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LOST IN TRANSLATION: CHINA'S STRUGGLE TO DEVELOP APPROPRIATE STEM CELL REGULATIONS

Dominique McMahon[*] *and Halla Thorsteinsdóttir*[†]

Abstract

This paper examines the regulations that govern stem cell use in China. We draw our findings from an analysis of government policies and documents, formal and grey literature, and thirty-nine interviews with Chinese stem cell experts. Although China developed research guidelines for embryonic stem cell research early on, it is still struggling to develop appropriate regulations surrounding the clinical translation of stem cell research. We identify the lessons that can be learned from China's experiences developing appropriate regulations for their stem cell sector, and show the importance of timely regulation and of regulation for each stage of product development from research through to clinical applications. We discuss the development of appropriate regulation, and the international significance of Chinese stem cell regulations.

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[*] PhD Candidate, Institute of Medical Science at the University of Toronto, and the McLaughlin-Rotman Centre for Global Health.

[†] Associate Professor, Dalla Lana School of Public Health, University of Toronto, and McLaughlin-Rotman Centre for Global Health.

1. Introduction

Emerging economies are increasingly important players in the stem cell field. With economic growth has come elevated rates of chronic disease and emerging economies have targeted policy and funding programs towards developing stem cell treatments for addressing diabetes, cardiac disease, and neurodegenerative conditions.[1] China has made great strides in stem cell research in recent years, creating over twenty-five new human embryonic stem cell lines and steeply increasing their annual publications in the stem cell field. China went from thirty-seven publications in 2000 to 1109 in 2008, becoming the fifth most prolific publisher on stem cells in the international scientific literature.[2]

There is an increasing international interest in understanding the scientific developments occurring in China, particularly in stem cell research. China has a growing number of world-class researchers in stem cell research, tissue engineering, and gene therapy, but has been widely criticised for allowing stem cell treatments without clinical evidence of their safety or efficacy.[3] Our previous analysis of the Chinese regenerative medicine field shows that China has built its stem cell sector through supportive government policies and funding, and through the development of strong research centres focused on developing therapeutic applications.[4] China has developed a pool of highly-trained researchers by aggressively drawing back to China scientists of Chinese origin who have worked or have been educated in leading institutions around the world. By participating early on in the field, China hopes both to develop much-needed therapies to many chronic diseases prevalent in its population, and to make progress towards becoming a knowledge-driven economy.

With the development of many new biomedical techniques comes a struggle to balance the scientific liberties that promote innovation with regulations that protect both human health and societal values. The development of regulations for new stem cell technologies has been no different. Deliberation on human cloning and human genetic manipulation surged around the world following the cloning of Dolly the sheep in February of 1997. Human embryonic stem cell research has been hotly debated in the United States, where federal funding for most such research was prohibited between 2001 and 2009. China too has struggled with the development of appropriate stem cell regulations, both for research and for clinical applications.

The development of China's stem cell regulations began at a time when biomedical ethics was gaining momentum in China. In 1995, China enacted a new law to increase prenatal genetic screening and reduce infant mortality which included a clause requiring informed consent of patients for medical procedures. Although this law shows growing integration of medical ethics in policy development, many

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[1] HL Greenwood et al, "Regenerative Medicine: New Opportunities for Developing Countries" (2006) 8 *International Journal of Biotechnology* 60-77; and B Landers et al, "Harnessing Stem Cells for Health Needs in India" (2008) 3 *Cell Stem Cell* 11-15.

[2] DS McMahon et al, "Cultivating Regenerative Medicine in China" (2010) 5 *Regenerative Medicine* 35-44.

[3] For example: N MacReady, "The Murky Ethics of Stem-Cell Tourism" (2009) 10 *The Lancet Oncology* 317-318; D Cyranoski, "Stem-Cell Therapy Faces More Scrutiny in China" (2009) 459 *Nature* 146-147; E Barclay, "Stem-Cell Experts Raise Concerns about Medical Tourism" (2009) 373 *The Lancet* 883-883.

[4] See note 2 above.

international critics saw parts of the law as eugenic because it recommended the sterilisation of couples "unfit" to have children.[5] In 1998, contention against the Chinese Eugenics Law culminated in a campaign to boycott the Eighteenth World Congress of the International Genetics Federation, to be held in Beijing.[6] Instead of cancelling the event, Chinese officials authorised several conference sessions to be devoted to open discussion of the law,[7] marking a turning point to a more "worldly attitude in Chinese bio-politics".[8] From 1998 to 2001, the government issued a moral statement calling for doctors to improve the benefit and protection of patients and declared a ban on human cloning. Chinese representatives also co-authored bio-policy documents on genetics and ethics with the World Health Organization (WHO) and the United Nations Educational, Scientific and Cultural Organization (UNESCO) about medical genetics, genomics, and embryonic research.[9]

Motivated by this growing interest in national bio-politics and bioethics and by pressure to regulate new successful controversial stem cell technologies,[10] China set out to develop its stem cell regulatory framework. As we will describe, China's regulations for stem cell research and development has been at times controversial both internationally and within China. This paper will examine the development of these regulations and discuss the lessons that can be learned from China's struggle to develop appropriate regulations for their stem cell sector.

2. Method

This paper is based on an analysis of face-to-face semi-structured interviews with stem cell experts in China, primary literature and grey literature, published statistical information, government documents and reports, government regulations, field notes and observations. Our analysis is based on a subset of a larger study on the regenerative medicine sector in China, including gene therapy, tissue engineering and stem cell research.[11] Interviews from this larger data set that did not discuss stem cell issues in depth were excluded (interviews that focused exclusively on gene therapy or tissue engineering).

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[5] The law was initially translated as "Eugenics Law" but could also be translated as "Health Birth Law." While the law aimed to lower incidents of genetic disorders through accesses to prenatal genetic testing, several parts (later changed) were seen as eugenic by the international community, including Article 10, which stated that a couple deemed unfit for childbearing due to genetic disease could only be married if they agreed to sterilisation or long-term contraction. The regulations are further discussed by B Su and DRJ Macer, "A sense of autonomy is preserved under Chinese reproductive policies" (2005) 1 *New Genetics and Society* 15-29; and by RZ Qiu, "Is China's Law Eugenic?" (1999) 52 UNESCO Courier 30 available at http://www.unesco.org/courier/1999_09/uk/dossier/txt07.htm (accessed 6 Mar 2010).

[6] C O'Brien, "China Urged to Delay 'Eugenics' Law as British Scientists Register Protest" (1996) 383 *Nature* 204.

[7] E Mansood, "Chinese Agree to Eugenics Discussion" (1995) 377 *Nature* 7.

[8] O Döring, "China's Struggle for Practical Regulations in Medical Ethics" (2003) 4 *Nature Reviews Genetics* 233-239.

[9] *Ibid.*

[10] Our interviewees indicated there was pressure to regulate what limitations there should be on embryonic stem cell research, particularly with respect to somatic cell nuclear transfer (SCNT) with non-human oocytes. Hui Zhen Sheng successfully used SCNT between a human cells and a rabbit oocyte in 2002, published in 2003. SCNT research was at the time highly controversial, see notes 30 and 31 below. See section 4.3 for more discussion.

[11] See note 2 above.

Interviews with thirty-nine key informants were used to formulate the conclusions of this paper. They were conducted with a wide variety of stem cell experts from research institutions, hospitals, firms, educational institutes, government agencies, policy institutions, regulatory agencies, patent offices and bioethics organizations. The bulk of our interview data was collected over two field trips to China in the summer and late winter of 2007, although we have continued collecting data – including interviews, policy documents, scientometric and other materials – until just prior to this article's publication.

Interviews were one to two hours in length, conducted in the language of choice of the interviewee (simultaneous translation to English was provided), and were digitally recorded with informed consent. Interviews were semi-structured to allow the interviewee to pose follow-up questions or to pursue questions relating to the interviewee's individual expertise. Interviews were transcribed and analysed using thematic analysis. Quotations from the interviews used in this paper are referenced with an interview number to maintain the anonymity of our participants.

3. The Development of Stem Cell Regulations in China

3.1 Research Regulations

Chinese stem cell regulations were developed following the initiation of two separate bioethics groups from Beijing and Shanghai. A bioethics committee in Beijing developed the "Ethical Principals and Management Proposals on Human Embryonic Stem Cell Research" and submitted it to the State government in September of 2001.[12] Another set of guidelines entitled "Ethical Guidelines for Human Embryonic Stem Cell Research" were simultaneously developed in Shanghai by the Bioethics Committee of the Southern China National Human Genome Centre and submitted to the State government in October of 2001.[13] The Ministry of Health responded by issuing "The Ministry's Four No's" on November of 2002, which clearly showed the State's opposition to human cloning, but did not set out specific regulations for other types of stem cell research:

> The Ministry of Health's Four No's: Under no situation, under no circumstances, will human reproductive cloning experiments be 1) endorsed, 2) permitted, 3) supported, or 4) accepted.[14]

These regulations stood as the sole directive on stem cell research for one year, until the Ministry of Health and the Ministry of Science and Technology jointly promulgated the "Ethical Guiding Principals of Embryonic Stem Cell Research" on 24 December 2003. According to our interviewees, these guidelines reflected the main ideas in draft guidelines submitted by the Beijing and Shanghai Bioethics groups,[15] and were developed in consultation with a group of bioethicists and researchers.

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[12] See note 8 above.

[13] Published in: Chinese National Human Genome Centre at Shanghai, Ethics Committee, "Ethical Guidelines for Human Embryonic Stem Cell Research (A Recommended Manuscript)" (2004) 14 *Kennedy Institute of Ethics Journal* 47-54.

[14] As in L Liao, L Li and R Zhao, "Stem Cell Research in China" (2007) 362 *Philosophical Transactions of the Royal Society B*. 1107-1112, at 1108.

[15] Also expressed by O Döring, see note 8 above.

China has among the most permissive regulatory environments for embryonic stem cell research in the world, and our analysis indicates this is well-aligned with Chinese culture which has little religious or cultural opposition to embryonic stem cell research. China's current research guidelines for embryonic stem cell research allow parthenogenetic split blastocytes, somatic cell nuclear transfer (SCNT) or therapeutic cloning, and the creation of embryos from the fusion of human genetic material with emptied non-human oocytes (cybrids). China requires informed consent from parents of discarded embryos or aborted foetal cells, and prohibits the use of embryos past fourteen days post fertilisation, the fusion of human and non-human gametes, and the implantation of research embryos into uteri.[16] Overall, these guidelines are very similar in nature to those of the United Kingdom. The creation of embryos is also regulated by guidelines on human-reproductive technologies.[17]

At only a page in length, the brevity of the embryonic stem cell research guidelines allow for ambiguity and our analysis shows that bioethicists and researchers have two main criticisms of these guidelines: their implementation and their enforcement.

The implementation of the guidelines is left to institutions that engage in stem cell research. Ethicists we interviewed indicated that while the guidelines require that a bioethics committee approve all stem cell research, the make up of this committee is only very generally described:

> Research institutions engaged in human embryonic stem cell shall establish an ethical committee, which consists of research and administrative experts in biology, medicine, law and sociology with the responsibilities for providing scientific and ethical review, consultation and supervision of the research activities related to human embryonic stem cells.[18]

Several of our interviewees felt that the oversight of stem cell research could be improved in two ways. Firstly, they indicated that instead of an expert in "sociology," one individual with ethics training should be specifically required on the institutional ethics review committee. Secondly, there should be oversight or review of these institutional boards by a government commission to ensure that there is no conflict of interest between the researchers and the ethics committee. In the words of one interviewee, currently "the people who do the research can set up the committee by themselves". [Interview 4]

Because the research guidelines are not law and cannot be legally enforced, it is unclear what recourse, if any, could be taken against anyone found operating outside of these guidelines. Several interviewees indicated that only qualified researchers should be allowed to conduct embryonic stem cell research and that the penalties for non-compliance with the guidelines should be clearly indicated.

> There is no process to check or to review that different institutes comply with these regulations…because they are not required to register, because there is no requirement for the qualifications, the qualifications of the science [or the researchers]. [Interview 3]

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[16] *Ethical Guiding Principles for Human Embryonic Stem Cell Research (China) 2003.* (Official English translation).
[17] *Guidelines on Human Assisted Reproductive Technologies (China) 2003.*
[18] See note 16 above.

While several ethicists would have preferred that stem cell research be more tightly regulated, it is important to note that we did not see any indication of non-compliance with these guidelines, and that researchers we interviewed indicated they found these guidelines to be sufficient and binding. In addition, we found that almost all stem cell research is government funded, which must comply with the government guidelines.

3.2 Clinical and Translational Regulations

Clinical regulations governing the use of stem cells in China have been ambiguous for the last decade and are not yet fully developed, making translation of new stem cell technologies from research centres to clinics difficult. Below we describe the development of these regulations and the impact of this ambiguity.

According to our interviewees, stem cells that were manipulated or cultured were originally treated as "drugs" in China and thus were subject to approval by China's State Food and Drug Administration (SFDA), following extensive clinical testing. Cells treatments in which the cells which had not been manipulated and were transplanted from patient-to-patient or patient-to-self were treated as a medical technique and fell outside the SFDA's jurisdiction. This seems to be because of the similarity of these treatments to several well-established bone marrow transplant treatments, such as the treatment of leukaemia. Mesenchymal cell transplantation was thus exempted from clinical trial testing, even for the treatment of diseases for which safety or efficacy had not been established.[19]

The development of these clinical regulations is also described by Chen in a recent publication.[20] Chen describes all applications for stem cell based clinical trials as falling under SFDA's authority until 2007, at which time stem cell applications were classified as a new medical technology and regulated by the Ministry of Health. In July 2007, the Ministry of Health placed documents on its website for public consultation that classified stem cell therapies as a Class Three medical technology, [21] suggesting that stem cell treatment and regulation may in the future fall under their jurisdiction and may require additional oversight.

In the absence of clear clinical regulation, our interviewees estimate that over 200 companies and hospitals have begun administering stem cell based therapies to patients. These therapies typically use mesenchymal, cord-blood or foetal cell extracts and are used to treat a variety of incurable conditions, including Lou Gehrig's disease, traumatic brain and spinal cord injury, diabetes, ataxia, multiple sclerosis, autism, Parkinson's, optic nerve hypoplasia and stroke. These clinics treat both domestic patients and international patients, and have treated well over 6500 patients in total, including several thousand international patients.[22]

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[19] Our description of the clinical regulation of stem cells is further supported by: J Qiu, "Injection of Hope through China's Stem-Cell Therapies" (2008) 7 *The Lancet Neurology* 122-123.

[20] H Chen, "Stem Cell Governance in China: From Bench to Bedside" (2009) 28 *New Genetics and Society* 267-282.

[21] See "Annex 1: Management Practices on Clinical Application of Medical Technology (draft)" and "Annex 2: The List of Category Three Medical Technology (draft)" available at http://www.moh.gov.cn/sofpro/cms/previewjspfile/mohyzs/cms_0000000000000000073_tpl.jsp?requestCode=19372&CategoryID=10596 (in Chinese only, accessed 5 March 2010).

[22] Patient numbers represent patients treated in two of three major stem cell clinics in China before March 2009 (see note 2 above). This estimate is conservative; while it covers two of the main clinics,

In May 2009, the Chinese Ministry of Health re-categorised all stem cell therapies as a Category Three Medical Technology,[23] placing allogenic, autologous, and xenogenic stem cell therapies under the direct responsibility of the Ministry of Health instead of under provincial or institutional responsibility.[24] Category Three is reserved for technologies that are deemed to be "high-risk," involve "major ethical issues" and for which "the safety and effectiveness by the norms of clinical trials" still need "further verification".[25] To our knowledge, the Ministry of Health is still designing their specific criteria for stem cell therapies, after which they will need to evaluate any available therapies against these criteria. It will therefore be some time yet before the enforcement of these new regulations changes the current practices of stem cell therapy centres in China.

During our field work in China in 2007, many researchers were unclear whether stem cells were at the time considered a drug or a medical technique, nor were they certain whether clinical use of stem cells fell under the jurisdiction of the State Food and Drug Administration, the Ministry of Health, or the Ministry of Science and Technology. Their confusion further demonstrates the lack of clarity surrounding clinical regulation, which researchers felt was a key challenge to the effective translation of stem cell research from the lab to the clinic. Our follow-up correspondence indicates that several years later in late 2009, researchers still do not find the regulatory guidelines sufficiently clear to carry their research forward to the clinic.

4. Discussion: Learning from China's Regulatory Struggle

4.1 Distinct and Clear Regulation Needed at Each Stage of Product Development

Our analysis indicates that regulation of stem cell research and use is important at every stage of the product development pipeline. Although Chinese experts developed regulations for embryonic stem cell research in 2001, the lack of clear regulation on stem cell applications has allowed controversial stem cell clinics to administer stem cell therapies to domestic and international patients and poses challenges for researchers interested in translating their work to clinical testing. Just as the top researchers are distinct from the clinics offering therapy, the regulations for research and for clinical applications are quite distinct, although this distinction is often missed.

Stem cell research regulations have long been confused with clinical regulations in China and we believe some of the criticism directed at Chinese stem cell clinics has been misdirected towards China's research regulations both internationally and within China. Our interviewees sometimes felt that enforcement of research regulations were insufficient, citing the clinical use of these cells by some hospitals. The stem cell

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including one that supplies a network of hospitals, it does not include all clinics in China and it is unknown how many patients in China have received stem cell treatment. We expect realistic estimates of patients treated to be much higher than reported here.

[23] D Cyranoski, "Stem-Cell Therapy Faces More Scrutiny in China" (2009) 459 *Nature* 146-147.

[24] Ministry of Health of the People's Republic of China. "Notice of the Ministry of Health Issued "Management Practices on Clinical Applications of Medical Technology" (2009) available at http://www.moh.gov.cn/publicfiles/business/htmlfiles/mohbgt/ s9507/200903/39511.htm (in Chinese only, accessed 28 Feb 2010).

[25] *Ibid*.

clinics mostly use adult autologous stem cells, or allogenic cord-blood or foetal cells, for which the research guidelines for embryonic stem cell do not apply. The clinical uses of these types of stem cells require separate regulation. This confusion is also present in the literature. In a letter to the journal *Nature*, Chinese researchers stated that "China already has clear stem cell guidelines", using the embryonic research guidelines and the reproductive technology regulations as examples.[26] The letter went on to describe that a few medical practitioners were using cells to treat patients "without government approvals or appropriate clinical trials" and stated that they believe this is a matter of law enforcement, but did not discuss what regulation, if any, applied to the clinical use of such cells. Although the material presented in this letter is not incorrect, a greater distinction between research regulation and clinical regulation would be highly beneficial to discussion about stem cell regulations in China. Our data extends only to within China but our discussions with researchers outside of China and our interactions at conferences suggest that the international community also fails to sufficiently distinguish between clinical and research regulation.

In addition to the rules for embryonic research and those for clinical or commercial use of stem cells, clear regulatory frameworks for pre-clinical and clinical trials are needed, for all stem cell types. Researchers indicated that they may delay clinical testing of their research for fear that rules would change during or after their clinical testing. If clear regulations for clinical testing are not quickly developed, this lack of clinical regulation may pose a significant challenge to researchers in China, who indicated interest in developing clinical protocols that would be scientifically acceptable to the international scientific community and that would adhere to domestic policies and regulations.

4.2 Cultural Impact on Regulation Development

China's cultural and societal values have been important to the development of their regulations. According to our interviewees, bioethicists designed regulations within the context of Chinese religion and culture while also taking into account international ethical norms.[27] Chinese culture does not typically perceive the embryo as having personhood, so embryonic stem cell research has not been hotly debated as a political or religious issue. Confucianism sees personhood as beginning with birth and our interviewees agree that embryonic stem cell research is well accepted by the general population while still conforming to international ethical standards, such as not using embryos past fourteen days post fertilisation.

China is more supportive of embryonic stem cell research than many other countries, not only for general forms of embryonic stem cell research, but also for other contentious forms of research including therapeutic cloning and SCNT, and the

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[26] L Cheng, "Ethics: China already has clear stem-cell guidelines" (2006) 440 *Nature* 992.

[27] It is obviously very difficult to clearly identify "ethical norms", particularly for a topic such as stem cell research where there is little consensus on what forms of research should and should not be allowed. We use this term here to illustrate areas of general consensus, such as not using embryos prior to fourteen days of development. Our interviewees indicated that they were willing to use some of these "norms" to inform their own policy.

formation of cybrids.[28] Our interviewees agreed that these forms of research pose no serious cultural or societal problems and that these forms of research are widely supported by the policy makers, researchers, and bioethicists in China, as well as by the general population.

The general population is also very supportive of new medical technology, particularly for currently untreatable or incurable conditions. The general population may also be highly supportive of technologies that are based around the idea of using the body to heal itself, which one interviewee said fit well with the concepts of popular traditional Chinese medicine. Our research leads us to believe that when stem cell therapies are ready for clinical application, there should not be any major cultural barriers to the uptake of these new therapies by the general population.

While research regulations are supported by many stake-holders in China, our analysis shows that this is not true for clinical regulations, which were criticised by some clinicians, bioethicists and researchers for allowing unproven stem cell therapies into the clinic. Some Chinese researchers feel that their reputation has been hurt by the availability of stem cell therapy in China. This is supported by our informal discussions with North American stem cell researchers, one of whom told us: "Chinese stem cell research is nothing but injecting patients with stem cells. It's not research".

4.3 Timely Development of Regulations

The timely development of regulations can have an important impact on the development of new technologies. Chinese researchers felt that the early development of permissive research regulations placed them at an advantage early on while other countries were still debating some forms of embryonic research. China has supported SCNT technology, including SCNT between human somatic cells and non-human oocytes, for research purposes since 2003. This was much earlier than the United Kingdom, for example, which did not allow cybrid research until its Human Fertilisation and Embryology Authority (HFEA) agreed to issue some conditional licences for this type of research in September 2007. This UK regulatory reform came four years after this type of research was officially endorsed by the Chinese state government and six years after SHENG Hui-Zhen first used SCNT to successfully revert an adult human cell to an embryonic state.[29] In the 2003 publication of this work, Sheng refers to the draft regulations from the bioethics group in Shanghai. These draft regulations are endorsed in the publication by the municipal government to support the ethics of her research.[30] Many of the researchers with whom we spoke

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[28] In 2002, over thirty countries declared they would not support a ban on reproductive cloning unless it also included therapeutic cloning, leading to worldwide debate. After significant debate, the United Nations finally declared a ban on all forms of human cloning that are "incompatible with human dignity and the protection of human life" in 2005. The declaration was not legally binding, and remains ambiguous to which forms of human cloning are "incompatible" with human dignity and the protection of human life. Through all these discussions, China remained supportive of therapeutic cloning.

[29] A Mandavilli, "Hui Zhen Sheng" (2006) 12 *Nature* 265. Capitalisation is used here to indicate the family name, which is listed first in Chinese tradition, but may come first or last in our references, depending on the publisher.

[30] Y Chen et al, "Embryonic Stem Cells Generated by Nuclear Transfer of Human Somatic Nuclei into Rabbit Oocytes" (2003) 13 *Cell Research* 251-263.

support the timely development of regulations and want to maintain international credibility of their work by showing their adherence to local regulation.

Compared to the development of research regulations, the development of clinical regulations has been lengthy. This delay in formulating clear clinical regulation has imposed challenges for the translation of stem cell research and has allowed controversial clinics to make stem cell therapy available. Classification of these therapies as "Category 3" medical technologies is a step towards tighter regulation but the development and implementation of clear clinical regulation is long overdue.

4.4 National Guidelines can have International Impact

National guidelines matter, not just for the Chinese population, but also internationally. Stem cell clinics in China indicated that a growing number of their patients are coming to seek treatment from overseas. This phenomenon, called "stem cell tourism", has allowed patients to obtain experimental treatments not allowed in their home countries where clinical evidence of the safety and efficacy of such treatments is considered insufficient. Because of the growing stem cell tourism industry, domestic regulation of the clinical use of stem cells – or lack thereof – has significant global impact for patients, the doctors who advise them and the healthcare systems that care for them upon their return. The International Society for Stem Cell Research (ISSCR) strongly condemns the administration of unproven stem cell therapies[31] and has produced a handbook to help inform doctors and patients about their options.[32]

As increasing numbers of patients seek out stem cell therapies in China, it is of great importance that the government ensure that the therapies being administered to patients by medical professionals are safe and effective. There is international concern that stem cell tourism may also hurt the credibility of stem cell research globally. Support for stem cell therapy could suffer if patients around the world have expectations that are inflated beyond what the current science can deliver, or if patients are harmed by unproven stem cell therapies.[33]

It is important to note that stem cell tourism is not unique to China; several countries around the world are also struggling to regulate unproven stem cell therapies.[34] China is but one example of a country allowing – or at least not inhibiting – stem cell clinics offering unproven therapies. The Dutch government put a ban on stem cell therapies being offered in private clinics on 1 January 2007.[35] Thailand's government is reviewing new regulations that would establish a scientific and ethical oversight

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[31] International Society for Stem Cell Research, "Guidelines for the Clinical Translation of Stem Cells" (2008), available at http://www.isscr.org/clinical_trans/pdfs/ISSCRGLClinicalTrans.pdf (accessed 8 March 2010).

[32] International Society for Stem Cell Research, "Patient Handbook on Stem Cell Therapies" (2008) available at http://www.isscr.org/clinical_trans/pdfs/ISSCRPatientHandbook.pdf (accessed 8 March 2010).

[33] We heard this message in our interviews and this sentiment is also expressed by Caulfield in A Silversides, "Stem Cell Hype Risks 'Backlash'" (2009) *Canadian Medical Association Journal*.

[34] For countries offering stem cell therapy, see for example: Table 2 from Ryan et al, "Tracking the Rise of Stem Cell Tourism" (2010) 5 *Regenerative Medicine* 27-33; or Table 1 from J Qiu, "Trading on Hope" (2009) 27 *Nature Biotechnology* 790-792.

[35] T Sheldon, "Holland Bans Private Stem Cell Therapy" (2007) 334 *BMJ* 12.

committee and require approval for all stem cell therapies.[36] Germany also approved new regulations for the clinical use of stem cell therapy in July 2008, although some loop-holes may still exist.[37] These therapies are a global business, but are facing increasing scrutiny. Certainly the governments of many countries – both those with and without stem cell clinics – will be interested to see how China implements the new regulations of May 2009 and how this will affect the availability of therapy.

5. Conclusions

The results of this research show the importance of shaping policy to respond to societal, cultural, regulatory, and ethical issues. Our study yields important lessons for China and other nations interested in developing regulation for new biomedical technologies: regulations should be timely, culturally sensitive, and should be developed for each stage of product development. Our paper shows that national regulations are important, and can have implications that far exceed a nation's political borders.

The developments of stem cell regulations in China for research and for clinical use have taken very different paths. Designed early on, the research regulations were permissive and culturally sensitive. While there remains room to improve the implementation and enforcement of these regulation, most researchers find the content sufficient to guide their work. Clinical regulations, on the other hand, have remained ambiguous, and, while new regulations should soon come into effect, it is still unclear what the impact of these new regulations will be. This ambiguity has allowed internationally controversial stem cell tourism practices to grow and has posed a challenge to the translation of research through to clinical testing.

As the world's fifth largest producer of scientific stem cell literature, there is a growing role for international collaboration with centres of excellence in China. Recognising China's accomplishment and contributions to the stem cell field, we suggest that international collaboration with leading scientific institutes in China could be mutually beneficial. We also believe that – as China is one of the main stem cell players, and because of the international significance of its national regulations – Chinese researchers and regulatory representatives should be involved in international discourse about stem cell regulation and translation to clinics.[38] With increasing globalisation, concerted efforts are needed globally to steer development of this emerging field.

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[36] See J Qiu note 34 above.
[37] N Stafford, "Germany Tightens Law on Stem Cell Treatments" (2009) 339 *BMJ* 2967.
[38] To some extent this is already occurring. Several Chinese members are present on the ISSCR board. BIONET is another notable example. Nonetheless, our observations show that Western researchers do not always consider China when setting conference agendas or for collaboration, sometimes based on misunderstanding of Chinese contributions to stem cell science.

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