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HUMAN GENOME ORGANISATION

ETHICS COMMITTEE

REPORT ON THE LAW OF THE PEOPLE'S REPUBLIC OF CHINA
ON MATERNAL AND INFANT HEALTH-CARE

San Francisco
25 November 1996

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1. At its meeting in San Francisco on 25 November 1996, the Ethics Committee (the Committee) of the Human Genome Organisation (HUGO) considered the law of the People's Republic of China on Maternal and Infant Health-care (the Law).

2. The members of the Committee had received in advance copy of the English language translation of the Law as prepared by the Legislative Affairs Commission of the Standing Committee of the National People's Congress of the People's Republic of China. The members of the Committee also had before them the following documents:
 - * Nianhu Sun (Professor, Department of Obstetrics and Gynaecology, PUMC Hospital, Beijing, China), International Opinion, "The Urgent Ethical Problem in China", published in *Human Genome Research and Society*, Proceedings of the 2nd International Bioethics Seminar in Fukui, March 1992, pp 149-151.

- * Ren-Zong Qiu, "China's Policy on Population and Bioethics" to be published in the Proceedings of the Symposium, Ethics in Human Genetics and Gene Analysis, October 9-10, 1991.
- * L R Brown, *Who Will Feed China? Wake Up Call for a Small Planet*, Norton, 1995, chapter 2.
- * Extracts from *Nature* (vols 383 and 384) and other scientific journals.

3. The Committee invited Dr Qiu Ren-Zong (China) to act as an observer during the Committee's deliberations. Dr Qiu explained the situation in China to which the Law was addressed. He made a detailed statement explaining the provisions of the Law. He answered questions put to him by members of the Committee. The Committee expresses its thanks to Dr Qiu for his attendance at its meeting, for his frankness in responding to the Commission's questions and for his willingness to conduct a dialogue with the Committee which it considered to be most fruitful.

4. The Committee acknowledges the difficulties which can arise in considering a translation of a law, such as that here in question. Dr Qiu made a number of observations concerning the possible mis-translation of provisions of the Law. The Committee also acknowledged that the Government and people

of China are faced with large problems affecting maternal and infant health-care. The solutions to those problems may only be fully understood with an awareness of the cultural values of the Chinese people and medical profession. Different societies approach problems affecting maternal and infant health-care in different ways having regard to the different resources that are available to be devoted to these subjects; different social and medical traditions which exist in such countries; and the different religious or philosophical principles which tend to guide governmental, professional and individual decision-making on such sensitive issues.

5. The Committee noted the strong statements which had been made by geneticists criticising the Chinese Law. For example they noted the statement presented at the conclusion of the 9th International Congress on Human Genetics in Rio de Janeiro, Brazil reported in *Nature*, vol 383, 19 September 1995 at p 204. The Committee reminded itself that many of the countries from which the signatories to the foregoing statement derived permit abortion in defined circumstances and conduct amniocentesis to discover the existence of genetic conditions which may result in an abortion. To this extent, developments have already occurred in countries other than China which appear to accept the legitimacy of medical conduct which contemplates a termination of pregnancy where (in the words of Article 18 of the Chinese Law):

- "1. The foetus is suffering from a genetic disease of a serious nature;
2. The foetus is with defect of a serious nature; and
3. Continued pregnancy may threaten the life and safety of the pregnant woman or seriously impair her health due to the serious disease she suffers from."

To this extent some, at least, of the problems addressed in the Chinese Law are not entirely unknown in other countries of the world. Accordingly, the Committee concentrated on those aspects of the Chinese Law which appeared to it to introduce significant changes over and beyond those which are presently accepted in other countries.

6. The Committee acknowledged that a number of provisions of the Chinese Law involve desirable statements of principle or law that are protective of the rights of mother and child and apparently conformable to international human rights standards and ethical principles. These include such provisions as:

"Article 21: Physicians and midwives shall strictly observe relevant operational procedures, improve the skills of midwifery and the quality of services so as to prevent or reduce maternal injury.

Article 22: If pregnant women cannot go to hospital for delivery, sterilised midwifery shall be practised by trained and qualified midwives.

Article 26: Personnel engaged in medical technical appraisalment must have adequate clinical experience and medical genetic knowledge and the professional title of physician-in-charge or above that title. ...

Article 27: The challenge system shall be applied in making medical technical appraisalment. Personnel

who have an interest with the person concerned and may affect a fair appraisal shall withdraw.

Article 31: Medical and health institutions shall ... take the responsibility for health-care of mothers and infants within the scope of their functions and duties, establish rules and regulations for performing medical and health services, raise medical technological levels and take all measures for the convenience of the people so as to provide better health-care services for mothers and infants.

Article 32: ... Sex identification of a foetus by technical means shall be strictly forbidden, except that it is positively needed on medical terms.

Article 34: Personnel engaged in health-care services for mothers and infants shall strictly abide by professional ethics and keep the secrets of the individuals concerned."

The Committee welcomed the above provisions of the Law. The Committee is of the opinion that those provisions conform to international human rights principles and universal ethical standards.

7. Whilst accepting that different cultures and religions can affect the approach of different countries to medical practice, the Committee took as the criteria for testing the Chinese Law the provisions of international human rights norms as contained in international law established by such instruments as the *International Covenant on Civil and Political Rights* (1966)¹, the

¹ See esp Articles 2,3,6,7,17 and 23.

International Covenant on Economic, Social and Cultural Rights (1966)², the *Convention on the Elimination of Discrimination Against Women* (1979)³ and the *Convention on the Rights of the Child* (1989)⁴. Local variations attributable to different cultures and histories cannot justify departure from the fundamental human rights expressed in international law such as are recognised in the foregoing instruments. Unfortunately, there are, in the Committee's opinion, certain provisions of the Chinese Law which infringe international human rights principles. These include:

"Article 9: Physicians, after performing the pre-marital physical check-up, [shall] give medical advice to those who are under the infective period of any target infectious disease, or who are under the morbid period of any mental disease; both the male and female planning to be married shall postpone their marriage for the time being.

Article 10: Physicians shall, after performing the pre-marital physical check-up, explain and give medical advice to both the male and the female who have been diagnosed with certain genetic disease of a serious nature which is considered to be inappropriate for child-bearing from a medical point of view; the two may be married only if both sides agree to take long-term contraceptive measures or to take ligation operation for sterility.

² See esp Articles 2.2 and Article 3.

³ See esp Articles 2, 12.1 and 16.

⁴ See esp Articles 2.1, 6 and 24.

Article 16: If a physician detects or suspects that a married couple in their child-bearing age suffer from genetic disease of a serious nature, the physician shall give medical advice to the couple and the couple in their child-bearing age shall take measures in accordance with the physician's medical advice."

The Committee is of the opinion that these Articles conflict with the basic ethical requirement that, before an invasive, potentially dangerous and serious procedure (such as termination of pregnancy) is adopted for medical reasons such termination shall have the fully informed consent at least of the mother. Although the sanction imposed by Article 10 of the Law is not entirely clear, read in its context it appears to involve a requirement of long term contraceptive measures or sterilisation as a pre-condition to marriage. The Committee draws a distinction between advice designed to assist a couple to make a fully informed decision and State enforced requirements of long term contraceptive measures or sterilisation. The latter appear to be inconsistent with universal human rights and universally recognised principles of ethics.

8. A further criticism of Article 16 of the Law concerns the procedural device adopted. The physician referred to is required to give what is called "medical advice". However, the couple are then obliged by the Law, in mandatory language, to "take measures in accordance with the physician's medical advice". The Law does not provide for any right of appeal or review. It is not appropriate to constitute a physician effectively the decision-maker enforcer of state policy with which an individual may

disagree. Although, again, the sanction is not spelt out, it must be assumed, from the mandatory language used, that sanctions of a criminal, social or financial character are contemplated. Thus, it has been suggested that the imposition of legal pre-conditions to marriage may be enforced in China by sanctions relating to the provision of housing, employment, medical and social benefits as well as the avoidance of stigma and social pressure. It cannot be assumed that the mandatory language in which the Law is expressed is intended to be ignored or to act only as advice to the affected mother or couple.

9. A question arose before the Committee as to whether the issues presented by the Chinese Law were within the competence of the Committee and of concern to HUGO. The Committee concluded that it was. The work of the Human Genome Project will facilitate the identification of genetic conditions and the provision of tests for their discovery. This will occur as the understanding of the Human Genome increases the number and variety of tests that may be applied to detect suggested genetic "defects" or conditions. It will be important to establish a number of basic principles to be applied in the use of such tests. These include:

- * Conforming to fundamental human rights norms as established by international law.

- * Upholding and defending the precious features of human diversity.
- * Maintaining the principle of informed consent to medical procedures affecting those who have, or may in the future develop, "defects" or conditions of a genetic kind.
- * Providing to those affected genetic counselling designed to protect their basic rights and to uphold their human dignity and integrity.

In the view of the Committee these fundamental principles are absent from the key provisions of the Chinese Law in the articles identified in par 7 above. The Committee calls its opinion to the attention of the Council of HUGO and recommends that its opinion be made known to the relevant authorities of the People's Republic of China.

10. In the opinion of the Committee, the appropriate course to respond effectively to the Chinese Law is to maintain a dialogue with the authorities of the People's Republic of China and not to reject or withdraw from that dialogue. It was in this spirit that the Committee welcomed the discussions with Dr Qiu. Whilst maintaining its strong opposition to the identified articles of the Chinese Law, the Committee committed itself to continuing the dialogue with Dr Qiu and with other experts in China in the hope of explaining the foundation of the Committee's opposition and

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of influencing changes in the Law which would maintain the provisions judged beneficial and delete those regarded as contrary to fundamental human rights and ethical principles.

SAN FRANCISCO
25 NOVEMBER 1996

(SGD) ON BEHALF OF THE COMMITTEE
PROFESSOR BARTHA MARIA KNOPPERS
CHAIR OF THE HUGO ETHICS COMMITTEE