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# Chinese Researchers Promote Biomedical Regulations: What Are the Motives of the Biopolitical Dawn in China and Where Are They Heading?

ABSTRACT. In the past five years, China has experienced increased efforts to regulate activities in biomedical research and practice. Background is provided on some of the key developments in Chinese bioethics especially in relation to genetics, stem cells, cloning, and reproductive medicine. This background sets the stage for a document entitled "Ethical Guidelines for Human Embryo Stem Cell Research," proposed by the Bioethics Committee of the Southern China National Human Gene Research Center, Shanghai, which is reprinted in this volume of the *Kennedy Institute of Ethics Journal*.

## BALANCING OPPORTUNITY AND RESPONSIBILITY

In the past five years, biopolicymakers in China have increased efforts to regulate activities in the biomedical sector. Ethicists, lawyers, and administrators have faced a number of challenges, from biomedical progress to transformations within society and pressure to respond to demands of international bio-business. Some of these have been addressed by researchers from the life sciences and bioethicists. These activities have produced material that is ready for international review (Döring 2003b).

A new wave of infrastructure building to regulate and monitor biomedical activities in China took off in 1998, when a Chinese Human Genetic Resources Management Office was jointly established by the Ministry of Health (MOH) and the Ministry of Science and Technology (MOST). This office formally is involved in all affairs that include trafficking of human biomaterial, but its effectiveness stands in question.

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China stipulated in the Protection of Genetic Resources Act of 1998 that biological material may be used only with the full informed consent of donors. It also reserved claims for all benefits derived from international biomedical research using Chinese sources. The same year, MOH published a Five-Point Declaration, banning all trials that involve human cloning.

Still Chinese commentators acknowledge a gap in the development of bioethics standards, which might generate additional complications within a highly internationalized and competitive environment, where ethical standards and practices diverge. In response to pressures from the biomedical markets, in particular pharma-related research, a matter of major concern is how to prevent Chinese citizens from mistreatment and China's biological resources and related knowledge from exploitation. A semi-official daily newspaper warned, "We must be aware that some scientists from developed countries make use of the ignorance and eagerness of their colleagues in the developing countries to carry out experiments banned in their own nations" (Rules to Protect Genetic Resources 2003).

Accordingly, Chinese subjects and researchers need to be protected from abuse by foreign and domestic companies or researchers, with their advanced experience in international trade and laws. China's wealth in bioresources and human capital is a mixed blessing for a developing country. Her potential strength goes together with vulnerability. Namely the rush to claim patents for and intellectual property rights to the resulting products and benefits fuels competition rather than scientific detachment and proper attention to the needs and claims of "vulnerable" groups. Accordingly, all recently published documents related to bioethical regulation expressly forbid commercialization of sensitive human biological material. A technical instrument to help restrain commercialism is the advanced patenting system that is expected to regulate and protect Chinese resources (Cf. State Intellectual Property Office 2002; Patent Law of the People's Republic of China, amended 25 August 2000, enforced 1 July 2001). According to the Director General of China's National Patent Office, Mr. Zhang Qingkui (personal communication, 12 November 2003), it is among the functions of this law to protect individuals' safety and moral norms in society and to ensure that science can contribute to the benefit of society, be it material or medical benefit.

Until the political crisis accompanying the outbreak of SARS (Döring 2003a) and under the previous rulership of Jiang Zemin, state propaganda favored biomedical research and development and neglected the public health care system, especially in the rural areas. This bias may be

gradually reduced in terms of a renewed concern for a healthy population. The goal to enhance the level of health protection, especially among the vast rural majority of impoverished and poorly educated citizens, could support conservative policymakers in their efforts to constrain the liberty of researchers and redefine the political agenda. However, there does not appear to be an expressed alternative to the dominating ideology of pragmatism and techno-optimism in Post-Mao's China.

## WHAT MAY AND WHAT MAY NOT BE DONE

European and American observers find it difficult to grasp the ongoing development in bioethics in China. Since we are facing a process rather than its results, the situation appears complex. Articles published in distinguished Chinese and international media do not fit easily into a coherent portrait. We understand that Chinese life scientists engage in human cloning (Mann 2003). Embryologists have transferred human cell nuclei into rabbit eggs (Weiss 2002; Cohen 2002). Research involving destruction of human embryos for the derivation of stem cells is taking place with no apparent public debate (Dennis 2002). Chinese and American reproductive doctors under the leadership of James Grifo have performed a medical experiment on a Chinese woman in Guangzhou, trying the method of somatic cell nuclear transfer (SCNT) (Zhang et al. 2003). This procedure could not be performed in the United States due to considerations of medical risks and ethical concerns (Weiss 2003).

On the other hand, official statements suggest a conservative and restrictive rather than a liberal policy. The Ministry of Foreign Affairs (2003) proclaimed, that human reproductive cloning is a "tremendous threat to the dignity of mankind and may probably give rise to serious social, ethic, moral, religious and legal problems." It warned that "The Chinese Government is resolutely opposed to cloning human beings and will not permit any experiment of cloning human beings." Given this discrepancy between policy and practice, greater efforts than in the past can be expected for effective monitoring and examination of therapeutic cloning and other sensitive procedures in China.

Regulations governing the practice of clinical biomedicine are comparatively more restrictive than those for research. On 1 October 2003, three new administrative regulations concerning reproductive medicine went into effect. They define, among other items, ethical principles in assisted reproductive technology and human sperm bank management, revising outdated regulations from 2001. It is stated that "human cloning

is forbidden." The regulations prohibit, in a clinical context, use of the technique of human egg nucleus transfer for infertility treatment. But they do not cover "basic research" in vitro, which falls under the authority of MOST (Leggett 2003).

The creation of human embryos is regulated in detail. Superstimulation—versus ordinary therapeutic stimulation—of ovaries is forbidden, and all procedures depend on informed consent from donor. For women younger than 35, only 3 embryos may be implanted. Embryos are created for the sole purpose of procreation, but "leftovers" may be donated to medical research, upon expressed wish of the donors. Commercial dealing is strictly banned (Döring 2004).

According to these regulations the Grifo experiment would be prohibited, even though it took place in a renowned Chinese clinic. Besides safety concerns the main ethical objection is that involvement of biomaterial from more than two parents would interfere with accepted concepts of parenthood and family. In fact, although the 2001 version of these MOH regulations did not specifically ban human egg nucleus transfer, a common moral assumption was made that blurring of the "natural" germlines of individuals or species would not be acceptable in any clinical setting.

Clearly, the positivistic principle "if an action is not illegal, by definition, it is legal" does not apply in China. Taking advantage of the fact that policymaking lags behind scientific and economic development, in terms of the entire legal and social infrastructure, amounts to biomedical adventurism.

## RESEARCHERS' ETHICS

Initiatives from Chinese researchers in the life sciences and bioethicists have been designed to reduce ambiguity and enhance ethics in practice. In 2001, two proposals for scientifically and ethically satisfactory regulations on human embryonic stem cell research were submitted to China's legislators.

In their Ethical Principles and Management Proposals on Human Embryonic Stem Cell Research, an interdisciplinary advisory group of leading scientists and ethicists from Beijing proposed draft guidelines for MOH and MOST (Döring 2003b). The document highlights the principles of general respect for human life at all stages, informed consent, safety, and effectiveness. It encourages biomedical research and bans "any form of gamete, embryo or fetal tissue trade." The document proposes standardized procedures, professional qualifications, and IRBs for all institutions that are involved in human embryonic stem cell research.

The second relevant document, the Ethical Guidelines for Human Embryo Stem Cell Research, which is reprinted in this issue of the *Kennedy Institute of Ethics Journal*, was submitted in 2001 by the Bioethics Committee of the Southern China National Human Gene Research Center, Shanghai.

The gist of the two documents is quite similar. They share a general esteem of human life; emphasize informed consent, confidentiality, and voluntary donation; set a 14-day deadline for the permissible destruction of an embryo; and ban the reimplantation of an embryo from research into a human uterus. Both documents also reject cloning for reproductive purposes but accept it for therapies. (Zhai 2004)

The Shanghai draft reflects issues of risk control in slight contrast to the more ethically inspired view of the Beijing guidelines. Interestingly, the first published version of the Shanghai guidelines (adopted on 16 October 2001) permits cross-species recombinant experiments (Article 13.5), whereas the revision (of 20 August 2002) deleted this clause: "fundamental research may be permitted" (cf. Bioethics Committee 2001).

Furthermore, Shanghai allows "human-animal cell fusion," if it is only used for basic nonclinical research. But any combination of human cells with animal cells for clinical purposes—e.g., for implantation into the human body—is prohibited (Article 14.4). Consequently, the creation of cross-species hybrids is allowed as long as they remain in vitro. Thus the proposed Guidelines support Shanghai's local researchers who are engaged in such projects. It is both noteworthy and consistent that the Shanghai proposal has been cited as a formal ethical reference in scientific publication of such research, even though it has not been accepted by MOST or MOH (Chen et al. 2003).

Finally, both the Shanghai and Beijing guidelines explicitly prohibit coercion of women into becoming pregnant and then choosing abortion, or into manipulating the method and time of abortion. These prohibitions obviously address a current (mal)practice, which violates the concept of informed consent. As far as ethical priorities are concerned, the guidelines seem to grant donors relatively greater attention than the protection of early human lives. Improvement of the practice of informed consent and patient protection is balanced with the freedom of research.

The most recent development in China seems to confirm the general direction of human embryonic stem cell research policy and supports the interpretation offered here. On 13 January, MOST implemented new "Ethics Guidelines for Human Embryonic Stem Cell Research," which cover all research activities in the territory of PRC. For the first time, it is stated in

official writing that "human reproductive cloning" is forbidden (article 4), while embryonic stem cell research is allowed. MOH's new regulations on reproductive medicine ban the transplantation of human ooplasm in fertility treatment. Thus, Chinese media reported in February the birth of the first and last "fourth generation test-tube baby" in central China's medical hub, Wuhan.

With the implementation of these recent regulations, as well as the Ministry of Foreign Affairs' strong political statement and the regulations on patenting and intellectual property rights, China does now, in principle, cover the main areas of biopolitical legislation in this area. The regulations seem to represent the majority of researchers" requests, although they may frustrate some who had hoped for even greater leeway. They also send a clear signal of competitiveness and compatibility of standards to the international research community. It should be noted, however, that the recent developments are not formal law, but "regulations" albeit with strong political authority. Any formal law that is going to replace these regulations in the near future most likely will follow the same line of consideration. (Translations of the new regulations are forthcoming at *www.ruhr-uni-bochumde/kbe*.)

## IMPLICATIONS

The fact that researchers have submitted proposals for ethical guidelines on stem cell research indicates a demand for biopolitical action in China. The vast majority of researchers in the life sciences are prepared to accept different and perhaps even more restrictive legal regulations in exchange for more effective guidance. It is understood that, on the national level, China's legal and administrative tools are still unprepared to deal with these issues in a comprehensive manner (personal communication with Hu Ching-Li, former Chinese WHO delegate and a coauthor of the Shanghai proposal, 24 November 2003). It may be the role of local initiatives to stimulate the process and to test the limits of moral tolerance in China's society.

On the national level, an institutional tension exists between MOST, with its concern for the quality and acceptability of science, and MOH, with its responsibility for patients and the clinics. Although both ministries jointly refute the commercialization of biomedicine, researchers are tempted to probe pragmatically into the options for cooperation with the pharma-industry. Conversely, a relatively restrictive moral attitude at MOH is understandable in light of its dedication to public health. The new regulations for assisted reproduction, with their associated implications for the control of research, have been released only by MOH. Owing to the

elevated status of this ministry—China's vice-president, Wu Yi, took charge of it during the SARS crisis—the political weight of its acts is significant. Nevertheless, MOH still has rather limited effect on research in the life sciences, because MOST is in charge of financial administration and monitoring. With regard to biopolitical consistency, however, MOST is now expected to make a move in response. Full endorsement of the Shanghai proposal by MOST would send a clear signal of provocation to MOH.

In general terms of bioethics, all proposed and approved documents reveal a "Chinese Rubicon" that defines the beginning of human integrity and worthiness of protection. The transfer of an embryo into the uterus seems to demarcate the line between research and medical treatment. Manipulation in vitro might be permitted, but implantation into the female system is a taboo. The use of cloning technology for human reproduction is most unlikely to be endorsed in China. The debate in other areas certainly will continue.

Finally, it should be noted that a limited focus on current proposals for biopolicymaking does not substitute a deeper cultural and social-political analysis. It reveals some major tendencies in the minds of leaders in the life sciences and bioethics in China. Observers should understand that the currently discussed ethical standards are embedded in the shared purpose of facilitating the life sciences by increasing their regular performance and raising the level of acceptance within the public. These attempts respond to the demand to regulate life sciences, after scandals and reports about irregular experiments have irritated the population, while the transforming society is dramatically in flux on all levels.

For all their merits these considerations do not represent China, Chinese people, or China's culture, in any significant sense. They do not draw on open public debates, comparable to those lead in Germany about the Law on the Importation of Human Embryonic Stem Cell Lines in 2002, nor do they account for reflections from social sciences. The vast majority of Chinese people have not received proper education to grasp the impact of biomedicine on their lives nor are they encouraged to discuss ethical standards. Researchers and bioethicists who are concerned about ethical and social implications of the life sciences express the visions and interests of a limited but influential group of people in China.

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