**Bioethical governance and basic stem cell science:**

**China and the global biomedicine economy**

**Professor Brian Salter**

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Professor Brian Salter
Global Biopolitics Research Group
Centre for Biomedicine and Society
King's College London

brian.g.salter@kcl.ac.uk

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## Introduction

The impressive growth of the global biomedicine economy has been paralleled by an increase in the intensity of the politics directed at determining how, where and by whom it should be governed. Among others, international organisations, regional groupings, transnational networks and nation states compete for influence and control over the governance of the bioeconomy and its potential wealth. Existing modes of governance are being overhauled, fresh ones created and new forms of knowledge generated to service the task of bioeconomy government. Such is the range and sophistication of the governance mechanisms required that two knowledge domains now co-exist: the bioeconomy itself and the governance knowledge that shapes its progress. Neither is sustainable without the other: biomedicine and bio-governance must be co-produced.

For novel fields of biomedicine, the knowledge production process from the basic science, through clinical experimentation and trials, to the therapeutic product is long, arduous and uncertain. At all stages in that process, there exists a potential triangle of tensions between science, society and the market: the science may prove to be inadequate, society unsympathetic or the market uninterested. As a result governance has to be co-produced with science since the chosen mode of governance can be critical in determining the success or failure of the biomedical innovation. At the national level, a state may choose governance interventions in terms of support for the science (investment, scientific workforce), mediation between the science and its cultural context (public consultations, bioethics committees), the maintenance of consumer confidence through the regulation of some or all of the stages of knowledge production (laboratory, animal testing, clinical experimentation, clinical trials, commercial production), and the stimulation of market interest through intellectual property regulation, venture capital support and public-private partnerships. Some of these modes of governance will be familiar to policy makers. Others will be quite new.

At the same time, the globalisation of all aspects of the knowledge economy of biomedicine means that governance intervention by a state is but one component in the political equation. Scientific activity and networks are international and collaborative; research materials such as oocytes and embryos form part of a global tissue economy (Andrews and Nelkin 2001; Waldby and Mitchell 2006); clinical trials are increasingly outsourced as part of the pharmaceutical industry's global strategy (Petryana 2005, 2006); financial institutions make their investment decisions in this field on a global basis (Kenney *et al* 2002); industrial interests are continually bio-prospecting for new forms of information on human and non-human biological material that can be commodified and traded (Parry 2005, 2006); and definitions of international intellectual property rights in biomedicine are challenged at political sites such as the World Intellectual Property Organisation (WIPO) and the European Patent Office (EPO) (Drahos 2002; May and Sell 2005; Salter 2007a). State level governance is therefore obliged to engage with international and global forms of governance.

For emerging economies such as China with only limited governance experience in the biomedical field, the interaction between the state and global levels of governance will be a critical factor in determining their position in the world bioeconomy. Given that the construction of global governance is rarely a neutral activity but rather one that reflects the political interests of the major players, new participants will have to work hard to influence the governance agenda in their favour. Much will depend on their capacity to construct an indigenous governance knowledge base.

In this paper I explore the position of China in the competition for influence over the governance of stem cell science, a health technology field with much therapeutic and economic promise, focusing on the evolution of governance to manage the tensions between science, society and the market in the early stages of the innovation process in basic science. Here the rules of the game are being evolved through a global debate about the values that should guide the science. Facilitated by the rise of bioethics, a moral economy of stem cells has emerged where standards are traded, cultural conflicts considered, and reconciliations achieved (Salter 2007b, 2007c). But as a novel form of governance, bioethics cannot assume that it has automatic legitimacy within the jurisdiction of states, such as China, who are new entrants to the stem cell bioeconomy. Rather, the legitimacy of bioethics has to be negotiated in the specific cultural and political context of a state with its own governance styles and preferences. Equally, if China is to compete effectively in the global governance of stem cell science, then it is obliged to recognise and engage with the established structures and procedures of international bioethics.

**Producing governance knowledge**

In the course of the evolution of a bioeconomy, the exchange and trade in scientific knowledge is dependent on the development of a governance framework of common standards regarding the definition and value of that knowledge. Without such harmonisation, either the bioeconomy will not work, or it will work only partially and inefficiently because the basis of exchange is confused or not known. However, the emergence of common standards of governance is not an automatic process guided by the objective needs of 'scientific progress'. Governance does not emerge from a vacuum but is politically constructed: it is a constellation of ideas and values that are created, assembled and configured to render the governance function legitimate and efficient when assessed in terms of scientific, economic and political goals. To that extent it is exposed to the normal vicissitudes of political life.

In this context, governance of the knowledge economy can be construed as the construction of 'systems of rule' for setting, monitoring and assuring the standards that enable its operation (Rosenau 1995: 1; see also Kerwer 2005). Importantly, these standards may be matters of fact (eg the criteria for agreed measures, protocols, classificatory systems and technical benchmarks shared by laboratories working in the same research field), of value (eg the criteria for determining the appropriate sourcing of human embryos for research) or, as frequently happens, a combination of both (Salter and Waldby 2007). In the case of the bioeconomy, the production of the governance knowledge from which the rule systems are constructed takes place through a range of governance agents that may include the formal institutions of international government, transgovernmental coalitions, private non-institutional

governance, international NGOs, public-private partnerships, global public policy networks, international knowledge institutions and epistemic communities (Dingwerth and Pattberg 2006; Forman and Segaar 2006; Miller 2007; Pattberg 2005; Salter 2007d). These agents may act singly or jointly to impact on any or several parts of the policy making process from agenda setting, through policy formation to policy implementation. Depending on what agents are involved and the authority they can bring to bear, the policies governing the global bioeconomy will draw on different types of legitimacy including the legal/rational, democratic, expert and moral and operate at regional, international and global levels.

The particular need to establish systems of rule for governing issues of moral value arises because the evolution of biomedicine is rarely culturally neutral. Novel developments in biomedicine may directly challenge existing cultural conceptions of human value, posit new ones or simply demonstrate the absence of a relevant moral framework to guide the science. In her study of the life sciences in the UK, US and Germany, Jasanoff notes the dawning recognition in all three political systems that some of the risks and promises engendered by the multifaceted advances in genetics and biotechnology, 'called for a new language of deliberation, *geared to the analysis of human values* rather than the benefits of the market, the facts of science, or the norms of law' (Jasanoff, 2005: 171, emphasis added). Without 'a language of deliberation' that is also capable of performing a governance function the new science is likely to encounter continuing political costs in the form of cultural conflict, vulnerable public trust and exposed future markets. Nor is the nation state the only constituency with an interest in the production of knowledge to service the rule systems of moral governance. Given the international nature of biomedical science, funding agencies, project collaborations, and scientific journals are increasingly aware of the importance of maintaining a presence in this governance territory.

However, the primary vehicle for the negotiation and resolution of the cultural tensions associated with biomedical advance has been the evolution of bioethics as an epistemic community acting through its transnational networks and bureaucratic linkages (Salter 2007b, 2007c; Salter and Jones 2005). (Here I am using Haas's definition of an epistemic community as 'a network of professionals with recognised expertise and competence in a particular domain and an authoritative claim to policy-relevant knowledge' within that domain (Haas, 1992: 3; see also Haas 2001; Verdun, 1999).) Through the production and dissemination of a particular kind of expert knowledge, bioethics has become the political means for the creation of a global moral economy where the trading and exchange of values is normalised and legitimated. Its ascent has been marked by a global infrastructure of high profile ethical statements launched from the platform of established international bodies, an awareness of the need to translate these statements into legal/bureaucratic form, and the proliferation of horizontal and vertical networks linking international and national levels of ethical governance. Supporting this infrastructure are examples of what Miller has termed 'international knowledge institutions' with the power 'to constitute social order by moulding the underlying epistemic frameworks that guide the definition of problems, the classification of social kinds, and the evaluation of social behaviours' (Millar 2007: 331; see also Barnett and Finnemore 2005). In the case of bioethics these take the form of bodies such as UNESCO's International Bioethics Committee (IBC) at the international level, the European Group on Ethics (EGE) at the regional level of the European Union (EU) and national bioethics committees.

Embedded to varying degrees within policy making structures, such institutions seek to exercise an independent influence on global discourses through what Jasanoff describes as 'processes of co-production' where epistemic and political authority are interwoven in the production of ethical statements (Jasanoff 2004).

Once the utility of bioethics as a form of global governance was established, it rapidly became unacceptable for an international organisation concerned with medical science not to have at least a reflective, if not a promotional, ethical function within its structure. The production of ethical knowledge became a condition for participation in the competition for control of this important new governance territory. Thus we find organisations such as the Council for International Organisations of Medical Sciences (CIOMS), the Human Genome Organisation (HUGO), the International Society of Bioethics (ISB), the World Medical Association (WMA) and the World Health Organisation (WHO) working hard to establish a profile in the global governance competition (see eg CIOMS, 2002; HUGO, 1996; ISB, 2000; WMA, 2002; WHO, 1997). The WHO has been particularly industrious in this field and in October 2002 launched its Ethics and Health Department 'to provide a focal point for the examination of the ethical issues raised by activities throughout the organisation' (WHO, 2008). The Department's functions include a global calendar of bioethics events, resources on research ethics and support for the annual Global Summit of Bioethics Commissions. Working through the WHO's six regional offices and what it terms 'regional ethics focal points', the Department provides linkage between the international and national levels of bioethics and facilitates the development of the emerging transnational bioethics network.

In the case of stem cell science, the level of inter-state competition for influence over the bioethical agenda can be gauged in terms of the intensity of governance knowledge production: what reports and debates have states formally initiated? A 2004 survey of the national bioethics committees (or equivalent bodies) of the EU's then 25 Member States shows that two thirds (16 states) had required an opinion from their national ethics committee (or similar body) on the ethical and policy issues involved in human embryonic stem cell science (European Commission 2004). In addition, two thirds had initiated, or intended to initiate, a public debate on the new technology (see also Hauskeller, 2004; Maio, 2004; Beckman, 2004). Finally, half of the Member States (13) had instigated both expert and public discussion on stem cell science. More widely, contributions to the global debate on stem cell science have come from the national bioethics committees of China, India, Israel, Singapore, and the United States (China, Ministry of Science and Technology and Ministry of Health, 2004; Indian Council of Medical Research, 2007; Israel Academy of Sciences and Humanities Bioethics Advisory Committee, 2001; Singapore Bioethics Advisory Committee, 2002; United States President's Council on Bioethics, 2002, 2004, 2005). Meanwhile, at the regional level of the EU, between1998 and 2002 the European Group on Ethics produced three influential reports on different aspects of stem cell research (EGE, 1998, 2000, 2002). And at the international level, both UNESCO's International Bioethics Committee and the Human Genome Organisation's Ethics Committee have produced position statements on human ESC science (HUGO, 2004; UNESCO, 2001).

It is therefore fair to say that the global production of knowledge pertaining to the ethical governance of stem cell science is substantial and continuing – certainly when

compared to other new areas of science. If, as a state such as China, you want to become a major player in stem cell governance as part of a strategy for entry to the global bioeconomy, then having a formally approved bioethical position that legitimates your policy stance is now a requirement of participation in the game. However, in developing such a stance, new players must recognise that the territory of bioethical governance is not open and unoccupied but dominated by the ideas and concepts that over the last decade have proved themselves able to produce a compromise between the requirements of scientific advance and the cultural sensitivities it has provoked. Even a cursory scan of the reports listed above shows a global convergence of perspectives and policies over time as compromises are reached and rule systems clarified (Salter 2007d: 293-4). Nor is this simply an expression of ideological power, since the rules thus generated are increasingly embedded in the assumptions and procedures of national and international bureaucracies.

**Global pressures and bioethical response**

In common with other emerging economies of the Asia-Pacific, the People's Republic of China has made biomedical science a central plank in its bid to become a dominant force in the global knowledge economy. In pursuit of this ambition, in January 2006 President Hu Jintao launched the PRC's fifteen year *Plan for medium and long term science and technology development (2006-2020)* with the goals of massively increasing R & D investment from the current 1.4 per cent of economic output to 2.0 per cent by 2010 and 2.5 per cent by 2020, reducing China's reliance on foreign technology and rapidly expanding its capacity for 'independent, indigenous innovation' (PRC 2006). At the same time, there is an acknowledgement in the Plan that China is weak not only in its basic science but also in many of the infrastructure components necessary for the economic exploitation of its scientific investment (Serger and Breidne 2007). Indeed, at the time the Plan was launched, the then Minister for Science and Technology, Xu Guanha, expressly recognised that China's basic science requires international support if China is to maximise the results from its scientific investment (Xu 2006). In the case of stem cell science, the combination of these two factors places a clear political premium on the development of a governance apparatus that will support and facilitate China's ambitions in the global knowledge market.

Investment in stem cell science there undoubtedly is, with spending over the 5 years up to 2010 projected to be between RMB 500 million (US $63 million) and RMB 2 billion (US $250 million) (UK Stem Cell Initiative 2005: 5). In 2004, the UK's DTI Global Watch Mission to China reported that stem cell science was 'booming' with government financing the building and modernisation of new stem cell laboratories, creating new university appointments with competitive salaries for 'returnees' from overseas, and providing money for research and venture-like capital funds to establish biotech companies owned by their researchers and universities (DTI Global Watch Mission 2004: 12). Given this investment in stem cell science knowledge production, a key question therefore is whether China also has the governance knowledge to support its ambitions with regard to both its domestic constituencies and the global constituencies of international funding agencies, scientists, publishers, consumers, and investors. For unless China's rule systems are at least compatible, if not harmonised, with those of the latter it will find it difficult to secure their trust and collaboration.

In this respect, the cultural acceptability of the rule systems that govern China's basic science and the means used to ensure their legitimacy assume considerable political significance. In Europe and North America, from the 1970s onwards the moral issues raised by novel developments in medical science were met by the rise of bioethics 'as a device for bridging potentially troublesome divides: among disciplines, professions, and institutions; and increasingly also among science, state and society' (Jasanoff, 2005: 188). Bioethics became the 'the common coin of moral discourse', as Jonsen puts it, for the consideration and legitimation of biomedical advance (Jonsen 1998: 333). Across countries, there was a common utilitarian emphasis on the identification of ethical procedures that could be used to address and perhaps resolve conflicting moral positions in ways that could be integrated with the policy process. However, arrangements vary for the organisation of the bioethics-policy relationship in terms of both proximity, and point of entry, to the agenda-setting, policy formation and policy implementation parts of the policy process. In the UK, the Nuffield Council on Bioethics is an independent body operating largely in the arena of public debate and agenda setting. In Germany, on the other hand, the National Ethics Council has a statutory position in policy formation as does the European Commission's European Group on Ethics. In the US, the President's Council on Bioethics lies somewhere in between, created by order of the President to advise on ethical issues related to advances in biomedical science and technology. None are involved in policy implementation but all to a degree fall within Haas's definition of an epistemic community as a network of professionals with authoritative and policy relevant knowledge (Haas, 1992: 3).

In China, the experience of bioethics as an aid to the governance of biomedical science has been much less straightforward, for reasons associated not just with the country's turbulent political history but also with the cultural context within which bioethics emerged. Early reports on Chinese bioethics provide contradictory interpretations of its emergence as a self-conscious epistemic community. In 1980 Engelhardt came to the conclusion that when measured against American disciplinary criteria bioethics in China did not exist (Englehardt 1980). A year later, in a sociological counterblast, Fox and Swazey argued that Englehardt's view was the product of an insensitivity to Chinese medical morality which, given its emphasis on communitarian rather than individualistic values, might be different from American morality but was no less valid (indeed, they suggested it was more valid) (Fox and Swazey 1981). Regardless of the truth of the matter (and both are probably saying the same thing but from different standpoints in American ethics), the fact of the reports themselves demonstrates the beginnings of an engagement between Chinese ethical thinking and American bioethical networks. This interaction continued throughout the 1980s and into the 1990s and, as we shall see, was complemented by an engagement also between China and the American influenced transnational networks of bioethics. The end of isolation for Chinese bioethics provoked a range of domestic responses characterised by, in some, a refocusing on traditional Chinese medical ethics and, in others, a positive response to the Western emphasis on individualism and human rights (Nie 2000). As with European and North American bioethics, few were actually antagonistic to the advance of biomedical science but rather offered different sets of values to guide its progress. In this context, the important question for the governance of stem cell science in China is not whether the plurality exists but which grouping within it, if any, is most closely aligned with the policy making

process, what form that alignment takes and what type of governance legitimation is thus produced.

Several international pressures coincided to help shape the answers to these questions. By the late 1990s, China's determination to play a leading role in global affairs meant that it was keen to contribute to the formation of international agreements, including biomedical guidelines. For the latter it required the bioethical expertise that could speak the language of the dominant Western bioethical community. That China was successful in mobilising such expertise is apparent in its co-authorship of the WHO's *Guidelines on ethics in medical genetics* (1998), the UNESCO's *Universal declaration on human rights and biomedicine* (2000) and the UNESCO's International Bioethics Committee's statement on *Human embryo research and international solidarity and cooperation* (2001) (Döring 2003). Bioethical expertise was also needed for its endorsement of the WMA's Helsinki Declaration on *Ethical principles for medical research involving human subjects* (2000) and its position statements during the lengthy manoeuvring leading up to the United Nations 2005 ban on human cloning for reproductive purposes (Ministry of foreign Affairs of the PRC 2003). At the regional level, in 1995 China took a leading role in the establishment of the East Asian Association of Bioethics, the forerunner to the contemporary Asian Bioethics Association, and has subsequently initiated bilateral bioethical conferences with Japan, Germany and the US (Zhai 2004: 6). Then in 2006 China achieved the apotheosis of bioethical respectability with its hosting of the International Association of Bioethics' 8th World Congress of Bioethics.

The integration of Chinese bioethics into the global bioethics community has gone hand in hand with the desire of leading Chinese stem cell scientists to achieve their own acceptance by the international scientific community. Governance and scientific knowledge have both sought recognition and legitimation from their international peers. Frequently educated in the West, such scientists are aware that the achievement of international funding, collaboration and publications in journals such as *Nature* and *Science* is dependent on their visible adherence to the governance standards of their scientific peers in other countries (Wang 2003). If the governance rule systems to assure such standards are to be convincing then clearly their formation and implementation in China need to be underpinned by governance knowledge, in this case bioethical knowledge, that has international respectability. Conversely, without such governance knowledge, scientists are dangerously exposed if in the eyes of their international constituencies they are judged to be failing to adhere to the appropriate technical and moral standards. It is at this point that the co-production of scientific and governance knowledge becomes both necessary and obvious.

A clear example of the political sensitivity and power of this epistemic conjunction is apparent in the response in 2001 to the creation by Chen Xigu in Guangzhou of human-rabbit embryos for which no governance rules then existed in China. Reacting strongly against the experiment, and reflecting the views of many of his colleagues, the then Vice-President of the Chinese Academy of Sciences, Zhu Chen (now Minister of Health), called for national ethical guidelines for genomic and stem cell research, observing: 'it is of great importance for a large country like China for this kind of work to be under strict regulation' (Abbott and Cyranoski 2001). It was not to be too long before this pressure from elite scientists produced governance results.

**Legitimating and consolidating governance**

Given the global credibility accorded bioethics as a vehicle for the formation of stem cell governance and the international pressures to which China is exposed documented above, the contribution of bioethics to the construction of state policy is to be expected – provided that bioethics networks are both developed and have access to policy making structures. The biomedical regulations and laws already in existence prior to 2001 suggest that at least some of these networks were already in place and acting to influence and support government policy making. These include: Ministry of Health (MOH), *Interim guidance on ethical review of biomedical research involving human subjects* (1998); Ministry of Science and Technology (MOST) and MOH, *Interim measures for the administration of human genetic resources* (1998); National People's Congress, *Law on practising doctors* (1999); State Food and Drug Administration (SFDA), *Drug clinical trial guidelines* (2000); and MOH, *Regulations on human assisted reproductive technologies* (2001) (Zhai 2004).

In 2001, following the Chen Xigu affair, two bioethical networks in particular mobilised to submit draft guidelines on human embryonic stem cell research to MOH and MOST. The first, an interdisciplinary group of leading scientists and ethicists from Beijing, produced their *Ethical principles and management proposals on human embryonic stem cell research* (Döring 2004: 43). The second, the Bioethics Committee of the Southern China National Human Genome Centre in Shanghai, submitted a document called *Ethical guidelines for human embryo stem cell research* that, interestingly, was subsequently published in the *Kennedy Institute of Ethics Journal*, an indication of the close links between Chinese and American bioethicists (Southern China National Genome Centre, Bioethics Committee 2004). With substantial overlap between the two proposals the policy advice was strong and coherent and resulted in the joint issue by the MOST and the MOH in December 2003 of the *Ethical guiding principles on human embryonic stem cell research* (MOST and MOH 2003).

To those familiar with the rules issued by other states, the content of the Chinese guidelines are instructive. They prohibit reproductive cloning but permit therapeutic cloning; permit stem cell experimentation on human embryos up to 14 days but forbid experimentation on older embryos; rule that all gametes and tissues must be voluntarily donated in accordance with the principle of informed consent and that research institutions proposing to experiment with human embryonic stem cells must establish an ethical committee to review the research; prohibit the implantation of human embryos used in stem cell research; and prohibit the buying and selling of human eggs, sperm, embryos and fetal tissue. With the exception of therapeutic cloning, which only the UK and a handful of other states have explicitly endorsed, China's position forms part of a global ethical consensus on the regulation of this aspect of stem cell science (Hennig 2006).

However, China's entry into this consensus has not been achieved without considerable and continuing debate within its bioethics community regarding the relationship between the values propagated by global bioethics and China's traditional cultural values. For example, when considering the issue of informed consent, the Western principle of individual autonomy interacts in interesting ways with the Confucian tradition where a person is never seen in isolation from their familial and social context (Fan 1997, Nie 2001, Tsai 2001). (A 2005 national survey of Chinese

scientists' attitudes about consent policy relating to human genetic databases found that 24 per cent agreed that the family's consent could take the place of the individual's consent (Zhang and Bao 2007: 65)). Equally, it is likely that the moral status of the human embryo in China is not as culturally uncontentious as is sometimes claimed by those pointing to the instrumentality of China's one birth family policy and the rigors of state population control through abortion (including enforced sterilisation in rural areas) (Cookson 2005). Rather, social research on attitudes to abortion among the Chinese population suggests a pluralism of views informed by a variety of ideological and philosophical traditions (Nie 2005). And Chinese bioethicists have argued that it is important that the value of the human embryo has to be weighed against its potential medical benefit (Qiu 2000). They have little hesitation in promoting China's traditional values in international fora nor in searching for compromises from their Western colleagues. Professor Qiu Renzong, probably expressed a consensus view held by the Chinese bioethical elite regarding the incorporation of Chinese values into the country's domestic ethical regulations when he stated that 'respecting a unique cultural context is no excuse for rejecting the general applicability of international ethical guidelines'. He continued:

> Such guidelines are a result of communication and debate among experts from different countries and cultures across the world, including China. As Confucius said, "human nature is similar, practice made them apart". Basic values such as respect, non-maleficence and justice are shared by western and eastern cultures alike'.(Qiu 2007)

Having established a common view of the standards that should guide a particular area of science, the next step is to ensure their continuing translation into policy. As Haas suggests in his work on epistemic communities, 'the application of consensual knowledge to policymaking depends on the ability of the groups transmitting this knowledge to gain and exercise bureaucratic power' (Haas 1992: 30). With regard to the production of governance knowledge for *policy agenda setting and policy formation*, the genesis of the guidance on embryonic stem cell science detailed above suggests that the bioethics community in China has gained a measure of access to the policy apparatus, certainly so far as basic stem cell science is concerned; access which has served as a channel for the flow of global values regarding regulatory principles in the human ESC field. To what extent has that access now been consolidated in lasting bureaucratic form capable of ensuring that governance ethical standards are not only authoritatively established but also monitored and assured through *policy implementation*? In the answer to that question lies a measure of the extent to which bioethics as an epistemic community has established a power position within the state apparatus.

In a carefully orchestrated symbolic act notable for its timing and venue, at the 8th World Bioethics Congress in Beijing in August 2006, Liu Yanfei, the Director of the MOH's science and education department, announced plans for China's first comprehensive system for the ethical review of biomedical science (Jia 2006). In January 2007 the MOH *Regulation on Ethical Review of Biomedical Research Involving Human Subjects* was duly introduced, embedded within which was the MOH Ethics Committee (Ministry of Health 2007). Although the Committee had existed in an advisory capacity since 1998 and had acted, for example, as the vehicle

for the development of the *Ethical guiding principles on human embryonic stem cell research*, the 2007 *Regulation on Ethical Review* gave the Committee and the new bureaucratic infrastructure of ethical review in China a formal legitimacy. It states that the MOH has established the Ethics Committee 'to reinforce the management of biomedical research ethics, to meet ethical standards of biomedical research, and to be responsible for the public health' (Appendix 4, section 1). Importantly, within its jurisdiction lie all international human biomedical collaborative projects (Appendix 3, section 26). In exercising its declared responsibility for human biomedical research, the Committee is to be supported by a network of ethics committees established in each provincial, autonomous-regional and directly-administered-city health bureau (Appendix 3, section 6). However, the relationship between the MOH Ethics Committee and the local government ethics committees is described as 'not superior-to-subordinate but one of professional guidance' (Appendix 3, section 13).

Nonetheless, despite this caveat regarding the power of the MOH Committee over the structure for which it is responsible, the *Regulation* provides a national framework on which China's bioethics community can build, if it is so inclined. Once developed, the national ethics committee structure could then act as the bureaucratic vehicle for the continuing implementation of biomedical regulatory policy. The indications are that this process is underway with the MOH Committee drafting constitutions for the proposed local government committees and principal investigator application forms; and monitoring and evaluating existing institutional ethics committees (Qiu 2007).

If bioethics in China is to enhance its power base and act as an agent of policy implementation in stem cell science as well as one of policy agenda setting and formation, much will depend, as Haas suggests, on how it plays the bureaucratic game. In moving into this phase of its relationship with governance development, bioethics will be concerned to produce a new type of ethical knowledge: one that is bureaucratic in its purpose and content and thus able to integrate easily with the bureaucratic discourse of government. Its first task will be to consolidate its position within the MOH and ensure that, where ethical judgements are concerned, the Ethics Committee is the primary decision making forum. The new *Regulation* recognises this right with regard to all MOH funded projects. It will be important that the same right is applied to other regulations that impact on basic stem cell science. In particular, governance of the supply side of human ESC research (oocytes, embryos and sperm) has a strong ethical component and also falls under the aegis of the MOH.

Bioethics has already been involved with this aspect of stem cell science regulation and, again, the influence of its global networks is apparent. In October 2003 the MOH introduced three new administrative regulations on reproductive medicine and IVF clinics that set out the ethical principles governing assisted reproductive technology (ART) and human sperm bank management. The creation of embryos is dealt with in detail. Superstimulation, as opposed to therapeutic stimulation, of the ovaries is forbidden and informed consent must be obtained from the donor. Embryos are to be created solely for the purpose of procreation but superfluous embryos may be donated for medical research, again on the basis of informed consent from the donor, but such embryos cannot be used for the purposes of reproductive treatment. Nor can they be traded (Ministry of Health 2003). All of these regulatory principles resonate strongly with the mainstream position of Western countries.

Although the implementation of these regulations is now backed by a licensing system, this has had its problems and the MOH Ethics Committee may feel it would stretch its bureaucratic resources if it became too closely involved in monitoring their effectiveness (Leggett 2003, Jia 2006). In addition, its ability to influence the delivery of stem cell governance is hampered by the fact that the majority of funding for the basic stem cell research comes not from the MOH but from the MOST. For its own part, and perhaps indicative of inter-departmental competition for bureaucratic control over the production of bioethics governance, the MOST has been active in developing its own bioethical agenda with the promulgation in 2007 of the *Regulation on misconduct in scientific research*: a high profile policy response to reported scandals over research fraud and plagiarism (MOST 2007, Cyranoski 2006a). The *Regulation* is to be supported by a science ethics committee and a supervision office responsible for a fraud investigation team, case discussion and handling, and the handing down of punishments for science frauds (China View 2006).

A key question, yet to be resolved, is how the bureaucratic infrastructure of ethical review sponsored by the MOH will relate to the procedures of its sister bureaucracy the MOST. Clearly both ministries are ambitious to develop forms of bioethics governance that they rightly see as a vehicle for China's, and their, enhanced status in the international scientific community. From the perspective of China's bioethics community, such a competition is to be welcomed if the consequent demand for their political services increases their value and the likelihood that their knowledge domain will achieve a permanent position in the policy process. In terms of the international credibility of Chinese bioethics, much will depend on how far the implementation of the policies it sponsors are achievable and how far they can be integrated across responsible bureaucracies. It is worth remembering that both the MOH and the MOST regulations lack statutory backing, as do the guidelines on human embryonic stem cell research, and for their effective delivery are obliged to rely on purely administrative authority. What might consequently be termed a 'governance knowledge gap' provides an opportunity for other members of the global epistemic community of bioethics to provide policy implementation support. In this respect, the bioethics community of the United States has been, and continues to be, a prominent player. For example, building on established institutional links between Chinese and American academic institutions, in October 2007 the American Association for the Advancement of Science (AAAS) and the China Association for Science and Technology (CAST) hosted a high profile joint conference and meetings in Beijing on the development of common ethical standards and practices, with a strong presence of American bioethicists (AAAS 2007).

**Conclusions**

In China, the co-production of governance knowledge and scientific knowledge in basic stem cell science is characterised by an active epistemic community of bioethics with an increasing ability to access the state policy making apparatus in terms of agenda setting, policy formation and, potentially, policy implementation. Informed and supported by a continuing interaction between Chinese and global networks of bioethics, particularly those of the United States, the production of bioethical knowledge in China is aimed at establishing the governance functions of standard setting, monitoring and assurance as solid bureaucratic components of the state regulatory policy acting in support of China's entry into this part of the global

bioeconomy. As the global pressures for China's adaptation to various dimensions of international governance consequent upon its engagement with the global bioeconomy have mounted, so China's bioethical epistemic community has evolved as part of the country's overall political response. Penetration of the state bureaucratic apparatus of the MOH and the MOST by the networks of that community has been achieved and is apparent both in the continuing production of ethically informed reports and in the introduction of structures with an ethics governance remit. Importantly for China's ability to compete in the global bioeconomy of stem cell science, the values embedded in its regulations and guidance (general and specific) for the conduct of basic stem cell research are readily compatible with the mainstream global position in the field. Such harmonisation of national and international ethical standards has been promoted by Chinese bioethicists and scientists alike, and supported by the state, as a necessary condition for the legitimation of Chinese stem cell science and the integration of China into the international scientific community – with all the benefits that can deliver. This is not to deny the plurality of positions that may co-exist within Chinese bioethical debates on stem cells but to recognise the nature of the view that is politically dominant.

Although the production of governance in China has clearly addressed the standard setting and monitoring functions, it is less obvious how these standards will be assured and enforced. With the MOH Ethics Committee only recently established, the creation of a bureaucratic infrastructure of ethics committees at regional and institutional levels with the appropriate constitutions and membership is a multi-level governance project still very much in the making. Much will depend on the investment and training provided in support of this process of policy implementation (Cyranoski 2005).

This paper has focused on basic stem cell science, the first stage of the biomedicine innovation process. Much will depend also on the ability of the bioethics community to influence the course of governance development in the subsequent stages of translational research where the tensions between science, society and the market may take more acute forms. Problems of public trust resulting from the inadequate governance of translational research would be bound to impact on national and international perceptions of basic stem cell research in China. The governance of one stage of the knowledge production process cannot be conveniently politically insulated from the governance of another stage. Given that Chinese medical scientists are already engaged in providing experimental stem cell therapy for spinal injuries, ataxia, stroke, brain injury and cerebral palsy (sometimes with the explicit admission that their clinical experiments have no clear theoretical basis and would not meet Western ethical standards (Watts 2004)), and with some Western scientists anxious to collaborate in order to test new treatments, this is already a politically sensitive area (China Stem Cell News 2008, Cyranoski 2006b). The suspect ethical standards of some foreign researchers in Anhui province have already raised questions about the ability of China's governance of translational research adequately to protect its population (Cyranoski 2006a). Dealing with such pressures will require an expansion of both the Chinese bioethics community's governance knowledge production and its bureaucratic networks beyond the MOH and the MOST to include the State Food and Drug Administration (SFDA) and other agencies.

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