has issued warning letters to several clinics and proposed new guidelines to address ambiguity around the degree of manipulation used to prepare the cells for autologous treatments and whether the fundamental biological properties have changed (Turner 2015). While concern has been raised that the FDA needs to 'play a more meaningful role in investigating businesses advertising 'stem cell' treatments', the American system is more effective than what is presently the case in Australia (Turner 2015). In other countries, such as Germany, the European Medicines Agency's Advanced Therapy Medicinal Products legislation would curb the most extreme of the activities in Australia.

In response to the growing concern about the number of Australian companies and medical clinics offering stem cell treatments outside the clinical trial framework, the TGA in early January 2015 conducted a public consultation on possible regulatory options to encompass autologous cell therapies (TGA 2015). A total of 80 submissions were lodged (70 published on the TGA website), encompassing a wide range of stakeholders including patients, doctors, researchers, and professional bodies. At the time of writing, more than one year later, the TGA was yet to release their recommendations. New clinics continue to open, existing practices expand their services, and the sector remains contested. As the Australian community awaits clarity around regulation and acceptable scope of practice, questions abound: Are the autologous cellular therapies a medicinal product whose manufacture should be overseen by the regulator or a legitimate medical practice? Should cells be prepared in

an accredited laboratory and/or according to manufacturing standards so that the patient and their medical team know exactly what is being injected? Should the clinician be able to ask for payment for yet to be proven therapies? Should a doctor be able to promote their unproven treatments via direct-to-consumer advertising? How do clinicians who undertake autologous cellular therapy justify and explain their practice and how do they decide whom to treat? How do they manage the hopes of the patients and their families? For those in the community who see accessing their own stem cells as a possible treatment option, they are left to fend for themselves as they navigate this unregulated marketplace.

Hope at Home: Patient Perspectives

For many Australians, the creation of an Australian market of hope was born from the frustrations at having to travel overseas to receive therapy. In Chap. 2, we discussed patients' and carers' frustrations, especially in regard to being unable to access potentially life-saving treatments. Many travellers share the view that experimental and innovative treatments are simply not embraced in Australia. As Audrey, who undertook treatment for multiple sclerosis in Germany, stated:

> And there's also that thing about Australia being a bit behind the times or a bit conservative when it comes to this sort of thing.

Another patient, Michael, who was contemplating travelling to Russia for a stem cell treatment for his multiple sclerosis, also expressed irritation at the delay in advancing stem cell therapies to the clinic in Australia. He explicitly describes his frustration at not being ill enough to be considered a participant in a registered clinical trial for multiple sclerosis:

> Well, in Australia, it's so backward in their attitude on things like stem cells which to me are just [going to] … have such a huge impact … It's not just the reticence of the hospitals: it's the bureaucratic health system; it's the government; it's … even the MS Society, total lack of desire to learn and to encourage people like myself to go out and do it. The one and only trial [in Australia], that's just a load of crap. I mean they're taking people who are

> wheelchair cases … Forget it! I'm not interested in waiting for another 10 years for the bureaucracy to pull their head out of the [sand].

Michael's annoyance at the time lag 'from bench to bedside' was not an uncommon response, reflecting the heightened hopes and expectations that stem cells represent. The frustration at waiting for clinical trials to demonstrate safety and efficacy, and the limited opportunity to participate in clinical trials in Australia, meant that patients often looked for ways to access possible treatments outside of the clinical trial framework, before their condition and quality of life diminished. Jenny expressed her frustration about an Australian clinical trial, which was exploring the use of autologous haematopoietic (blood) stem cell therapy for multiple sclerosis, being shut down by health authorities due to ethical concerns (Sparkes 2014). In this approach, patients have their bone marrow collected and frozen prior to having chemotherapy to 'kill' then 'reboot' their 'MS-ridden immune system'. The stored bone marrow is then returned to the patient with the aim of halting the progression of multiple sclerosis. As Jenny explains below, her inability to participate in the multiple sclerosis clinical trial in Canberra, despite having been given the preliminary treatment, meant that she explored options overseas and found a clinic in India that was willing and able to treat her, providing possibly greater care than she received at home:

> I was one of the ones picked for Canberra to go through the stem cell transplant … [They] actually started me on the pre-chemo … prior to the actual transplant itself, to see that my body can cope with the chemo. And then Canberra pulled the pin on me. So I'd already by that stage had accepted the fact that I no longer could conceive and, you know, because, once you're put through the chemo, that sort of halts all those sorts of things. So I was quite frustrated … because Australia wasn't operating it so … my partner had done research on the internet, and we found … [a clinic in Bangalore] was a legitimate place to go. They answered all of our questions. I could ring them up. I could ring the neurologist on my phone and speak to him direct. Like, in Australia, you can't do that. There's just no way. So I would ring him and constantly question him, and they, and it was a protocol that I needed to go through for my transplant. So they were doing exact same treatment [initially offered in Australia] but in a different country.

Jenny also explained her frustrations with the Australian healthcare system:

> Nothing can be fast-tracked. We're talking about Australia, honey … I just pray that no-one gets these neurological diseases here in Australia because, you know … we're fighting against a losing battle. I mean I had the Health Minister of Australia [say], 'No, honey, I'm sorry, we can't help you.'

As the Australian autologous stem cell industry gained a foothold around 2011, the choice for patients appeared to change. Organisations such as the Adult Stem Cell Foundation, a then registered charity (its charitable status revoked in 2015) began to actively promote domestic clinics, particularly following the closure of X-Cell (ACNC 2016; Chap. 5) However, not all Australian patients saw such advertising as an endorsement for stem cell treatment. Madeline, who had early stage multiple sclerosis, describes her reaction after being the target of a social media campaign instigated by the Adult Stem Cell Foundation:

> I've been quite shocked, actually, that Australia allows autologous stem cell transplants … I wasn't really aware of that until I had it pop up in my Facebook feed the same weekend as the, *The Age* [newspaper article came out] which wasn't … critical enough of the quacks I didn't think … and I may have got the red mist … I was highly offended that that was popping up in my feed and it was offering me a clinical trial. And I'm like, 'That's not a clinical trial. That is not a registered clinical trial because that's not registered on the clinical trials database and that's not been put through a human ethics committee'.

Unmet patient demand for a treatment is undoubtedly one of the main drivers of the emerging autologous stem cell industry in Australia. The experience of Madeline helps to illustrate the influence of the media in raising awareness about unknowns and potential risks in this emerging field. The role of social media and how it conflates media coverage of stem cell science will be discussed further in Chap. 8. Although media outlets have more recently aired stories with a cautionary tone (ABC *7.30 Report* 2014a, b; Australian Financial Review 2014), many high profile stories

present stem cell interventions, particularly those occurring in Australia, in an uncritical manner acting almost as an extension of the clinic's promotional activities, as Madeline noted above. The Australian media has also regularly portrayed stem cells as a possible solution to help those suffering from arthritis or to heal sporting injuries. A tabloid current affairs show on a major television network ran a story entitled *Arthritis: Stem Cell Treatment* in which the doctor providing the treatment stated, '[S]tem cell therapy is the future in treating many things in the medical world. We take stem cells from fat and place them where we need treatment.' The story also stated that stem cell treatment was 'a breakthrough treatment that's been tipped to replace surgical procedures in effectively curing the degenerative joint disease' (Today Tonight 2013). Links to this footage were placed on the website of the featured clinic, lending much legitimacy to the procedure and its practitioner. Several other clinics have also used links to media appearances, including those featuring celebrity clients, to promote their treatments. While there are no statistics on how many unproven stem cell therapies are taking place in Australia, the number may be significant. One prominent provider stated in a conference biography that he 'injected his first patient with adipose derived stem cells in April 2009' and treats six patients per week on average (New South Wales Stem Cell Network 2013). Conservatively, this could mean that over the past six years, one clinic alone could have treated over 1500 people. With over 40 such providers operating in Australia in 2016, the numbers of patients receiving treatment could stretch to several thousand. In order to explore the experience for Australian patients we will now examine Andrea's story.

The Experience of Undertaking Stem Cell Treatment in Australia

For patients, the experience of undertaking stem cell therapy 'at home' may be viewed differently to embarking on treatment abroad. While some demands such as the need to travel long distances and the associated expenses may be reduced, and some comfort gained by removing perceptions around the 'quality' of the healthcare they will receive, the challenge

of pursuing treatment and its costs while balancing work and personal commitments can still present a substantial issue for those accessing treatment at home. The following story of Andrea, who sought stem cell treatment in a major Australian capital city to manage her chronic pain—mainly sciatica from a back injury—illustrates the interplay between the patient and doctor and what is actually involved in the pursuit of treatment. Like so many patients, Andrea became aware of stem cell therapies through noticing an advert when searching for information online:

> Well I … liked this page because of the Botox and … then they kept posting me things about stem cells and, for osteoarthritis and sciatica, and this, and that. And I thought, 'Oh? All right.' So I looked into it a lot. I Googled … I did about two months' worth of research … It wasn't every day for, what, two months or so; it was, you know, mainly on the weekends. And I spoke to a couple of other people. I think there's a website, there's a page that I'm on for chronic pain sufferers and somebody mentioned that a friend of hers had it done in America and was happy, like she was overjoyed with the results. But they used stem cells from the [bone] marrow. So I started talking to her and spoke to her friend who said that it was worth it for the sciatica, and I thought, 'Look, I'll give it a go for the sciatica.' At least it, I didn't think it would work for the arthritis pain, to be honest, but I had a feeling it would work for the sciatica.

Andrea also sought advice from her local family doctor before ultimately deciding to visit a prominent clinic that promoted the use of stem cells obtained from liposuction for treatment:

> He had heard of it but didn't know much about it. And he said, 'Well what do you think?' I said, 'Well I'm gonna give it a go.' … He said, 'Okay, let me know how you go.'

We can observe that Andrea sought expert guidance about stem cell therapy, but the doctor's lack of awareness about the issue, or genuine belief that the treatment could pose no harm, meant that Andrea advanced towards her therapy with few checks and balances (similar to the experiences recounted in Chap. 2). When asked about the benefits, risks, or possible downsides from the treatment at the Australian-based clinic, Andrea said there was little mention about the risks:

> The benefits, yeah, to a point, but not the risks. And I actually looked up risks myself but … it was minimal … from what I gathered. I mean I didn't read medical journals on it; I just [read] what was on the internet and quite a bit of … it was on the internet. But it's still experimental. So … there wasn't really a lot of downsides though. Just mild tingling, which I did get on my legs. But, no, that wasn't the downside. No. The downside was the [liposuction]. I wanted more information on the liposuction.

Consistent with the experience of Australians who sought treatment abroad (Petersen et al. 2014), Andrea did not raise risks in the context of physical harm associated with the administration of the stem cells, but rather the cost of the treatment and the pressure of undertaking work with her painful condition. As she reflects on the possible cost of a follow-up treatment where the doctor offered to use some of her stored cells:

> I don't have the money for it at all. So to spend another $2,000 that I don't have and pay that off … you know, it's overwhelming. I'm working full-time shift work … running off my feet, you know, through, for eight and a half hours a day—all sorts of shit, working with chronic pain. It's exhausting. I don't have time to socialise or even find a boyfriend, or anything, 'cause I'm too tired … It's, it's a lot. It's, it's huge for me, you know. I'm not, I'm certainly not rich. I'm on my own. One income. And I have a lot of expenses. I'm paying, my friend lent me money to move to [major capital city] so I'm paying her back $11,000. And I'm also now paying for the procedure, and perhaps an extra $2,000 to thaw out my own stem cells.

In this context of living with chronic pain, as well as work and financial pressures, Andrea went on to describe her experience of the initial liposuction procedure:

> I stood there while he marked my body and he said, 'Is this the part that bothers you the most?' I said, 'Well no, that's where I've got the most fat, apparently.' He goes, 'Yeah, you don't have much.' So they took fat off basically my love handles, you know. Ugly word, isn't it? And then also, you know, while he was doing it, the liposuction, he, there wasn't enough fat so he took some off my stomach which was already flat anyway but he took some off like the bottom part. But they didn't give me enough anaesthesia.

> I have a very high tolerance to any sort of drugs due to being on morphine for so long and I felt everything that they did. Everything. It was horrendous. And I was, I was nearly in tears. I said, 'This is so violent!' And he says, 'What? What are you talking about?' He said, 'There's supposed to be a fluid motion like a violin.' I said, 'No, it's more like a machete.' So it was really, really painful. In the end, I couldn't stand it anymore. I said, 'Stop! I've had enough. Right now, stop!' And he said, 'No, no, no, we're nearly done, nearly done.' So he stopped when he was ready but I wasn't happy … it hurt. It was burning. The nurse was saying, 'Oh my God', she said, 'you can feel it!' I said, 'Yes!' So, and, when they were putting the cannulas in, oh my God! That was like being knifed. I felt all of them all over me and that was, that was even worse.

After the surgery Andrea recalls that:

> Then I was sitting down in a room for, I don't know, a little while. I think I had a cup of tea or coffee … And then my friend came to visit and, while she was there, they put a, you know one of those butterfly things that they do in hospitals with an IV, to attach the IV into my arm. And so that's [when they put] … half of the stem cells … into the bag along with the solution so intravenously, if you know what I mean, and the other half was injected into me … with a, a needle, a syringe. I had it on my left butt, like my buttock … And the other part, like I said, was put into my spine but I believed it was in the wrong place 'cause I'm still feeling a lot of pain in the … spine … It took a long time for the IV to empty 'cause I couldn't leave until all of it was in me. So that's about four hours I think.

Reflecting on her treatment, Andrea spoke of the clinician, for whom she was thankful as he gave her the treatment at a lower rate than other patients, as he knew she had difficulty paying:

> He knows I couldn't afford this so … instead of charging me the $10,000, he only charged me three, but that's, that's still a lot for me. And also I think 'cause he liked me as well, you know. Yeah, we got along really well but, and I know that other people were paying, when I was there, there was this man getting his knee done and he paid the actual, what, I think it was nearly $10,000. It's heaps … I don't have, you know, $3,000 or I don't, certainly don't have $10,000 you know. We didn't really get into it too

> much [because] … he was trying to get me to do, to go onto I guess he was recruiting people to, if he had 10,000 people signing [his petition to Medicare—a publicly funded universal healthcare scheme] then Medicare might consider putting [stem cell therapy] on, you know, medical funding. Well I think they do because he wants this to be a success for him. Like they do five of these a day so, and he wants it to be a success.

Andrea's experience of undertaking unproven stem cell treatment in Australia helps to highlight how the treatment market is sustained and developed. From her experience we can observe how online marketing and advertising were central in helping her decide to undertake treatment. The offering of 'cut price' surgery could be interpreted as a compassionate act, or a commercial strategy to create a patient endorsement for stem cell therapy. Indeed, the doctor's attempt to get Andrea to sign a petition raising concerns about the financial costs of treatment can be seen to be motivated more by the desire to make the business of selling stem cell treatments a 'success' rather than to develop an efficacious treatment. As Andrea's story highlights, in many ways the Australian market for unproven stem cell therapies shares many similarities with the clinics and companies abroad and is sustained by demand from frustrated patients seeking a solution for their affliction, all enabled by the high hopes of the providers. In the next section we examine how Australian providers view their practice and that of others offering 'stem cell' treatment.

Legitimising Therapies: Provider Perspectives

In this section, we examine how the Australian providers see themselves and how they have sought to legitimise their provision of unproven stem cell treatments. As we outlined in the previous section, the Australian patients who are seeking unproven stem cell treatments do so in the hope that their quality of life may be improved. As we have noted, the majority of autologous cell therapy clinics in Australia use cells derived from the adipose (fat) tissue obtained from the patient's own body following liposuction—often referred to as stromal vascular fraction (SVF)—to treat a number of conditions, such as problems with knees, wrists, migraines,

and a number of other diseases and illnesses (Bright et al. 2014; Munsie and Pera 2014).

Similar to the experience of the 'accidental' advisors (Chap. 3), and to that of some of the treatment providers in China (Chap. 6), providers in Australia commented that their patients had 'unrealistic' expectations. For example, Geoff, a provider, commented:

> People ring constantly and many of them have got extraordinarily unreal expectations of stem cells. That's with patients generally … this cult of the magic bullet that is out there, that the stem cells is going to be the be-all and end-all of everything. And, of course, trying to tone down their expectations … and make a realistic picture is difficult.

From this experience we can observe how patients' hopes and expectations can place the provider in a difficult situation. Many had experienced challenging consultations where patients insisted on treatments for conditions that the doctor didn't feel comfortable treating or where there wasn't clear evidence to recommend a stem cell therapy. As Geoff went onto explain, he was very clear on what could or could not be treated with autologous cell therapy:

> From rheumatoid arthritis to multiple sclerosis and motor neurone disease, and a whole range of other things that we're not really equipped to treat at this point in time … The evidence just isn't there as yet and the techniques are not … effective enough for us to treat those sought of things … unfortunately we have to send them, turn them away.

Another provider, James, described an episode where he refused treatment to a teenage elite athlete who was being pressured by their father to have autologous cell therapy for a chronic condition. James went on to voice concern not only about the selection of suitable patients, but also whether consent for such an 'experimental' procedure could be compromised if the patient was taking drugs that could impede their 'understanding' of what was involved:

> Spinal injury … I wouldn't treat that … Recently we had enquiry, [about] a person that ruptured the transverse ligament between C1 and C2 because they'd been told by the doctors the person needed spinal fusion to avoid

> paraplegia … I didn't want to treat their ligament with stem cell injection, which I thought was being extremely ambitious and putting this person at risk … I also don't treat chronic pain, if people are in pain I won't take their blood. I won't treat patients who are currently taking narcotics … because their perception of pain and their view of the world is distorted; if you are going to embark on an experimental treatment like stem cells, you really have to have a proper understanding of your treatment and what it involves.

The decision of these providers to restrict their practice to specific conditions is consistent with what Munsie and Pera (2014) had previously described where the vast majority of autologous providers in Australia limited their practices to alleviating painful joints. As these examples illustrate, providers must navigate a complex ethical landscape and balance patient hopes and expectations of yet-to-be-proven treatment, while also continuing to treat other patients for whom they felt their approach was justified, albeit also unproven. As Mathias, a provider, explained, he deals with these encounters by using his professional training:

> So what you do first is you behave like a doctor. So you examine them first time. Assess them first. And then you say, 'Well, basically, has … all this been addressed?' You know, for example, … the multiple sclerosis one: you try and find out has she got a visual problem … Now, if that's the case and they've got visual problems, and they're happy to go, you give them information. You, I don't tell them this will make you better, but I tell them … 'this is what the evidence is.' So I'm actually acting as a sieve. I'm not recommending anything.

It is interesting to note the provider's self-description as a listener who lets the patients make up their own minds. This is similar to the stance adopted by the 'accidental' advisors whom we discussed in Chap. 3, namely facilitators of 'informed choice'. However, while the doctor may not be recommending a treatment, the fact that the treatment is being considered in a commercial clinic raises significant issues of conflict and challenges the notion of 'informed choice' as the seller of the treatment is also relaying information about the safety and likely benefit of the treatment.

Providers were also keen to create a boundary between legitimate and 'less legitimate' providers whom they referred to as 'cowboys' only interested in money, rather than advancing the field. As James boasted:

> One of our biggest referral sources is another stem cell provider [in same city] who people have already been to see. They come to me for a second opinion and they often sign up on the day that they're there for the treatment [at his clinic] because they find that they don't have confidence in this other group. They feel the other group is all about money and not about science or research.

Several of the providers noted that they were justified in providing their treatment because they 'trained' or obtained a 'licence' from groups in Australia or overseas that they believed were well established in this area. As James explains, he decided to use cells derived from bone marrow rather than adipose tissues, as the majority of other Australian practitioners do, because he was impressed by an American company and their 'research' after he had gone on a 'bit of a fact-finding tour':

> I'm, [using] totally autologous stem cells. And, in my particular area, I'm only providing that. ... So a lot of people are using adipose stem cells or stromal vascular fraction. The company I got the licence from, they had some good reasons for deciding to do some research into bone marrow for joint treatments. And … they've developed that process quite a long way. They've been treating people since 2006. So I, use bone marrow but that's because that's basically because that's the company's basic research line.

In attempting to maintain the boundary between legitimate and illegitimate clinics, and defend their right to practice, several of the providers stressed that they were driven by altruism rather than by the profit motive. These providers emphasised that they could charge patients more for their services, but only charged a minimal amount to cover costs in an effort to alleviate the patient's condition or to help give them hope when all other methods may have failed. This can be clearly seen in Andrea's story and how the clinician sought to recruit her to his Medicare petition. A number of the providers expressed the view that others are 'cowboys' only interested in economic profit, while *they* were committed to the science and patient welfare—a perspective which is at odds with the reality that all were involved in commercial transactions for treatments outside mainstream evidence-based medicine.

Providers' Views on Regulation

The question of how autologous stem cell treatments are viewed by regulators is crucial to the establishment of their legitimacy. Are they an accepted medical practice, where doctors can administer them within the confines of their professional judgement, or are they a yet to be proven medicinal product whose manufacture and administration should be subject to regulatory oversight? As we have already argued, the nature of the current TGA exemption has created ambiguity around autologous cell therapy and marketed stem cell treatments in Australia. As these products are currently not recognised as 'therapeutic goods', there is effectively no requirement for standards to be met regarding how the cells are processed, manipulated, stored, and administered; nor for the patient to be fully informed of the experimental nature of the procedure, or to be provided with ongoing care—leaving the patient vulnerable to exploitation. For some Australian providers, such as Mathias, the current regulatory exclusion of all autologous cell therapies was a source of disbelief:

> One of the things that really astounded me was TGA guidelines … I really can't believe that the TGA have actually done that, so I'm really very interested to know who was the driving force behind that one.

For a number of providers, this disbelief about the current guidelines was also accompanied by an unease regarding the self-regulation of autologous cellular therapies. In lieu of any action by the TGA, there have been calls for the development of a code of conduct to self-regulate the industry (Tuch and Wall 2014). Those who advocate for regulatory change or the continuation of the status quo all agree that the introduction of greater measures to safeguard the industry, such as standardising cell manufacturing and restricting the advertising of treatments to consumers, is required. However, some providers, such as James, were cautious about the prospect of a policy of self-regulation in regard to unproven treatments:

> If you look at a lot of professional bodies who self-regulate, invariably they run into the problem of, as a body, they didn't think they were doing anything wrong even though the greater community need not have agreed to

> that particular view. So I think self-regulation is important in terms of continuing medical education and sharing best practice information to make sure the patient's safety is always paramount. But I don't trust anybody that says they self-regulate. It's like giving lunatics the keys to the asylum, you know … politicians, barristers, you know, any, any large professional body that … regulates itself invariably should lead to concerns.

Other clinicians advocated for a more conventional regulatory model with independent oversight, as operates in some other jurisdictions. As Geoff commented:

> Well I … think there should be something of a blend of both. I do have faith that … the practitioners can self-regulate, so long as they can get together and formulate a series of protocols. But then you need some … legislative authority to be able to enforce them. There's no point having a series of guidelines or protocols, or rules, if there's no way of having them enforced. And so I think that's where … the legislators need to become involved, is to give some force to that. However, I will be vehemently opposed to a mob of bureaucrats sitting down and working out regulations for anything in the health industry. That would be a recipe for disaster.

Another provider, Peter, acknowledged that there may soon be a change in the regulations and that he needed to seek ethics approval and develop a recognised research programme if he wished to continue practicing:

> They'll come after me … I have to write an IRB [application for ethics approval] … I'm having a bit of time off to write the IRB so I can get registered with a university and say I'm doing a research program. 'Cause they really can't come and close me down. I'm too old to have these buggers assing around.

Despite exhibiting a range of views on how unproven stem cell therapies should be regulated, providers mostly felt that the current 'medical practice' exemption gave their therapies and clinics *less* legitimacy. The providers saw strong and more appropriate regulation that was comparable with other jurisdictions (such as the European Union), as an important strategy in establishing legitimacy and the creation of an Australian mar-

ket. The ultimate goal of the Australian autologous stem cell industry was not only the creation of a strong domestic market, but the possibility of creating a global market where Australia could be a centre for stem cell tourism in the Asia-Pacific region. As James reflected:

> Generally, I think that … the policies that are in place do protect the patient and do provide a satisfactory standard of care. I think Australia, because of its predictable and consistent … regulatory atmosphere, has quite a lot of stem cell providers. So I know of multinational companies that view Australia as a base for bringing stem cell tourists from south-east Asia, Singapore and Hong Kong, you know, high net worth individuals and use Sydney as their destination. And the … stable Australian economy and political situation, is better than Syria and Romania, so it's a good advertisement.

Contested Hope and Regulations

The hopes of those wishing to establish a domestic stem cell therapy industry in Australia have long been labelled by critics as unethical and operating in a regulatory 'loophole', leading one journalist to ask whether the Australian stem cell industry was a 'new frontier in stem cell therapy or false dawn' (Elder 2015). In response to calls for action to address the regulatory ambiguity, the TGA in early 2015 released a discussion paper describing five potential regulatory models (TGA 2015). These models, with escalating regulatory oversight, were proposed to tackle issues associated with autologous cell therapies, such as the lack of evidence to support efficacy and safety—either direct safety impacts or safety issues incidental to the therapy—the inappropriate advertising of yet to be approved therapeutics, the large sums patients were being charged, and the lack of monitoring and reporting of adverse outcomes for recipients of the cell therapy (see Table 4, Appendix). Interested parties were asked to provide feedback during an eight-week consultation period. In all, 80 submissions were received: 14 from professional bodies; 12 from researchers, institutions, or hospitals (including one lodged by co-author MM of this book); 4 from industry groups; 4 from consumer

groups; 20 from manufacturers, suppliers, or healthcare practitioners providing autologous stem cell therapies; 21 from patients; and 5 from government bodies or other stakeholders. All submissions that were not marked as confidential were posted on the TGA website (TGA 2015). Coinciding with the conclusion of our research, this public consultation provided a unique insight into the contrasting hopes of a diverse group of stakeholders.

Broadly, the submissions reflected two main ideological positions. The first was the position of 'moral pioneers' (Rapp 1999), held predominantly by patients and providers, who were forging ahead with the strong belief that through this 'experimental' phase of trial and error, new treatments would eventually be established. The second ideological position, held by many researchers, professionals, and industry bodies, was that new innovative treatments will come from stem cell research, but this must be maintained by a responsible approach to translation, where protecting the safety of patients and establishing the efficacy of the treatments *before* being widely administered are paramount. These experts and associations almost universally expressed the view that it is unethical and unprofessional to market such unproven stem cell treatments directly to patients, and they called on the TGA to adopt one of the more stringent regulatory options.

Seeking Hope or Salvation?

The submissions from patients and providers illustrate a joint commitment to helping each other seek salvation through trial and error favouring status quo or the lowest level of regulatory change. The patients were seeking cures and better quality of life, or a sense of peace that they have tried and not left wondering if the 'treatment' may have worked for them. Providers were seeking to establish legitimacy for their treatments and the creation of a lucrative business for this emerging industry. Indeed, what was particularly interesting about the patient submissions was the use of anecdotal evidence and the rhetoric of rights. For example, one of the patient submissions stated that he wanted to be able to use his 'own body parts to heal my own body' and did not want to see 'options

for patients' limited; furthermore, he encouraged the TGA not to 'deny patients access to treatment that may have a significant benefit'. Although this and many other submissions are publicly available on the TGA website, we have elected not to include the name of those making submissions as we have not directly sought their permission (TGA 2015).

We also observed that the patient submissions provide a somewhat skewed representation as the majority were from people, including the gentleman quoted, who had undergone stem cell treatment as a research participant in a clinical trial listed on the Australian New Zealand Clinical Trials Registry. This particular clinic operates a hybrid model—where they conduct ethics committee-approved clinical research with no fee to participate—as well as sell treatment for several thousand dollars to those who do not meet the inclusion criteria for the clinical trial but would still like to try. This clinic and its business model is distinct from many of the other Australian providers. Therefore, this clinic's practices, and very likely their patients' experiences, were atypical of the main Australian autologous sector. However, many patients who made a submission were clearly concerned about a restriction on access to the stem cell therapies. As one patient wrote in their submission, stem cell treatments must remain 'available to the public in Australia' and not be 'regulated out of existence' because of the disputes and different opinions between several professional bodies.

The denial of access was not the only concern. Some patient submissions argued that because their condition had improved following treatment, there was no question that access should be *broadened*, as the provision of stem cell treatments could save money for both patients and the Government alike. One patient submission referred to the 'vast amount of money this treatment [for osteoarthritis] would save in unnecessary [knee] replacements', adding that 'it would be good if it received Medicare [universal healthcare] funding'. Views were also expressed that whatever regulatory changes were implemented, there should be no extra costs involved for the providers and patients. As we observed in the earlier section on Andrea's experience, the financial situation of many patients can be precarious.

With stem cell therapies under threat, patients relied on anecdotal evidence, an emotively powerful tool in helping to recruit people to a

cause (Moore and Stilgoe 2009). In the creation and protection of the Australian market, which can also be observed overseas, the rhetoric of rights, especially the 'right to try' or the seeking of compassionate access has emerged. Given that autologous stem cell therapy is already available in Australia as an option, many patients felt that they had the right to choose and access stem cell therapy irrespective of the evidence, cost, and safety. For example, one patient stated in their submission:

> The fact that autologous stem cell therapy is available in Australia, as a treatment option, is I believe respecting my rights as an individual to choose what treatment regime to follow … I am confident that this therapy was the right choice for me … that it is my body healing itself even though there are no guarantees.

Patients were not the only ones seeking to use the rhetoric of rights to help advance and continue access to unproven stem cell treatment. One of the providers stated in their submission, '[P]atient rights groups see the use of autologous cell therapies as a basic right and will not support options that limit their availability.' This emphasis on patient rights finds parallel in other countries. In the USA, the 'right to try' movement has been instrumental in creating legal rights for patients to access experimental treatments where safety and efficacy have not been established (Adriance 2014). In Europe, especially in Italy during the Stamina controversy, the argument that patients had 'the right' to access unproven stem cell treatments was also prominent (Abbot 2013; Chap. 5). In Italy, activists took their claims to the European Court of Human Rights in order to assert their 'right to life' to be able to access this unproven stem cell therapy on compassionate grounds (Rial-Sebbag and Blasimme 2014). In Europe, such cases have been unsuccessful, but in the USA 'right to try' laws have become a part of law in several states. If the regulatory environment changes in Australia, following the regulatory review, Australia too may see a rise in patient activists seeking to cement their 'right to try' within Australian law so as to gain compassionate access to these unproven treatments.

Exploitation of Loopholes or Medical Innovation?

While many patients advocated for the right to access to unproven stem cell therapies in their submissions, the providers insisted that their practices were a medical 'innovation' that could be best managed by 'self-regulation' and warned that it was 'essential that regulation does not stymie innovation and the ability to run proper trials'. Another provider was even more strident in his submission stating that:

> It is a fallacy to suggest that clinical trials discover new treatments. New treatments are discovered in the process of medical innovation … Under the present arrangement the public has access to treatments before they are measured in clinical trial. The public is not missing out … changing the Excluded Goods Order … would not increase research into stromal cells, it would decimate it … The very small number of complaints from consumers vindicates the conduct of medical practitioners and emphasizes the relative safety of the procedures … [patients should decide if they should] invest their time and money.

This provider also went on to accuse those who criticise commercial provision of unproven treatment as using 'gossip and untruths fuelled by self-interested groups who fear loss of prestige and government funding'.

Not surprisingly, the remaining submissions mostly urged the TGA to implement one of the higher levels of regulatory oversight to curb what was described repeatedly as 'unethical and unprofessional' marketing of unproven treatments to patients and the need to 'offer a balance between patient safety and promoting entrepreneurism'. One submission from a patient advocacy body noted that increased regulatory oversight was required to:

> '[F]acilitate the development of innovative new treatments in a safe manner, ultimately ensuring that safe and equitable access to potentially effective therapies can be accessed through the public health system so that all patients who need it can access it, rather than only those who can afford it.

Australian providers were seen as exploiting a regulatory 'loophole', similar to the situation that pertained in Germany that enabled X-Cell to operate (Chap. 5). Even before the TGA public consultation, these ten-

sions played out in the public arena, in particular during an Australian television programme, *Insight*, that screened in 2014. In this programme, an audience which included patients, providers, and scientists was assembled and asked 'whether current stem cell treatments are a cause for hope—or just misleading hype' (SBS 2014). During the subsequent discussion, the question of innovation and how changes to Australian regulations could stifle scientific progress was raised. This led to the following exchange between a prominent provider and an outspoken critic who is also an Australian doctor. The provider argued:

> Sometimes we practice medicine and we see things happen and we say, oh, why did that happen? And if I do it again will it happen again? And quite often we really don't know why we have got some improvement, but just because we don't know the science behind it doesn't mean to say that it doesn't work.

The Australian clinician critical of those selling unproven treatments, responded:

> A definition of pseudo-science right there, we've just heard the definition of pseudo-science … science is not always definitive and we can never speak in absolutes, but what we can be clear about is whether there's a benefit and the only way to do that is with a placebo controlled randomised, often crossover trial, a technically approved and well-regulated trial that's then published, subject to review and replicated elsewhere. If cowboys have activities in their own rooms and do things that aren't being supervised, and certainly not intended or approved by the TGA, the activities that are occurring in a number of doctors' premises were not intended by the exemption order … This is an unproven therapy for which people are taking money and I take exception to that.

It is highly contentious to argue that innovation and patient access should occur at the potential expense of patient safety and clinical efficacy. As we saw in an earlier section, the appeal to 'the helping clinician' has been an important trope in the continued expansion of unproven stem cell therapies in Australia. For example, a patient submission suggests that any regulatory change should:

> Take into account how much is being done by reputable doctors in this field, and how many patients are being helped, who would otherwise be living with crippling side effects of their arthritis.

Such an appeal is difficult to dismiss as there is limited public data on adverse events and the efficacy of treatments—although as we have described there is currently no requirement for providers to report a poor outcome and no instrument for collating such data. Providers in Australia, like elsewhere around the globe, are offering hope. The selling of unproven stem cell treatments tends to rely on creating support for the industry by promoting the fear of missing out. On the one hand, various interested parties, including patients and their carers, scientists, and providers want better care for patients—and this generally requires the long process of undertaking clinical trials in order to ensure that research findings are translated into treatments that are safe and effective. On the other hand, there are pressures to ensure that Australia reaps the benefits of a rapidly emerging stem cell treatment market—one that could be stifled by regulations. But does Australia really want to build a new sector on hollow promises? Wouldn't it be more prudent to prove safety and efficacy of any treatment before it is sold to patients? Does premature adoption of non-evidence–based practice risk the future of the sector? As we have observed over the past few sections, 'hope' has a political dimension and is intimately tied to the perceived potential of stem cell treatments.

Hope, 'Regulation', and the Future of Stem Cell Treatments

The creation of the Australian market for unproven stem cell treatments, similar to other jurisdictions, has been underpinned by hope, and the actions of diverse stakeholders with different investments in 'regulation' and related visions of futures involving stem cell treatments. In this chapter, we have seen three contrasting hopes about the direction of the Australian treatment market of unproven stem cell therapies. Patients hope that unproven stem cell treatments will improve their future quality of life. Providers hope to legitimise unproven stem cell therapies in order

to create a thriving future industry. Critics of the current regulatory situation, on the other hand, hope to protect patients and the future of stem cell science by seeking to establish the safety and efficacy of treatments before they are sold to the public.

In this and the previous chapters, we have highlighted a strategic shift in the use of legitimising strategies in the emergent stem cell treatment market. No longer are hopes premised on the establishment of certain accredited facts and forms of evidence, but rather based on the language and symbolism of an imagined positive future (Brown 2005). In the creation of the Australia market we can see the workings of 'hope' in regard to stem cell therapies, which many see as a kind of 'silver bullet', offering positive prospects to those who have no or few options. The Australian experience suggests that patients, providers, and critics are seeking to change the materiality of the present in order to help create an imagined future that reflects their particular sense of hope. Indeed, the hopes held by our three main groups of actors—patients, providers, and critics—are ones focused on connecting the materiality of the present with the future, because for them taking action in the present *can* bring about positive change in the future (Antelius 2007: 324).

For Australian consumers, stem cell treatments have become a 'hope technology', in a similar way to which In Vitro Fertilisation (IVF) has been described as a technology that embodies hope (Franklin 1997). Although IVF and stem cell treatments may be contrasting medical technologies, stem cell treatments are as yet unproven, and IVF is a widely accepted medical procedure (albeit one that does not work all the time). However, both stem cell treatments and IVF engender hope which compels people to transform their world as it is felt to bear upon them, in order 'to convert given-ness into choice' (Jackson 2008: xxii). We would contend that this hope, especially in the context of stem cell treatments, is most evident when patients rely on anecdotal evidence and patient testimonials rather than scientific evidence. As we saw with the submissions of patients during the recent TGA public consultation, one of their biggest fears of regulatory change was denial of access to the technology, no matter the state of the supporting science, as this would amount to a denial of hope. The patients sought to protect access to their hope technology and this is reflected in their adoption of the language of rights.

Our findings and observations on the emergent autologous stem cell treatment market in Australia highlight the challenges faced by those aiming to regulate the field. Stem cell treatments epitomise the hopes invested in technologies that promise to alleviate human suffering, yet, as critics note, those who hold these hopes are potentially vulnerable to exploitation, particularly in a commercial setting. Many of the critics of the Australian market of unproven stem cell treatments share the view that stem cell therapy holds great future promise, but seek to modify the current regulatory regime in order to protect patients and create a framework that will create legitimacy for stem cell treatments. As these critics argue, safety and efficacy must be first established *before* these treatments are widely administrated to patients, and there needs to be oversight measures, such as the mandatory reporting of adverse events and a ban on direct-to-consumer advertising. While they look forward to the development of a legitimate stem cell therapy market in Australia, these critics disagree with what they perceive to be the current pseudoscientific approach characterising the provision of treatments.

In the next and final chapter, we taking a closer look at current responses to the emergent stem cell treatment market and their limitations in responding to the context in which patients seek unproven treatments. As we emphasise, there is an urgent need to reframe 'stem cell tourism', which has suffered from simplistic characterisations and 'blind spots' in regard to the factors that shape human actions.

References

Adult Stem Cell Foundation. (2014, June 22). Facebook post. http://www.facebook.com/adultstemcellfoundation. Accessed 26 Feb 2016.

Abbot, A. (2013). Stem-cell ruling riles researchers. *Nature, 495*(7442), 418–419.

Adriance, S. (2014). Fighting for the "right to try" unapproved drugs: Law as persuasion. *Yale Law Journal Forum, 124*, 148.

Antelius, E. (2007). The meaning of the present: Hope and foreclosure in narratives about people with severe brain damage. *Medical Anthropology Quarterly, 21*(3), 324–342.

Australian Broadcasting Commission. (2014a, September 16). Questions raised about a clinic offering stem cell treatment using fat from liposuction. *7.30 Report*. http://www.abc.net.au/7.30/content/2014/s4089015.htm. Accessed 26 Feb 2016.

Australian Broadcasting Commission. (2014b, October 6). Stem cell treatment for AFL players draws medical and market criticism. *7.30 Report*. http://www.abc.net.au/7.30/content/2014/s4101497.htm. Accessed 26 Feb 2016.

Australian Charities and Not-for Profit Commission. (2016). Queensland charity revoked by national regulator, 17 September 2015. http://www.acnc.gov.au/ACNC/Comms/Med_R/MR_142.aspx. Accessed 26 Feb 2016.

Australian Financial Review. (2014, August 27). Stem cell therapy a primitive art. *Technology.* http://www.afr.com/technology/stem-cell-therapy-a-primitive--art-20140826-jcylc. Accessed 26 Feb 2016.

Bianco, P., & Sipp, D. (2014). Regulation: Sell help not hope. *Nature, 510*(7505), 336–337.

Bright, R., Bright, M., Bright, P., Hayne, S., & Thomas, W. D. (2014). Migraine and tension-type headache treated with stromal vascular fraction: A case series. *Journal of Medical Case Reports, 8*(1), 237.

Brown, N. (2005). Shifting tenses: Reconnecting regimes of truth and hope. *Configurations*, *13*(3), 331–355.

Connolly, R., O'Brien, T., & Flaherty, G. (2014). Stem cell tourism—a web-based analysis of clinical services available to international travellers. *Travel Medicine and Infectious Disease, 12*, 695–701.

Daley, G. (2012). The promise and perils of stem cell therapeutics. *Cell Stem Cell, 10*(6), 740–749.

Elder, J. (2015, April 5). Is a loophole in stem cell law helping new therapy to thrive, or allowing dubious science? *Sydney Morning Herald*. http://www.smh.com.au/national/health/is-a-loophole-in-stem-cell-law-helping-new-therapy-to-thrive-or-allowing-dubious-science-20150404-1m9oez.html. Accessed 6 Apr 2015.

Franklin, S. (1997). *Embodied progress: A cultural account of assisted conception*. London/New York: Routledge.

Jackson, M. (2008). *Existential anthropology: Events, exigencies and effects*. Oxford: Berghahn Books.

Lysaght, T., Kerridge, I., Sipp, D., Porter, G., et al. (2013). Global bionetworks and challenges in regulating autologous adult stem cells. *Cell Stem Cell, 13*, 647.

McLean, A., Stewart, C., & Kerridge, I. (2014). The emergence and popularisation of autologous somatic cellular therapies in Australia: Therapeutic innovation or regulatory failure? *Journal of Law and Medicine, 22*(1), 65–89.

McLean, A., Stewart, C., & Kerridge, I. (2015). Untested, unproven, and unethical: The promotion and provision of autologous stem cell therapies in Australia. *Stem Cell Research & Therapy, 6*(1), 1–8.

Moore, A., & Stilgoe, J. (2009). Experts and anecdotes the role of "anecdotal evidence" in public scientific controversies. *Science, Technology & Human Values, 34*(5), 654–677.

Munsie, M., & Pera, M. (2014). Regulatory loophole enables unproven autologous cell therapies to thrive in Australia. *Stem Cells and Development, 23*(S1), 34–38.

New South Wales Stem Cell Network Workshop Booklet. (2013). *Cellular therapies for musculoskeletal injuries*. http://www.stemcellnetwork.org.au/past_events/workshops/17thWorkBookfinal.pdf. Accessed 26 Feb 2016.

Petersen, A., Seear, K., & Munsie, M. (2014). Therapeutic journeys: The hopeful travails of stem cell tourists. *Sociology of Health and Illness, 36*(5), 670–685.

Rapp, R. (1999). *Testing women, testing the fetus: The social impact of amniocentesis in America*. New York/London: Routledge.

Rial-Sebbag, E., & Blasimme, A. (2014). The European Court of Human Rights' ruling on unproven stem cell therapies: A missed opportunity? *Stem Cells and Development, 23*(S1), 39–43.

Snyder, E. Y. (2011). The risk of putting something where it does not belong: Mesenchymal stem cells produce masses in the brain. *Experimental Neurology, 230*, 75–77.

Sparkes, L. (2014, February 26). Push for Australia to provide multiple sclerosis treatment. *7 News Investigations*. https://au.news.yahoo.com/a/21714395/push-for-australia-to-provide-multiple-sclerosis-treatment/. Accessed 25 Feb 2016.

Special Broadcasting Commission [SBS]. (2014, July 15). Stem cells. *Insight*, Episode 22. http://www.sbs.com.au/ondemand/video/294368323527/insight-stem-cells. Accessed 26 Feb 2016.

Therapeutic Goods Administration. (2013). *Excluded goods order no1 of 2011*. Canberra: Commonwealth of Australia. https://www.tga.gov.au/therapeutic-goods-excluded-goods-order-no-1-2011. Accessed 9 Mar 2016.

Therapeutic Goods Administration. (2015). Consultation—The regulation of autologous stem cell therapies. https://www.tga.gov.au/consultation/consultation-regulation-autologous-stem-cell-therapies. Accessed 26 Feb 2016.

Today Tonight. (2013, June 24). Arthritis stem cell treatment. *Channel 7*. http://www.todaytonightadelaide.com.au/stories/arthritis-stem-cell-treatment. Accessed 26 Feb 2016.

Trickett, A. E., & Wall, D. M. (2011). Regulation of cell therapy in Australia. *Pathology, 43*(6), 627–634.

Trounson, A., & Harvey, R. P. (2008). A critical time for stem cell research in Australia. *Cell Stem Cell, 2*(2), 118–122.

Tuch, B. E., & Wall, D. M. (2014). Self-regulation of autologous cell therapies. *Medical Journal of Australia, 200*(4), 196.

Turner, L. (2015). US stem cell clinics, patient safety, and the FDA. *Trends in Molecular Medicine, 21*(5), 271–273.

8

Re-framing 'Stem Cell Tourism'

Stories of patients in search of new treatments are inherently newsworthy, and even more so if they involve controversy. Consequently, citizens' efforts to obtain stem cell treatments, especially if these are outside their home country, were bound to attract media attention. These are seemingly desperate individuals who believe they have been denied 'hope' by their doctors and who have decided to submit themselves to unconventional treatments (and associated risks) offered by those who are seen to be operating at the margins of medicine, often in countries presumed to possess loose or non-existent ethical principles and regulations, such as the imagined 'Wild East', described in Chap. 6. Further, as we noted, the recent growth of clinics in a number of countries offering autologous treatments, using cells from the patient's own body, offers a new option for patients—in some cases, obviating the need for overseas' travel (Chap. 7). As we complete this book, hopeful stories about stem cell treatments continue to circulate, with reports appearing almost daily recounting 'miraculous' recoveries or dramatic improvements following treatments. For example, a news article declared that a women's blindness had apparently been reversed by a stem cell treatment using cells from

A. Petersen et al., *Stem Cell Tourism and the Political Economy of Hope*, Health, Technology and Society,
DOI 10.1057/978-1-137-47043-0_8

her own bone marrow. The news article also notes that the physician was administering such treatments without 'following the usual steps of clinical studies', and that 'he said, 60 percent of his 278 patients with macular degeneration, glaucoma and other diseases have regained some sight' (Cohn 2016).

Perhaps because of recent media attention given to stem cell treatments, and the potential for news stories to play out in ways unfavourable to dominant portrayals of how science should develop and translate into treatments, it was also inevitable that such stories would be the focus of growing concern among those who have a stake in established medical scientific and clinical practices. In recent years, there have been occasional reports in the scientific literature of patients suffering harm—infection, aberrant growth of cells, and even death—following stem cell treatments (Chap. 1). In at least one case, which we examined (Chap. 5), this precipitated the closure of a clinic offering such treatment, namely X-Cell. However, these reports have not been the focus of sustained media coverage and, thus far, have not led to a public backlash against stem cell science itself, although the potential exists—which is evidently of great concern to many scientists, clinicians, and others with a stake in the future of the field (Chap. 3). Rather, public discourse has been shaped by particular constructions of 'the problem': on the one hand, determined/heroic efforts of patients who have been 'denied' the 'right' to access a promising new treatment and who are offered hope by compassionate 'pioneering' doctors trying to develop and use innovative approaches; on the other, the risks posed to patients who have pinned their (false) hopes on the unproven, and hence, potentially ineffective and unsafe treatments ('snake oil') offered by 'charlatans' seeking to profit from patient desperation. What has been missing from the discourse on 'stem cell tourism' has been appreciation of the complex, dynamic character of the phenomenon so described, and of the sociocultural and politico-economic factors that have enabled and sustained (and could also potentially undermine) the market of unproven stem cell treatments, particularly from the perspective of consumers—those patients and carers who invest their hopes and future in stem cell research.

As we noted at the outset (Chap. 1), in undertaking our analysis, we have sought to identify factors that have tended to be left out of the

dominant framing of 'stem cell tourism' and to consider how this phenomenon may be re-framed so as to offer a better appreciation of why individuals pursue stem cell treatments and whether authorities' concerns are both justified and proportionate to the possible risks, the high costs, or lack of purported benefit. Our approach has involved examination of the views and experiences of those who have travelled or considered travelling for a stem cell treatment and of those who are consulted by patients and carers about such treatments. We have also examined case studies of countries where stem cell treatments are offered (Australia, China) or had been offered (Germany), which has revealed a diverse array of factors that help sustain, and that may undermine or at least dampen, the market of stem cell treatments. As explained in Chap. 1, 'stem cell tourism' is part of a rapidly expanding global health and medical travel industry comprising many specialisms, that is enabled by wider changes in healthcare provision in many nations and internationally, involving the interlinked processes of deregulation, digitalisation, globalisation, and privatisation. It is in this context that citizens are called upon to play their part in the project of advancing health—in preventing illness, in using available resources, including digital and other technologies to manage their health, and in caring for themselves. Responsible citizen-consumers are expected to become and are indeed becoming less reliant on traditional trusted sources of advice—generally state-based actors—and are electing to undertake their own research and treatment decisions in the healthcare market (Chap. 2). The rhetoric of 'patient empowerment', 'consumer choice', and self-responsibility in health and care indeed demands this, by creating a new 'architecture of choice' where individuals are *compelled* to invest their trust in unconventional sources and unknown others. Unsurprisingly, those who have been diagnosed with serious, life-limiting conditions soon turn to the internet in their search for information and treatments as well as family and their communities for related financial assistance to support their quest.

As our research revealed, among the factors helping to sustain this market is a context in which those who suffer debilitating and otherwise untreatable conditions perceive that there are few or no options, feel they have been abandoned by local doctors, encounter optimistic stories of other patients who have received treatments (via patient networks and

testimonials posted on providers' websites), and find communities that support their endeavours to gain treatments (Chap. 2). For virtually all, however, 'doing nothing is no option', with patients or their carers feeling compelled to explore all avenues and, in some cases, deciding that undertaking treatment is 'worth the risk' or that risks are relatively small. While some turn to trusted advisors, such as scientists, clinicians, and patient organisations, as we found, they do not generally provide unequivocal advice in regard to treatments, despite their evident concerns and empathetic stance, preferring instead to adopt a distanced, 'non-directive' role in their endeavours to 'manage hope' (Chap. 3). However, as we noted in Chap. 2, such factors singly or in combination may not be sufficient to encourage travel, as other considerations such as perceptions of the potential of treatment to improve or not one's quality of life, the costs of treatment, where it is being offered, and concerns about providers and what they are actually offering, may be of overriding significance. The academic literature on 'stem cell tourism' thus far has had little to say about those who consider treatment but decide against it—hence the novelty and value of our work. Further, we know little about those who have travelled overseas to undertake treatment but, for whatever reason, do not make their views public. During the course of our research we did encounter such individuals, who appeared to be willing to share their story informally but resisted participating in a formal interview. In one memorable example, someone who had spent hundreds of thousands of dollars raised through their community expressed that he 'felt a fool' for pursuing treatment from which he gained no substantial benefit. He also felt embarrassed that his community had rallied to support his travel and that, in hindsight, the money raised could have been better spent on his long-term care. That is why we believe it is important to gain insight into how patients and carers experience the treatment journey, including the country where the treatment is undertaken, the clinical setting, the treatment itself, post-treatment care, and the responses of the family, community, and healthcare providers when one returns home—themes explored in Chap. 4.

As we reported in that chapter, those embarking on treatments take 'a leap of faith' in that there are many uncertainties with travel abroad, and expenses and risks associated with long-haul flights when one is ill. There are very practical issues associated with the decision to travel, including,

in some cases, the need to raise funds to cover costs of travel and accommodation for oneself, family members, and/or carers, and negotiating tight time frames for organising flights. Then there are further pragmatic matters to deal with when one arrives at one's destination, such as cultural and language barriers, accommodation, and the context and delivery of treatment—which may be experienced variously as positive or as confronting and even 'horrific', with stories of, for example, unsanitary conditions, challenges of communication, cultural shock, and unforeseen financial costs (Chap. 4). As our analysis revealed, the treatment journey is far from uniform and predictable; however, it is clear that early decisions, for example, about the country or the provider, can have profound ongoing implications for patients and their families. Regardless of the country of destination and which provider delivers the treatment, the journey is one characterised by considerable uncertainty and an investment of trust in those whom one may know little about (other than what one has been told by other patients or that is available on provider websites), whose motives may be unclear, and who deliver a treatment or series of treatments purportedly involving stem cells that entail procedures that may be highly intrusive (e.g. lumbar puncture, where the cells are injected directly into the cerebrospinal fluid that surrounds the spinal cord and the brain). Recognising that patients and carers are confronting the unfamiliar and may possess various uncertainties, some providers have devised strategies for making the unfamiliar familiar, including, as in China, the use of concierge services to assist with language difficulties and dietary requirements, the adoption of personalised forms of communication, the provision of detailed explanatory information about care, and the creation of communal spaces or the offering of leisure activities to foster sociability (Chap. 6).

As it happens, patients and carers may experience various benefits from their journey *apart* from the treatment itself, including positive social interactions with other patients, the exposure to another culture, a level of care and support that they may not have encountered before, and a sense of having done *something* when doing nothing would have been experienced as a failure (Chap. 4). While we would not deny the value of these subjective, non-clinical benefits of the treatment journey, it should be acknowledged that they are 'delivered' via a trust relationship that is

underpinned by an economy of hope. This is an economy where patients effectively submit their bodies to strangers in the hope of a future positive outcome and, consequently, where the potential for financial exploitation and physical harm is acute. As noted, few patients and carers could recount such details as the provenance of the stem cells (i.e. the source of the cells or how they were prepared) and the method of their storage, and few appeared to have asked their providers questions such as their qualifications, success rates with other patients, potential complications of the treatment, how their costs were calculated, and so on.

The Shifting Landscape of the Stem Cell Treatment Market

During the course of our Australian research, undertaken between 2012 and 2015, the dimensions and operations of the stem cell treatment market changed in a number of respects. Changes included shifts in policies in provider destinations, seemingly in response to factors such as concerns about public representations (e.g. 'Brand China' in Chap. 6) and the rapid rise of 'on-shore' providers of autologous treatments marketed as an 'ethical medical treatment' option (Chap. 7)—a trend evident in a number of countries (Bianco and Sipp 2014; Munsie and Hyun 2014). Further, various controversies during this period including, notably, the Obokata case, where a researcher was found guilty by a panel of the RIKEN research institute in Japan for research misconduct in relation to the generation of stem cells via an innovative method (stimulus-triggered acquisition of pluripotency, or STAP), underlined the ever-present pressures on researchers working in the field of stem cell science, particularly in relation to translating research into widely hoped-for treatments (Normile 2015). The imperative for researchers to take their findings from 'bench top to bedside' as quickly as possible, and yet meet established standards of evidence and ethical practice, provides the backdrop against which stem cell clinics offering novel treatments have flourished. Many patients and their families are evidently frustrated by the apparent slow pace of science and, consequently, turn to novel options—a situation that is ripe for exploitation.

Recent developments in the stem cell field highlight the significance of positive public representations for those with an investment in the future of stem cell science as well as those with a stake in the current treatment market. As governments, scientists, and clinicians recognise, the question of how treatments are portrayed in the public arena is crucial for the future of the field of stem cell science—especially in establishing and maintaining community confidence in the potentially decades-long scientific endeavour that will be required to realise the hoped-for treatments. Providers, too, have an investment in the management of public representations, and evidently wish to distance themselves from the negative portrayals of their practices (Chap. 7). Thus, the question of whether providers are seen as exploiting 'loopholes' in order to 'dupe' 'vulnerable' patients, or offering a relatively safe option and, consequently, 'hope' to those who otherwise have none, becomes crucial in the battle of representations regarding the provision of autologous stem cell treatments. The concept of the 'political economy of hope' that has underpinned our analysis acknowledges the close linking of individual outlooks, aspirations, and practices with wider sociocultural and politico-economic processes, which can only be sustained by the actions of many actors and their networks, including scientists, clinicians, the biotechnology industry, governments and, crucially, the enrolling of individual patients and patient communities into fundraising efforts. In this respect, digital media is playing an increasingly critical role. As these developments reveal, the economy of hope underpinning the market of stem cell treatments can only be sustained insofar as there is a supportive sociopolitical environment. It is here that the media, including increasingly digital media, has come to play a vital role: for providers in advertising their treatments directly to consumers ('direct-to-consumer advertising'), and for individual patients and groups of patients in sharing stories and creating optimism regarding the promises of stem cell treatments.

We, and others, have explored the techniques of direct-to-consumer advertising, which include the use of carefully crafted images and text, including patient testimonials, and the failure to offer scientifically verifiable data to support claims (e.g. Petersen and Seear 2011; Lau et al. 2008). However, the role of social media such as Facebook, Twitter, and YouTube in the stem cell treatment market has received little attention in

the academic literature to date. While individual champions of stem cell research and treatments have used the media to considerable effect, some gaining leverage from an established celebrity profile—the American actor Christopher Reeve in the US being the earliest and most prominent—social media has added a new dimension to patient activism. Such media enable ordinary citizens to generate their own content, build a profile, and promote stem cell treatments and particular providers. An example is the case of the Australian Kristy Cruise, whose plight to embark on a stem cell treatment for her multiple sclerosis in Russia after being purportedly 'denied' treatment by an Australian hospital achieved prominence following her appearance on the television programme *60 Minutes* in 2014. Our analysis of the Cruise case has revealed that social media may provide a powerful means for ordinary citizens to establish a following, to generate positive narratives about stem cell treatments and to create 'communities of hope' that may mitigate against official, regulatory-focused discourses of risk–benefit and trust (Petersen et al. 2015a). This is especially so when, as with this case, social media are linked with more established media, such as television. As our analysis revealed, television coverage served to give prominence to the issues and offered overt support for Cruise's plight both in the programme commentary and by way of web links to Cruise's own webpage and information sources and videos that were generally supportive of her situation. Web-based information such as this, we contend, offers a sense of immediacy, personalisation, and audience connection that has no parallel with traditional media used in isolation and, when linked with such media, contributes to a story's endurance and potential impact long after the original programme and events have played out (Petersen et al. 2015a). New audiences may be introduced to optimistic stories such as this one while gaining no insight into how events unfold over the longer term, including the eventual success or otherwise of Cruise's treatment, or information that may later arise about the provider's clinic and their treatments that have the potential to shape the views of patients and carers.

Our analysis of the various dimensions of 'stem cell tourism', including rapidly evolving strategies of marketing and de facto advertising enabled by digitalisation (patients' promotion of particular clinics or providers), has led us to question current ways of understanding and responding to

this phenomenon, including the very terms and language used to frame debates. In particular, the simplistic characterisations and dichotomies that have typified discussion and that shape responses, particularly in popular media portrayals, need to be challenged, since they limit appreciation of the issues at stake—which go beyond the provision of stem cell treatments, to public representations of and responses to new and emerging biomedical technologies in general. The contending metaphors of stem cell science to describe the treatments ('magic bullet' or 'miracle cure', or alternatively, 'snake oil', depending on one's evaluation) and the providers (typically 'quacks', 'rogue operators', or 'cowboys') are not limited to this field. Similar metaphors are found, for example, in portrayals of cloning and genetics and reflect widely shared hopes, expectations and fears attached to scientific research, especially where this involves 'tampering with Nature'. The image of Mary Shelley's *Frankenstein*'s monster and Aldous Huxley's *Brave New World* scenario of embryonic engineering find parallel in contemporary concerns about the ramifications of individuals submitting themselves to unproven treatments. However, we are entering a new era where the stakes regarding the public definition of the significance of new technologies are especially high, since citizens have been 'empowered' via the internet and their social media-enabled communities to influence, if not establish, the terms of debate about treatments and their value. From the perspective of those contemplating treatment, the clinics and doctors offering hope and help may be highly regarded, even considered pioneers, as they are at least 'prepared to do something' to help. This is particularly acute for those patients and carers who believe they are running out of time or, in the case of children, have only a narrow window of opportunity in which to change the course of the condition from which the patient is suffering.

Authorities' Responses to 'Stem Cell Tourism' Thus Far

Science bodies and, to a lesser extent, regulators, have long recognised the phenomenon of 'stem cell tourism', but have struggled with how best to respond. In particular, they have grappled with the issue of how to address

the emergence of sophisticated online 'direct-to-consumer' advertising, offered by providers whose competence is unknown and motives unclear, and meet the needs of the frustrated, internet-savvy patients who are researching their healthcare options. While the scientific community has responded with patient handbooks and dedicated websites such as the ISSCR's *A Closer Look at Stem Cells* (Table 3, Appendix), these relatively static sources of information, in comparison with the more emotive use of patient testimonials and selective promotion of positive patient stories (see Chap. 6), may be of limited value, especially when there is jurisdictional regulatory ambiguity surrounding these services and how they are overseen.

To date, some national regulatory authorities have made various responses to growing local markets for unproven stem cell treatments. For example, as early as 2007, the Dutch government banned unproven stem cell therapies in private clinics due to associated health risks and a lack of proven effectiveness (Sheldon 2007). In 2011, Germany consolidated its regulatory response to unproven stem cell treatments by the enforcement of new regulations in line with the European Union advanced therapy medicinal products legislation, which effectively shut down the stem cell tourism industry (Mummery et al. 2014; Scherer et al. 2013) (Chap. 5). In Italy, there has been an extraordinary public tussle between the Italian Medicines Agency (Agenzia Italiana del Farmaco), scientists, politicians, celebrities, supporters, and the children's families regarding the rights of sick children to access unproven treatment from the Stamina Foundation (Margottini 2014; MacGregor et al. 2015). In Australia, the official response to the burgeoning domestic autologous stem cell industry has been mute (Munsie and Pera 2014). While a public consultation was conducted in 2015 on possible ways to regulate the autologous cell therapy industry by the peak government body responsible for ensuring all therapeutic goods in the Australian marketplace meet acceptable standards of safety and quality, in November 2016, a final report had not yet been released (see Chap. 7). Furthermore, while some of the advertising practices appear to be in breach of current medical profession standards, and even consumer protection laws, the Australian authorities are yet to take a stand, adopting a 'wait and see' approach. In other jurisdictions, such as the USA, the regulation of autologous cell therapies appears to

be more stringent than that in place in Australia. In 2014, the Food and Drug Administration in the USA issued draft guidance statements clarifying that autologous cell therapies utilising cells obtained from fat tissue fell within their remit (Turner 2015). Other countries, notably Japan, have specifically introduced legislation designed to accelerate commercialisation of regenerative medicine through 'conditional approval' of promising cell therapies (Konomi et al. 2015). Although there is an obligation to meet manufacturing standards, without the need to first demonstrate efficacy, questions have been raised about whether the evidentiary bar has been set too low, exposing patients to exploitative practices and risking removing the incentive to ensure a rigorous scientific basis for stem cell-based products (McCabe and Sipp 2016).

In the absence of harmonised global regulations, efforts to curb or restrict the provision of unproven treatments is largely limited to providing information via the internet to better arm the 'consumer', who, it is assumed, will rationally 'weigh up' all options to reach an 'informed' decision. However, bioethics principles, such as respect for autonomy through the promotion of 'informed choice', which generally inform both debates and policy, are found to be wanting in this context. What exactly does being 'informed' mean in the global mediated market of stem cell treatments, where patients have few options and consult diverse sources, and where providers use sophisticated strategies to attract 'customers' such as 'search engine optimisation' and direct-to-consumer advertising employing carefully crafted messages and images, including patient testimonials recounting positive experiences (Chaps. 2 and 6)? Is information alone sufficient to guide actions when strong emotions are involved? For patients and their families, is 'doing nothing' ever an option? (Our research suggests at least for some it is not.) And, if not, how should authorities respond? More fundamentally, in light of our research, we ask, what is at stake in our current conception of 'the problem' and its solution? Who or what needs 'regulating', and by what means and to what ends should this regulation occur? And, who (which bodies, authorities, organisations) should undertake this regulation? Do the practices of 'regulation' have unintended consequences, such as encouraging providers to explore innovative and dynamic ways of marketing treatments or encouraging patients to take unnecessary physical and financial risks? Does imposing

greater regulation increase the costs and thereby restrict development of innovative stem cell and regenerative medicine approaches?

Our research suggests that the current dominant approach to the provision of unproven stem cell treatments, focusing as it does on tempering 'consumer demand' for stem cell treatments by encouraging citizens to think twice and adopt a cautious, risk averse approach, rather than responding to the factors that shape the production, supply, and distribution of treatments, is limited in a number of respects. First, the underlying rational actor model, that assumes that individuals rationally weigh up and autonomously assess all options before reaching a decision, is problematic in failing to account for the dynamics of markets in contemporary neoliberal societies. This includes the workings of advertising and innovative promotional strategies in the marketing of treatments and their reliance on the manipulation of the emotions (especially fear and hope), perceptions of limited time to access treatments, the influence of families and communities (including especially patient communities) on individual decisions, changing relations of trust in healthcare, and the many and conflicting conceptions of 'evidence' and 'success' in regards to stem cell treatments (Chap. 3). The tendency to stereotype and demonise providers as 'charlatans' whom, it is often claimed or assumed, aim to 'dupe' or 'exploit' 'vulnerable' or 'desperate' patients has paternalistic overtones and serves to create a polarity of viewpoints that does not do justice to the complex dynamics of the stem cell treatment market, and may, we argue, drive providers underground and create a black market of treatments. As our research emphasises, there is a need to critically interrogate commonly used, and largely taken-for-granted terms used in debate about the stem cell treatment market such as 'trust', 'evidence', and 'success' as well as common distinctions such as 'legitimate' versus 'illegitimate' and 'true' versus 'false' employed in assessing treatments, and seek to make clear what is at stake in a particular definition of 'the problem' and how 'it' should be resolved. There is a need for greater understanding of the context that underpins new unproven treatment markets, which both creates opportunities for new providers to flourish and generates a demand for the treatments that they offer. How may one foster 'legitimate' clinical research in promising technologies and facilitate patient participation beyond simply promoting clinical trials?

Second, the assumption that responses are based upon knowledge that is settled and generally shared by the different stakeholder communities within the stem cell treatment field should be questioned. The stem cell treatment market is characterised by competing claims about evidence, efficacy, safety, and trustworthiness. In our analysis, we foregrounded the significance of *uncertainty* in this market—about what exactly is being offered, about the benefits and risks of treatments, and about the competence, motives, and trustworthiness of those who offer them. All science and medical decision-making involves some level of uncertainty—the importance of which scientists themselves have acknowledged (Palmer and Hardaker 2011)—but this is especially apparent in the field of stem cell treatments, which are largely unproven and may have a varying level of risk depending on the condition, the source of cells, and the route of administration. Indeed, many experts question that 'stem cells' are even present in many of the preparations used by commercial clinics. For individuals, uncertainty is also a feature of their decision-making. Patients and carers often feel uncertain about their treatments, most evidently in often not knowing the details of their treatment, such as the source of the stem cells, and, in many cases, simply invest trust in their treatments and those who provide them. Those who offer patients and carers informal advice also evidently possess uncertainties, especially in regard to how best to respond to the patients who consult them about stem cell treatments (Chap. 3). And, patients' comments suggest that their local doctors, too, possess uncertainties about stem cell science and the stage of the treatment market and so are unable to offer clear advice (Chap. 2). While there have been calls to provide additional training for doctors on stem cell science and the premature sale of unproven treatments (Levine and Wolf 2012; Zarzeczny and Caulfield 2010), and it has also been raised that a professionally trained stem cell counsellor could more objectively assist those contemplating stem cell tourism, as well as support prospective clinical trial subjects and their families (Scott 2015), there remains uncertainty about where patients can turn for advice. We suggest that this uncertainty, along with the ambiguous regulatory landscape offers providers with an opportunity to exploit those who have few options but whose hopes are buoyed by marketing the promise of benefit—as seen in the case of X-Cell (Chap. 5). Acknowledging that uncertainty

exists in science and in new treatment markets, including in regards to the process of clinical translation, we suggest, is essential in any effort to develop means for addressing the consequences of the provision of unproven treatments.

Thirdly, in employing 'top-down' models of information dissemination—which involve accredited experts disseminating information to an assumed ignorant or unaware public—current approaches to communication on science and technology issues fail to fully acknowledge citizens' possession of knowledge about, or perspectives on, their medical conditions and possible treatments and providers, acquired via their own research endeavours and their increasing political activism. Science communication in the field of stem cell treatments, as in other areas of science and technology, is largely based on the deficit model of public understanding; that is, individuals are assumed to need more or better information to assist their decision-making about new technologies. The deficit model takes many forms and is continually reinvented since those who develop communication strategies generally fail to understand the perspectives of those with whom they seek to 'communicate' and the wider context within which the process of communication occurs, including the constraints on dialogue posed by authorities' own science-policy institutional culture (Wynne 2006). Our research has revealed that individuals learn about treatments and providers from various sources, including other patients, provider websites, news media, and the providers themselves. With the emphasis on 'empowering' citizens in healthcare, patients and their families are using the internet, social media, and their patient communities to become active, critical and knowledgeable consumers of health information and technologies—although this knowledge is of a different kind to that possessed by accredited experts. Further, as we have found, patient communities create narratives that often challenge experts' and authorities' accounts, as we note in our discussion of the Cruise case (Chap. 8). Such stories, which are often optimistic in regard to treatments, may rapidly circulate via the internet and social media, and may prove difficult to dislodge, especially if celebrities are involved. In Canada, for example, an analysis of news coverage of the retired ice hockey player Gordie Howe's travel to Mexico in 2014 to receive stem cell treatment after suffering a stroke found that stories

presented a largely uncritical perspective on the efficacy of stem cell treatment (Rachul and Caulfield 2015). While many groups have attempted to assist those contemplating stem cell treatments (see Table 3), these attempts may not be as readily available or as compelling to the prospective patient as those of the commercial providers. As the authors argue, such coverage may serve to heighten patients' expectations of treatments that cannot be supported by science and may shape policy responses, such as granting patients immediate access to treatments and expediting translation (Rachul and Caulfield 2015: 9).

Patients' recent efforts to direct and control the research process presents a major challenge to how medical research is undertaken and to the notion that only accredited experts are able to produce and 'own' scientific knowledge. Assisted by new media, patients are generating and aggregating their own data, in the process upending the business models that underpin traditional research. Online resources such as PatientsLikeMe and CureTogether allow disease- or condition-specific communities to shape research priorities, to compare treatments across different conditions and to share health experiences and to thereby contribute to the creation of communities of hope. Through their participation in such endeavours, citizens may also unwittingly become clinical subjects in global research endeavours that exploit the possibilities of 'big data' analysis enabled by Google and other search engines. As PatientsLikeMe explain, this 'for profit company' ('with a "not just for profit attitude"') makes its money by selling the data it collects on patient experiences of disease to companies that develop or sell products to patients. As its website explains, 'these products may include drugs, devices, equipment, insurance, and medical services' (PatientsLikeMe 2015). Thus, while citizens may believe themselves to be 'empowered' by such patient-driven research endeavours—to control research that will produce findings of general value to patients—the longer-term collective impact of such endeavours may not deliver the expected benefits, especially if patent-protected innovations allow access to only the relatively few who have the requisite resources to pay for them.

In short, when responding to emerging treatment markets, authorities need to take into consideration the complex realities of the myriad illness experiences that drive patient demand. To forgo this risks counterintuitively producing the conditions for the growth in the markets that

regulatory bodies, and those seeking to protect patients from exploitation, are in fact trying to curb. These challenges are further compounded in the case of stem cell science by two competing factors: the need to address the unabated and exaggerated expectations which sustain unregulated treatment markets; and yet, the imperative to attract interest and long-term investment in the field in order to maximise the possibility of translating promising stem cell science to safe and effective therapies for diverse patient populations.

Consequently, we suggest that those who develop policies and strategies in relation to 'stem cell tourism' need to pay much greater attention to how early treatment markets operate in contemporary global healthcare and to the significance of the emergent forms of citizenship and sociability enabled or facilitated by the internet and social media. It needs to be asked, what forms of governance should be developed for the early global market of stem cell treatments? Should particular authorities take the lead on initiatives? Do national governments still have a role to play or should this be left to supranational bodies (e.g. science organisations, the World Health Organization, the World Trade Organization)? What strategies are needed to bridge the often-adversarial views, both offline and online, of science-based professionals and patients in order to encourage a more sophisticated understanding of the stem cell tourism phenomenon? How can consumers be more empowered to ensure their rights, in the event of an unsatisfactory outcome, are upheld? While we have no clear answers to such questions, they urgently need asking and demand careful consideration since the stakes are high—for individual patients and families considering treatments and for scientists, clinicians, and others who are committed to advancing human health.

References

Bianco, P., & Sipp, D. (2014). Regulation: Sell help not hope. *Nature, 510*(7505), 336–337.

Cohn, M. (2016, February 18). Woman's blindness apparently reversed by stem cell treatment. *The Baltimore Sun*. http://www.baltimoresun.com/health/bs-hs-stem-cells-for-eyes-20160201-story.html. Accessed 26 Feb 2016.

Konomi, K., Tobita, M., Kimura, K., & Sato, D. (2015). New Japanese initiatives on stem cell therapies. *Cell Stem Cell, 16*(4), 350–352.

Lau, D., Ogbogu, U., Taylor, B., Stafinski, T., et al. (2008). Stem cell clinics online: The direct-to-consumer portrayal of stem cell medicine. *Cell Stem Cell, 3*(6), 591–594.

Levine, A. D., & Wolf, L. E. (2012). The roles and responsibilities of physicians in patients' decisions about unproven stem cell therapies. *Journal of Law & Medical Ethics, 40*, 122–134.

MacGregor, C., Petersen, A., & Munsie, M. (2015, December 13). Patient access to unproven stem cell treatments: A human rights issue? *Eurostemcell*. http://www.eurostemcell.org/commentanalysis/patient-access-unproven-stem-cell-treatments-human-rights-issue. Accessed 4 Mar 2016.

Margottini, L. (2014, October 7). Final chapter in Italian stem cell controversy? *Science News*. http://www.sciencemag.org/news/2014/10/final-chapter-italian-stem-cell-controversy. Accessed 4 Mar 2016.

McCabe, C., & Sipp, D. (2016). Untested and overpriced: Japan issues first constitutional approval of stem cell product. *Cell Stem Cell*, *18*. doi: http://dx.doi.org/10.1016/j.stem.2016.03.006

Mummery, C., Van De Stolpe, A., Roelen, B., & Cleavers, H. (2014). *Stem cells: Scientific facts and fiction*. London: Academic Press.

Munsie, M., & Hyun, I. (2014). A question of ethics: Selling autologous stem cell therapies flaunts professional standards. *Stem Cell Research*, *13*(3), Part B: 647–653.

Munsie, M., & Pera, M. (2014). Regulatory loophole enables unproven autologous cell therapies to thrive in Australia. *Stem Cells and Development, 23*(S1), 34–38.

Normile, D. (2015, February 10). RIKEN announces penalties related to stem cell fiasco. *Science*. http://www.sciencemag.org/news/2015/02/riken-announces-penalties-related-stem-cell-fiasco. Accessed 24 Feb 2016.

Palmer, T. N., & Hardaker, P. J. (2011). Discussion meeting issue "Handling uncertainty in science". *Philosophical Transactions of the Royal Society A, 369*(1956), 4681–4684.

PatientsLikeMe. (2015). How does PatientsLikeMe make money? http://news.patientslikeme.com/faq-item/faq/how-does-patientslikeme-make-money. Accessed 20 Feb 2016.

Petersen, A., & Seear, K. (2011). Technologies of hope: Techniques of the online advertising of stem cell treatments. *New Genetics and Society, 30*(4), 329–346.

Petersen, A., MacGregor, C., & Munsie, M. (2015). 'Stem cell miracles or Russian roulette?: Patients' use of digital media to campaign for access to clinically unproven treatments. *Health, Risk and Society, 17*(7–8), 592–604.

Rachul, C., & Caulfield, T. (2015). Gordie Howe's stem cell "miracle": A qualitative analysis of news coverage and readers' comments in newspapers and sports websites. *Stem Cell Reviews and Reports, 11*(5), 667–675.

Scherer, J., Seitz, R., & Cichutek, K. (2013). Autologe Zellpräparate: Wenn Ärzte "Arzneimittel" im OP oder am Krankenbett herstellen. *Deutsches Ärzteblatt, 110*, A872–A876.

Scott, C. T. (2015). The case for stem cell counselors. *Stem Cell Reports, 4*(1), 1–6. doi:10.1016/j.stemcr.2014.10.016.

Sheldon, T. (2007). Holland bans private stem cell therapy. *British Medical Journal, 334*, 12.

Turner, L. (2015). US stem cell clinics, patient safety, and the FDA. *Trends in Molecular Medicine, 21*(5), 271–273.

Wynne, B. (2006). Public engagement as a means of restoring public trust in science—Hitting the notes, but missing the music? *Community Genetics, 9*, 211–220.

Zarzeczny, A., & Caulfield, T. (2010). Stem cell tourism and doctor's duties to minors—A view from Canada. *American Journal of Bioethics, 10*, 3–15.

Appendix

A. Petersen et al., *Stem Cell Tourism and the Political Economy of Hope*, Health, Technology and Society,
DOI 10.1057/978-1-137-47043-0

Table 1 Overview of interviewees who had travelled for stem cell treatments. All information was self-reported by the patients and/or carers at the time of interview[a]

Pseudonym	Patient or carer	Condition (or person and condition for whom they cared)	Destination	Source of stem cells	Type of stem cells	Method of delivery
Alexander	Patient	Degenerative neurological disorder affecting peripheral nerves	USA	Autologous	Haematopoietic (bone marrow)	PICC (peripherally inserted central catheter that directs the cells to a vein near the heart)
Andrea	Patient	Osteoarthritis and sciatica	Australia	Autologous	Stromal vascular fraction (derived from fat)	IV[b] and lumbar puncture[c]
Audrey	Patient	Multiple sclerosis	Germany	Autologous	Haematopoietic (bone marrow)	IV and lumbar puncture
Bruce	Patient	Spinal cord injury	Germany	Autologous	Haematopoietic (bone marrow)	IV
Catherine	Patient	Spinal cord injury	Germany	Autologous	Haematopoietic (bone marrow)	Lumbar puncture
David	Carer	Wife with Parkinson's disease	China	Allogenic	Cord blood derived treatment not completed as patient and carer changed their minds	IV and lumbar puncture
Donna	Carer	Husband with rare neurological condition	Germany	Autologous	Haematopoietic (bone marrow)	Lumbar puncture

Pseudonym	Patient or carer	Condition (or person and condition for whom they cared)	Destination	Source of stem cells	Type of stem cells	Method of delivery
Eloise	Carer	Child with autism	Mexico	Allogenic	Foetal	IV
Greg and Suzanne	Patient and carer	Degenerative neurological disorder affecting peripheral nerves	China	Allogenic	Placental	IV and lumbar puncture
Ivan and Vlasta	Carers	Child with cerebral palsy	Germany	Autologous	Haematopoietic (bone marrow)	IV and lumbar puncture
			China	Allogenic	Cord blood derived	
			Thailand	Allogenic	Cord blood derived	
Jackie and Philip	Carers	Child with autism	China	Allogenic	Cord blood derived	IV
Jenny	Patient	Multiple sclerosis	India	Autologous	Haematopoietic (bone marrow)	IV in neck
Joshua	Patient	Chronic autoimmune disease affecting peripheral nerves	Israel	Autologous	Haematopoietic (bone marrow)	IV
Kimberly	Carer	Child had nerve paralysis	China	Allogenic	Cord blood derived	Lumbar puncture
Lara	Patient	Multiple sclerosis	Germany	Autologous	Haematopoietic	Lumbar puncture
Maria	Patient	Multiple sclerosis	USA	Autologous	Haematopoietic	IV infusion
Natalie	Carer	Child with cerebral palsy	Panama	Allogenic	Cord blood derived	IV
Rebecca	Carer	Husband with motor neuron disease	Thailand	Allogenic	Placental	IV and lumbar puncture
			Australia	Autologous	Stromal vascular fraction (derived from fat)	

Table 1 (*continued*)

Pseudonym	Patient or carer	Condition (or person and condition for whom they cared)	Destination	Source of stem cells	Type of stem cells	Method of delivery
Russell	Carer	Child with cerebral palsy	USA	Allogenic	Cord blood derived	IV infusion
Simone	Carer	Partner with quadriplegia	India	Allogenic	Human embryonic	IV in hand intramuscular and lumbar puncture
Stephen	Patient	Spinal cord injury	Germany	Autologous	Haematopoietic (bone marrow)	Lumbar puncture

[a]'Traveller' interviews comprised a total of 21, conducted with 24 people (9 male, 15 female). Of these, 11 were patients and 13 were carers. Destinations comprised the following: Germany (7), China (5), the USA (3), Australia (2), Thailand (2), India (2), Israel (1), Mexico (1), and Panama (1)

[b]'IV' refers to an intravenous injection, usually via the arm, that delivers cells into the bloodstream

[c]'Lumbar puncture', in these cases, refers to an injection into the patient's spinal cord that delivers cells into the cerebrospinal fluid, which exists around the spine and in the brain

Table 2 Overview of interviewees who had considered travelling for stem cell treatments but had not done so at the time of interview[a]

Pseudonym	Patient or Carer	Condition (of person / condition for whom they cared)	Contemplated destination
Alistair	Carer	Child with paraplegia	USA
Axel	Patient	Spinal cord injury	China
Barry	Patient	Radical prostatectomy	Australia
Cameron	Patient	Chronic obstructive pulmonary disease	Australia
Carl	Carer	Mother with dementia	China
Diana	Patient	Stroke	Australia
Duncan	Carer	Child with autism	Mexico
Evan	Carer	Child with hearing loss	Europe
Felix	Patient	Multiple sclerosis	China
Gerald	Patient	Optic nerve problem	China
Graham	Patient	Spinal cord injury	USA
Gwen	Patient	Multiple sclerosis	Germany
Jack	Patient	Early stages of motor neuron disease	Russia
Janine	Patient	Optic nerve damage and reduced vision	China
Jessica	Carer	Child with autism	Mexico
Jillian	Carer	Husband with myotonic dystrophy	USA
Jocelyn	Carer	Friend with multiple sclerosis	Australia
Louise	Carer	Partner with motor neuron disease	China
Lucy	Carer	Child with epilepsy and additional medical problems	USA
Madeline	Patient	Multiple sclerosis	Australia
Melanie	Patient	Lymphoedema	Cuba
Michael	Patient	Multiple sclerosis	Russia
Nicole	Carer	Child with cerebral palsy	Mexico
Paula	Carer	Husband with dementia	China
Sean	Patient	Spinal cord injury	Germany
Stefan	Patient	Multiple sclerosis	Australia
Vivian	Patient	Visceral myopathy and stenosis	Mexico

[a]'Non-traveller' interviews comprised a total of 27 (14 male, 13 female). Of these, 16 were patients, who shared their own stories, and 11 were carers, who shared a story about someone they cared for, such as a child, partner, other family member, or friend. Contemplated destinations comprised the following: China (7), the USA (4), Australia (6), Mexico (4), Germany (2), Russia (2), Cuba (1), and Europe (1)

Table 3 Overview of online educational resources designed to assist those wanting to find out more about how stem cells are being used in medical research and in the clinic

Organisation	Resource	URL
Californian Institute for Regenerative Medicine	Stem Cell Basics[a]	www.cirm.ca.gov/patients/stem-cell-basics
Canadian Stem Cell Foundation	Towards Treatments[a]	stemcellfoundation.ca/en/toward-treatments/
EuroStemCell	Stem Cell Fact Sheets[a]	www.eurostemcell.org/stem-cell-factsheets
International Society for Stem Cell Research	A Closer Look at Stem Cells website[a,b]	www.closerlookatstemcells.org
International Society for Stem Cell Research	Patient Handbook on Stem Cell Therapies[b]	www.closerlookatstemcells.org/patient-resources/
Knoepfler Lab Stem Cell Blog	What Are Stem Cells?	www.ipscell.com/what-are-stem-cells/ www.ipscell.com/scope-global-stem-cell-outreach-program-for-education/
National Health and Medical Research Council (Australia)	Stem Cell Treatments – A Quick Guide for Medical Practitioners[b]	www.nhmrc.gov.au/guidelines-publications/rm001
National Health and Medical Research Council (Australia)	Stem cell treatments – Frequently asked questions[b]	https://www.nhmrc.gov.au/guidelines-publications/rm001a
National Institutes of Health (NIH)	Stem cell basics	stemcells.nih.gov/info/basics/pages/basics1.aspx
National Stem Cell Foundation of Australia and Stem Cells Australia	Australian stem cell handbook[a,b]	http://www.stemcellfoundation.net.au/about-stem-cells/stem-cell-treatment-information/handbook
Stem Cell Network (Canada); University of Alberta, and Albany Medical College	Patient booklet – What You Need to Know About Stem Cell Therapies	http://www.amc.edu/academic/bioethics/documents/SCPatientBookletFeb_2014.pdf

[a]Increasingly, resources are being tailored to illustrate how stem cell research is being used for specific diseases and conditions
[b]Co-author MM has been involved in the development of these educational resources

Table 4 Overview of TGA's 2015 proposed options for the regulation of autologous cells in Australia

Effect of option	Option 1	Option 2	Option 3	Option 4	Option 5
Advertising restricted to health practitioners only[a]	No	Yes	Yes	Yes	Yes
Requirement to meet standards in the *Therapeutic Goods Act*	No	No	Yes	Yes	Yes
Requirement to report adverse effects	No	No	Yes	Yes	Yes
Need to demonstrate safety prior to treating patients	No	No	No	Yes	Yes
Need to demonstrate efficacy prior to treating patients	No	No	No	No	Yes
Requirement to meet manufacturing standards	No	No	No	No	Yes

[a]Practitioners and clinics are still subject to other Australian regulations regarding advertising, for example, Australian Health Practitioner Regulation Agency and Australian Competition and Consumer Commission

Index

A. Petersen et al., *Stem Cell Tourism and the Political Economy of Hope*, Health, Technology and Society,
DOI 10.1057/978-1-137-47043-0

G

H

I