The Bioethical Vacuum: national policies on human embryonic stem cell research in India and China

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Abstract
Developing countries have sought to profit from the *bioethical vacuum* that has come about when President Bush in 2001 called for a moratorium on federal funding of human embryo stem cell research (hESR). Seizing the opportunity, both China and India started to invest proportionally many available resources in advanced technology and hESR, in the hope to achieve economic success. We argue that for the following reasons this field is hazardous especially for large developing countries:

a. Capital resources are relatively important to poorer countries;
b. Lucrative applications are not guaranteed: losses are harder to compensate in countries with little surplus;
c. The benefits of possible profits may not go to the needy;
d. It may be harder for China and India to advance in these advanced fields because of their institutional history in the field of science and technology;

e. Even if applications are successful, there is a chance of developing countries becoming so-called techno-coolies: supplying standard advanced technologies, using human resources that are rare elsewhere in the world;
f. A rush to grab the emerging opportunity obtained as a result of the *bioethical vacuum* may lead to overlooking appropriate monitoring and regulatory measures, hampering the formation of long term international collaborations and public trust.
Secondly, we discuss government policies on the institutional aspects of hESR that have made China relatively attractive to foreign investors compared to India. In the concluding part, we discuss various dimensions of bioethics with regards to hESR, and how governing bodies mobilise cultural resources as economic capital.

**Introduction**

Before the political and economic reforms in China and India during the last quarter of the 20th century, the immense capital injections into pioneering fields of science and technology from abroad and at home were unimaginable. Both the socialist reforming regime in China (since 1978) and the Hindu nationalist regime in India (in the late 1990s) encouraged public and private financial ventures in the fields of information technology and molecular biology.

Arguments concerning the development of new technologies have been framed in terms that privilege the development of the nation-state. For example, until less than a decade ago, taking into account the size of their respective populations, in China no use was found for cloning technologies. Although the technique of, for instance, interspecies cloning of carps in China had become common practice, Qi Yaqiang, a demographer at Peking University, argued that China should not extend cloning technology to making people in the laboratory. After all, China had no need for more people, but required better education (Mann 2003). Attitudes toward cloning, however, changed in November 1998, when James
Thomson of the University of Wisconsin announced the isolation of embryonic stem cells [ESCs]. And suddenly, cloning - or, in this case more precisely, somatic cell nuclear transfer (SCNT) - seemed to promise more lucrative prospects and widespread application in the shape of freshly bred spare-organs and gene therapy.² Developments in stem cell technologies now began to mobilised in support of policies that emphasised the improvability of the quality of people’s health, in line with population policies which no longer just emphasise the ‘quantity of the national population.’. But the question of whether applications of the new genetic technologies would benefit the gross population in these large developing countries was not a part of the official political debate.

When in 2001 President Bush announced a moratorium on the federal funding of stem cell research, both China and India were ready to jump into the bioethical vacuum that had come about as a result of what were regarded as Western moral scruples about the value of fertilised human cells. At this point the economy of bioethics in national policy-making became of great relevance to policy-makers. Since then, in both nation-states protagonists of hESR indicated the suitability of their cultural national heritage to the development of modern biomedical

² The success of cloning using nuclear transfer (the same technique used to produce Dolly the sheep) showed that the nucleus of a differentiated cell, for example a skin cell, from an adult, can be reprogrammed and reprogrammed into an embryo-like cell that can give rise to all cell types and tissues (Wilmut 1997: 810–813).
technologies. Thus, Vinod Skaria declared: ‘The epics and innumerable religious texts that are in many parts of the world acclaimed as having scientific value, may partly be the reason for the scientific temper inculcated in this part of the world’ (Scaria 2002), while some Chinese scientists claimed as common knowledge that: ‘In the Confucian tradition, human beings achieve personhood only when they're able to participate in society. By this way of thinking, fetuses aren't human - they're part of Nature’ (Mann 2003; Qiu 2006; Sleeboom-Faulkner 2007). Expressions of bioethical scruples regarding the use of the embryo are hard to find, and seem to form no obstacle to the advance of hESR. But although hESR would bring benefits to those suffering from Parkinson’s, Alzheimer and other diseases, as will become clear below, in both countries the most basic health care facilities seem to be unreachable by a large part of their populations.

The bioethics of hESR has been discussed at length in Western countries (Cf. Holland et al 2001) and some Asian countries (Bender et al. 2005; Salter 2007, 2008), but no comparative studies have been made on the economic exploitation of cultural and bioethical differences by governments, who are also in a position to design regulations for research. This paper explores the issues regarding the relative risks of large developing countries channelling a large proportion of public resources into the development of advanced genetic technologies, and discusses

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3 It is unlikely, however, that no moral scruples exist at all. In a 1993 survey 41% of Indian people strongly disagreed to abort a four-months old fetus if it was not suffering from any diseases (Macer 1994: 184-187).
government strategies in different academic cultural contexts. In doing so, this paper hopes to shed new light on the economy of bioethics in policy-making and research institutions.

**Human Embryonic Stem Cell Research (hESR) in India and China**

*India’s hESR*

India is a developing country with a population of over one billion, a large part of which lives in poverty and has little access to modern medicine (WHO 2007). On the other hand, India is counted among the most industrialized countries in the world, with the largest pool of English-speaking scientific and technical professionals outside the United States. It has a well-established pharmaceutical industry and continues to be the world leader in the information technology sector, which has generated a burgeoning bioinformatics industry. In fact, India's information technology, computer software and service industry grew from about $500 million to more than $6 billion in exports over the 1990s (*The Economist* 2003: 57).

India's biotechnology and pharmaceutical industries are in a position to prioritize and develop pioneering technologies. Thus, the US Department of Health in 2002 announced that the US federal government would fund 64 existing stem-cell lines created opportunities for stem cell research in India. Reliance Life Sciences
(RLS) in Bombay (though based in Bangalore) had available seven stem lines derived from embryo donors and the National Centre for Biological Sciences (NCBS) in Bangalore, which has been working on stem cell lines since 1999, and three stem lines derived from frozen embryos. RLS, backed by the powerful Reliance Group, ranks third among the top-10 institutes world-wide working on stem cells, and is the first company in India to market cord blood stem cells in the form of Relicord.4

Although at a nascent stage, stem cell therapy is a rapidly growing field in the Indian market, and currently there are over 40 institutions and hospitals involved in stem cell research (Dey 2007). The main features of the strategy for stem cell research in India are characterised as follows:

- to promote basic and translational research in the country;
- to establish a Centre of Excellence (CoE);
- to create virtual network of centres;
- the generation of adequate human Embryonic Stem Cell (hESC) lines; and,
- human resource development through training and short and long term overseas fellowship.

To boost the public-private partnership effort in the country, the Department of Biotechnology has initiated a new scheme called Small Business Innovation

4 Relicord is a product used to treat patients with disorders like thalassemia or leukaemia (Chaturvedi 2002: 32).
Research Initiative (SBIRI). SBIRI is to provide support to high risk – preproof –of –concept research and the late-stage development of research in small and medium companies, lead by innovators with science backgrounds (Express Pharma 2006).

Both the government and private industry have invested heavily in research institutes studying stem cells. In 2002, the Ministry of Health earmarked over US $30 million over five years for genomics, stem cell and structural biology research. And the funding was to be divided among various research centres and medical institutions under the direction of ICMR, and would focus, among other diseases, on leprosy, tuberculosis, rheumatic fever and thalessemia (Chaturvedi 2002).

In terms of investment in the biotechnology sector, India has expanded its R&D base to about 25% in its 2005 research budget allocation – the highest rise in Asia and comparing favourably with that of China (16%) and Korea (10%). It has increased its budgetary allocation for medical biotechnology from 13% in its Ninth Five-Year Plan to 36% in its Tenth Five-Year Plan. The priority of research has also moved to a greater emphasis on the clinical application of stem cells and the commercialization of a tissue culture programme (Salter et.al. 2007, Nair 2001). The estimated market of stem cell research applications in India is $500 million. The stem cell market is growing at a rate of 15 per cent per annum and is expected to hit $540 million by the year 2010 (Dey 2007). Major stem cell research facilities are available at PGIMER, Chandigarh, SGPGIMS, Lucknow, KEM Hospital, Mumbai and L.V. Prasad Eye institute, Hyderabad. In embryonic stem cell research, NIRRH, Mumbai, the National Centre for Biological Sciences, Bangalore, NCCS, Pune and in cancer stem cells, Indian Institute of Sciences (IISc), Bangalore are some of the
leading institutes. In 2003, the Ruby Hall Medical Research Centre, a subsidiary of Pune-based Ruby Hall Clinic, and Denmark-based biotechnology company Mesibo formed a 49:51 joint-venture with the aim to establish India's largest cord blood storage facility at Pune.

Research, health and regulation

The World Health Organization (WHO), an international aid institute, in its 2002 report on Genomics and World Health urged member states to build genomics and bioinformatics capacity for research towards their own health priorities in order to address global health inequities (WHO 2002). The report emphasized that India can and has already begun to translate its successes in software technology into bioinformatics capability. But for obtaining broad support among the population, it is crucial that it will prioritize the country's health needs and strategic entry points.

As summarised by Acharya et al. (2004: 2), an estimated four million people are living with AIDS in India, over two million people are infected with malaria per year, and over 420,000 Indians die annually from tuberculosis.\(^5\) On the other hand, chronic diseases like cancer, diabetes and heart disease are also prevalent in India, whose rising health threat is hoped to diminish through the development of therapies in the promising fields of stem cell research and genetics. Both of these broad categories of disease, i.e. infectious diseases and chronic diseases, present R&D

opportunities for India. The questions here are whose and what needs are R&D organisations going to address, and whose interest a focus on stem cell research would serve in the long run?

The stem cell therapy industry in India is booming without being constrained by any binding regulation. Unorganized, unscientific ‘research’ is frequently being passed off as therapy. In recent years there have been a number of press reports of unethical practices in stem cell therapy and research in India. Regarding unethical practices around stem cell research in India, Dr. Vasantha Muthuswamy, the Senior Deputy Director General of ICMR, said ‘we want to promote stem cell technology but not in this scandalous way’ (Srinivasan 2006). *Guidelines for Stem Cell Research and Therapy (2007)* in India have been formulated jointly, by the Department of Biotechnology (DBT) under Ministry of Science and the Indian Council of Medical Research (ICMR) (Kumar 2008). These guidelines address the derivation, propagation, differentiation, characterisation, banking and use of human stem cells for research and therapy. According to the guidelines, depending on the source of stem cells and nature of experiments, the research on human stem cells is classified under permissible, restricted and prohibitive categories. The research pertaining to adult and umbilical cord blood stem cells is classified as permissible, but requires approval from an Institutional Bioethics Committee; human embryonic stem cells research falls under a more restricted category. It can be carried out with the approval of Institutional Committees and the National Apex Committee. Research pertaining to reproductive cloning and research involving the introduction
of animal embryos in humans have been classified under the category of prohibitive (DBT-ICMR 2007, Sharma 2006).

In India’s regulatory history, the focus of hESR debate has been on the US-funding of Indian stem cell lines and its future possibilities, rather than on the possible bioethical issues at home, though some provisions were made. As the Indian government was concerned about the possibility of the rampant sale of stem cells from aborted foetuses and frozen embryos in IVF clinics to the US (Chaturvedi 2002: 31), strict research guidelines were added. Guidelines stipulate that though medical termination of pregnancy (MTP) of the foetus is permitted according to the MTP Act of 1971, pregnancy may not be terminated for research or transplantation. Spare embryos from artificial reproductive technologies (ART) and IVF clinics are indicated as the main source for stem cell research (ICMR 2003: 3-4). Scientists may harvest human embryos for research before day 14 of gestation with the informed consent of the donor. And as pointed out above, all projects have to be approved by institutional ethics committees and the national bioethics panel (National Apex Committee [NAC], ICMR). Additionally, researchers are expected to share with the donor the commercial benefits that flow from embryonic stem cell lines.

Although the guidelines intend to provide a mechanism to ensure that research within human stem cells is conducted in a responsible and ethically sensitive manner and complies with all regulatory requirements, there is still a lack of guidelines for commercial activity and clinical therapy in India (Dey 2007). It is
significant to note that the DBT-ICMR’s *Guidelines for Stem Cell Research and Therapy (2007)* is a soft law and is not legally binding until approved by parliament. With the lack of clarity in the guidelines about penal sanctions, widespread violations are taking place regarding both stem cell research and therapy. These violations are committed both at public and private institutions. Examples are the well publicised case of Geeta Shroff’s clinic in New Delhi, making unsubstantiated claims of having cured hundreds of patients suffering from Alzheimer’s disease, paralysis and Parkinson’s disease using embryonic stem cell therapy, and the case of the All India Institute of Medical Sciences (AIIMS), a premier public medical institute based in New Delhi also claiming without substantiation to have conducted stem cell therapy using Positron Emission Tomography technique (Srinivasan 2006).

A recent case was highlighted by a report, which shows how a private health care institute, the Life Line Hospital in Chennai has entered into questionable clinical applications in violating DBT-ICMR guidelines. Life Line Hospital is believed to have obtained its stem cells from another private institute, Nichi-In, which has ICMR’s approval to conduct only basic research on stem cell biology (Pandya 2008).

In short, although India has in place regulation for stem cell research, its inadequate capacity for enforcement renders it relatively toothless.

*China’s hESR*

China is a developing country with a population of approximately 1.3 billion people. A large part of its people lives on the edge of poverty with even less access to
modern medicine than the Indian poor. However, China is the world’s fastest industrializing country, with a fast growing pool of scientific and technical professionals that is increasingly proficient in English. China has a fast growing pharmaceutical industry, and a rapidly developing information technology sector. In China, the field of stem cell research is less controversial than in Europe and the US, and the government has erected state-of-the-art laboratories, created university appointments with tempting perks, and continues to provide the funding for establishing new biotech firms.

Though most research focuses on agricultural technology, Beijing has been spending millions of dollars annually to offset and advance its biomedical research. Between 1996 and 2000, the central government invested over 1.5 billion Yuan ($180m) in biotechnology, as part of its main programme to kick-start the sector (The Economist 2002). In February 2000, the government announced an additional $350 million funding for genomics and biotechnology through its priority 863 R&D programmes over the period 2000-2005 (WHO 2002: 106). China’s annual investment in stem cell research has been estimated at between US$4 and 10 million with 300 researchers working in 30 separate institutions with a dramatic increase being planned. Between 2005 and 2010 China’s Ministry of Science and Technology (MOST- the main source of public research funds) is expected to spend

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6 China’s spending on biotechnology in 2002 totalled $272.4 million, up from $31.5 million in 1986 (Red Nova 2003).
between US$63 million and US$0.25 billion, depending on how productive the science turns out to be (Salter 2008, UK Stem Cell Initiative 2005).

In late 2002, the Chinese Government approved the setting up of the country's first state-run stem cell bank in Tianjin, aiming at developing treatments for various diseases and the set up of a stem cell transplant centre. Since then, Chinese scientists have made rapid progress in many areas of stem cell research and foetal stem cell banks can now be found in a number of Chinese regions, including Beijing Municipality and Shandong and Guangdong provinces. In 2004 the 863 Program, the key Technology R&D Program, and the 973 Program were the three biggest MOST programs, constituting 72% of MOST’s total R&D funding allocation (Salter 2008). In addition, regional governments play a significant role and the State’s Natural Science Foundation of China (SNSF, Guojia Ziran Kexue Jijin) is a substantial source of funding for basic science (providing one-third of the total basic science budget, about US$0.25 billion in 2002).

Stem cell research is mainly conducted at national and elite university laboratories. The Peking University Stem Cell Research Centre, Sun Yatsen Medical University, Shanghai No 2 Medical University and the Xiangya School of Medicine at South Central University in Changsha, Hunan province, are reportedly the most progressive in the field. The Ministry of Health in late 2002 reported the successful production of embryonic stem cell systems at the Stem Cell Research Centre of the Second Hospital attached to Sun Yat-sen University. The centre was early to succeed in inducing mice embryonic stem cells to develop on into
hematopoietic stem cells, an achievement considered of great value to the development of hematopoietic stem cell transplants in clinical practice (Wang Qian 2002). The same hospital attracted world-wide attention when under the leadership of an American researcher, James Grifo, an infertile woman was made pregnant with triplets through somatic cell nuclear transfer (SCNT). Though in the U.S., the FDA had admonished Grifo, as the use of this technique on humans is banned in the U.S., Sun Yat-Sen University had approved the experiment (Weiss 2003: A10).

In 2003, the team of foreign-trained scientist Sheng Huizhen of Shanghai Second Medical University,7 was reported to be the first in using somatic cell nuclear transfer (SCNT) to create hybrid embryos, fusing human skin cells with a rabbit egg, for scientists to retrieve embryonic stem cells (China Daily 2003). Though controversial in the Chinese press and among Chinese researchers (interview with A, embryologist at Sun Yat-sen University, 30 April 2007), a report appeared in the peer-reviewed scientific bimonthly Cell Research (and highlighted in a news report in the journal Nature) expressing the hope that the new method would facilitate the mass-production of ‘human’ embryo stem cells (Chen 2003: 251–263).8

7 Sheng studied in Australia and worked for 11 years at the U.S. National Institutes of Health before returning to Shanghai in 1999 to head a stem cell research centre.

8 Cell Research is a journal affiliated with the Shanghai Institute of Cell Biology and the Chinese Academy of Sciences.
In Southern China's Hunan province, the Xiangya School of Medicine, reported similarly great achievements. For instance, the School claimed that it had cloned a human embryo two years before the U.S. company Advanced Cell Technology Inc (ACT) had announced its cloning success. Lu Guangxiu, who directs a large fertility clinic, declared that her team had grown embryos to a 200-cell ‘blastocyst’ stage, large enough to harvest hESCs (Lu et al. 2003). If in need of research materials, Lu simply asked some of the dozens of women who walked through her door each day to donate their leftover eggs. Lu claimed that five percent of her cloned embryos develop into blastocysts. In 2007, according to the Xiangya research team establishing human embryonic stem cell lines, the number of reliable human embryonic stem cell lines available in their laboratory numbers over a hundred (interview, Prof. D, 28 March 2007).

Nevertheless, great optimism about scientific advancement is hardly called for. Though Chinese scientists have produced transgenic rabbits, goats, cows, and even hard-to-clone rats within a few years (Zhou et al. 2003: 1179), human-embryo research is still in its infancy in many ways. Not one of the new generation stem cell researchers trained abroad claims China to be a world leader in the field at present (interviews with over 30 stem cell researchers in 2007). And even though China acquired the necessary technologies to produce transgenic animals and pharmaceutical proteins decades ago, it has shown hardly any signs of the production, let alone commercialization, of such proteins.
Research policy and bioethical regulation

Considering these on-going research activities, the restrictive regulatory policy of the Ministry of Science and Technology (MOST) may come as a surprise (Cf. Doering 2003). On 1 October 2003, the MOST and the Ministry of Health (MOH) promulgated new regulations for reproductive medicine and human sperm bank management (MOH 2003). Though they do not have legal status, they do have strong political authority. These guidelines explicitly prohibit reproductive cloning, specifically mentioning the exclusively experimental use of the technique of SCNT in humans, while emphasizing that only spare embryos from ART/IVF may be donated to medical research upon the express wish of the donors only (MOFA 2003).

In January 2004, MOST implemented the new ‘Ethics Guidelines for hESR, explicitly forbidding ‘human reproductive cloning’ (art. 4), while allowing ESR within a period of fourteen days since fertilization or nucleus transfer (art. 6). Thus, while in vitro embryo research, including SCNT, is permitted, the implantation of the embryo in question into the uterus is not. Furthermore, any trade in human gametes, fertilized eggs, embryos and foetal tissues is prohibited (art. 7) (Legal

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9 A summary of the ethical guidelines that regulate hESR are available at:
Applied to the aforementioned examples, Grifo’s practice of SCNT and Lu’s nonchalant way of obtaining embryos do not tally with the current guidelines. On the other hand, the question comes to mind as to what extent biomedical research in China is directed at remedying the abominable state of current healthcare provision (Blumenthal & Hsiao 2005; Liu & Rao 2006).

In the regulatory area of stem cell therapy China, similar to India, has salient, and in international medical circles, sensitive gaps. In Beijing, a medical scientist, Huang Hongyun, and in south China’s Shenzhen, the Beike Hospital are involved in the lucrative activities of providing stem cell therapy for Chinese patients and medical tourists from all over the world, claiming to help patients with spinal injuries, ataxia, stroke, brain injury and cerebral palsy (Watts 2004; Cyranoski 2006; http://www.stemcellschina.com). Though sometimes accursed of clinical experimentation, these practices mainly flourish for their lucrative work on the basis of the despair of patients with life threatening diseases and the patient’s families. As patient records in these hospitals are closed, and scientific explorations into the nature of the therapies are not explored, these therapy providers can hardly be subsumed under the category of science. Nevertheless, the potential for bioethical exploitation in these hospitals and controversy around their practices call for regulation and supervision by independent organs of oversight.

In short, China’s regulation for hESR is based on soft guidelines, not legislations. There is no licensing system for hESC research, no effective infrastructure for hospital monitoring no inspection at all for stem cell research in laboratories, while
ethical expertise at a local institutional level is only in a nascent stage in metropolitan urban areas and hardly functioning elsewhere. And as not all hESC research is funded by the Ministries (MOST and MOH), bioethicists, such as Qiu Renzong and scientist Liu Bin, now call for a broader national framework for setting up such guidelines (interview, 16 November 2007).

Just as does the Indian government, the Chinese government also faces sensitive and controversial issues regarding the prioritization of the country's health needs. Shortly after the start of the reforms associated with the Deng era, in 1978, the healthcare system of China collapsed (Pongor 1987). Though Chinese economic growth has lifted about a third of its population out of poverty, in the countryside, 90% of the population is uncovered by health care insurance; in the cities the percentage is approximately sixty (The Economist 2004). This situation has hardly improved since. According to the WHO ranking of the public-health systems in 191 countries, China was placed at 144, while India, which has half China’s GDP per head, came in at 112. And even though China has no shortage of medical facilities, its sources may be spread too thin. Though twice as many children in India die in the first few months of life and twice as many mothers die in childbirth, there are huge disparities between the regions. While, as for health care, China’s coastal areas are nearly as well off as some Western countries, in other regions, besides


11 China has 1.6 doctors per 1,000 compared with 0.4 in India, and 2.4 hospital beds per 1,000 people compared with India’s 0.8 (The Economist 2004).
undernourishment, diseases such as tuberculosis, measles and snail fever have re-emerged. Though compared to India few, the Chinese government estimated that only 840,000 Chinese people are HIV carrier, while the WHO estimates that this number could rise to 10 million by the end of the decade (Meng & Chen 2004). Similar to the changing health situation in India, chronic diseases such as cancer, diabetes and heart disease are on the increase among the wealthy and pose a rising health concern. In China too moral choices are to be made and long-term public health care strategies to consider.

**Governance and the institutional planning of hESR**

Sufficient and sustained investment is a fundamental requirement for leadership in science and technology. Despite major investment efforts by their governments, the to science and research allocated quantities have been limited compared to richer welfare societies. In this respect China and India remain ‘developing’ countries. When it began to step up support for hESR, the Chinese government still fell far behind more ‘developed’ countries in its commitment to R&D. China only spent US$12.5 billion (1.1% of its GDP) on R&D in 2001 (*China News 2001*). From 2000 to 2005, the government provided research in biotechnology with about 10 billion
Funding for research and development (R&D), then, has shot up, both as a percentage of the GDP and in absolute terms (See Table 1).

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<th>Year</th>
<th>R&amp;D (Billion Yuan)</th>
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<td>2006</td>
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In February 2006, the State Council issued the National Medium-and Long-Term Programme for Science and Technology Development (2006-2020) [Guojia Zhongchangqi kexue he Jishu Fazhan Guifan Gangyao (2006-2020)]. China planned to become an innovative nation in the next 15 years and a world power in science and technology by the middle of the 21st century. The Outline Programme announced that the Annual R&D is expected to be 900 billion Yuan in 2020, or 2.5% of its GDP, while progress of science and technology is expected to contribute 60 percent or more to the country’s development. Together with IT, the Outline emphasises biotechnology as its main priority.

12 Mainly through the funding schemes of the Ministry of Science and Technology (MOST, over 5.7 billion Yuan), the China Petrochemical Development Corporation (CPDC, 1 billion Yuan), the National Science Foundation of China (1.5 billion Yuan), the Chinese Academy of Sciences (500 million Yuan) and local governments (1 billion Yuan) (Finpro, available at: www.finproevents.fi/tiedostot/default/finpro1000000260.pdf).

A major question for large developing countries therefore is how to invest relatively scarce resources without being overtaken by competitors in the long run (Bhutta 2002). In other words, to what extent were China and India in a position to have a chance to succeed in becoming world leaders in developing stem cell technologies, and to what extent would the allocation of scarce financial resources in this area respond to the wishes of their respective populations?

The Indian researcher Ramachandran and the Chinese researcher Yang Xiangzhong made clear that they are worried that the investment into biotech research may increase, but that a lack of a broad interdisciplinary basis and also a lack of co-operation between scientist and a concerted research effort at home, will render it ineffective (Yang 2004; R. Ramachandran 2000). Furthermore, in India worries exist that scientists may just turn into techno-coolies in the service of foreign conglomerates, and stay behind in the production of useful research results (Rajan 2007). Similarly, bioengineered products in China may not be the result of avant-garde research either, but a matter of the outsourcing of science research highly on the value chain of production (Ross 2007). Virender Chauhan, director of the New Delhi-based International Centre for Genetic Engineering and Biotechnology (CGEB) complained: Almost all the biotech products so far have

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14 According to the economist newspaper, the approximately twenty genetically engineered medicines approved for sale in China ‘are little more than high-tech knock-offs of rich-country inventions, introduced when China had little interest in intellectual-property rights’ (The Economist 2002).
been indigenous versions of existing products. It is beyond any Indian drug firm to even think of bringing out a novel product, let alone new drugs’ (Kalshian et al 2002). They may just produce cells, not stem cells, and publish no scientific papers in leading peer-reviewed journals (Ramachandran 2000). For, it is the relative advantage that is important in reaching the forefront of scientific development: can developing countries afford that?

Answering these questions also requires knowledge about why and how various countries attract investments. For, compared to the PRC, India seems to be much less successful in attracting capital. Even though the investment in biotech start-ups in India has grown over the last decade and the government has injected much capital into the biotech sector, biotech companies in India are finding it difficult to secure enough venture capital from local investors. The total amount of venture capital invested into the biotech sector in India is only a small part of the total. Instead, the money is pumped into local IT ventures. According to Vijay Angadi, managing director of ICF, an Indian venture capital firm, from 2001 to 2003, India's biotech industry won just $50 million of the estimated $1.8 billion in total venture capital spending (Wallace 2004). Perhaps this was due to the global uncertain atmosphere around biotechnology at the time and the long wait required for returns. However, other countries seem to be capable of attracting funding. And US private-equity companies that have shown an interest in biotech start-ups are not

15 Since its inception in 1986, for example, India's DBT has invested $500 million toward R&D projects in national labs.
often interested in India's biotech start-ups. Amidst a global turndown in investment in the biotech sector, the money is increasingly getting funnelled into ‘proven’ locations, i.e., politically stable environments without a history of scandal, which does not include India (Wallace 2004). In comparison, China has been more successful in attracting investors. In the next sections we discuss science-policies in the two countries, emphasising policies on hESR.

**Stem cell research policy in China**

To understand China’s relative success in attracting collaborators in the area of stem cell research it is important to observe its institutional embedding. After pointing out some similarities between the hESR situation in China and India, we discuss science policies on the organisation of knowledge, division of labour and research regulation in China that seem to make a difference. In view of the descriptions above, it is clear that India and China share various characteristics and are in a similar situation vis-à-vis decisions to be made about stem cell research:

- Both are large developing countries and have implemented radical economic reforms over the last decades;
- Both have problems of overpopulation and health care provision;
- Efforts are made in both countries to combine government and private efforts in various areas of research and the development of modern science and technology in particular;
- Both have jumped into the bioethical void regarding stem cell research;
- Both have strict regulation for the movement of genetic materials abroad, but are less strict in implementing bioethical guidelines at home;
- Both profit from a symbiosis between IVF provision and the development of stem-cell research;
- Governments in both countries encourage hESR, allowing the use of both spare-embryos and cloned embryos for research.

One way of attracting expert knowledge is tempting overseas students to return. In its attempt to entice researchers back to their motherland, in September 2002, the government started a recruitment drive to attract two hundred scientists from abroad with the promise of western-style salaries (The Economist 2002; Cao 2004). China has acquired technological expertise in the area of genomics through their return, such as Deng Hongkui, Pei Duanqing, Zhang Yu, Li Lingsong, Gao Shaorong, and Liu Jia'en who now head key laboratories in the field. Additionally, attracting Western-trained scientists in the embryo biotechnology field, not only means acquiring up-to-date expertise and technology, but also a particular mentality for teamwork and collaborative research (Cho 2002; Sleeboom-Faulkner 2008). Furthermore, the government encourages interactions such as collaborative research, conferences and joint publications between centres and other research laboratories through funding and promotion incentives (Anon. 2005).

A typical set-up among leading hESR laboratories involves the following ingredients:
- a partnership of a foreign-trained expert with a local Chinese researcher;
- a start-up government investment;
- a sufficient supply of embryos;
- re-investment of capital in lucrative trade to become independent; and,
- collaboration with foreign companies.

For example, after working in Belgium and the United States, Liu Jia'en collaborated with Chen Dongfeng to establish the Shanhai Huide IVF Clinic in October 2001 with an initial start up investment from the government of RMB 50 million (about $ 6 million). Performing over 3,600 operations at RMB 30,000 (approximately $ 3,600) apiece, they project a net profit of RMB 50,000 (about $ 6,000) for their first year (Cho 2002). From these operations, Liu Jia’en collected a large number of high quality embryos and reinvested profit into developing human embryonic stem cell research and into therapies for profit. Leaders with similar set-ups include Deng Hongkui at Beijing University, Li Lingsong at Beijing Medical University, Zhang Yu at China’s Capital medical University, Gao Shaorong at Beijing’s National Institute of Biological Sciences (NIBS), and Pei Duanqing at Sun Yatsen Medical University.

The limited means for funding make it important for the government to concentrate on a few fields of genomics only and just invest in a few select centres (interview Professor C, 4 April 2004). Although the gap between embryo research in China and other countries is not that great, bringing these technologies through

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16 Even though most scientists, when asked, did not object to their name being mentioned in our publications, some of the interviewees we refer to as A, B, etc., as we do not wish to attract attention to scientists personally.
clinical trials and into the market requires expertise in a wide variety of disciplines, from molecular, cellular and developmental biology, to immunology and genetics, transplantation biology and clinical medicine. Chinese stem-cell researchers seem to divide up the disciplinary field. Deng Hongkui from Beijing University examines how the body directs stem cells to differentiate (interview, 16 March 2007); Lu Guangxiu and her team in Changsha, in addition to creating new lines of stem cells, similarly, focuses on creating embryos (interview, 28 March 2007). In Beijing’s University Stem Cell Research Centre, Li Lingsong has been working on the creation of neural stem-cell lines for treating spinal-cord injuries. Though research results are still unverified and in various cases has been severely criticised as wasting tens of millions of RMB (Chen 2007), a division of labour, the fervent belief in their scientific applicability and the possibility of commercialising these research results encourage an increasingly open atmosphere of reciprocity and exploratory developments attractive to international collaborations.

The relatively undeveloped level of the research base and the comparatively low level of government investment into the basic research infrastructure could make China, in the long run, internationally uncompetitive in hESR. Nevertheless, its strategy of concentrating on a limited number of research hubs has yielded more solid foundation in basic science in Beijing, Tianjin, Shanghai and Guangzhou (and perhaps also in Nanjing, Changsha and Wuhan). These centres are considered preferable locations to recruit national and international talents to establish research clusters and centres, reflected in state research funding and in the international reputation (Hong 2008). In other words, a government strategy that stimulates an
institutional infrastructure through its powers of re-distributing resources may improve its chances of attracting foreign and domestic expertise.

*Stem cell research policy in India*

Recently, in India more effort has been put into systematically coordinating hESR through government policies. Thus, the Department of Biotechnology (DBT) has submitted a proposal to set up a government stem cell priority fund, at the Indo-UK stem cell workshop organized jointly by India and Britain in early 2005. The funding for stem cell research, thus far provided through the DBT, also includes the ICMR and other agencies, and possibly the Department of Science and Technology (DST) and the Defense Research and Development Organisation (DRDO) (Deccan Herald 2005). The National Task Force on Stem Cell Research, chaired by L.V. Prayed Eye Institute’s Dr D. Balasubramanian, considered at least 30 per cent of the surplus from the Rs 500-crore biotechnology budget for the year (Hindu Business Line 2005). The Task Force is putting together stem cell city clusters that share facilities, ideas, clinical opportunities and business opportunities. The city clusters could be promoted at Bangalore, Hyderabad, Vellore, New Delhi and Pune-Mumbai (Ibid). Furthermore, the June 2005 visit of Dr Ambumani Ramadoss, Union Minister for Health & Family Welfare to the US, is projected as an important step in the formulation of a stem cell research policy in India. The University of California San Francisco (UCSF) will train Indian scientists in the field of regenerative and stem cell research. Stating that he wants India to become the world’s hub of stem
cell research, Minister Ramadoss emphasised that, unlike in the US and most European countries, stem cell research does not face the same legal and funding constraints in India. But because the Indian government is conscious of the fact that hESR will raise ethical issues, it has been argued that an exploration is needed on how stem cell research regulatory mechanisms elsewhere, such as in the US, could be implemented in India (Today’s Stem Cell Research 2005).

Risk and reputations of hESR

Here we return to the issues of the bioethical vacuum and its various meanings. If India is so attractive to investors for her liberal attitude to the bioethics of stem cell research, why look for ways to implement a hESR regulatory mechanism resembling those of the USA? Before discussing this issue of ‘whose bioethics’ we are talking about in the conclusion, we shall refer to some of the latest developments in India that may be giving stem cell research in India a murky image.

In India only recently a single set of guidelines for clinical practice has been negotiated, partly, as a result of the mushrooming of clinics that claim to use stem cell resources to cure diseases ranging from spinal injury, diabetes, neurological problems, heart ailments, to Parkinson's and Alzheimer's diseases (or such as L.V. Prasad Eye Institute claiming to cure blindness using stem cells). According to

17 The 2002 ICMR guidelines (Health Ministry) and those of the 2001 DBT (Science Ministry) diverged, which some clinics had exploited to begin clinical treatments.
Vasantha Muthuswami, head of basic medical sciences at the Indian Council for Medical Research (ICMR) in New Delhi, many private clinics that are offering stem-cell therapy have never contacted the ICMR: No one has a clear idea of what clinical studies are being carried out where, and how they are being evaluated (Jayaraman 2005: 259). But it must have been very embarrassing for the ICMR when The Times of India announced that top heart surgeon Panangipalli Venugopal at New Delhi’s All India Institute of Medical Sciences (AIIMS), just a block away from the ICMR, had used stem cells to treat thirty-five patients during bypass surgery with an ‘injection method’ without its permission (Biospectrum 2005).

Apart from the lack of supervision over hESR, there are concerns about research procedures and the quality of cells used in stem cell therapy. Without the insurance that the basic research is done to prove the safety and efficacy of the therapy, it is feared that Indian research practices will suffer from a bad reputation. Muthuswami’s statement illustrates the problem: ‘We are flooded with applications from doctors who want to use stem cells but they do not say where they get the stem cells from or how they are going to use them’ (Rediff.com 2004). There is also concern among scientists that India’s strong civil society organizations and NGOs will take charge, and that the ‘anti-biotech brigade’ will create regulations that are not in the interest of stem cell research. For this reason, calls are voiced for the private sector, which has the most to gain from the stem cell technology, to develop voluntary guidelines ‘to see that the benefits of stem cell research is harnessed in an ethically appropriate and socially responsible manner’ (Shantharam 2005).
A main obstacle for hESR laboratories in both China and India has been obtaining adequate supplies of high quality embryos. Also in China this has created a demand market for human embryos that remains insufficiently regulated. Although a number of ethics groups have raised public awareness on the ethical issues related to hESR, recently created laws cannot be expected to be effective. The 1998-regulation of the trade of genetic materials and embryos are implemented relatively effectively, and largely stemmed the unruly export of genetic materials. The barter of genetic materials at home, however, has continued and does not seem to be under government control or dispute. In exchange for human embryos, hospitals and clinics seek strategic partnerships with university laboratories for technology and joint credit on publications. This form of collaboration is encouraged by research funding policies that encourage applications for funding based on partnerships between IVF clinics, hospitals and research centres (stem cell researcher, Prof. B, Capital University of Medical Sciences, 25 November 2007). Although this situation could in principle force mutual surveillance and mutual help in setting up effective bioethics institutions, such as properly functioning ethical review boards, it also leads to potential conflict when research laboratories are unwilling to share their findings, clinics become negligent regarding the informed consent process around embryo and oocyte donation, and hospitals become too eager to give in to patient’s wishes to enrol in the trials of new therapies (interview Professor C, Military Academy of Medical Sciences, 4 April 2004).

In the PRC the MOH and the MOST are the main regulating agencies for human embryo and transgenic therapeutic research in China. But regulations can be
ignored when sensitive embryo-based studies are conducted with little or no institutional review, and when researchers suffer no consequences for violating the institutional or national regulations or guidelines that do exist. Competition for resources and funding also leads institutes to protect their research materials and keep their results to themselves until they have published their results in major journals and attracted sufficient investment. In order to become more credible, governments have begun the process of creating national committees to enforce regulations and set up and supervise local institutes with their own panels responsible for violations (interview, Prof B, 25 November 2007). Such basic infrastructure is hoped to guide the emerging stem-cell therapies through clinical trials, and avoiding a rush into the research clinic or even to the market before the basic science has been verified following internationally acknowledge procedures.

Conclusion

Bioethics and the mobilization of the cultural as economic capital

Economic development is achieved by incorporating cultural and bioethical dimensions of society into the planning of the national economic infrastructure through research guidelines and regulation. Indian and Chinese governments have mobilised cultural and institutional resources in order to compete globally in pioneering fields of technological developments and applications, shifting the boundaries of bioethical sensitivities regarding experiments with life to their
comparative economic advantage. Although both countries have started to stimulate the development of biotechnology, China, to a somewhat greater extent than India, has consistently tried to follow particular institutional policies in the large metropolitan centres earmarked for international collaboration:

- Tempting native experts abroad to return and by making possible part-time jobs for foreign expertise;
- Investing into the knowledge infrastructure and joint-ventures: academic standards, joint-research and academic co-operation nationally and internationally;
- Dividing up tasks and sharing scarce materials to prevent doubling research efforts and wasting resources; and,
- Setting up a system of research regulation and bioethical guidelines.

Although some successes have been booked in institutionalising bioethics in some large reproductive centres (Li & Lu 2005; Tu & Lu 2006), uncertainty remains about the unofficial practices in nearly all stem cell research centres, which makes international collaboration a liability for commercial corporations and academic institutions with a kosher image to protect. Thus, a bioethics expert from a large pharmaceutical company related how plans for hESR in Shanghai were halted in 2007 (conversation E, October 2008). Furthermore, little is known about what happens to economic compatibility if its permissive economic culture is thought to cover secretive research practices, the commodification of embryos through barter, the pressuring of couples in IVF clinics, and illegitimate clinical experimentation.
Both China and India have problems with the implementation of bioethical regulation for stem cell research and therapy. As stem cell science moves from the laboratory to the clinic and the experimental treatment of patients, in both China and India it does so in a governance vacuum (Padma 2006). As discussed, this vacuum gives rise to the disputable research practices of scientists such as Dr Geeta Shroff in New Delhi and Huang Hongyun in Beijing and institutions such as Life Line Hospital in Chennai and Beike in Guangzhou (Pandya 2008, Padma 2006, Ramesh 2005; Watts 2004; Cyranoski 2006; http://www.stemcellschina.com). Available regulatory and monitoring arrangements to govern human clinical experimentation in stem cell science in China and India are unclear and vary from institution to institution. But precisely this regulatory unclarity provides opportunity and scope for adventurers aspiring to become global players in this new area of expertise, which at the same time is problematic in terms of sustainable international collaborations and public trust.

The discussions around the bioethics of hESC are complex. In the discussion on hESR bioethics has at least four meanings: first, the bioethical justice of faltering healthcare; second, the bioethical morality of treating an embryo as a clump of cells; third, the bioethical freedom of human embryo donation; and, fourth, bioethical cleanliness of research regulation. Observing the channelling away of resources from a needy healthcare system, many critics ask whose health problems are targeted by hESR. For in China and India urgent and widespread diseases could be cured by relatively simple and cheap means, which would be a ‘bioethical’ option. On the other hand, as reiterated in newspapers and media discussions, governments...
in India and China would not suffer from American religious and moral scruples about the use of embryos to the extent that the situation would necessitate a moratorium on the state funding for hESR. In this sense this paper speaks of hESR in China and India as filling ‘bioethical vacuum’. Although it should be pointed out that in China and India various views exist on the value of the embryo, including ones that regard the embryo as sacred, a majority follows the political leadership in their materialist views of the embryo (Bhardwaj & Macer 2003; Nie 2005; Sleeboom-Faulkner 2007).

But if it really would be true that the embryo is socio-culturally accepted as a clump of cells, the question arises as to why create national ethics committees and establish research procedures that protect these biological entities? After all both China and Japan had guidelines on abortion before the rise of hESR. Ironically, it is not usually the general public, whose voices are rarely heard, but researchers and governments who call for bioethics to see their interests protected in at least three different ways. First, governments may find it of national importance to keep genetic materials in the country, organised through a system of licenses and consent forms. Second, embryos and oocytes have personal, economic and social values (Waldby & Mitchell 2006) also to non-religious populations that are in no position to bargain with their healthcare providers. To protect the exchange between researchers and embryo donors it is necessary that consent rules exist for donation to prevent financially weak donors from donating more than they can afford to, and researchers from trading biomaterials. And, third, even if researchers do not want to be confronted with the personal and social values about human embryos, research
regulation is still required to maintain an aura of respectability in an international context. The bioethical vacuum therefore is not as empty as it appears at first glance.
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