

研究ノート

Law on Regulating Human Cloning Techniques in Japan

by

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I. Introduction

Since the G8 Summit in Denver, it seems that there has been a broad consensus in Western countries on the prohibition of cloned human individuals. Many countries have taken appropriate steps to ban the creation of a 'copy' of another human being⁽¹⁾. Nowadays, however, the question seems to be whether the creation of certain embryos for research would be acceptable or not. On one hand, It is widely believed that embryonic stem cells have a unique and mind-boggling skill and then have the capacity to reproduce indefinitely into what we call stem cell lines. These

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- (1) This drives us to the question why one can ban it. But to discuss the reason as a whole is beyond the scope of a brief note. We need to mention here two things. First, some critics are concerned about efficiency and safety. Scientists have cloned some animals, but success rates have been extremely low. Few of the reconstructed embryos develop, some develop abnormally, and some die at or soon after birth. No one has yet cloned a primate. It is clear that cloning a human involves tremendous risks. However, this cannot be a compelling reason for banning human cloning, since issues of efficiency and safety may eventually be resolved. It is necessary to analyse further the reasons why human reproductive cloning is so widely judged to be ethically unacceptable. Secondly, the attempt to subvert a natural reproductive process could desecrate the dignity of human life. It is true that humans inherit half of their genetic information from each parent when a sperm fertilizes an ovum, and that the human species has benefited from the natural reproductive system that ensures the transmission of diverse genetic information between generations, but, according to this explanation, one cannot stop banning a cloned human individual when parents wish to replace an aborted foetus, dead baby or child killed in an accident. See, Hisatake KATO, 'Clone Ningen Kinshi Riyu no Ho-Tetsugaku teki Ginmi' p. 12 in *Seimei Rinri* No. 9. 1 1999., Katsunori KAI, 'Clone Gijyutsu no Ohyo to (Keiji) Ho teki Kisei' pp. 26-36 in *Gendai Keijiho* No. 14 2000.

cells could, in theory, be grown into any cell type in the body, repairing damaged nerves, tissues, and organs. If a patient who suffers from an incurable disease obtains the human clone embryo identical to the patient's own, he or she could be rescued owing to no rejection at transplantation. On the other hand, some critics say breaking or manipulating human embryos to harvest embryonic stem cells desecrates the dignity of human beings and therefore such conduct should be ethically unacceptable.

II. Japan's legislation

According to 'The Law Concerning Regulation Relating to Human Cloning Techniques and Other Similar Techniques'⁽²⁾, which came into force on the 6th of June 2001, Japan has adopted a double standard policy on the issue. Transferring 4 types of embryo into the uterus of an individual human female or animal shall be a punishable offence⁽³⁾. However, creating and using 9 types of embryo including the 4 types mentioned above could be widely accepted in compliance with 'The Guideline for the Handling of a Specified Embryo', which came into force on the 5th of December 2001. This Guideline states that the creation of a human or human-like clone would be unacceptable. It seems that human cloning is developing at quite an alarming rate and in order to monitor growth in this field, all jurisdictions have been left to the Guideline except for the most serious cases.

The Guideline actually prohibits the transfer of all specified embryos into the uterus of a human female or an animal. It admits to the development of only one type of embryo, which is an 'animal-human chimeric embryo' and is perfectly within the current law and legislation regarding the cloning of embryos. It is true that the guideline is not legally binding, but with regard to research being undertaken, financial assistance from

(2) See, in particular, Katsunori KAI, 'Hito-Clone Gijyutsu-to Kisei-Ho ni tsuite' pp. 87-95 in *Gendai Keijiho* No. 24 2001.

(3) Prof. Kai describes this offence as 'non-substantive crime' or 'crime-obstacles' (Id. at 89). It seems that the utilization of criminal law is necessary to protect not just coming generations but such a new supra-individual asset per se against a new risk.

the government will be revoked if that research contravenes the guideline. In other words, the institution concerned may be requested to return the money it had received. Regulations like this seem to some academics appropriate because criminal sanctions should be utilized as a last resort. Moreover, the Guideline can be modified easily and quickly in accordance with the status quo of embryo research.

III. Provisions⁽⁴⁾

Section 3 prohibits the transfer of the following 4 types of embryo into the uterus of a human female or an animal.

- (1) A human somatic clone embryo -a human embryo made by means of replacement of the cell nucleus of a human egg with that of a human somatic or fetal cell.
- (2) A human-animal amphimictic embryo -an embryo made by means of fertilization between human and animal gametes.
- (3) A human-animal hybrid embryo -an embryo made by means of replacement of the cell nucleus of an animal egg with that of a human cell.
- (4) A human-animal chimeric embryo -an embryo made by means of aggregation of a human embryo and an embryo or cells of animal.

Section 4 prescribes that the Government must take measures to ensure the proper handling of the other embryos in addition to embryos listed above. (These embryos are called 'Specified Embryos')

- (5) A human split embryo -a human embryo made by means of separation of human blastomeres or of splitting of a human embryo.
- (6) A human embryonic clone embryo -a human embryo made by means of replacement of the cell nucleus of a human egg with that of

(4) Most of the material treated herein are derived from the web-site 'http://www.mext.go.jp/a_menu/shinkou/seimei/index.htm'. There are several provisions on administrative criminal sanctions. Prof. kai argues that there is no criminal sanction to protect individual information. But to argue this point would carry us too far away from the purpose of this short paper. We may leave the details to the site.

a human embryonic cell.

- (7) An animal-human hybrid embryo -an embryo made by means of replacement of the cell nucleus of a human egg with that of an animal cell.
- (8) An animal-human chimeric embryo -an embryo made by means of aggregation of an animal embryo and human cells.
- (9) A human-human chimeric embryo -an embryo made by means of aggregation of a human embryo and another human embryo or cells.

The main measures listed on the Law are,

- (1) to establish the Guideline concerning the handling of 'Specified Embryos' in consultation with the Council for Science and Technology Policy, Cabinet Office,
- (2) to oblige researchers who intend to handle 'Specified Embryos' to notify their plan to the Government, to suspend handling as long as 60 days after their notification, and to notify the disposal of 'Specified Embryos' to the Government,
- (3) to enable the Government to give orders to modify or terminate a handling plan, if it does not meet the Guideline,
- (4) to enable the Government to ask researchers to submit a report of the handling, and to investigate their laboratory.

Penalties are as follows.

- (1) Any person who transfers certain embryos (as mentioned in Section 3) to the uterus shall be imprisoned no longer than 10 years or be fined no more than 10 million yen, or both.
- (2) Any person who neglects notification to the Government or violates the order from the Government concerning the handling of Specific Embryos shall be imprisoned no longer than 1 year or be fined no more than 1 million yen.
- (3) Any person who violates the suspension requirement after submission of the plan shall be imprisoned no longer than 6 months or be fined 500,000 yen or less.

IV. Comment

According to the Law, it is not even prohibited to transfer certain embryos into a uterus except for only the 4 types in Section 3. Scientists

can research all embryos in terms of the statute law, though the Guideline restricts them for the time being. Perhaps westerners think it very strange that Japan accepts in vitro human embryo research very widely. In Japan there may have been an assumption that embryonic research should march forward from the first. Three points seem to be helpful in attempting to sketch out the grounds⁽⁵⁾.

Firstly, the need of regenerative medicine. To say nothing of the great power of embryonic stem cells, embryonic research could help the patients who suffer from not only incurable disease but from other various disease.

Secondly, the need of sterility treatment. Infertile couples could be assisted by transferring human split embryos or human embryonic clone embryos. This treatment is not prohibited by the current Law. It is quite natural for infertile couples to want to give birth to a child using cloning techniques.

Thirdly, the comparison with abortion problem. In Japan, The Mother Body Protection Law prescribes legal abortion especially for physical or economical reasons. Every year more than 400,000 foetuss have been legally aborted de facto. It may be nonsense to discuss the dignity of a germ of human beings in the country where even the foetus is thought of as a slight thing.

V. Conclusion

In Japan, there is no comprehensive legislation concerning the handling of human reproduction. This area has been left to the rules of the Japanese Society of Obsterics and Gynecology. 'The Law Concerning

(5) We may note, in passing, that this area is very competitive internationally. Scientists in every country tend to be scared of losing the competition. It seems that they are afraid to be behind the time. Some of them may desire to research to obtain their honor or finances. The government in Japan may also want to support them in the light of recovery from economic recession. Too many restrictions can be the disturbance of free research and competition.

Regulation Relating to Human Cloning Techniques and Other Similar Techniques' has become the first legislation in this country. However, there are apparently some areas to be revised in this Law. It should have contained ethical principles to guide researchers. Furthermore, it is necessary to prohibit Japanese people from cloning humans abroad. According to the current Law, they cannot be punished even after they return home. Although the Law shall be modified within the three years after its enforcement, it is no doubt high time we had an international convention to regulate human cloning techniques, especially on the creation of cloned human individuals. It is possible to control the application of scientific and technological breakthroughs to human reproduction, even though no one may perfectly block that of these techniques.

REFERENCES

Shinichi ISHIZUKA, 'Hito-Clone to Keiji-Ho Kisei' pp. 16-19 in *Hogaku Seminar* No. 573 2002.

Saku MACHINO, 'Hito ni kansuru Clone Gijyutsu-to no Kisei ni kansuru Horitsu' in *Hogaku Kyoshitsu* No. 247 2001.

Satoko TATSUI, 'Seimei-Kagaku-Gijyutsu no Tenkai to Keiji-Ho teki Kisei' in *Horitsu Jiho* Vol. 73 No. 10 2001.

Kumiko OGUSHI et al., *Hito-Clone Gijyutsu wa yuru sare ru ka*, Ryokufu Shuppan, 2001.