

Legal Regulations on the Advanced Science and Technology

- Regulations on Life Science -

Summary

Our report centered on legal restrictions on advanced science and technology, especially life science and technology. The discussion covered several problems that require legal considerations. The two main themes were the types of possible restrictions and the way to justify such restrictions. Our discussion can be summarized as follows:

<1> Current status of life sciences and strategy

Life science and technology have been a strategic field of study in many countries and considered, in particular, as a major source for industrial competitiveness. Perspectives and policies on reproductive medical technology have been quite different from those on life science and technology as a whole. While stringent restrictions have been imposed in European countries, consensus development has been extremely difficult in the U.S., instead leading to movements toward the promotion, commercialization and further development overseas of advanced reproductive technology in the private sector. At the same time, in light of growing efforts for unified regulations in Europe, it is likely that a standard will be formed for life science and technology used to shed light on reproductive medicine.

<2> Details and History of Regulations in Several Countries

Regulatory laws have been established on reproductive technology in Britain, France and Germany. Nonetheless, the scope of such regulations varies, although slightly, from country to country. They differ in such details as the object of restriction. It is thought, however, that the current regulations are competent enough to handle cloning technology.

<3> Legal views in Japan

The Constitution, civil code, criminal code and medical laws were discussed in connection with such regulations in Japan.

<4> Limitation on legal restriction

Cloning technology was discussed in relation to academic freedom and other rights. It is considered that even academic freedom should be subject to a certain degree of restriction and that, in social application of cloning technology, not only application but also research should be covered by regulations without exception.

<5> Objects of restriction

When considering regulation of cloning technology, we reviewed every possible aspect of reproductive technology as a whole, including related technologies that would require regulation, instead of focusing on cloning technology alone.

<6> Grounds for regulation

[Safety]

Safety related to cloning technology involves concerns about genetic influences on children and later generations. Somatic nuclei, in particular, are extremely susceptible to genetic defects and highly likely to suffer damage during the course of daily life. Humans developed from a genetically disturbed body nucleus face the possibility of succumbing to adverse effects all over the body. We have examined several examples of regulations implemented to focus on such genetic effects (on statistical grounds).

[Social order]

In contrast to conventional reproductive technologies, which had maintained the family structure from the past, the new cloning technology makes the relationship between the donor of a body nucleus and the cloned baby highly similar to that between monozygotic twins. It is the first attempt in history to genetically invent such relationships, which would essentially disturb social order.

[Conclusions on justifications for regulation]

For the above two reasons, it is acceptable to regulate cloning. In asserting regulation, "human dignity" as a justification should be paraphrased in more practical terms (e.g., abuse of human embryo and indivisibility of the human body).

<7> Supplement: Legal responsibilities of researchers

Little discussion has been made in Japan on the responsibilities of researchers in advanced science and technology. For the application of regulations on advanced technology, we need to review our problems in a new perspective.

[Weighted liability arising from negligence]

The legal liability of researchers should be examined separately from that of the 'professional liability' of experts such as physicians and lawyers, because they are quite different in nature.

[General liability arising from negligence]

In general criminal and civil cases, a common interpretation is established concerning foreseeability and duty to avoid risk. For the introduction of regulations on researchers, it is essential to form a new standard.

<8> Guidelines by the government and academic societies

As part of regulatory methods, guidelines are considered to have no legal effects. In our discussion, we have reviewed guidelines on science and technology, especially the ways in which guidelines should be implemented in an effective manner. Lastly, we examined technical standards in connection with the scope of judicial review on administrative discretion.

<9> Consensus development effort for regulation

We discussed efforts required to reach a consensus in the public whether regulations should take the form of laws or guidelines.

[Interested parties required for consensus development]

Interested parties to take the initiative in consensus development effort were categorized into three groups: (1) directly interested parties, (2) other interested parties and (3) non-interested professionals. We pointed out the importance of clarifying claims from these parties.

[Consensus development methodology]

Conventional and new consensus development methods were introduced, including technology assessment and consensus conferences.

While we were in the process of reviewing our discussion, many new topics have attracted public attention, including unconfirmed news; the Ishikawa Prefectural Animal Science Institute and Kinki University jointly succeeded in cloning a cow using body cells (July 5, 1998); an international group composed of scientists from Japan, the U.S., Italy and Britain cloned at least 50 female mice (July 23); a U.S. scientist declared at a scientific conference that he would clone himself (September 6, Nikkei); scientists at Tokyo University and the Japan Science Foundation succeeded in producing organs such as kidneys from an undivided embryonic cell in a frog and confirming their growth after transplanting them to another frog (September 13); Wisconsin University successfully isolated ES cells from a human embryo, and cultured and grew them (November 6); a U.S. investment company and U.S. researchers announced that they would set up a cloning technology center in Hokkaido (December 1); HFEA of the British government submitted a report recommending permission to produce human tissues using cloning technology (December 18); a Korean university transplanted nuclei from female body cells and eggs and observed division until the egg cells were divided into quarters (December 15); Wisconsin university at Madison transplanted body cell nuclei from four different mammals into bovine eggs, divided them and successfully developed them into embryos (December 28); a private enterprise cloned a cow using a body-cell nucleus (January 8, 1999); researchers at Tottori university have grown a human spermatogonium in a mouse (February 2); Italian physicians produced five humans by in-vitro fertilization after growing human spermatogonia in a mouse (March 17). Under these rapidly changing circumstances, the establishment of principles regarding life science and technology is strongly urged in order to prevent social conflicts.

Life science and reproductive technology are being discussed at the Council for Science and Technology, Science Council and Health Science Council. Discussions will be deepened in the future for these problems. We hope our report will serve as a material for these discussions.

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In addition, we would like to note that a number of specialists gave lectures at our institute and that the contents of these lectures will be compiled in a book.