# Legal Regulations on the Advanced Science and Technology
# - Regulations on Life Science -

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## INTRODUCTION

(Authored by Minoru Kuniya and Mami Oyama)

1. Achievements by the National Institute of Science and Technology Policy in Research and Survey on Science & Technology and People & Society

Along with the rapid progress recently achieved in science and technology (S&T), the resulting advantages and disadvantages have an enormous impact: S&T affects both society at large and the lifestyle of the individual person. On the other hand, society itself has pressured S&T to meet requirements and come under regulation.

The Japanese national government has already addressed the issue of considering the relationship between S&T and people & society, and has declared in the "Fundamental Principals of Science and Technology Policy" (decided at a Cabinet Meeting in April 1992) and several Recommendations of the Council for Science and Technology that it is an important issue in S&T policies to achieve harmony between S&T and people & society. Specifically, Recommendation Nos. 5 (1971), 6 (1977), 11(1984), and 18 (1992) of the Council for Science and Technology, as well as the Science and Technology Basic Law established in 1995, stress harmonization between S&T and people & society.

As specific actions to cope with this issue, technology assessment, which will be discussed in Chapter 2 of this report, attracted widespread attention and was also put into practice in Japan starting in the 1970s. We have to acknowledge such technology assessment as an initial measure taken that was aimed at harmonization between S&T and people & society since it is able to analyze both the advantages and disadvantages of S&T. (Note that in the US, technology assessment was considered as a measure for issuing early warnings against potential hazards caused by S&T.)

When looking at individual fields, the life sciences is a field in which the relation between S&T and people & society is especially significant, and for which investigations have been conducted in the various government ministries, offices and divisions concerned. This issue will be later discussed in Section 1, Section 1 of Chapter 1 "Present Status and Strategies for Life Sciences."

Since its foundation in 1988, the National Institute of Science and Technology Policy (NISTEP) has considered this relation "between S&T and people & society" as one of the key themes that should be addressed in our researches and surveys. NISTEP has conducted a variety of studies, including among others: public opinion surveys on the relation between S&T and people & society, followed by analysis of the data thus obtained; international comparison in terms of social awareness to S&T; studies of influences of S&T on people and society; and surveys on public opinion towards S&T for improving quality of life.

For the key study results obtained, we published reports entitled "Social Awareness to Science and Technology" (1989) and "Comparison between Japan, the US and Europe in Social Awareness to Science and Technology" (1992). In these reports, we analyzed public opinion on the basis of the data obtained from the study of social awareness to S&T and pointed out, among others, that S&T is expected to greatly contribute to social developments and an improvement in the living standard of people, and that what is important for the scientific and technological developments is to contribute to people's life while ensuring safety. In a later report entitled "The Influence of Science and Technology on People and Society" (1994), we analyzed people's awareness of S&T, based on which we analyzed several new yardsticks, e.g. value judgment, factors and functions which are considered important to harmonize S&T with people & society, and we pointed out, among others, the importance of paying attention to adverse effects of S&T on people and society, e.g. effects on the mental aspect of people and their self-esteem. In another report entitled "A Survey on the Public Opinion towards S&T for Improving Quality of Life" (published as an interim report in 1995 and final report in 1996), we pointed out the importance of promotion measures in the fields of environmental preservation, health & medical service, disaster prevention and social welfare, and also pointed out the necessity of identifying the needs of

people in daily living and of providing information regarding life-related S&T.

The current circumstances require not only studies focusing on analysis of data obtained from public opinion surveys but also further advanced studies which enable us to respond to social changes triggered by scientific and technological developments and also to address those social issues that are expected to be resolved by S&T. Regarding life sciences (including cloning technology), information technology, and waste & environmental conservation related issues, for example, studies which utilize new approaches and are based on specific cases and administration-involved cases, as well as policy proposals, are required. The present Policy Study was conducted on the basis of our awareness of these new issues.

2. New Approaches and Social Interest

(1) New Ways of Approaching Science and Technology

In response to social changes resulting from scientific and technological developments, there has recently been an increasing interest in a new research field called STS (Science, Technology and Society). However, its precise definition has not yet been established. Some people consider STS as "research and education on the social aspects of S&T from the viewpoints of cultural and social sciences" (quoted from "What is Science?" authored by Hideto Nakajima).

When looking back on its history, it is acknowledged that this theory originated in an attempt to introduce ways of analyzing various S&T issues from different angles, and was created in the 1970s in several universities and other relevant institutions in the UK in an attempt to inject new energy into science education (so-called SISCON: Science in a Social Context).

In the US as well, social expectations of scientific and technological developments that had continued since victory in World War II became questionable starting in the 1960s, which, together with the introduction of these trends in the UK, facilitated the debut of programs to study the relation among science, technology and society (STS) at universities throughout the 1960s and into the early 1970s.

The main direction in recent STS theory with regard to what the relation between S&T and people & society should be, changed from the policy to upgrade people's understanding of S&T (i.e. specialists enlighten citizens) to the direction of improving communication between S&T and society and encouraging citizens to participate in decision making on scientific and technological issues. Awareness of the importance of information disclosure and accountability (i.e. the obligation of specialists to provide explanations to citizens) is currently well established.

In addition, when considering the fact that today, the disadvantages of S&T, e.g. problems of the global environment, bioethics, and international technological friction, attract substantial attention, it is acknowledged as being essential that all people from general citizens to public policy-makers understand the social problems related to S&T. The times are moving in the direction of accepting the reality of S&T.

Here, we should not overlook the role that 'Mode Theory' played in the development of this new STS theory. This made an attractive debut in the 1990s and was proposed in a book co-authored by Michael Gibbons (who at the time was Director of the Science Policy Research Unit, Sussex University, UK) and entitled "The New Production of Knowledge" (the Japanese translation under the supervision of Shin-ichi Kobayashi is entitled "The Modern Society and Creation of Knowledge: What is Mode Theory?"). In this book, a social format organizing scientific and technological activities is regarded conceptually as a 'mode.' Mode 1 refers to a format of science in which studies and evaluation are performed in accordance with values and methods provided by groups of researchers within the existing academic fields. The authors of this book pointed out the appearance of Mode 2, which is a new format of science which targets actual problem solving and social application. Mode 2 made its debut because there exist many problems for which the existing Mode 1 failed to give any explanation and these problems were progressing, e.g. environment related problems, medical insurance related problems, and so-called 'Big Science' which has become more significant in recent years. Mode 2 is a trans-disciplinary way of targeting problems. Mode 2 is a research activity format that focuses on the side of utilizing knowledge. The appearance of Mode Theory may make people more aware of the problem-resolving viewpoint when using many academic approaches (i.e. both cultural & social scientific approaches and natural scientific approaches) when they think of what S&T should be.

Evaluation of STS itself is controversial since scientists who function as subjects of STS studies have argued against the theory, while others have voiced disagreement against portions of it. Nevertheless, we need to pay attention to STS since this has brought new viewpoints to S&T policy studies. What is worthy to mention in particular is the possibility that new methodologies may result from competition between several different fields since the methodology of STS is characterized by its trans-disciplinary concept. Some of these examples include history of science and technology, philosophy of science and technology, and policy of science and technology, since in these fields such studies have already been initiated. In addition, novel academic fields which did not exist in the past are proposed, which include laws of science and technology, economics of science and technology, politics of science and technology, ethics of science and technology, and popularization of science and technology (refer to "What is Science?" by Hideto Nakajima). We consider it necessary to give considerations to these new academic fields when conducting research and studies of S&T policy, although we cannot yet identify their actual stand.

In parallel to the appearance of the above-described new academic trends, substantial changes have occurred in the environment surrounding S&T over the past 10 years or so. In the economic society, when facing economic problems in particular, increasing expectations have been placed on S&T to play a role in activating industries, and each country has formulated strategic policies one after another to support advanced S&T. On the other hand, there has been an increasing number of issues requiring international cooperation, e.g. patent and standards, and there is an argument that in the fields of life sciences and information technology, some limitations are necessary for the implementation of high-standard studies and the utilization of the results of such studies. For this purpose, it is very much required that S&T policies be decided not solely on the basis of evaluation made by specialists in particular fields, but be subject, upon their decision, to information disclosure and accountability and to reflect people's opinion. A substantial portion of recent S&T administration has been spent handling these new issues that were not taken into account in the past.

(2) New Themes and Approaches

NISTEP has been engaged, as stated above, in a variety of studies regarding the relationship between S&T and people & society, and considers that there exist many themes in diverse fields which we should study in the future. While giving consideration to the above-described changes that have occurred in the circumstances surrounding S&T, we, the 2nd Policy-Oriented Research Group in particular, decided that our study will target technological fields for which actual problems requiring prompt resolution currently occur or for which it is foreseeable that such problems will occur in the very near future. When NISTEP received assessment by the Evaluation Committee on Organization in 1998, the Committee pointed out that an advisory function is one of the roles of our institute. In order for us to fulfill this function, we believe that our institute is expected to address the above stated types of technological fields. In addition, we have to mention that since these technological fields selected as our new themes provide a relatively large number of administrative cases and that we may encounter legislation or systematization mid-way through the investigation, our policy institute, which is positioned in-between general academic institutes and administrative agencies, has the advantage of fully exercising an impartial mandate.

We also consider, of course, that our studies in these fields will build upon demonstrated findings and knowledge within the framework of the general investigation of the relationship between S&T and people & society, and will thus contribute to well-balanced research of the general arguments, which have been active, and demonstrations regarding this relationship.

Upon the decision made on our future study themes, we considered two major categories: 1) advanced S&T which is promoted primarily by the national government, e.g. nuclear energy development and space development; and 2) advanced S&T for which the national government takes a relatively neutral position to consider nationwide promotion and regulations. We cannot determine to which category individual S&T

fields belong. However, we can expect that in the latter category, S&T studies produce principals, whereas the former category gives opportunities of application of such principals. Our Group therefore decided to first conduct studies in the fields of Category 2) and then, on the basis of the results thus obtained, conduct studies in the fields of Category 1).

The S&T fields of Category 2) are extremely diverse and we cannot therefore perform studies covering all fields. As such we have to select representative fields from a specific point of view then study these fields sequentially. Through the course of our decision making, attention was paid to the fact that "regulations" constitute an important part of recent S&T policies. It has been considered that research does not go well with regulations; however, when studying those S&T fields belonging to Category 2) which currently cause social problems, we have to consider regulations in almost all such studies.

The S&T fields belonging to Category 2) can be roughly divided into 3 groups in terms of how these studies are related to regulations. The first group consists of S&T fields for which it is considered socially necessary to regulate the studies themselves. An example of this group is the life sciences, which has recently produced hot debate in society because of reproductive medical technology and the creation of cloned embryos. (It should be noted that all fields included in this first group do not require social regulations for implementation of studies themselves, but that individuals want to formulate prompt action to regulate studies in some fields.) The S&T fields in the second group are those for which not studies but study results have a substantial influence on society and various regulations are thus considered necessary at the stage of applying such technology to society. An example of this group is information technology. (It should be noted that differentiation between the first and second groups may be difficult.) The third group includes S&T fields in which it is expected that study results be reflected in regulations. Contrary to the first and second groups, it is expected that in S&T fields of the third group, application of study results to the society is expected under certain regulations in order to contribute to people's safety and humankind's welfare, even before such study results have yet achieved an intended level. Examples of this third group are environmental S&T and earth S&T.

The relation between advanced S&T, the results of which are hardly foreseeable, but have an enormous influence on people and society, and "regulations" has rarely been discussed except in specific fields (e.g. regulations of nuclear power). It is therefore significant to organize general ideas about advanced S&T and regulations upon investigation of S&T policies. This is also significant in order to foresee various problems which may occur. In the present Policy Study, we selected life sciences as our study theme, which is hottest among the above-described themes, and in particular focused on cloning technology in the field of reproductive medical technology. In the future, we plan to study the other fields sequentially on the basis of the present study results.

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# REGULATIONS ON LIFE SCIENCES

## Chapter 1: Possible Regulations

### Part 1: Legal Regulations

#### Section 1: Present Status and Strategy of Life Sciences

(Authored by Minoru Kuniya and Mami Oyama)

1. Present Status of Life Sciences

The life sciences (note that life science technology is called "life sciences" in the Japanese national government's policies) are intended to unravel the complicated and delicate mechanisms involved in life and reproduction. At the same time, the study results of the life sciences are applied to diverse fields including, among others, medical care, environmental preservation, agriculture/forestry/fisheries, and other industries.

When looking at the recent trends in research and development of the life sciences field, we recognize substantial accumulation of scientific knowledge and we can see the possibility that all life-related phenomena may be uniformly understood according to certain common principles. This is because it has become evident that all life-related phenomenon result from common actions: DNA, proteins and other relevant molecules in the organism undergo interactions in good order over time while receiving stimuli from outside the organism.

These developments in the life sciences were triggered by Watson and Crick (awarded the Nobel Prize for Medicine and Physiology in 1962) who discovered the structural model of DNA in 1953.

DNA is a double-chained molecule, with half of each chain being phosphoric acid and the other being a sugar. The chain consists of combinations of four bases. The subsequent discovery of restriction enzymes, which cut DNA molecules having specific base sequences (combinations), resulted in epoch-making progress in genetic engineering. In 1973, Cohen and Boyer first succeeded in gene recombination, and in 1979, the gene for human insulin was identified. A variety of achievements in diverse areas were attained over an extremely short period of time.

On the basis of findings and knowledge obtained so far, research and development in the life sciences is now progressing in directions aimed at understanding microscopic life-related phenomena on a molecular level in vivo; understanding complicated life-related phenomena such as embryonic development, disease onset, ecological systems and other life phenomena that result from orchestral combinations of these microscopic life-related phenomena; and understanding evolution and diversity in the biosphere.

Regarding future trends, it is anticipated that research and development will intend to understand basic in vivo molecules controlling complicated life-related phenomena, including, among others, DNA, protein, glucose, lipids, through the use of analytical methodology; and to explore the meaning of information, e.g. information of DNA base sequence, information of positioning of genes on chromosomes, and information contained in the three-dimensional structure of proteins. A specific example of the latter R&D objective is to deepen understanding of life-related functions controlled by DNA's specific base sequence. (In fact, research into gene function, and studies at the gene level to analyze the mechanisms involved in the development of the individual are actively performed, and industries utilizing biotechnology, e.g. production of drugs and foods through the use of gene recombination technology, have already made their debut.)

Along with progress in understanding the functions and structures which biological molecules possess, it is also anticipated that regarding life-related phenomena which occur as a result of the complicated correlation among many different factors such as development, disease onset and ecology, research and development will intend to elucidate many different aspects of the individual's life and the status of the ecological system as a group of individuals through the use of a comprehensive methodology involving study methods at the molecular, cellular and organism levels. In addition, on the basis of scientific findings on high-level functions of the individual or of etiologic factors, research and development will aim to control and design such functions, or to prevent and treat diseases. (Cloning technology and other relevant technologies which have attracted substantial attention in recent years are also related to identification of cellular-level phenomena during the developmental process as well as manipulation techniques at this level. This represents remarkable advancement in the life sciences.)

NISTEP conducted the Sixth Technology Forecast Survey (in June 1997) by questionnaire and predicted the time of realization for important topics in the life sciences field on the basis of responses obtained from specialists and other qualified individuals. Regarding hot topics in the

life sciences field, the forecasted realization time (expected year) was 2010 for development of drugs to prevent the onset of certain types of carcinomas, 2015 for utilization of information on the individual's gene structure for diagnosis and treatment, 2015 for widespread use of a method to increase stem cell number in a test tube for the purpose of using stem cells in treatment, and 2021 for clinical application of organ regenerating technology utilizing self-cell proliferation.

Similarly, in the fields of health, medical care and welfare, the forecasted realization time (expected year) is 2011 for widespread use of biological and immunological therapies which are effective in controlling cancer, 2013 for practical use of effective methods against cancer metastasis, 2014 for widespread use of gene therapies to control malignant tumors; 2007 for development of an HIV vaccine, 2010 for widespread use of methods of eradicating viruses from the blood, 2012 for practical use of gene therapies for the treatment of gene deletion diseases, 2020 for practical use of oral gene treatment; 2013 for development of a completely implantable-type artificial heart, 2018 for practical use of a completely implantable-type artificial kidney, 2016 for development of an artificial liver (with an extracorporeal liver function supporting device) which can be used continuously for extended periods; and 2023 for practical use of artificial cells possessing organ characteristics.

Trends noted in North American and European countries also indicate an acknowledgment of the importance of the life sciences and in particular, it is recognized that life sciences play important roles in creating novel frontier industries which may contribute to strengthening of the economy. Accordingly, international competition is currently very severe, particularly in such fields as originating intellectual property rights.

In Japan, the "Life Science Related Research and Development Basic Plan" (decided by the Prime Minister) in August 1997 selected the following areas that the nation should address with particular interest and effort in the life sciences field: research and development (R&D) of living things as an integrity system, including among others, R&D of the brain, cancer, embryonic development, ecological system and the biosphere; and R&D of fundamental biological molecules including the human genome. In addition, the Plan mentioned the necessity of giving considerations to creation of cloned individuals and other bioethics-related topics.

2. Trends in Life Sciences Strategies in Major Countries with Special Regard to the US

(1) Life Sciences Strategies

Considering the present status of the life sciences, each country tries to address issues in this field in a strategic manner. In this section, we will briefly review life sciences strategies over the world, focusing on the US where there exists overwhelmingly enormous potential for this field.

We cannot discuss world S&T strategies without first mentioning US S&T strategies. Here, we will therefore look back briefly on the history of the US general S&T strategies and in particular, on the history of life sciences related strategies to such an extent as necessary for discussion on what regulations for life sciences should be.

Since World War II, the US has taken the initiative in S&T by promoting major projects (e.g. nuclear power development, space exploration) supported by excellent manpower which fled to the US from Europe and its own huge national power. The fields that were remarkably superior were national defense and basic research. It is acknowledged that the superiority of these fields spun off industries of private origin.

When entering the 1980s, however, the US suffered from both a trade deficit and fiscal deficit, leading to a reduction in its national economic power. This in turn made both national government and non-government parties alike afraid that US industries were relatively less competitive with those of other major industrial countries. In response to the concern, new S&T strategies were formulated one after another during the times of the Reagan and Bush administrations. The "President's Industrial Competitiveness Committee Report" (Young Report) in 1985 presented specific strategies in the initial stage. The "State of the Union Message" by President Reagan in 1987 declared the "competitiveness initiative." For specific research fields, the "superconductivity initiative" was announced in the same year, which aimed at realization of practical use of high-temperature superconductivity, a technology recently discovered at the time (note that in the following year, the superconductivity competitiveness law was established). Subsequently, the US strongly emphasized these attitudes to its own S&T strategies in S&T related conferences and other discussions within the international framework.

These US policies on S&T can be roughly summarized as follows: internally, i.e. inside the nation, promotion of cooperation among public sector, private sector and academic world, acceleration of transfer of national research results to private industries, intensifying protection of intellectual property rights, and strengthening of human resources; and externally, i.e. outside the nation, protection of patents, requirement for symmetrical access, and proposals on international cooperative plans of large-scale projects (e.g. SSC plan, space station plan, international nuclear fusion plan).

What attracted attention under these circumstances was the fact that specific strategies regarding biotechnology were formulated during the Bush Administration. Specifically, the "Report on Biotechnology Polices" (President's Competitiveness Committee, Chaired by Vice President Quayle) was announced in February 1991. The key topics of the Report are stated below, and closely reflect US biotechnology policies at the time.

1) Foster competitiveness and commercialization by new discoveries including new biotechnology

2) Reconsider allocation of the Federal Government's funds to biotechnology researches in the fields of agriculture, clinical medicine, energy, and environmental survey.

3) For the Federal Government's research plans, continue to give priority to basic science, which will receive more support; and more consideration than ever to financially support developments of technologies contributing to realization of practical use and to expansion.

4) Announce principles for management of biotechnology (i.e. planned introduction of organisms possessing modified genetic characteristics into the natural environment).

5) Base regulations on the Four Principles for Regulatory Examination (e.g. a principle of minimizing regulatory burdens) as stated in the Report and protest against any attempt to build a new law system.

6) Protest against programs which will eliminate motives for new drug development.

7) Make every effort to protect manufacturing method patents in the field of biotechnology.

Since the inauguration of President Clinton from the Democratic Party in 1993, the US political priority has shifted to computer network and environmental/disaster prevention technologies. It is considered, however, that there has been no change in the basic positioning of strategies for life sciences technology as advanced S&T: life sciences technology strategies are positioned in relation to general S&T strategies which aim at strengthening US competitiveness.

In addition to the above-described overall strategies, life sciences related large-scale projects have been promoted. Representative of these individual projects is the "Human Genome Analysis Plan" which was started in 1988. This project is promoted by the National Institutes of Health (NIH) and the Department of Energy (DOE), with the objective of sequencing the entire human genome (which sums up a total of 3 billion base pairs) to provide a complete map of human genetic information. It is planned that in 2005, sequencing of the entire human

genome will be complete. (In concert with the US policy, several European countries and Japan also are currently promoting human genome analysis projects.)

Review of changes over time in the US Federal Governmental budget for S&T policies by individual objectives reveals the highest increase rate of approximately 30% for health related budget (including the field of life sciences) from $9.226 billion in 1991 to $11.920 billion in 1996. National defense related budget remained large as an absolute value but showed a decrease over the same period of 4%: $39.328 billion to $37.791 billion. The budget for space exploration, which was the lion of the day, recorded an increase over the same period of approximately 20%, from $6.511 billion to $7.871 billion, although in recent years it has shown very little growth. In light of the above-described R&D potential that the US has, and also in comparison to the standards of R&D as compared to Japan, it is recognized that the US has achieved overwhelming supremacy in the field of life sciences (Figure).

European and other countries also actively promote life sciences related R&D activities in parallel with information technology, although the details of activities of these countries will not be discussed here.

Figure: Comparison of S&T standards among Japan, Europe and the US

| In the development & application field also, Japan is superior to Europe but comparison between the US and Japan indicates that except for the production & machinery field, Japan needs to endeavor more and more. |
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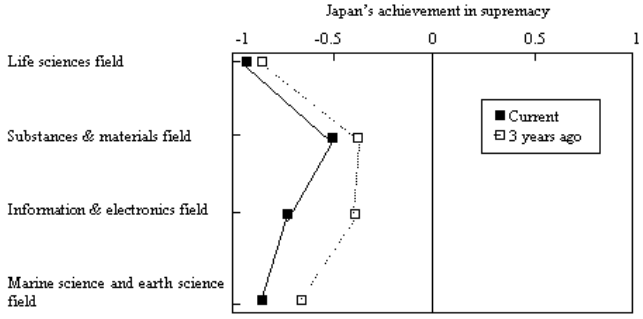
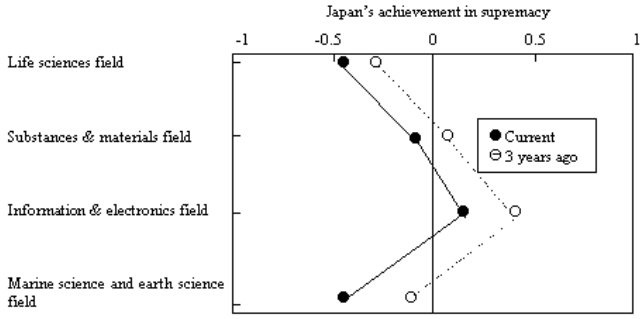
(1) Comparison between the US and Japan




(2) Comparison between Europe and Japan




Data Source: Report of Survey on Actual Status of Research Activities in Japan in the Year of 1995, Science and Technology Agency

(2) Status of Reproductive Medical Technology

The authors have so far discussed the trends in life sciences as a whole, which covers diverse topics over a wide area. Reproduction supporting S&T, a topic of the life sciences field, differs from the above-described general S&T strategies, however. In Europe, careful discussion about application of reproductive medical technology started in the 1980s and legal regulations were formulated concerning its application starting in the 1990s. These legal regulations will be described later in Section 2. Here, the authors will mention the events in the US since these are unique.

In the US, there already existed serious antagonism regarding artificial abortion, i.e. between pro-choice and pro-life supporters. Although the Supreme Court adjudicated legalization of artificial abortion valid (Roe Judgment in 1973), subsequent Supreme Court judgments permitted some regulations in accordance with individual state laws. To date there are no fixed policies or legal regulations formulated by the nation. On the other hand, the National Research Act was established in 1974, which resulted from discussions about pre-birth examination for genetic diseases and what the limits of studies using human subjects should be. In connection with the Act, it is prescribed that medical institutions have an obligation of establishing guidelines and institutional review boards (IRBs). In this manner, the system to cope with ethical issues in the medical care field has been built up. Research conducted in the US at that time contributed to the establishment of the concept of bioethics.

Under these circumstances, the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research was organized in 1981 through to 1983 and undertook diverse discussions and investigations regarding "health care" and "research." However, the Biomedical Ethics Advisory Committee (BEAC), which was established in Congress following the President's Commission, was disorganized and did not issue any report. Since then, in the US no opinion regarding reproductive medical technology has been submitted. Under these circumstances, the US Government did not announce any national policy and it discontinued national research funding in the field of reproductive medical technology, studies of which therefore have been promoted by private funding. At present, application of reproductive medical technology is very active in the form of venture business. For example, DNA fingerprinting is a reproductive medical technology business born in the US and is commercially utilized in Japan also. In the future, life sciences related business is likely to be undertaken in diverse regions irrespective of country borders.

The birth of a cloned sheep in 1996 triggered arguments for and against human cloning. In the US, President Clinton immediately made a

proposal to ban cloning related studies. However, a bill of legislation to outlaw cloning was rejected due to differences in opinions between the Democratic and the Republican Parties. Possible future legalization in the US is thus not clear. It has already been reported by the mass media that some private companies are attempting to undertake business based on the application of cloning technology (refer to an article of the Mainichi Shinbun: "Attempt to clone a man in Japan" dated December 2, 1998).

These circumstances are not conducive to the nation's strategies for life sciences. We have to take into account these issues, however, when we investigate legal regulations on application of life sciences in Japan. As the Warnock Report in the UK points out, which the authors will discuss later, it is highly likely that the needs for reproductive medical technology (which is expressed as "surrogacy" in the Warnock Report) will remain in changing forms, despite what ideas a nation has. Even if there are regulations placed on medical care or there are actual limitations to surrogate mothering therapies, people may go to foreign countries where such therapies are easily available. We have to therefore consider the possibility that regulations in only one country may not resolve problems. (According to the book "Laws on Artificial Reproduction" by Michiko Ishii, at a center offering surrogate mother services, located in the suburbs of Los Angeles in the US, 4 Japanese couples had 4 babies by 1990 and an additional 9 Japanese couples had attempted to do so; while at a hospital located in Seoul in the Republic of Korea, a total of 4 Japanese couples received or requested surrogate mothering therapies.)

3. Relation between Life Sciences and People & Society (With Special Regard to Government Related Activities)

(1) When investigating life sciences and legal regulations, those concerning reproductive medical technology are significant in particular, from the viewpoint of the above-described global S&T strategies. In Section 2, the authors will therefore review what types of investigations have been conducted to address issues of reproductive S&T in industrialized countries. In Section 3, the authors will discuss viewpoints on which to base investigations of legal regulations in the field of reproductive S&T in Japan, in light of the fact that to date no legal regulations have been formulated. Prior to the review and the discussion, the authors consider it useful to review retrospectively Japanese regulations on reproductive medical technology and even more widely, what investigations were conducted in Japan with regard to the relation between life sciences and people & society.

The relation between life sciences and people & society is not an entirely new issue to Japan. Researcher, private companies and governmental agencies have already been engaged in relevant investigations which were ahead of their time. In this section, the authors will mainly review the governmental actions involved in the "relation between life sciences and people & society." The Table in the next page chronologically lists governmental recommendations, reports, councils, and the establishment of laws and ordinances, together with some overseas movements. As the Table shows, some issues were already submitted for examination, and partial discussion has already started. The authors would like to take these issues as reference when discussing the main topic. (Events in the square parentheses occurred overseas.)

Table: Chronological Table on Relation between Life Sciences and People & Society

| | |
|---|---|
| April 1971: | Recommendation No. 6 of the Council for Science and Technology proposes "life sciences." |
| | February 1975: Ashiroma Conference held in the State of California in the US, and is related to gene recombination.] |
| June 1976: | [NIH in the US decides on guidelines for gene recombination.] |
| | September 1976: Investigation of regulations on recombinant DNA is started in Japan. |
| July 1978: | [World's first ever externally conceived baby (test-tube baby) is born in the UK.] |
| August 1979: | Recommendation in response to Advisory Opinion No. 8 of the Council for Science and Technology is published: "On the Basis of Promoting Policies for Gene Recombination Studies" (guidelines for gene recombination experiments) |
| April 1983: | A Round-Table Conference on Life and Ethics is organized by the Japanese Ministry of Health and Welfare (MHW). |
| May 1983: | At the Williamsburg Summit in the US, regarding PA (Public Acceptance) of advanced technology, Prime Minister Nakasone proposes organization of the "Life Sciences and People Conference." |
| October 1983: | At Tohoku University, an externally conceived baby in Japan is born. |
| March 1984: | The First Assembly of the Life Sciences and People Conference is held (followed by a total of 6 assemblies, with the 6th one held in May 1989, a report of which is presented to the Summit each time). |
| | [In the US and Europe, reproductive medicine regarding in vitro fertilization starts to come into active controversy.] |
| September 1985: | The MHW's Round-Table Conference on Life and Ethics issues a report (after a total of 18 meetings). |
| March 1986: | A Round-Table Conference on Life Sciences and People is established by the Council for Science and Technology. |
| December 1987: | The 1st Report by the Round-Table Conference on Life Sciences and People is published (and followed by 3 reports). |
| July 1988: | The National Institute of Science and Technology Policy is founded. From the beginning, the relation between S&T and people & society is one of the major themes that NISTP addresses. |
| November 1988: | Tokyo International Symposium on Life Sciences and People is held. Academic Association of Bioethics is organized. |
| May 1989: | The 6th Assembly of the Life Sciences and People Conference (the last assembly) is held. |
| February 1990: | A clinical research group on brain death is established in the Prime Minister's Office. |
| June 1990: | At the Round-Table Conference on Life Sciences and People, an outlined summary report is prepared (a total of 19 reports). This Conference has since finished. |
| 1990-1994: | [Laws concerning advanced reproductive medical technology are established in the UK, Germany and France.] |
| February 1994: | The MHW decides on the "Guidelines for Clinical Studies of Gene Therapies." (The Ministry of Education also establishes guidelines at universities in June.) |
| February 1997: | [In the UK, success in creating a cloned sheep is reported (note that the cloned sheep was born in July 1996).] |
| March 1997: | Science Council decides to discontinue subsidizing cloning research. |
| | The Policy Committee of the Council for Science and Technology decides to withdrew allocation of research budget to creation of cloned human individuals. |
| | [US President Clinton issues the President Order to discontinue Federal Government funding of cloning research.] |
| April 1997: | Health Science Council is established. Subsequently, an Advanced Medical Care Technology Evaluation Committee is organized within the Council. |

[At the European Council, a Protocol to prohibit use of technology for the purpose of human cloning is signed.]

May 1997: [The World Health Organization (WHO) adopts a resolution to prohibit application of cloning technology to humans.]

June 1997: [At the Denver Summit, a declaration to ban closing is made.]

[In the US, a bill of legislation to outlaw cloning is submitted to Congress (but subsequently rejected).]

July 1997: The Council for Science and Technology recommends a life sciences research and development basic plan.

September 1997: Within the Council for Science and Technology, a Bioethics Committee is established.

November 1997: [UNESCO makes the "Universal Declaration on the Human Genome and Human Rights" including a ban on human cloning.]

January 1998: Within the Bioethics Committee, a Cloning Subcommittee is organized.

June 1998: The Cloning Subcommittee issues an interim report.

July 1998: The Bioscience Group of Science Council issues a report.

In Japan, a cloned cow is successfully born.

November 1998: The 2nd Bioethics International Summit Assembly is held.

[In the US, isolation of ES cells (embryonic stem cells) from human embryos and growth of these isolated ES cells under culture are successfully performed.]

December 1998: [In the Republic of Korea, experiments to create human cloned embryo are conducted.]

Within the Bioethics Committee, a human embryo subcommittee is organized.

(2) As clearly indicated by the chronologic table, investigation of the relation between life sciences and human society can be traced back to Recommendation No. 6 of the Council for Science and Technology (note that the authors omitted prior investigations to this recommendation, which focused on medical ethics.) This Recommendation proposed promotion of life sciences, which initiated specific actions that prompted various individuals in different segments of society to consider the influence of life sciences on people and society. An early example of these reactions was that from 1971 to 1973, when the All Nippon Buddhist Association annually held a symposium on life sciences and Buddhism.

Immediately after that, the Ashiroma Conference was held in the US to discuss what regulations should be imposed on gene recombination experiments from the viewpoint of researchers. On the basis of the discussion of this Conference, NIH first issued guidelines for experiments on gene recombination. Subsequently, this movement spread over to many other countries. In Japan also, the Ministry of Education and the Council for Science and Technology initiated investigations for setting guidelines.

In addition to these safety related investigations, Japanese Prime Minister Nakasone proposed organization of the "Life Sciences and People Conference" at the Williamsburg Summit in the US, in April 1983. On the basis of this proposal, "the First Assembly of the Life Sciences and People Conference" was held at Hakone in Japan in May 1984, and consisted of 4 sessions: (1) present status and future of life sciences, (2) significance of life sciences to society, (3) significance of life sciences to the individual, and (4) international cooperation on life sciences. This was important since these discussions were driven by top-leaders. The discussion results of this 1st Assembly was reported to the following London Summit. Subsequently, a total of 6 assemblies of the "Life Sciences and People Conference" were held in different countries (2nd: Bioethics (in France), 3rd: Neuroscience and ethics (in West Germany), 4th: Towards international ethics for the sake of studies concerning humans (in Canada), 5th: Human gene DNA sequence-various ethical issues, and 6th: Earth environment and bioethics (in Brussels, Belgium)).

For conferences at the level of specialists in Japan, a "Round-Table Conference on Life and Ethics" was organized by the Ministry of Health and Welfare (MHW). This Conference held 18 meetings for discussion and issued a report in September 1985. The report consisted of (1) various issues concerning organ transplantation, (2) medical care when approaching death, (3) problems related to brain death, (4) development of reproductive medicine, (5) treatment of genetic diseases, (6) relation between medical doctors and patients, (7) harmonization of medical progress and ethics, and (in a separate chapter) various viewpoints on life. As indicated by the report, the conference covered diverse topics.

Subsequently, in the Council for Science and Technology also, a "Round-Table Conference on Life Sciences and People" (Chairpersons: Michio Okamoto, followed by Wataru Mori, both of whom were members of the Council for Science and Technology at the time) was organized. The Conference held a total 19 meetings. This Conference was not intended to draw conclusions, but to report the progress of their discussion to the Council for Science and Technology, the chairperson of which is the Prime Minister.

Subsequently, investigations on the relation between life sciences and people & society was transiently suspended for a while. This was because during this time attention focused on new topics such as environment related issues and problems surrounding brain death, or on individual topics. (The present chronological table does not include events related to the environment or brain death.)

The next peak of discussion occurred after the birth of the first cloned sheep, which took place in the UK and received considerable media attention. This development in research created a number of debates that remain unresolved. Furthermore, the birth of the sheep is considered an epoch-making event since it resulted in initiation of experiments using human ES cells and thus, raises issues not only related to cloning but also to that involving human reproduction. The authors will introduce the status of investigations that resulted from this event later in this Policy Study Report, as appropriate.

The overall picture indicates that Japan is not always behind the US and European countries in life sciences related investigation, and in some areas, Japanese activities may be positioned at the forefront of the discussion on life sciences and society. Although Japan has often overcome considerable challenges, it has not always been able to respond successfully to difficult problems, which may at the time seem unavoidable. Accordingly, when we consider the past experiences that Japan has had and what Japan hopes to define itself as in the future, we expect as a country to take self-directed actions at an appropriate time. For the moment, we have to pay special attention to the fact that Europe considers the relation between life sciences and society in the framework of reproductive medical technology, and have drawn some conclusions such as establishment of laws and legal regulations, whereas Japan does not take any such actions. We therefore have to return to the starting point to assess whether issues of cloning technology fall under those of reproductive medicine or those of life sciences. In this Policy Study Report, detailed discussion of individual technologies will only be made for cloning technology. Comprehensive discussion will be further required, however, regarding what the relation should be between investigation of reproductive medical technology and investigation of life sciences.

## Section 2: Details and History of Regulations in Several Countries

### 1. History until Legislation (by Individual Country)

The birth of the first externally conceived baby, i.e. the test-tube baby, in the UK in July 1978 triggered a round of arguments over advanced reproductive medical technology in the US and in European countries.

Regarding reproductive medicine, artificial abortion and contraception were already the focus of arguments starting in the 1960s and in Europe, artificial abortion laws were established in succession in several countries. The argument was a social issue over the woman's freedom to choose whether or not to have a baby, since the abortion technology itself was already existing. On the other hand, the first baby conceived out of the mother's body had an enormous impact on society as did the first performance of heart transplantation surgery in South Africa in 1967, since both were regarded as signaling an advanced medical revolution. These events also raised the issue of whether such advanced medical science technology is acceptable by society.

Regarding reproductive medical technology, each country conducted its own investigations and called for legislation to control reproductive medical technology including in vitro fertilization. Specifically, starting around 1984, several countries established their own councils consisting of well-informed persons from many fields to discuss the issue. On the basis of their reports, the legislative bodies of these countries made a variety of examinations and amended their legal systems to regulate advanced medical technology in 1990 through to 1994. From now on, the authors will present in brief the status of investigations performed in major countries (mainly according to documents provided by Mitsubishi Kasei Institute of Life Sciences) and in the subsequent sections, will introduce outlines of legislation in each of these countries and the basic ideas underlying the legislation.

The authors will discuss legal issues related to application of reproductive medical technology (with special regards to human cloning technology) in Japan in Section 3 onwards. We should therefore, prior to such discussion, briefly describe the status of legal regulations in foreign countries. However, for background the relevant references and documents listed in the Table on the following page are provided. In this Section, the authors will only introduce information necessary to gain a view of the overall picture. Nevertheless, we have found that when laws in foreign countries are introduced, representative reports which indicate and organize the basic ideas behind the establishment of such legal systems in these foreign countries (although not all ideas stated in these reports were employed) or decisions of constitutional courts have so far not been introduced in detail. The authors will thus explain these points.

Table: Investigations of Regulations on Reproductive Medical Technology in Major Foreign Countries

1. UK

   1984: Warnock Report

   1986: Consultation Paper

   1987: White Paper (indicating the framework of legislation)

   1989: Pokinghorn Report (regarding use of aborted embryos for research)

   1990: Establishment of Act

2. Germany

   1985: The German Federation Medical Association sets guidelines for in vitro fertilization and embryology.

   1985: Benda Report

   1988: The Federation-State Working Group Report (surrogacy banning is added to embryo protection)

   1990: Establishment of Act

3. France

   1982-: National Advisory Committee on Life Sciences and Medical Ethics

   1985-: Open forums, etc. sponsored by the Government are held.

   1988: Bureban Report

   1991: Lenoir Report

   1992: Bill proposed by the Ministry of Justice is submitted.

   1993: Mattei Report

   1994: 3 Acts are passed by Parliament.

Reference Information: the US

1979: The Ethics Advisory Board (EAB), Department of Health & Human Services, issues a report (in which in vitro fertilization is approved).

(1983:The President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavior Research issues a report on genetic engineering.)

1988-1989: The Biomedical Ethics Advisory Committee (BEAC) is established in Congress (but is disorganized and fails to issue a report)

### 2. Outline of Legislation in Each Country

Outlined below are legal systems in the UK, Germany and France (for comparison, refer to Reference 1).

(1) UK

<Form of Act>

In the UK, the "Human Fertilization and Embryology Act 1990" established in 1990 provides regulations. (The information described below

is derived from data and documents provided by the Life Sciences Department of the Japanese Science and Technology Agency.)

The Act regulates the general handling of embryos and gametes in connection with human fertilization and development of embryos. If the prescribed conditions are met, research using embryos and gametes and practice of reproductive medicine are allowed after obtaining licenses from the administrative authority to do so.

The Act prescribes the activities governed by the Act in connection with embryos and gametes individually.

<Prohibitions in Connection with Embryos>

In connection with embryos, bringing about the creation of a human embryo, or keeping or using an embryo are prohibited (Article 3-(1)). In addition, placing a live embryo other than a human embryo in a woman (and placing any live gametes other than human gametes in a woman) is prohibited (Article 3-(2)).

The Act also prescribes that a license cannot authorize keeping or using an embryo after the appearance of the primitive streak (i.e. an embryo at 14 days after fertilization), transplanting a nucleus to an embryo, or keeping an embryo in an animal body (Article 3-(3)).

<Prohibitions in Connection with Gametes>

Except in pursuance of a license, storing any gametes, using gametes (excluding cases of providing treatment services between the man and the woman concerned), mixing gametes with the live gametes of any animal, and placing any gametes in the woman are prohibited (Article 4).

<Establishment, etc. of the Administrative Authority>

The Act prescribes the foundation of the Human Fertilization and Embryology Authority which is entitled to make a judgment of granting licenses to activities using embryos and gametes. The Act also prescribes penal codes (penalty of imprisonment or fine) to behaviors violating the prescribed rules.

<Activities for which Licenses may be Granted>

License for treatment, storage and research may be granted (Schedule 2).

In the course of providing treatment services, a license may authorize using and examining gametes (i.e. mixing sperm with the egg of a hamster, or other animal specified in directions, for the purpose of testing the fertility or normality of the sperm, but only where anything which forms is destroyed when the test is completed and, in any event, does not exceed the two cell stage), bringing about the creation of embryos in vitro, keeping embryos, testing embryos, and placing of an embryo in the woman. A license may authorize keeping gametes and embryos.

In addition, for the sole purpose of research, a license may authorize bringing about the creation of embryos as well as keeping and using embryos.

<Surrogacy>

The Surrogacy Arrangements Act 1985 prohibits, among others, surrogacy arrangements for profit-making purpose and advertisement on offering surrogate mothers.

<Recent Moves>

For handling of human cloning, the licensing body has indicated its policy of not granting licenses for bringing about the creation of embryos outside the body for the purpose of creating cloned humans, or keeping or using such embryos.

(2) Germany

<Form of Act>

In Germany, the "Embryo Protection Act" established in 1990 provides regulations. (The information described below is derived from "Embryo Protection Act: Overseas legislation Vol. 30, No. 3" authored by Junko Saito.)

This Act is a special criminal law, which lists individual prohibitions in connection with various reproductive technologies and prescribes criminal penalty (imprisonment or fine) against violations. This Act prescribes diverse prohibitions against a variety of technologies in connection with embryos and gametes.

<Handling of Germ Cell Lines>

This Act as a rule prohibits any artificial changes to be made in the genetic characteristics of human germ cell lines and prohibits the use of such changes for fertilization (Article 5).

This Act as a rule prohibits artificial gender selection through the use of identified sperm cells (Article 3).

<Various Reproductive Technologies such as Artificial Insemination>

This Act prescribes regulations regarding various reproductive technologies such as artificial insemination and prohibits the following: artificial fertilization of an egg cell retrieved from a woman for any purposes other than pregnancy of that woman; artificial introduction of human sperm cells into a human egg cell; and retrieval of an embryo for the purpose of transplanting the embryo into another woman (Article 1). It also prohibits artificial insemination using sperm from a dead man (Article 4).

In addition, the Act prohibits artificial insemination in a surrogate mother or transplantation of an embryo to a surrogate mother (Article 1).

<Handling of Embryos>

For handling of embryos created outside the body or embryos taken from the woman, the Act prohibits selling such embryos as well as transferring, obtaining, or using such embryos for any purposes other than that required for maintaining such embryos. It also prohibits development of a human embryo outside the body for any purposes other than pregnancy (Article 2).

<Handling of clones>

The Act prohibits artificially bringing about the creation of embryos which possesses the same genetic characteristics as those of other embryos, fetuses or humans, and also prohibits transplanting of such embryos to the women (Article 6).

<Handling of chimeras and hybrids>

The Act prohibits inducing cell fusion of multiple embryos (including human embryos) which possess different genetic characteristics, and producing embryos, which are able to undergo mitosis, by fertilization between an animal gamete and a human gamete. It also prohibits transplantation of embryos thus produced to a woman or animal, and transplantation of human embryos to animals (Article 7).

(3) France

<Form of Act>

In France, three acts collectively called the "Bioethics Act" were established in 1994, which are based on common ethical principles and provide comprehensive regulations over the entire advanced medical technology field (organ transplantation and reproductive technology). (The information described below is derived from "Total Picture of French Bioethics Act: Overseas legislation Vol. 33, No. 2" authored by Miyuki Ohmura.)

The three acts are "Human Body Respect Act," "Transplantation and Reproduction Act," and "Registered Data Act." These acts introduced relevant prescriptions into the Civil Code, the Penal Code, and the Health and Medical Care Code.

The "Human Body Respect Act" incorporated principles providing the foundation to regulate various advanced medical technologies, into the Civil Code, and related criminal regulations into the Penal Code.

The "Transplantation and Reproduction Act" incorporated regulations on technologies related to removal and transplantation of organs, reproductive medicine, pre-delivery diagnosis, gene examination and any other relevant matters, into the Health and Medical Care Code.

The "Registered Data Act" incorporated, within the same ethical principles, special regulations, among others, regarding procedures to be followed when utilizing personal medical information for studies, into the Information Protection Act.

These changes made in the French legal system resulted from substantial amendments such as changes in civil law principles. It is therefore difficult to introduce them in the organized manner used for the UK and Germany. Instead, the main points of the amendments will be examined by individual major code.

<Amendment of the Civil Code>

A philosophy constituting the basis of regulations was incorporated. The amended Civil Code secures the superiority of the individual, prohibits invasion of the dignity of the individual, and secures respect for the individual from the very beginning of life (Article 16). It prescribes the rights according to which the human body is given respect and the rule of making the human body inviolable (Article 16-1). It prohibits invasion into the integrity of the human species, eugenic behaviors intended to organize selection of human beings, and conversion of genetic characteristics leading to any change in descendants of humans (except for studies aiming at prevention and treatment of hereditary diseases) (Article 16-4).

Furthermore, in connection with issues related to the contract act and the Family Act, the amended Civil Code invalidates all contracts made for the purpose of reproduction and pregnancy for others (Article 16-7). It also prescribes that in the case of medically assisted reproduction in which a third party is involved as a donor, no parent-child relation is to exist between the donor and the baby thus born (Article 311-19). (This issue will be discussed again in Section 5, Item 3-(2).)

<Amendment of the Penal Code>

The amended Penal Code prescribes penalty of imprisonment and fine against the behaviors listed below.

Implementation of eugenic activities intended to organize selection of human beings (Article 511-1).

Practice of obtaining human embryos by gaining equivalent value to this action, offering embryos thus obtained, and transfer of such embryos for value (Article 511-15). Creation of human embryos outside the body for industrial or commercial purposes and use of such embryos (Article 511-17).

Creation of human embryos outside the body for the purposes of examination, research and experiments, and performance of experiments with human embryos (except for the case of testing an embryo of a man/woman couple for the purpose of reproduction ) (Articles 511-18 and 511-19).

<Amendment of the Health and Medical Care Code>

This Code prescribes the rules pertaining to reproductive medicine. It is prescribed that medical assistance to reproduction shall be performed to meet the request made by a man/woman couple to be parents, provided that this man/woman couple are alive, in the range of reproductive age, are married or can show evidence that they have lived together for at least 2 years, and give prior consent to embryo transplantation or artificial insemination (Article L152-2).

It is prescribed that creation of an embryo outside the body is only allowed when such creation is within the range of scope of the objective to be achieved by medical assistance for reproduction and also follows the objective (Article L152-3).

It is also prescribed that a man/woman couple who obtains an embryo is not allowed to know the identity of the man/woman couple who donates the embryo, and vice versa, and is not allowed to pay remuneration to the couple who donates the embryo (Article L152-5).

It also prescribes necessary administrative procedures: collection, treatment, storage and transplantation of gametes shall only be performed by nonprofit public or private health organizations or institutions which have obtained licenses from the administrative authority to do so (Article L673-5).

<Recent Moves>

In response to recent advances in cloning technology, the National Ethics Advisory Committee examined the relevant issues and submitted "Recommendations on Reproductive Cloning" to the President, in which the Committee made a statement that human cloning violates Article 16-4 of the Civil Code and also mentioned the criminal penalty prescribed in Articles 511-1 and 511-18 of the Penal Code.

(4) Status of Responses by International Organizations

In addition to actions taken in individual countries, international activities are undertaken, which will in brief be described below (according to the data and documents provided by the Life Sciences Division of the Japanese Science and Technology Agency).

< Council of Europe >

At the Council of Europe which consists of European countries, a treaty which controls in vitro fertilization and handling of human embryos, i.e. the "Convention on Human Rights and Biomedicine" was signed in April 1997. This Treaty prohibits creation of human embryos for the

purpose of research. Thirteen countries of the 40 in Europe signed this Treaty.

In January 1998, the "Additional Protocol to the Convention on Human Rights and Biomedicine" was signed, which prohibits all cloning technology for the purpose of creating genetically identical humans. (Twenty-four countries signed the Protocol.) (Note that the above-stated number of countries which signed the Treaty and the Protocol are as of November 5, 1998.)

<World Health Organization (WHO)>

In May 1997, the World Health Organization (WHO) adopted the "Resolution Concerning Cloning Technology," according to which no application of cloning technology to human beings is acceptable.

<Denver Summit>

At the Denver Summit held in June 1997, French President Chirac proposed a human cloning ban as an agenda at the Summit and the other attending countries agreed with this proposal. The Summit adopted the "Eight-Country Summit Declaration" which emphasizes the necessity of national activities and international cooperation to prohibit nuclear transplantation of somatic cells for the purpose of creating descendants.

<United Nations Educational Scientific and Cultural Organization (UNESCO)>

In November 1997, UNESCO adopted the "Universal Declaration on the Human Genome and Human Rights" which is a general declaration regarding handling of the human genome and human rights. This Declaration prescribes that no research or its applications concerning the human genome will prevail over respect of human rights, fundamental freedoms and human dignity of individuals or, where applicable, of groups of people and that practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted.

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3. Thoughts Supporting Legislation

(1) UK: Warnock Report

(i) In the UK, the Warnock Report of 1984 was the earliest regarding advanced reproductive medical technology. (At a local government level, the Warler Report was issued in Victoria, Australia.)

The Warnock Report was concerned with the results of investigations and discussions by an advisory committee, consisting of 16 members with Mary Warnock as the chairperson, which was organized at the request of the UK national Government in July 1982. The Committee investigated and discussed future possibilities in medical and scientific developments in connection with human fertilization and embryology, and evaluated the social, ethical and legal significance of results attained by such developments as well as any relevant policies. The Warnock Report was issued in June 1984. (The information described below is derived from "A Question of Life" authored by Mary Warnock and translated by Koji Uwami, with the Japanese version published by Kyodo Shuppan.)

The Committee consisted of a philosopher, a theologian, an administrator, a midwife, 3 medical doctors, 2 psychologists, a medical researcher, a head of an examination division, a social worker, 2 lawyers, a person from a foster parent association, and a foundation director general. Considering the fact that there were diverse opinions in different sections of the society, the Committee tried to collect testimonies from as many organizations as possible and at the end of the Report, attached is a list of 254 organizations or associations from which they obtained testimonies, and the statement that they additionally received 659 letters and documented comments.

The Report addressed the following issues in connection with technologies to treat infertility: (a) common problems; (b) individual technologies, such as (1) artificial insemination, (2) in vitro fertilization, (3) egg donating method, (4) embryo donating method, (5) surrogacy, (6) application of infertility treating technologies (discovery of hereditary diseases, gender identification, and gender selection), and (7) cryopreservation of sperm, eggs and embryos; (c) problems, studies, and future prospects in scientific research; and (d) regulations of contraceptive treatment services and studies. At the end of each chapter, recommendations based on the conclusions were stated.

Each chapter consisted, for individual technologies, of (1) definitions and details, (2) opposing opinions, (3) supporting opinions, and (4) conclusions based on opinions of the Advisory Committee and matters requiring attention. These conclusions vary in nature depending on technologies, from those which are very concise to those which are extremely long. The members of the Advisory Committee reached a consensus regarding almost all issues. When a small number of members had different opinions, they were stated in the section entitled ″expression of different views″ at the end of the Report.

(ii) The opinions of the Committee on individual technologies are outlined as follows. First of all, the Advisory Committee's opinions on technologies to treat infertility are introduced.

1) Artificial insemination: Artificial insemination by a donor (AID; the sperm for artificial insemination comes from a donor) in accordance with the statutory licensing authority's licensed/approved procedures at a proper medical institution should be permitted.

2) In vitro fertilization: The Committee recommends continuous provision of in vitro fertilization in accordance with similar licensing/approval and examination procedures as those recommended in connection with the rules for AID.

3) Egg donating method (i.e. a method according to which a matured egg is taken from a woman donor, the egg is fertilized in a test tube in the presence of the semen taken from the infertile woman's husband, and the resulting embryo is then implanted into the uterus of the infertile woman): The Committee recommends that this method be accepted as an approved technology to treat infertility in accordance with similar licensing/approval procedures as stated above and under the supervision of the relevant authority.

4) Embryo donating method (note that there are several methods of donating embryos and one example is as follows: when a woman and her husband are infertile, both an egg and a sperm are donated and the resulting embryo is implanted into the uterus of the infertile woman): The Committee recommends that this method be accepted as a technology to treat infertility in accordance with similar licensing/approval procedures as stated above and under the supervision of the relevant authority.

5) Surrogacy: The Committee recommends a call for legislation to prescribe the following actions in the UK as a crime whether they are performed for profit-making or non-profit-making purposes: to recruit women for surrogate mothering; and to establish or organize any institution intended to help individuals or couples who want to use surrogacy services, find surrogate mothers. Since all surrogacy contracts are illegal, the Committee recommends to establish laws which invalidate such contracts in court.

Only for surrogacy, among the above-listed technologies, 2 members expressed different opinions from the recommendations made by the Committee. Their opinion was: no matter what recommendations were made by the Advisory Committee, the demand for surrogacy may remain in changing forms or even increase; it is therefore wrong to totally close all doors to provide surrogacy as a treatment measure for infertile couples and the authorities should have the power to grant licenses to all non-profit-making institutions which help surrogacy contracts.

(iii) Next, the authors will introduce what was reported by the Committee in the chapter regarding problems, studies, and future prospects in scientific research. The Committee's discussions about this matter were complicated and no consensus was achieved. The authors will therefore provide a detailed introduction.

(a) The opinion against research using human embryos was predominantly based on the premise that human embryos are human beings and as such research using human embryos is morally wrong. In addition, the opponents of research using human embryos noted that many people show instinctive resistance against studies which manipulate creation of a human life, and are afraid that there may be the following risk: scientists may try to create hybrids or may tamper with the reproductive process in order to play with theories of artificial selection or eugenic selection.

On the other hand, the opinion in favor of research using human embryos was based on a diverse range of ideas. Some claimed that a human embryo does not have any personal character but is a complex of cells and therefore, there are no reasons why we should protect the identity of these cells. Others commented that when using human embryos for research purposes, greater respect should be given to such human embryos than to experimental animals, although such respect is never absolute and should be weighed with the expected benefit of such research.

(b) The Advisory Committee first acknowledged that embryos existing inside the living body are given some protection under Common Law, and then discussed about embryos outside the body. As a result, the Committee recommended that human embryos be given a certain level of protection. Specifically, the Committee recommended that research using human embryos outside the body as study subjects and handling of such human embryos shall be permitted only when such research or handling is licensed or approved by the statutory licensing authority: in other words, use of human embryos outside the body without obtaining a license or approval shall constitute a crime. (A)

According to the technical conclusions drawn by the Advisory Committee, the Committee recommended that attention be directed to the appearance of the primitive streak (which is noted on the $15^{th}$ day of fertilization) and recommended that any human embryo derived from in vitro fertilization, whether it is frozen or not, shall not be allowed to live beyond the $14^{th}$ day of fertilization onwards if such an embryo is not to be placed in the woman's uterus for the purpose of reproduction, and that no studies will be permitted using human embryos which are alive beyond the $14^{th}$ day of fertilization. The Committee continued to recommend that use of any live human embryo beyond the $14^{th}$ day of fertilization derived from in vitro fertilization as a subject of any study or for any other purposes shall constitute a crime. They also recommended that no embryo which has been used for study purposes shall be placed in the woman's uterus under any circumstances.

In the case of embryo handling, the following three types of embryos require particular caution: reserve embryos (extra embryos) obtained as the result of in vitro fertilization; embryos created outside the body for the sole purpose of research; and embryos created by chance in studies, the primary objective of which was not creation of an embryo. The Advisory Committee recommended that the reserve embryos can be used in studies, provided that the method of using or disposing such reserve embryo shall be approved by the donor. For the other types of embryos, there was no consensus of opinion within the Committee, which therefore issued the following recommendation on the basis of the opinion of the majority: a law shall prescribe that keeping or using these types of embryos will only be permitted for a period not later than the end of the $14^{th}$ day of fertilization, under the condition that all regulations prescribed by the statutory licensing authority will be observed. (B)

(c) Regarding the conclusions drawn by the Advisory Committee, there existed ″expression of different views.″ For (A), 2 members expressed the differing opinion that experiments using human embryos will not be permitted, whereas handling of human embryos for the sole purpose of implantation will be permitted. For (B), 4 members did not agree with the opinion that studies using human embryos other than the reserve embryos may be permitted.

As described above, all members of the Committee agreed with implementation of all technologies to treat infertility, with the exception of surrogacy, whereas they had different views regarding studies using human embryos. In the chapter ″studies and future prospects in scientific

research," the Report mentioned, among others, fertilization between different species, development outside the body, cloning, embryonal biopsy, nuclear transplantation, and prevention of hereditary diseases as future possible technologies. The Committee did not make any particular recommendation regarding cloning on the premise that artificial cloning of human embryos is not conducted.

On the basis of the above-described Warnock Report, including recommendations made in chapters not mentioned here, the "Human Fertilization and Embryology Act 1990" was established. For surrogacy, the "Surrogacy Arrangements Act 1985" already prohibits recruiting women for surrogate mothering for commercial purposes but permits recruiting for non-profit-making purposes, which is less stringent than the recommendations made by the Warnock Report. However, the Surrogacy Arrangements Act 1985 expressly stipulates that it is illegal for third parties to negotiate or facilitate any surrogacy for payment, which was controversial.

(2) Germany: Benda Report

In Germany, a report issued by a federal government council, which was entrusted with investigation of present status and future issues to be addressed in connection with in vitro fertilization, gene analysis and utilization of such analysis in treatment (commonly known as the Benda Council), was important in laying the foundation for legislation, prior to establishment of the Embryo Protection Act. (The information described below is derived from "Let's think of pre-birth diagnosis," a report issued by the Reproductive Technology Study Team, Bioethics Study Group, Mitsubishi Kasei Institute of Life Sciences.)

The Benda Council was organized in May 1984 at the co-request of Hans A. Engerhart, Minister of the Federal Ministry of Justice, and Heintz Rezenhuber, Commissioner of the Federal Science and Technology Agency. The chairperson of the Council was Erunsuto Benda, a former commissioner of the Federal Constitutional Court. The Council consisted of a total of 19 members, whose diverse professions included scientists, medical doctors, individuals involved in the Protestant Church or the Roman Catholic Church, philosophers, lawyers, and representatives of management and labor. The Council held 19 meetings and submitted a report entitled "In vitro fertilization, gene analysis and gene therapy" in November 1985.

The Benda Report includes conclusions and recommendations for legislation based on these conclusions, with regard to three issues, namely: (i) in vitro fertilization and family; (ii) regulations for implementation of studies using embryos; and (iii) introduction of genetic engineering. The conclusions and reasons for drawing the conclusion are outlined below.

(i) In vitro fertilization and family

Outlined conclusions: In vitro fertilization between spouses is as a rule not a problem. However, artificial insemination by a donor (AID) or in vitro fertilization using an egg provided by a donor may cause a number of problems and shall only be permitted under certain conditions. No one will be entitled to deprive the resulting baby of a right to know his/her own identity. Donation of an embryo shall only be acceptable when such donation will improve the embryo's change of survival under extenuating circumstances and the couple who are going to receive the embryo has a strong commitment to raising a baby born from the embryo as their own child. The Council objects to a surrogacy system.

As described above, the Council was in favor of in vitro fertilization between spouses but was against in vitro fertilization between non-spouses. The reasons for this conclusion were that in vitro fertilization between non-spouses removes biological maternity/paternity, which may endanger the child's sense of belonging and identity, and therefore is not in the interest of the child.

(ii) Regulations for implementation of studies using embryos

Outlined conclusions: Creation of any human embryo for research purposes shall as a rule be unacceptable. However, experiments using embryos will be accepted only when such experiments will be useful for discovery, prevention and elimination of diseases of the embryo concerned, as well as for obtainment of medical knowledge which is clearly of an advanced level (to which some Council members were opposed). Storage of frozen human embryos may only be allowed in the future in either of the following two cases: (1) when placing an embryo in a woman is transiently impractical and it is expected that the frozen fertilized egg be placed in the woman within 2 years; or (2) when it is reasonable to make an attempt of placing an embryo in a woman during the next menstrual cycle or following ones in order to increase implantation rate. Cloning through the use of any procedure will be unacceptable. Similarly, forming chimeras or hybrids from animals and humans will be unacceptable.

In its introduction section, the Benda Report stressed the judgment made by the federal court that when freedom of research conflicts with any of the other basic rights protected by the Basic Law, the former right will never be superior to the latter, and confirmed that "freedom of research" can be limited by the following: protection of life and body; respect for autonomy of the individual concerned; considerations of the happiness of children; and more importantly, protection of human dignity. Under this basic philosophy, the Council acknowledged that studies using embryos are useful for discovering treatments of cancer, immunological disease, hereditary disease and other relevant conditions, but regarding creation of embryos for research purposes, the Council indicated that it favors prohibition, as a rule, since such research may use human life as a means of achieving its own goals. The Council prohibited storage of frozen human embryos except for the above-described cases (1) and (2) because such freezing and storage may damage an embryo, or may bring into question the legitimate identity of a child derived from such an embryo. In addition, storage was prohibited by the Council for the purpose of preventing production of reserve embryos, which could be used for research purposes. Furthermore, the Council prohibited creation of clones, chimeras and hybrids since such creation is extremely experiment-oriented and therefore a substantial violation of human dignity.

(iii) Introduction of genetic engineering

The Council considered that introduction of genetic engineering is never a problem as far as a series of restricted conditions are met, e.g. obtainment of informed consent from the subject. However, the Council called people's attention to various problems resulting from genetic engineering, and stressed the necessity of considering if screening for hereditary disease may lead to unreasonable discrimination against the subject concerned, if a subject should have the right not to know his/her own hereditary constitution, and other relevant matters.

As described above, the Benda Report outlines restrictions on reproductive medicine and freedom of research based on highly ethical reasons, i.e. the necessity of giving considerations to the happiness of children in (i) and the necessity of protecting human dignity in (ii).

The Benda Report also included two important viewpoints that contrasted with the consensus of the Council. The first was of Council member Walter Dorfuller, a geneticist and professor at the University of Koln. He objected against the idea that freedom of research is to be controlled by a law (criminal law) and protested against the contents of the Report. The other viewpoint was that of Council member Peter Paterzen, a psychiatrist at Hannover Medical College. He expressed favor for the Report itself but had some doubts about surgical in vitro fertilization treatments which fail to consider the mental factors involved in infertility. At the same time, he expressed his own opinion that studies using human embryos should be more strictly controlled.

Regarding in vitro fertilization (i), the Embryo Protection Act prohibits donating eggs, creation of embryos for the purpose of donating such embryos, and surrogacy. In these respects, the Act reflects the stand of the Benda Report. On the other hand, the Act does not expressly set forth prohibition of artificial insemination using sperm from a donor and accordingly, the Act does not completely reflect the Report's opposition to in vitro fertilization between non-spouses. Regarding regulations for implementation of studies using embryos (ii), the Act incorporates the contents of the Report, and prohibits human cloning, and forming chimeras or hybrids between humans and animals. Regarding the issue of handling of embryos for research purposes, the Benda Report did not propose stringent prohibition: the Report stated that creation of embryos for research purposes will as a rule be prohibited, whereas experiments using embryos will be accepted only when such experiments are deemed useful for discovery, prevention and elimination of diseases of the embryo concerned, as well as for obtainment

of medical knowledge which is clearly of an advanced level. On the other hand, subsequent discussion leading to legislation moved toward the direction of prohibition and the Act prohibits not only creation of embryos for research purposes but also use of embryos.

(3) France: Bureban Report

In France, three reports were submitted to the national government during the preparatory process of the Bioethics Act which was established in 1994. The process leading to legislation in France is outlined below. (The information described below is derived from: "Actions taken in industrialized countries to cope with reproductive technology" Studies on Life, People and Society, authored by Jiro Nudeshima et al. (Mitsubishi Kasei Institute of Life Sciences); "Structure of Advanced Medical Regulations in France" authored by Jiro Nudeshima, Horitsu-Jiho Vol. 68, No. 10; "Background of French legislation leading to the Bioethics Act ? interview with Mrs. Lenoir" Jurisuto No. 1092; and "Bioethics and Laws in France" Kokugakuin Hogaku Vol. 34, No. 5 and Vol. 35, No. 2.)

Of the three reports, the Bureban Report was first submitted in 1988. In 1986, President Chirac requested the Conseil d'Etat (the Legislation Bureau/Administrative Supreme Justice Council) to draft a law covering various aspects of bioethics for human organ donation, including life and death. In the Conseil d'Etat, a committee was organized. In 1988, the Bureban Report established its basic philosophy, including "rights of a human body," on the basis of which a bill consisting of 89 articles was submitted in 1989. (In this bill, assisted reproduction and pre-birth diagnosis were individually addressed and constituted independent chapters.) This bill caused arguments not only among those involved but also in the general public. There was strong protest by cautious individuals who claimed that this draft was incomplete and that opinions from relevant individuals and the general public were required. Accordingly, the national government judged it impractical to immediately introduce this bill in Parliament.

The second investigation results were submitted as the Lenoir Report in 1991. This report was based on investigation from the viewpoint of comparative law, and consisted of three sections. Section 1 was concerned with, among others, the current circumstances surrounding embryos and the human genome, the current status of artificial reproduction and organ transplantation, issues related to gene examination and pre-birth diagnosis, issues involving information processing and computer-aided processing of individuals' personal gene data, and issues related to death and euthanasia. Section 2, together with attached data of comparative law, identified countries in which legislation was enacted, countries in which only guidelines announced by medical associations or other relevant organizations were observed, and laws, if any. Section 3 was a proposal which differentiated fields for which immediate legislation was considered necessary from those which required a certain length of time to allow deliberation since sufficient discussion had not yet taken place. The fields which were considered to require immediate legislation were those for which no regulations existed, such as organ transplantation including not only removal of organs but also other matters, and information processing, and illegal practical fields such as gene information files and computer data. The reason why these practices were illegal is because at the time in France all information obtained in connection with medical care had to be kept strictly confidential and medical doctors were not allowed to transfer any information for any purposes other than medical care related purposes, e.g. they were not allowed to transfer such information even for research purposes (note that this was amended according to legislation). On the other hand, discussion of artificial reproduction drew out a great variety of opinions, due to the positioning of the human body, which was then related to various issues of reproductive selection and a couple's freedom to choose abortion. The Report concluded, however, that artificial reproduction was not a field which was sufficiently mature to call for legislation.

In light of this Report, the national government introduced a bill (which did not include pre-birth diagnosis and embryo-related research but only prescribed assisted reproduction) in Parliament in March 1992. In November 1992, the First Reading of the National Assembly adopted three bills, which constitute the current three acts (which introduced regulations on pre-birth diagnosis and embryo-related research).

Subsequently, the general election in 1993 resulted in a change in political power (from the social party to the conservative-centrist force). The then new President Paradieu entrusted Assembly member Mattei, who belonged to the majority, to head an investigation to determine whether the new administration should take over adoption of the bills or reconsider them from the very beginning. The third report, i.e. the Mattei Report, was submitted to the President in November 1993. The Mattei Report, as a result of reexamination of the bills adopted by the former Assembly, basically supported the bills and concluded that regarding the prohibition of embryo-related research in particular, the new administration should follow these bills. In the end, little amendment was made to the bills.

In June 1994, the Bioethics Act was passed by the French Parliament. Several members of the Assembly, however, applied for an examination of the constitutionality of these bills. Their arguments are described below.

First of all, regarding the prescribed regulations on medical assistance to reproduction, several principles including, among others, the embryo's right to live, the embryo's right to be treated equally, respect for the integrity of a human being, and protection of genetic characteristics, the family's rights, and the rights in connection with the health of children were questioned. The Constitutional Council concluded that the legislation provides substantial protection for embryos regarding its formation through fertilization, transplantation and storage and that the Constitutional Council did not have the authority to raise questions about the regulations formulated by the legislation. At the same time, the Constitutional Council indicated the following: there exist no constitutional principles nor regulations which damage the protection of genetic characteristics; the Preamble to the Constitution of 1946 will not hinder development of a family through the utilization of an embryo provided from a donor; it is not considered that prohibition of searching for a donor will violate the child's right of health; and even if the legislative body prescribes that with regard to decisions to be made concerning studies for medical care purposes, the administrative committee should have a collective view, and such decision will be effective as long as the jurisdiction of the committee is not neglected. Secondly, regarding the prescribed regulations on pre-birth diagnosis stipulated by the Transplantation and Reproduction Act, the relation between pre-birth diagnosis and the right of embryos or fetuses to live was questioned since pre-birth diagnosis may facilitate artificial abortion. The Constitutional Council concluded that this Act does not accept a new form of abortion and that these regulations are constitutional.

Next, regarding the civil law-related principles, etc. for medically assisted reproduction which are prescribed by the Human Body Respect Act, the anonymity of a donor was questioned in connection with the principles that individuals assume personal responsibilities and the child's right to identify his/her parents. The Constitutional Council concluded that this Act does not set forth any condition to identify a parent-child relation in the case of medically assisted reproduction and also pointed out that the Constitution does not ban prohibition of setting a parent-child relationship between a donor and a child derived from the donor nor prohibition of calling for a donor's responsibilities.

In addition, the Constitutional Council made its judgment that the entire law (consisting of the three Acts) is constitutional since these Acts prescribe the superiority of the individual, the necessity of respecting the individual from the very beginning of life, the principles that the human body is inviolable, has integrity and is not to be treated as property, and the integrity of the individual as part of a species: these Acts protect the dignity of individuals secured by the Constitution and in other words, promote implementation of the constitutional code within its scope of application.

4. Summary

(1) The contents and historical background of the regulations provided in the above-described countries are summarized below. Generally speaking, the European legal systems concerning reproductive technology show a positive attitude toward acceptance of practical reproductive medical technology, whereas the regulations strictly control studies.

Even in the area of reproduction assisting technology, however, each country has its own policy regarding which reproduction related items are legally regulated. As listed in Reference No. 1 entitled "Outline of Legal Systems," it is convenient to divide reproduction assisting technology into the following items when considering the overall picture: (1) storage and use of gametes; (2) gender selection; (3) post-death artificial insemination using stored gametes; (4) change in germ cells; (5) creation of a human embryo outside the body; (6) removal of

embryos; (7) storage, use and examination of embryos; (8) creation of cloned humans; (9) creation of chimeras and hybrids; (10) artificial insemination; (11) donating an embryo; and (12) surrogacy. At least one country has established legal regulations for each of these items. The UK, Germany and France have all established legal regulations regarding Items (4), (5), (7), (8), (10) and (12) (note that some of the countries prohibit Item (8) on the basis of legal interpretation), although these countries substantially differ from one another in terms of the specific actions taken in accordance with these regulations (e.g. regarding Item (12) surrogacy, the UK prohibits only commercial surrogacy, whereas Germany and France prohibit all forms of surrogacy).

Regarding the justification and philosophy resulting in establishment of legal regulations, in particular, these three countries substantially differ from one another. It cannot be claimed that similar regulations are set forth because they share similar ideas. In each of the countries, prior to legislation, a committee or council was organized to discuss these matters from a comprehensive viewpoint and to submit reports. These reports indicate distinct character and individuality. The Report in the UK was extremely practical: it introduced various public opinions and divided them into pros and cons, for each of which acceptability was discussed (the introduction section of this Report stated that social barriers against introduction of new technology are absolutely necessary and at the same time, stressed that moral feelings are not universal). The Report in Germany concluded that the protection of life and body, the respect for autonomy, the considerations given to the happiness of children, etc. shall have priority over the freedom of research, and in particular, ruled out creation of embryos for research purposes since such research may turn life into a means of achieving something else. The Reports in France focused on the necessity of respecting the dignity of the individual, and the principles that the human body shall be inviolable and not treated as property.

These reports summarized their own conclusions and included the different opinions raised, in addition to the opposing opinions on those issues where a consensus was not reached. Relative evaluation of these reports reveal that the German Report recommended the most stringent regulations, whereas the Report in the UK drew relatively modest conclusions. In Germany, the opinion opposing regulations on the freedom of research was introduced. In the UK, there was opinion calling for regulations on studies using embryos.

The authors also found some changes made in the philosophy regarding regulations when the laws or acts were established as compared to that stated in the reports (i.e. prohibition of surrogacy was relieved in the UK, experiments using embryos were completely prohibited in Germany, and prescribed regulations regarding pre-birth examination and embryo research were added in France). In France, the application for examination of unconstitutionality was made at the very last stage of legislation. These results may indicate that legislation was never an easy process.

One of the factors which may have played an important role when legal regulatory systems were evaluated in these countries was the opinion from the religious world. In Germany, individuals with affiliation to the Protestant Church or the Roman Catholic Church were members of the Council. In the UK and France, no such representatives of the religious world were included on the council or committee. It is therefore considered that in each of these countries, the council or committee described in this section was not the sole means to forming a consensus but various opportunities were set for discussion. In light of these facts, the authors do not consider that the outlines described in this section are necessarily complete enough to understand the basic philosophy in the individual countries, although these outlines may help provide insight to part of the overall picture.

Application of cloning technology is expressly prohibited in German Law. In the UK and France, the national government announced its legal interpretation, which resulted in prohibition in the real world of applying cloning technology to humankind.

〈Reference Information〉

In the US, despite advanced studies of medical technology and life sciences technology, investigation of legal regulations has been discontinued. The President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research was organized in 1981, and issued 5 reports concerning allocation of health care and 5 reports regarding research over a period from 1981 to 1983. However, the Biomedical Ethics Advisory Committee (BEAC), which was established in Congress in 1985 following the President's Commission, was disorganized and did not issue any specific report. Since then, no government reports regarding reproductive medical technology have been submitted in the US.

For reproductive medical technology, the President's Commission submitted a report regarding genetic engineering in 1983. This report was the result of a request made by representatives of the three major religious faiths in the US, i.e. Protestant, Roman Catholic and Jewish, to President Carter to investigate genetic engineering. The report made the following statements:

1) It is quite evident that genetic engineering is a challenge to individuals and families.

2) The fact that genetic engineering has a possibility of contributing to human happiness is a logical reasoning for promotion of genetic engineering.

3) Application of genetic engineering can be similarly regarded as diagnosis and treatment as with other technologies, but careful caution should be exercised when considering any procedure that changes genes which will be transmitted to descendants.

4) Any manipulation intended not to correct gene deficits but to make an attempt at improving a normal individual is problematic. Once the door to such improvement is opened, there is a risk that, without any definite principles, manipulations may be undertaken in an attempt to create the perfect human being.

5) The criticism that the human is performing the part of God is valuable since this reminds us of the principle that an enormous power is always associated with an enormous responsibility.

6) The majority of current experiments regarding gene manipulation are performed on the assumption that they are safe if careful attention is paid during experiments. If one opposes these experiments, then this assumption needs to be proved.

Subsequently, in 1995, President Clinton established the National Bioethics Advisory Council (NBAC) which was intended to make recommendations to the national government regarding bioethical problems resulting from biological and behavioral research (note that this Council was temporarily organized until October 1999). It is understood that this Council was established in response to a request made by Congress, which required organization of an advisory body involved in protection of privacy of gene information obtained in connection with human genome analysis in the Human Genome Project. Following its establishment, the Council worked in a timely manner, e.g. in 1997, in response to the request made by the President, the Council issued reports and made recommendations in connection with the birth of the first cloned sheep.

(2) The authors so far have described the currently effective legal systems in several foreign countries and the philosophy represented by the reports submitted prior to legislation that resulted in the legal systems, in light of which the authors would like to discuss what regulations should be imposed on life sciences in Japan. Key countries in Europe have already established legal systems to control life sciences-related studies and as we have already described in the previous section, the authors consider it necessary, in Japan also, to impose some regulations on such studies.

As stated in the Warnock Report in the UK that "if someone pretends to behave as if moral feelings are universal whether this is based on religion, philosophy or humanistic brief, such appearance is deceptive," it is not always likely that a uniform philosophy will be acceptable regarding what and how regulations should be imposed. On the other hand, in the EU and UNESCO, there is a clear move toward international regulations to be imposed on life sciences under the leadership of the industrialized European countries, on the basis of the

already established legal systems. The authors consider that Japan should first search for regulations which are suited to Japanese conditions, e.g. in terms of religious and cultural status, and the Japanese legal system, while referring to the regulations enforced in several European countries and the philosophy leading to those regulations, and after that, Japan should promote international cooperation. This may be important in particular when focusing on the fact that across the world, many countries consist of people following religions other than Christianity or Judaism: these countries may refer to Japan's way of seeking out its own philosophy to impose regulations on life sciences.

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## Section 3: Investigation in Japan from the Legal Viewpoint

The progress achieved in reproductive science and technology has brought about situations for which existing legal systems are not expected to cope. As a result of this, responsive actions are taken on the basis of inferential interpretation of the existing legal systems or the necessity of new legislation is stressed with the aim of coping with matters to which none of the existing laws are applicable.

Regarding application of reproductive technologies including, among others, in vitro fertilization, artificial insemination, donation of sperm and eggs, and surrogacy, as well as regarding studies using fertilized eggs, embryos and any other relevant matter, various reports have already been published from the viewpoints of the Constitution of Japan, Japanese criminal and civil laws, and other regulations. These reports contain the legal viewpoints for reproductive medicine and for research and development in advanced science and technology fields. In this Section, the authors will introduce some key reports and summarize the points stressed in these reports.

(1) Constitutional Viewpoint

The following 3 reports address this matter from the viewpoint of constitutional law.

<1> Akira Hasegawa "Freedom and Regulations in Artificial Reproductive Medicine" (Comprehensive study supported by subsidies for scientific research in the year 1993: (A) Research Result Report "Legal Problems Surrounding the Right of Personality in Reproductive Medicine"; Research supported by these subsidies will be hereinafter referred to as "Subsidized Research" )

<2> Hiroyuki Takai "Constitutional Analysis of Reproductive Medical Problems" (Subsidized Research)

<3> Ichiro Hokimoto "Gene Manipulation and Law"

Hasegawa's report <1> stresses that the important issue to be addressed in connection with utilization of artificial reproductive medicine is the individual's freedom of selection, which is a fundamental human right. In other words, this report takes the stand that any regulation imposed on activities of the individual must be justified only when such activities under regulation will violate the individual's rights: regulations to be imposed on artificial reproductive medicine should be the minimum necessary to secure the individual's freedom of selection to the maximum extent, and free utilization of artificial reproductive medicine should be accepted.

The report by Takai <2> acknowledges that the Constitution of Japan looks to the family as the foundation of public order: the State cannot be allowed not to intervene in reproduction of any form as long as such reproduction has been consented by the individuals concerned, but such intervention by the State shall not be contrary to the Constitution. The report points out the following 3 articles which may be related. (Of these 3 articles of the Constitution, Articles 13 and 24 are related to reproductive medicine and Article 23, to research and development of advanced science and technology.)

(a) The right to the pursuit of happiness prescribed in Article 13 of the Constitution of Japan

As part of what constitutes this right, there exists the right of personal autonomy and the right of autonomy, according to which the individual has the right to make his/her own judgment regarding his/her specific personal affairs, without interference by the public power. These affairs can be divided into the following categories: those which are involved in the treatment of the individual's own life and body; those which are involved in forming and maintaining a family; those which are involved in reproduction; and those which are involved in any other matters.

(b) The principle of equality of the sexes prescribed in Article 24 of the Constitution of Japan

Examination is required to determine if regulations based on biological characteristics may facilitate or accelerate oppression of the woman.

(c) The academic right guaranteed in Article 23 of the Constitution of Japan

From the viewpoint of protecting gametes, embryos, fetuses and any other relevant matter which lead to the birth of a child, imposing regulations on reproductive medical studies and implementation of such studies may be allowed in many cases.

On the other hand, careful considerations are required to impose regulations on utilization of gametes or embryos which will not be used in reproduction. (For example, imposing regulations on the basis of objectives is not permitted, whereas the possibility of imposing regulations on means or procedures may be investigated.)

In addition, Hokimoto's report <3> asserts that securing the rights of scientists to perform studies is based on the principles of the Constitution. His report discusses how and under what conditions studies which become limitless and opposed to other people's or citizens' health and safety as well as to social ethics, can be controllable. This report points out the necessity of people's control over studies of gene manipulation related to germ cells and any other relevant studies, and proposes the necessity of both control by people and control through the use of administrative procedure laws.

As described above, the viewpoint of relation to the Constitution indicates that the right of personal autonomy and the right of autonomy (that the individual corresponding to a parent shall have) described in Article 13 of the Constitution of Japan and the academic freedom guaranteed in Article 23 of the Constitution of Japan are the issues that need to be considered when using reproductive medical technology. (The relation between advanced science and technology and academic freedom will be described in detail separately.)

(2) Viewpoint of Civil Code

The following reports address this matter from the viewpoint of civil code.

<1> Michiko Ishii "In vitro fertilization between non-spouses and problems in connection with the Family Act" Horitsu-No-Hiroba, September 1997 Issue

<2> Michiko Ishii "Artificial insemination in relation to the Parent-And-Child Act" Case Study Times No. 92

<3> Norio Higuchi "In vitro fertilization between non-spouses: artificial insemination, family and laws" Horitsu-No-Hiroba, September 1998 Issue

<4> Norio Higuchi "Artificial insemination and parent-and-child relationship" Jurisuto No. 1059

<5> Yasuko Hitomi "Parent-and-child relationship in artificial insemination" Case Study Times No. 747

<6> Kouki Sugano "Validity of surrogacy agreements in relation to public policy or good morals" (Subsidized Research)

<7> Hidehiro Takashima "Problems in gamete donating agreements in the case of in vitro fertilization between non-spouses" Horitsu-No-Hiroba, September 1998 Issue

<8> Yutaka Tejima "Notes regarding informed consent" (Subsidized Research)

<9> Kunihiko Shoji "Regulations on artificial reproductive medicine in Japan: some characteristics and problems" (Subsidized Research)

<10> Takuo Yamada "Necessity of legal regulations: from the view point of civil code" Sanka-to-Fujinka, April 1998 Issue

From the viewpoint of civil code, the key issues requiring particular attention are involved in (i) the legal position of a child in connection with the Family Act and (ii) the validity of gamete donating agreements or surrogacy agreements (in relation to public policy or good morals). The issues to be addressed from the viewpoint of civil code are therefore not related to advanced research and development but to reproductive medicine.

(i) Legal position of the child in connection with the Family Act

Report <1> above, by Ishii, points out that identification of the mother and/or the father in the case of in vitro fertilization between non-spouses is an issue to be addressed in connection with the Family Act. In Japan, there exist no specific laws concerning the parent-child relationship for artificial insemination: for the father, a child will be presumed to be the child of the husband according to the presumption of legitimacy prescribed in Article 772 of the Civil Code and for the mother, a mother-and-child relation will be based on the fact of delivery (which was a Supreme Court Judgment on April 27, 1962). However, there are cases in which doubts may be raised, e.g. artificial insemination using sperm derived from not the husband but a donor, in vitro fertilization which is performed after death of the husband using sperm of the husband which has been retained, or delivery using an egg derived from not the wife but a donor that is fertilized in vitro. In addition, this report focused on the right of the child thus born to know the donor of the gamete and the issue of not violating the privacy of the donor, and stresses the necessity of new legislation to define the parent-child relationship for children born through artificial insemination (note that this matter is also stressed in Ishii's report <2>).

Similarly, the report by Higuchi <3> focuses on the issue of defining the legal position of a child (identification of the parents, identification of the individual who has the obligation of bringing up the child, and inheritance), the child's rights (the concern that the child may be discriminated against, the concern that merchandising of the child or treating the child as a product may occur, and the right of the child to know the facts related to his/her own birth), and future influences on society as a whole. This report then indicates that the existing Japanese legal parent-child relationship will not be able to accommodate these changes, which is problematic. (The same problem is pointed out by Higuchi's report <4>, which introduces US precedents, and by Hitomi's report <5>. Yamada's report <10> stresses problems involving the parent-child relationship and the child's interests.)

(ii) Validity of gamete donating agreements or surrogacy agreements (in relation to public policy or good morals)

The report by Sugano <6> introduces foreign cases regarding the validity of surrogacy agreements. In the US, the High Court of New Jersey State adjudicated (on February 3, 1988) in the case of Baby M that the surrogacy agreement was contrary to public policy or good morals and therefore invalid, whereas the High Court of California State made the judgment (on May 20, 1993) in the case of Baby C that the surrogacy agreement was not contrary to public policy or good morals. In Germany, the Embryo Protection Act prohibits surrogacy. In the UK, the Surrogacy Arrangements Act prohibits any surrogacy agreements for the purpose of profit making and prohibits any advertisements for the purpose of recruiting surrogate mothers. In these two countries, surrogacy agreements will not be illegal as far as they violate these prohibitions. In France, the Court of Appeals adjudicated (on May 31, 1991) that surrogacy services were contrary to public policy or good morals. This report <6> introduces that in Japan also, some academic individuals are not in favor of surrogacy as it may be contrary to public policy or good morals and it stresses the following matters to be taken into account when evaluating this issue: nature of value to be received in exchange for surrogacy services; morality of bearing a child who is to be handed over to others; shock given to the child when he/she is aware of the details of his/her own birth; human rights of a surrogate mother; informed consent from a woman who wants to be a surrogate mother; and concern of endangering children's welfare. The report concludes that surrogacy agreements should be considered invalid because they are contrary to the order of marriage and of parent-child relationship and therefore are contrary to public policy or good morals (in accordance with Article 90 of the Civil Code).

Takashima's report <7> discusses gamete donating agreements in the case of in vitro fertilization between non-spouses. It claims that establishment of a gamete donating agreement requires individual parties who want to make the agreement and their expression of will to make the agreement and that these factors for the establishment of the agreement are not in themselves problematic. However, the report also claims that in order for the agreement to be effective, the detailed acts prescribed by the agreement shall be identifiable and feasible and in addition, shall not be contrary to peremptory norms of the laws (jus cogens) nor to public policy or good morals. The report continues to point out that the agreement may therefore be judged invalid because it is contrary to public policy or good morals, when matters taken into account in connection with public policy or good morals indicate the waiving of parental power (which endangers the family order and destabilizes the child's legal position) and the placing of commercial value on gametes (which, in particular, involves medical invasion required for donating an egg and may indirectly force the needy to donate gametes).

This report <7> also stresses that even if the gamete donating agreement is considered to be not always contrary to public policy or good morals, there exists another legal problem in that it is not appropriate to surrender the gamete in a forced manner.

(iii) Others (Accountability of medical doctors)

In addition, the report by Tejima <8> discusses the accountability of medical doctors, although this is not an issue only applicable to reproductive medical technology but also to damage claims in malpractice suits. The obligation of medical doctors to provide explanations can be divided into four categories: (a) accountability as an obligation to avoid results; (b) accountability as presupposition for obtaining consent; (c) accountability as presupposition for transfer; and (d) accountability as subsequent report (reporting the outcome). Informed consent is included in Category (b). Problems involved in informed consent are as follows: insufficient availability of data that should be required, ways in which medical doctors provide information, intellectual aspects of patients who receive information, and attitude in which a decision is made.

In addition, the report by Shoji <9> introduces the voluntary regulations regarding productive medicine which were proposed at the meeting of the Japanese Association of Gynecology and Obstetrics.

In summary, both regarding (i) the legal position of the child in connection with the Family Act and (ii) the validity of gamete donating agreements or surrogacy agreements (in relation to public policy or good morals), there exist no established views in Japan and accordingly, the above reports identify the current problems and point out the necessity of future discussion and calling for necessary legislation.

(3) Viewpoint of the Penal Code

The following reports address this matter from the viewpoint of the penal code.

<1> Toshio Yoshida "(Legal) character of pre-transplantation human early embryos and some relevant problems: in the interest of the Criminal Law" (Subsidized Research)

<2> Hisao Kato "Creation of 'a human's life' and problems in connection with the Penal Code: with special regards to legal protection of 'fertilized eggs' and 'early embryos'" (Subsidized Research)

<3> Katsunori Kai "Models of (criminal) regulations on reproductive medical technology" (Subsidized Research)

<4> Katsunori Kai "Necessity of legal regulations: from the viewpoint of the Penal Code" Sanka-to-Fujinka, April 1998 Issue

<5> Kinko Nakatani "Necessity of legal regulations: To what extent are these legal regulations allowable?" Sanka-to-Fujinka, April 1998 Issue

<6> Kinko Nakatani "Development of a life and the Penal Code" Gendai-Keibatsu-Hotaikei 3

<7> Fumio Kanazawa "Moral and legal position of human embryos" Hogaku-Ronso of Okayama Shoka University, February 1995 Issue

<8> Hisao Kato "Reproduction assisting actions (technology) and legal protection of fertilized eggs and early embryos" In the book entitled "Modern medicine and medical affairs law system", editor Masayoshi Ohno

From the viewpoint of the penal code, the key issues requiring particular attention are involved in (i) the legal character of fertilized eggs or early embryos and (ii) permissibility of and legal regulations to be imposed on studies using fertilized eggs or early embryos as well as application of reproductive medical technology (e.g. surrogacy).

From the viewpoint of the penal code, to what extent reproductive medicine and advanced research and development should be allowable and which penal provisions should be appropriate in the case of violations are discussed.

(i) Legal character of fertilized eggs or early embryos

The report by Yoshida <1> introduces different theories regarding the legal character of pre-transplantation early embryos: a theory which claims that personal character exists from the time of fertilization and therefore, the pre-transplantation early embryo is an individual who has rights; a theory which accepts that the pre-transplantation early embryo has some special position which is not identical to that of a human; and a theory which claims that the pre-transplantation early embryo is the property of the parents. This report stresses that the early embryo is a latent human but is different from people in reality and therefore, the early embryo should not be in a position where it constitutes an individual possessing fundamental rights. However, at the same time, it is not appropriate that the early embryo be regarded as property, for which the crime of destroying things is applied in the case of damage. This report <1> stresses the necessity of new legislation to protect the early embryo. (Reports <6> and <8> above also discuss legal problems involving the development of life.)

Report <2>, by Kato, focuses on legal protection of "fertilized eggs" and "early embryos." In Germany, the Embryo Protection Act prescribes regulations on the cells in the individual stages from eggs and sperm through to fertilized eggs and early embryos before implantation, and the Penal Code imposes regulations on post-implantation placenta, embryos and fetuses. In Japan, the members of the Japanese Association of Gynecology and Obstetrics proposed at a meeting their voluntary regulations concerning fertilized eggs and early embryos. The current Penal Code in Japan prescribes the crime of abortion, which provides protection of the fetus. (Note that the legally protected interests are to secure the safety of life and body for both the fetus and the mother.)

This report <2> introduces different theories: a theory which regards the life as a subject under legal protection and recognizes that the individual starts at the time of conclusion of implantation; and a theory which regards a fertilized egg not as a fetus but as an "organism" unique from that of humans or fetuses and accordingly, damaging the fertilized egg should constitute a crime of destroying things. Kato's report stresses that since the pre-implantation fertilized egg has the potential of being a human, application of the crime of destroying things is not appropriate and that other legislative resolution is desirable.

(ii) Permissibility of and legal regulations to be imposed on studies using fertilized eggs or early embryos as well as application of reproductive medical technology (e.g. surrogacy)

Kai's report <3> introduces systems employed in foreign countries. In the UK, a form of administrative penal code is used: the statutory licensing authority is established, the required procedures for obtaining a license are defined, and acts violating the prescribed licensing are punishable. In Germany, a special penal code form is employed, in which criminal regulations are prescribed. In the UK, a license can authorize certain studies using embryos before the appearance of the primitive streak (i.e. an embryo before the time at 14 days after fertilization, at which point it is considered that the embryo starts to develop as an individual). In Germany, however, using embryos for purposes other than reproduction and studying embryos are totally prohibited on the ground of respecting the dignity of the individual. This report concludes that the UK system may be more appropriate to Japan than the German system of prohibiting all uses and studies of human embryos, when considering the nature of the Japanese Penal Code, i.e. intentions of imposing regulations that are not too restricted and of waiting for the final action, and in view of academic freedom as guaranteed by The Constitution of Japan. (Note that Yoshida's report <1> points out a possible occasion in which a study of a human embryo may be permissible even if the embryo is at the stage after the time point of the appearance of the primitive streak.)

In addition, Kai's report <3> introduces that in the UK, the Surrogacy Arrangements Act imposes penalties on negotiation of any surrogacy for payment and in Germany, the Embryo Protection Act imposes penalties on individuals who attempt artificial insemination for, or transportation of a human embryo to, a surrogate mother. This report claims that it is necessary in Japan also to impose criminal punishment on commercial abuse. (Kai's report <4> introduces the Japanese style of regulatory model that was proposed by Subsidized Research.)

Report <5> by Nakatani introduces legal systems employed in foreign countries and points out ethical and legal problems regarding in vitro fertilization, for example: surrogate mothering; pros and cons for implementation of an operation to reduce the number of fetuses in the case of multiple pregnancy; for and against the means of intentionally having a baby boy or girl; problems related to so-called "designer baby" (according which a fetus at the age of 8-12 weeks of pregnancy is artificially aborted and brain cells or other tissues are isolated from the fetus for the purpose of using them in the treatment of Parkinson's disease, etc.); pros and cons for donating eggs derived from a dead women or donating aborted fetuses; and problems involved in pre-implantation diagnosis and gene therapy. This report stresses the urgent necessity of taking legal actions which can cope with the rapid progress in reproductive medicine.

In addition, Kanazawa's report <7> argues that although the human embryo should be protected as a human's life from the viewpoints of morality and the Constitution and therefore, the national government should have the obligation to protect it, none of the actually established laws give such protection to the human embryo. Accordingly, this is an area to which none of the current legal regulations can apply. This report continues to argue that at present, implementation of various studies using human embryos is not illegal, but this does not mean that studies using human embryos are legal and researchers are entitled to manipulate human embryos in any way or to create a chimera between humans and other animal species. New regulatory legislation is therefore called for and the report proposes that such new legislation should be based on the UK type administrative regulations and examination system for licensing and should impose a criminal punishment on an especially material violation.

In summary, with special regard to (ii) permissibility of and legal regulations to be imposed on studies using fertilized eggs or early embryos as well as application of reproductive medical technology (e.g. surrogacy), the reports evaluate the legal system in foreign countries, i.e. the UK and Germany, and compare the two countries: in Germany, all uses of embryos and all studies of embryos are prohibited, whereas in the UK, certain studies using embryos can be authorized. Some of the reports prefers the direction toward the UK type regulatory system, i.e. granting licenses to certain types of studies, when considering the nature of the Japanese Penal Code, i.e. intentions of imposing regulations that are not too restricted and of waiting for the final action, and also in view of academic freedom as guaranteed by the Constitution of Japan. The other issues require resolution by new legislation.

(4) Viewpoint of Medical Affairs Law

The following books address reproductive medicine from the viewpoint of medical affairs law.

<1> Hiroshi Ohtani "Medical practices and laws (new version)"

<2> Tetsu Ueki, editor "Textbook on medical affairs law" (with special regard to "Chapter 6: Advanced medicine and brain death")

<3> Masayoshi Ohno, editor "Modern medicine and medical affairs law system" (already described in (3))

From the viewpoint of medical affairs law, proposals are made under an independent legal system, which is separate from the Constitution or the Penal code. Here, the authors would like to introduce these proposals in accordance with the book by Ohtani <1> which discusses the latest reproductive medical technology.

From the viewpoint of medical affairs law, generally, a medical act will be legal only after the act satisfies the following 3 conditions: (1) a medical act will be associated with hazards to the individual's mental and/or physical aspects and therefore, shall only be allowable when it is necessary and useful to maintain or improve health, i.e. the issue of medical applicability; (2) a medical act shall only be performed by medically established methods, i.e. the issue of validity of medical technology; and (3) a medical act will be associated with invasion into the individual's mental and physical aspects and therefore, the patient concerned shall decide if he/she will accept it or not, i.e. the issue of the patient's right of autonomy. A therapeutic act by a medical doctor will not be legal unless it satisfies all 3 requirements.

From the above-described point of view, reproductive technology regarding artificial insemination and in vitro fertilization as a critical medical case is evaluated for medical applicability and for legal acceptability, which results in the conclusion that these reproductive technologies may be medically applicable since they are necessary to remove mental pain due to lack of capability of having a child and therefore, that it is difficult to control these reproductive technologies according to the currently effective laws. In connection with in vitro fertilization, how to handle a fertilized egg which is not implanted into the uterus of the woman is controversial: some claim the necessity of some legal regulations to be imposed on such handling, whereas others argue that there are no reasons for legal protection of such an embryo itself since it is before implantation.

Regarding whether some legal regulations must be imposed on reproductive medicine or not, ethical discomfort or vague anxiety is not sufficient for discussing this issue and instead it is necessary to define whose benefits will be lost by the medical treatment concerned and to identify the details of the benefits. At the same time, flexibility should be maintained in considering which legal regulations are necessary when it is evident that the medical treatment concerned will cause the loss of someone's benefits. Regarding cloned babies, for example, assuming that the dignity of the cloned baby as the individual is respected, then there are no legal reasons for opposing cloned babies. Considering the fact that society is never absolutely right nor perfect in relation to its utilization of results of new technology, it is the opinion of the authors of this book that we should be careful in imposing any legal framework to studies of life sciences and development of medical technology.

(5) Others

There are additional reports published which address this matter from the viewpoint of law: some focus on several law fields and others, on legal systems regarding reproductive science and technology in foreign countries. (The reports regarding overseas legal systems have been introduced in Section 2.2.)

<1> Kiyoko Kinjo "Reproduction related freedom and rights in the case of in vitro fertilization between non-spouses" Horitsu-no-Hiroba, April 1998 Issue

<2> Kiyoko Kinjo "Bioethics surrounding the start of life: Bioethics and Laws"

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## Section 4: Limits of Legal Regulations

### 4A: Restrictions on Freedom of Learning & Research

(1) Limiting studies of life sciences means limiting research activities, i.e. limiting freedom of research. Academic freedom is guaranteed in Article 23 of the Constitution of Japan. This is specifically regarded as part of mental freedom (i.e. freedom of conscience, freedom of expression, freedom of religion, etc.) and direct limitation of the freedom should require evident justification. Ultimately, total evaluation of such limitation is required, which includes evaluation of the tradeoff between public benefit obtained from such limitation and those damaged by such limitation, methods of imposing limitation, and any other relevant matters. None of the currently effective laws or regulations expressly impose restrictions on research itself and accordingly, careful and substantial examination is required. (The Nuclear Reactor Regulation Law is an example of a law that primarily controlled studies at universities and research laboratories for a while after its establishment since there existed, at the time the law was established, only a small number of practical uses of the technology that were intended to be controlled by the law. This Act is frequently referred to when discussing restrictions on research. However, as will be described later, this Act does not control research itself.)

(2) Academic freedom usually consists of (1) freedom of learning & research, (2) freedom of presenting research results, (3) freedom of teaching, and (4) autonomy of universities. Regarding the subject of these rights of freedom, as the Supreme Court in the Poporo case adjudicated that "the reasons why it is stipulated that academic freedom is guaranteed are because in part, it is intended that the freedom is guaranteed widely for all the people… and because in particular, it is intended that the freedom is guaranteed at universities" (Supreme Court judgment on May 22, 1963), learning & research at universities and at academic society meetings are not the only subjects of these rights of freedom. (In recent years, as described in a section entitled "Academic Freedom" in the book "Basic Law: Commentary of the Constitution" authored by Shin-ichi Takayanagi and Keigo Ohama, there is an increasingly prevailing theory which claims that academic freedom is not guaranteed as any special privilege of the faculty members of universities but this guaranteed academic freedom aims at achieving freedom from the citizen's viewpoint inside research laboratories and educational institutions.)

Regarding academic freedom, a variety of theories and case precedents were concerned with the pre-War academic control by the national government of social science and cultural sciences, and with the post-War freedom of learning and autonomy at universities. In recent years, more discussion has focused on control of freedom of learning & research in connection with advanced science and technology, e.g. control in

the fields of large-scale technology such as nuclear energy, gene technology such as gene recombination, and reproductive technology such as in vitro fertilization. Among these, the issue of regulating experiments of gene recombination is a focus of active discussion as described below.

One of the relatively early reports focusing on this issue presents the following view: "we have to say that the situation in which 'research' such as experiments of gene recombination which may be a threat to human life/survival is freely performed without adequate control would be a problem. However, such conflict between academic freedom and the other value may not frequently occur when considering the nature of scholarship. Even if 'too much' academic freedom should bring about 'adverse events,' such adverse events should as a rule not be controlled by any means of power but instead be voluntarily resolved by individuals involved in academic studies. The above-described situation as examples in academics should be an issue regarding which the administrative power or the legislative power cannot intervene without reasoning, and should primarily be determined on the basis of autonomy or independent judgment of scholars and of the center of learning (i.e. universities and research laboratories). If the political power attempts to establish standardized rules through laws and regulations to control the way of learning, then advancement in academic studies and therefore general development of culture may be inhibited." (Quoted from the book entitled "Lectures on the Constitution" authored by Naoki Kobayashi.)

The background of this view is deeply rooted in the philosophy in favor of academic freedom itself, as stated below: "Academic freedom is supported by the awareness that creative freedom is essential for pursuing truth and also implies the reasonable justification that the conscience and judgment of specialists involved in research and teaching should take priority over political or administrative judgments or requirements. Accordingly, a social atmosphere which fails to respect the duties and independence of researchers based on the above-stated justification may reduce social power supporting academic freedom. What is utmost important for supporting academic freedom is respect and expectation of the general society for academic studies." (quoted from the same book as described above).

Regarding the issue of controlling studies of life sciences, however, it is increasingly necessary to evaluate this matter separately from the general principles because of the following reasons: (i) application of cloning technology (as will be described later) is associated with important problems which affect the life and death of humankind and for this reason, people do not support the idea that conclusions are drawn only on the basis of the conscience and judgment of specialists; (ii) studies of life sciences have so far been primarily performed at universities, whereas their center has been shifted to, especially at an accelerated rate in recent years, private enterprises (including medium- to small-sized companies such as venture businesses); (iii) evaluation of the trends in studies of life sciences indicate the existence of international corporate strategies, with US companies being as the center, to establish venture businesses through the utilization of state-of-the-art technology; and (iv) regarding cloning technology, UNESCO also indicates its intention to reinforce regulations (note that UNESCO submitted "Recommendation Regarding the Position of Scientific Researchers" in 1974).

(3) Many scholars of constitutional law claim that academic freedom is absolutely free as long as it involves mental activities, but academic freedom is only relatively free when it is related to selection of research methods (refer to "Academic freedom and autonomy of university" authored by Yukio Matsui, Jurisuto No. 1089) and when it involves various external activities which are visible to the outside and are necessary to conduct studies (refer to the book entitled "The Constitution" by Akira Ueda and Ichiro Asano) since in these cases, academic freedom may conflict with legally protected interests. As specific examples, experiments on living humans and violation of privacy are cited. The main theories published so far regarding limitations of academic freedom with special regards to gene recombination can be divided roughly into the following two categories.

(i) Theory of voluntary ruling

<1> Shin-ichi Takayanagi and Keikichi Ohama "Academic freedom" in the book "Basic Law Commentary of the Constitution"

<2> Masanari Sakamoto "Constitutional Theory 3"

<3> Naoki Kobayashi "Lectures on the Constitution"

<4> Takashi Narushima "Academic Freedom"

<5> Yoshiaki Yoshida "Discussion about The Constitution of Japan: new version"

<6> Tomoyoshi Morita: "The Constitution of Japan"

(ii) Theory of national regulation

<7> Koji Tonami "Constitutional problems in connection with regulation on science and technology" Jurisuto No. 1022

<8> Koji Tonami "Constitution and academic studies as well as science and technology"; Yoichiro Higuchi "Lecture on Constitutional Study No. 4: Guaranteeing Rights No. 2"

<9> Nobuyoshi Ashibe "Academic freedom No. 1" Hogaku-Kyoshitsu No. 157

<10> Takeshi Kobayashi and Toshikatsu Minami, editors "Current Status of the Constitution of Japan"

The above-listed reports and books discuss the issue of regulating academic freedom from various viewpoints and stress the points that will be discussed later in this POLICY STUDY. Here, the authors would like to introduce several points which also involve our investigation in this Report.

The report authored by Tonami <7> refers to the fundamental law in Germany and justifies regulating life sciences-related technology in particular because of "human dignity" (and therefore concludes that manipulation of fertilized eggs or human genes is unethical). Report <8> argues that regulations of life sciences-related technology are based on the prescribed provisions to protect rights (e.g. the right of life, protection of family and the right of personality) in the Constitution and that behind these provisions, the principle of respect for human dignity exists (and therefore concludes that limits of life sciences-related technology must be defined by laws). Regarding this point, the authors consider it difficult to regard human dignity as a direct reason for regulation, since human dignity itself is abstract and as will be described later, it is recognized that many life sciences-related technologies, e.g. in vitro fertilization, cloning technology, and analysis of human genomes involve human dignity (note that this matter will be discussed in detail in Section 6.3).

Assuming that effects of science and technology cannot be fully foreseeable in advance, Tonami's report <7> claims that range and extent of damage can be great and serious, which requires regulations by the nation. On the contrary, Sakamoto claims in <2> that because such effects cannot be foreseeable, there is no reason for the nation to impose regulations on science and technology. Since effects of advanced science and technology cannot be fully foreseeable and in addition, the currently accepted common view (i.e. the idea of research) is always open to criticism, it is expected as a matter of course that ultimately, the nation may need to take all responsibilities for working out solutions.

Tonami's report <7> lists the following reasons why regulations should be imposed by laws: (a) for the purpose of defining limits of science and technology; (b) for the purpose of restricting the freedom of research, a human right; (c) because it is difficult to determine limits of regulations; (d) because public opinion must agree with the control of science and technology and in this respect, establishment of a law is the most appropriate; and (e) because respecting voluntary judgments of researchers may discourage them from being active toward research.

On the other hand, another report by Tonami <8> claims that it is inadequate to work out comprehensive resolutions for science and technology as a whole and accordingly, regulations need to be reexamined on the basis of a variety of actual experiences. A choice between two positions, either regulations by law or voluntary ruling, may encounter many difficulties.

(4) In light of the above-described views, the authors would like to fully examine the following 3 points that should be taken into account when investigating regulations on the freedom of research.

(i) What danger and harm would occur if research (or technology) is left to stand (i.e. is not regulated), and which benefits would be lost if such regulations are imposed?

(ii) In cases where regulations are required, which types of regulations would minimize burdens given to the individuals to be regulated and still be effective?

(iii) Is research only regulated or is research by researchers simultaneously regulated as part of the framework of regulating the general public?

Regarding (i) and (ii), since substantial differences are noted among individual science and technology fields, for which the necessity of regulation is now under discussion, we need to investigate them individually and specifically. The authors consider it difficult to have comprehensive discussions about life sciences induced risks and confusion in the social order since experiments of gene recombination, reproductive medical technology such as in vitro fertilization and surrogacy, and cloning technology would violate substantially different legal and social benefits. The authors will discuss these issues while showing specific examples: (i) will be discussed in Section 6 and (ii), in Section 5. The authors will discuss (iii) in Section 4B.

The basic position of this POLICY STUDY Report is that generally, even "the freedom of learning & research" may be regulated for the sake of public welfare, provided that the contents of technology in question are analyzed in detail and advantages resulting from such regulation as well as how such regulation is imposed are identified.

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4B: Regulation of Technology at the Stages of Research and Practical Use

(1) When investigating regulation of research activities, it is considered useful to divide the process of science and technology into two categories, i.e. research, and application of technology (in order to utilize the results of research), according to which views should be placed separately. Regarding life sciences, there exist many difficulties in dividing them into these two categories. On the other hand, it is not unnatural for general science and technology to be divided into the two.

Specifically, it is appropriate to divide application of advanced technology into two stages, i.e. one at which researchers apply the technology concerned in order to increase scientific knowledge and findings and the other at which not only researchers but also various types of people (including engineers) apply the technology concerned by incorporating it in specific processes such as production. Technology at each of the stages would have the following impacts on the society.

(i) Technology at the stage of research

Individuals who apply the technology at this stage primarily comprise researchers at universities. The size of laboratory, financing, and manpower is small. Should an accident occur, the extent of damage is expected to be minimal.

(ii) Technology at the stage of practical use

Individuals who apply the technology at this stage primarily comprise engineers working at private enterprises. The size of plant, financing, and manpower is considerably large. Should an accident occur, there exists the possibility that such an accident may bring about severe damage.

For example, animal experiments of cloning technology has made progress with an aim of improving reproductive technology for animals, which has resulted in discussion about creation of a cloned human baby. At present, there have been reports concerning production of cloned animals such as cattle and sheep, and of differentiation of human embryos up to specific stages of development. Creation of a cloned human baby has not been undertaken. Although this example may be conceptual, it suffices to demonstrate that it is not adequate to discuss regulation of research activities under circumstances where, as in this example, there exist confusion between the stage of research (i.e. fundamental research) and the stage of applying such technology to practical use in the society.

(2) The relation between research and application of a new technology which is the product of such research has been discussed and explained in a relatively simplified manner. Various research activities have been appreciated since they put useful ideas, which society has long looked for, such as provision of consumer goods, transportation and telecommunication, to practical use in an effective and efficient manner, or they increase options of measures to facilitate such realization. When looking at individual types of research, whether a particular technology is to be applied or not has been decided on the basis of results obtained from (a) research to bring about the creation of the technology that is expected to be applied to society or (b) research from the viewpoint of examining that technology. In addition, it has been accepted that there is another type of research (c) which has a role of providing an alternative technology or a supplementary technology when a problem occurs or may occur at the time of application of the original technology.

When taking nuclear energy development as an example, we can say that there existed reactor engineering research and other relevant research which forms the base of nuclear energy development (a), and that along with this engineering and environmental safety research was undertaken (b). In surrounding areas, material research, monitoring research and research of instrumentation control technology was performed (c). Accordingly, in order for a particular technology to be applied in society, a variety of well-established fields related to the technology have to be fully studied, as shown in the above-described example, and it must also be considered to be in the interest of the entire society.

On the other hand, research activities have been highly evaluated even if they do not directly give rise to any specific social utility such as production, since they promote the wisdom of humankind and thereby have further extensive impact on society. As a matter of course, many of the results of research in this category brought about inventions which could drastically change the root of human society because of unintended use of these results. In recent years, national governments of several countries have strategically focused on promotion of research which is expected to have an extensive impact rather than research which is undertaken from the beginning to achieve a specific objective.

(3) Regarding regulation of research related to a new technology and of application of the technology, there are specific cases in which the above-described circumstances are taken into account: application of technology at the stage of research is intentionally, i.e. as a matter of policy, separated from application of technology at the stage of practical use, and then, the latter is as a rule made the subject of regulation while on the former, restrictions are relaxed when special conditions are met.

(i) Nuclear energy development: An example of the old "Nuclear Reactor Regulation Law"

The old "Law Concerning Regulation of Nuclear Source Material, Nuclear Fuel Material and Reactors (Nuclear Reactor Regulation Law)" (established in 1957) prescribed that a person who intends to install a reactor shall obtain permission for such installation from the Prime Minister or any other relevant individual (in Article 23), shall obtain license regarding the design and construction methods (in Article 27), and shall be subject to pre-operation inspection and regular inspection (in Articles 28 and 29). The Japan Atomic Energy Research Institute, however, was allowed to install a reactor without obtaining permission for the installation (note that the Institute had to obtain a license regarding the design and construction methods and had to follow other relevant requirements). This was because the Japan Atomic Energy Research Institute was established under a special law, and was intended to perform research and other relevant activities related to nuclear energy development in a comprehensive manner. The Institute had already been organized as a foundation in 1955 before the establishment of the Law, and had accumulated substantial achievements in nuclear energy related research, which was extremely limited in Japan at the time. It was therefore prescribed by the Law that this Institute did not need to obtain permission for installation of a reactor. Subsequent amendments, however, require the Institute to obtain permission for reactor installation, as does anyone else who intends to install a reactor.

<Note> The Nuclear Reactor Regulation Law strictly limits exposure of radiation to the human body in order to prevent radiation hazards under the regulatory system by this Law: installation of a facility that produces exposure levels beyond the prescribed permissible level is prohibited; and activities which cause exposure of the operators concerned to levels beyond that prescribed are restricted. Regarding nuclear reactors for which utilization for medical research is licensed by the regulatory authorities, however, it is authorized that large quantities (which exceed the permissible exposure dose) of neutrons and any other relevant substances taken out from the reactor may be used in irradiation treatment of patients with brain tumor or any other relevant disease (note that currently, some research reactors including JR4 of the Japan Atomic Energy Research Institute have obtained this license).

(ii) Research of poisonous substances: The Poisonous and Deleterious Substances Control Law

The Poisonous and Deleterious Substances Control Law stipulates that only those manufacturers that have been officially registered as manufacturers of poisonous or deleterious substances shall be allowed to manufacture specified poisonous substances (in Section 1 of Article 3-2) and that only those importers that have been officially registered as importers of poisonous or deleterious substances shall be allowed to import specified poisonous substances (in Section 2 of Article 3-2). On the other hand, individuals who receive licenses from the prefectural governor as being entitled to manufacture or use specified poisonous substances for scientific research (i.e. the researchers of specified poisonous substances) are allowed to manufacture or import such poisonous substances.

(4) Of course, it is a matter of policy to differentiate, in terms of regulation, technology at the stage of research from technology at the stage of application for practical use, and such differentiation is not a legally essential condition. Generally, regulations on research are frequently relaxed in the following situations: <1> when application of a new technology provides extremely great utility for society; <2> when there is strong social demand for promotion of research with an aim at obtaining knowledge about effects of a particular technology prior to its application; <3> when it is considered that comprehensive regulation for the sake of practical use may cause great hindrances to research; <4> when it is acknowledged that generally, research constitutes small-scale experiments performed within a laboratory room and also is greatly diversified, the safety of which can be secured when research is performed under the supervision by specialists having sufficient and extensive knowledge such as researchers and also under regulatory conditions; and <5> when it is considered feasible that a system sponsored by the nation or an institution equivalent in authority to the nation may work as appropriate.

Usually, (fundamental) research differs from application of technology at the stage of practical use because all processes of the technology concerned at the stage of research are not applied all together at the same time. In the case of life sciences, for example, experiments or studies are frequently performed for individual detailed processes such as development and differentiation. If research of each process in detailed steps can be performed even if the entire process concerned is regulated, then such research can in many cases be useful.

Under these assumptions, the authors would like to address the following issue from the general viewpoint: For which types of research are measures to relax regulations required when regulating advanced technology? Of course, this investigation should be made for individual technologies according to their individual characters.

The first character of a technology is that which is highly likely to be applied in society in the future, although confirmation of safety of the technology is required. An example of this is manufacture of new drugs or foods through the use of gene recombination. In this case, application of new technology requires development of safe organisms and methods which are more appropriate to achieve the set objectives and the gathering of relevant information. Accordingly, it is not unfair to consider measures to relax regulations for the purpose of promoting research required for the development and the information gathering, which differs from regulations to be imposed on technology at the stage of practical use.

The other character of a technology is that in which results caused by application of the technology will not be accepted by society for the time being whatever the underlying reasons behind the research. An example of this nature can be technology which is only intended to harm or kill humans. In this case, the reasoning is that if it is decided not to apply the technology concerned to practical use, then it is not necessary to promote research related to that technology. There is little necessity to relax regulations at the stage of research since restrictions are to be imposed at the stage of practical stage.

(5) On the basis of the above-described view, the authors would like to investigate cloning technology. Usually, there rarely exist a combination of a single objective with a single method to achieve that objective of research. Various methods are used to achieve an objective and the same method can be used in several studies having different objectives. Regarding cloning technology, therefore, there can be studies which use cloning technology not for the purpose of creating a cloned human baby but for other purposes. Whether such studies are specific, since they identify the different objectives to that they aim to meet, or general since they intend to look into the truth, their promotion is as important as promotion of fundamental research of the other life sciences as long as results of such studies may elucidate mechanisms involved in, for example, human development or differentiation of cancer cells.

At the same time, we have to pay special attention to the recent change in quality of science and technology. The traditional types of science and technology indicate clear differences between the stage of fundamental research performed at university laboratories and the stage of technology development for application to practical use in terms of financing, human resources, and facilities, all of which have to be upgraded when transferring from the research stage to the practical stage. In addition, decision making and responsibilities are clearly different between the two stages (e.g. nuclear energy-related research, space-related research). In recent fields of science and technology, the borderline between research and practical use are not well-defined, which brings about a gradually increasing number of cases in which research results can be directly applied to society (e.g. life sciences, information technology). With special regard to life sciences, the possibility of producing an immediate effect on humankind cannot be ruled out. In cloning technology, for example, the cloned sheep was produced when the research concerned was completed.

Considering these facts, the authors' basic view is, as described above, that since there exist regulations imposed on ordinary citizens, it is unavoidable that researchers are also regulated within the range of these regulations, in accordance with the potential danger caused by application of cloning technology.

(6) There are several laws and regulations which limit research activities by researchers as part of the framework of regulating the ordinary citizen. For example, legal controls of specific substances limit the use of those substances (e.g. the Law of Prevention of Radiation Hazards regulates the use of isotopes for research purposes), and thus limits certain experiments (e.g. tracer experiments). It is not unreasonable either that regulatory control of those consequences generated by the use of a specific material (e.g. the Radio Law regulates generation of radio waves) limits studies using such materials (e.g. study of radio waves). It is therefore not correct to consider that these regulations damage academic freedom.

On the other hand, we consider it difficult to impose restrictions only on the side of research in a certain area in which practice is generally permitted. We cannot imagine any circumstances under which practical application of a certain technology in a specific field is allowed but into which research of such technology is not permitted. We do not believe that the Constitution of Japan, which is currently in effect, will accept such circumstances.

For example, if frozen storage of sperm or ova, assistance in donating sperm or ova, artificial insemination, pre-birth examination, and elimination of a fertilized egg are widely permitted generally and legally (note that actually in Japan, artificial insemination and in vitro fertilization are performed under certain limitations) on the assumption that each individual has the right to control his sperm or her ova, it may be difficult to regulate only those studies in which sperm or ova are handled (and those of applying cloning technology in particular).

Of course, it is possible, because of the reasons stated in the previous sections (1) through (5), to utilize a law which generally prohibits any measures leading to creation of a cloned baby in order to regulate not only the creation of such a cloned embryo but also any series of relevant studies. Such regulation will require, needless to say, identification of the two aspects, i.e. social benefits and violation of the legally protected benefits which are attributable to reproduction-related medical care technology, such as artificial insemination and in vitro fertilization, and cloning technology: comparison of these two aspects is mandatory for creating reasonable regulation. (Journalism frequently uses the expression "regulation of cloning studies" when they discuss regulations on cloning. We think it necessary to clarify whether this purely means "studies of cloning only" or refers to "application of cloning technology which includes cloning studies," in order to avoid any unnecessary confusion when evaluating regulations.)

(7) Finally, the authors would like to discuss problems associated with restrictions on the freedom of learning & research. Comparison of regulations on research with those on application of technology (including research) reveals that in the former, researchers are the subject of regulation. In the latter, however, only ordinary citizens are the subject of regulation, in which there exists the advantage from the viewpoint of legal technology that immediate considerations need not be given to the attributes of the researcher. In the case where researchers are considered to be the potential subject of regulation, careful investigation of research activities is required, as indicated by the fact that there have been no regulation acts purely intended to control research. From the viewpoint of regulation in particular, it is highly likely that "legal responsibilities of researchers" may be identified, which may create various issues to be addressed. This point will be discussed in detail later in Section 7 as supplementary discussion.

Regarding the position and responsibilities of researchers, as indicated by the recommendations issued by UNESCO and other relevant statements, it has been considered that they occupy a privileged position and assume more ethical responsibilities than ordinary citizens. Along with the debut of life sciences-related problems, it becomes necessary to discuss legal responsibilities, in addition to this privileged position and the highly ethical responsibilities, of researches as in medical doctors, lawyers and other relevant professions. This is a new issue which we will have to face in the future and figure out resolutions. However, it may require a substantially long time for the individuals involved to reach a consensus regarding this new issue.

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## Section 5: Investigation of Subject in Regulating Technology (with Regard to Reproductive Medical Technology)

### 1. Investigation of Subjects in Regulating

The authors have already stressed in the previous sections that when regulating the freedom of learning & research, it is important to examine the necessity and modality of regulation for individual technologies to be the subject of such regulation. We will investigate modalities which fit to individual technologies in this Section and the necessity of regulation for individual technologies in Section 6. When discussing legal regulation, these two factors, i.e. modality and necessity, are closely interrelated to each other. Accordingly, even when focusing on only one of the factors, the authors will discuss the other factor as appropriate. We consider it natural to first discuss the necessity of regulation and then move onto the issue of modality; however, since the technologies to be regulated are complicated, we instead will first discuss the modality of regulation while giving explanation of these technologies.

This POLICY STUDY Report was intended to investigate regulations on life sciences. From this Section onward, regulations on individual technologies will be discussed, for which it is unavoidable to limit the scope of investigation. As described in the introduction, the authors will thus focus on cloning technology in particular. However, when discussing cloning technology, it is desirable to take a wider look at reproductive medical technology with the aim of positioning cloning technology within the context of the entire reproductive technology field. For this reason, the scope of technology discussed in this Section will be reproduction-related science and technology including that surrounding cloning technology. The authors consider that the way of investigating the scope of this technology in this Section is necessary also for investigating regulations to be imposed more extensively on life sciences in general.

Regarding technology which has already been developed, it is generally reasonable to trace back the chronological cause-and-effect relationships as shown in the example of "chronological evaluation of the development & growth system" in the next section and to impose comprehensive regulations at appropriate stages. The examples based on this idea include the views that experiments regarding manipulation of a fertilized egg should not be allowed past 14 days post-fertilization and that a special position should be granted to an embryo once it is formed since life starts at the time of formation of the embryo. On the other hand, considering the fact that advanced science and technology such as life sciences has made rapid and great progress, it is not always appropriate to examine regulations on life sciences only within the framework of such chronological technology systems. Attention must be paid to the high possibility that among individual chronological acts, those which become serious problems to humankind may exist side by side those which do not cause problems but produce extremely beneficial technology to humankind if such acts are carefully undertaken. It is therefore necessary to carefully classify and examine potentially problematic acts at individual stages of development and growth, on the basis of chronological cause-and-effect relationship (which requires understanding not from a linear view but from an overview). Of course, it is difficult in the present Report to examine the specialized technology necessary for such regulation and therefore, it only presents approximate relation between cloning technology and representative surrounding technologies necessary for discussing legal regulation of application of cloning technology. The authors would like to introduce our evaluation as an example indicating how cloning technology is examined as a subject of regulation on the basis of how extensive life sciences surrounding cloning technology are analyzed.

When introducing our evaluation, the authors will make the following attempts in particular: <1> to separate as distinctly as possible the subjects of regulation (i.e. gametes, embryos, fetuses, etc. at the stage of development and growth which are the subjects of regulation) from the acts to be regulated (e.g. fertilization, nuclear transplantation, and implantation) for the purpose of investigation (since we think that this separation is important when discussing methods of regulation); <2> not to focus only on technology which is directly involved in creation of cloned human babies but to take a wider look at surrounding technologies; and <3> to point out a possibility that evaluation of these surrounding technologies may encounter bioethical problems in addition to legal and ethical problems involved in cloning technology (for example, implantation of a fertilized non-human egg in the woman raises bioethical problems, which is a different issue from examining problems involved in cloning technology itself).

When considering regulations to be imposed on research of life sciences, with special regard to reproduction-related research, and on application of technology, it is necessary to review the types of cells as the subject of regulation, chronological changes of these cells during development, and technology to be regulated, for the purpose of identifying problems in each category. First of all, chronological changes in the process of human development will be shown in the table on the next page.

2. Technologies and Acts which can be Problematic, and their Evaluation

The technologies and acts which can become problems in connection with the chronological changes in cells throughout the process of human development will be listed below. In the list, individual subjects of regulation are first classified into categories of cells produced during the process of development and growth. In each of this first-grade category, technologies and acts using these subjects are classified into second-grade categories by reference to the overseas legislation cases. In each of the second-grade category, several examples of specific experiments or studies are shown: in this third-grade category, the expression "(consumed)" indicates "disposed after experiment."

{Note} Definition of symbols in each category are as follows:

* : An event which occurs in the natural reproductive process.

(>): An act of removing from the human body or an artificial manipulation which may produce cells which, after such act or manipulation, will continue to follow the human development process.

(<): An act of returning to the human body.

*: Technologies or acts which lead to the creation of a cloned human baby.

#: Technologies or acts which may entail ethical problems for reasons different from those associated with application of cloning technology, e.g. surrogacy, fertilization between human gametes and animal gametes, transplantation of embryos produced by such fertilization into humans or into animals; transplantation of human embryos into animals, and creation of human chimeras.

Table: Chronological Changes in the Human Development Process

| |
|---|
| <Man><br><br>Reproductive stem cell > spermatogonium … sperm (germ cell) > Fertilized egg<br><br><Woman><br><br>Reproductive stem cell > oogonium … ovum (germ cell) > Fertilized egg<br><br>>Cleavage division period (two-cell state, four-cell stage, eight-cell stage, morula)<br><br>>Blastocyst (one week after start of cleavage division: consists of a trophoblast located on the surface and an inner cellular mass. Taking a cell out from the inner cellular mass and culturing it will produce an embryonal stem cell (ES cell) which possesses totipotency.)<br><br>>Transplantation of an embryo into the woman > Implantation (appearance of the primitive streak: 2 weeks after start of cleavage division) > Fetus (which possesses primordial germ cells) > Delivery<br><br>{Note that embryos in the cleavage division period and in the stage of blastocyst are called early embryos.} |

{Notes} For the purpose of facilitating understanding of the above table, the cell types are explained below.

- Reproductive cells: Cells which are formed during gametogony and are of two kinds, i.e. an ovum and a sperm (which are called gametes).
- Primordial germ cells: Reproductive stem cells which are formed in the fetal period.
- Somatic cells: All cells constituting the body with the exception of sperm, ova, and reproductive stem cells producing sperm and ova (and primordial germ cell in the fetal period).
- Stem cells: Cells which exist in animal tissues, possess the ability to undergo cell division, have no limitation on their life, and are able to differentiate into specific types of cells to which the original stem cells belong. (In other words, cells which have limited ability of differentiating into cells within the system where the original cells exist, e.g. in the neurological system, the endocrinological system, the blood system, and the immunological system.) Note that reproductive stem cells and embryonal stem cells (ES cells) have totipotency, i.e. these types of stem cells are able to differentiate into all types of cells.
- Primitive streak: A form which appears during the process of development and differentiation: it appears when the mesoblast and the endoblast start to differentiate after the ectoblast has already differentiated. The ectoblast differentiates into nerve cells, skin, etc. The mesoblast differentiates into blood vessels, muscle, etc. The endoblast differentiates into gastrointestinal tracts, internal organs, etc.

(A) Reproductive Stem Cells, Spermatogonia / Oogonia of Human

<1> Storage

<2> Use Use for the purposes of experiments and research (consumed)
Use for the purposes of tests
Production using animals (e.g. introduction of human spermatogonia into a mouse testicle to allow them to grow) (>) #

<3> Forming gametes *

(B) Gametes

<1> Storage (# for post-death reproduction)

<2> Use Removal of an unfertilized egg from the mother's body
Use for the purpose of artificial reproduction (artificial insemination, in vitro fertilization) (>)
Use for the purpose of experiments and research (consumed)
Artificial change in genetic characteristics (consumed) #
Use for the purpose of tests (e.g. fertilization between a human sperm and a hamster ovum to examine if the fertilized egg is normal)
Fertilization between a human gamete and an animal gamete (>) #
Fertilization of gametes with artificially changed genetic characteristics (>) #
Transplantation of a nucleus of the somatic cell, etc. to an unfertilized egg to create a cloned embryo (>) *

<3> Fertilization *

(C) Fertilized Eggs Prior to Initiation of Cleavage Division

<1> Storage

<2> Use Removal of a fertilized egg from the mother's body
Use for the purpose of artificial reproduction (surrogacy) (>) #
Use for the purpose of experiments and research (consumed)
Use for the purpose of tests (e.g. pre-birth diagnosis)
Artificial change in genetic characteristics (>) #
Removal of a nucleus from a fertilized egg and transplantation of the nucleus to an unfertilized egg (for the purpose of creating a cloned embryo) (>) *

<3> Formation of an embryo *

(D) Embryos

<1> Storage Storage of a cloned embryo (<) *
Storage of extra embryos

<2> Use {Naturally formed embryos}
Removal of an embryo from the mother's body (>)
Removal of a nucleus from an embryo and transplantation of the nucleus to an unfertilized egg (for the purpose of creating a cloned embryo) (>) *
Artificial division of an embryo in the cleavage division period in order to create a cloned embryo (>) #
Artificial change in genetic characteristics (>) #
Use for the purpose of artificial reproduction (surrogacy) (>) #
Use for the purpose of experiments and research (consumed)
Use for the purpose of tests (e.g. pre-birth diagnosis)
{Artificially created embryos}
Creation of an embryo outside the body through the use of in vitro fertilization
Creation of a cloned embryo by transplanting a nucleus of the somatic cell (derived from born human babies) to an unfertilized egg *
Creation of cloned embryos through the use of nuclear transplantation using nuclei obtained from fertilized eggs, embryos, and fetuses *
Creation of coloned embryos by transplanting a nucleus of the ES cell *
Creation of an embryo by fertilization between a human gamete and an animal gamete #
{Nuclear transplantation}
Transplantation of a normal embryo into the mother's body (<)
Transplantation of a cloned embryo into the mother's body (<) *
Allowing gametes with artificially changed genetic characteristics to unite to form an embryo and transplanting the embryo into the mother's body (<) #
Transplantation of a human embryo into an animal #
Allowing a human gamete and an animal gamete to unite to form an embryo and transplanting the embryo into a human or an animal (<) #

<3> Formation of an individual *

<4> Removal and disposal of embryos (corresponding to artificial abortion)

{Note} In this first-grade category of 'embryos,' embryos existing in the mother's body (i.e. naturally formed embryos), artificially embryos, and transplantation of these embryos to the mother's body are covered. Accordingly, some of the acts listed here may also be listed in the other first-grade categories.

(E) Stem Cells (by Focusing on Special Cells at the Stage of Forming Embryos)

$ Embryonal stem cells (ES cells) [which are produced by culture of the cells in the blastocyst stage after removal of an embryo]

<1> Creation

<2> Storage

<3> Use Use for the purpose of experiments and research (consumed)
Use for the purpose of creation of organs or any other relevant purposes
Removal of a nucleus from the ES cell and transplantation of the nucleus to an unfertilized egg (for the purpose of creating a cloned embryo) (>) *
Creation of a chimera individual (a human chimera, a chimera between a human and an animal) #

$ Stem cells by individual tissue systems (normal stem cells and EG cells)

<1> Storage

<2> Use Removal of stem cells formed in individual tissue systems during the fetal period (>)
Removal of primordial germ cells formed during the fetal period (=Refer to EG cells) (>)
Use for the purpose of experiments and research (consumed)
Use for the purpose of creating of organs and any other relevant purposes
Removal of a nucleus from the EG cell and transplantation of the nucleus to an unfertilized egg (for the purpose of creating a cloned embryo) (>) *

<3> Differentiation and expression as somatic cells *

(F) Individuals (Fetuses)

<1> Use (prohibited and punished as illegal abortion, etc.)

<2> Testing Pre-birth diagnosis

<3> Research Removal of a nucleus from a fetal somatic cell and transplantation of the nucleus to an unfertilized egg (for the purpose of creating a cloned embryo) (>) *
Removal of stem cells of individual tissue systems (>)
Removal of primordial germ cells (>)

<4> Artificial abortion (based on the Mother's Body Protection Act)

<5> Use of artificially aborted fetuses and stillborn babies in research

<6> Natural delivery *

(G) Somatic Cells

<1> Storage

<2> Use Removal of a nucleus from a somatic cell and transplantation of the nucleus to an unfertilized egg (for the purpose of creating a cloned embryo) (>) *

(H) Others

Creation, storage, and use of EG cells as well as transplantation and implantation of EG cells to the mother's body

Transplantation of an animal embryo to a human #

Partial transplantation of human somatic cells to animal embryos #

Manipulation of cells of animal individuals

Products obtained from the above-listed research and technology do not only lead to creation of cloned human babies but may be utilized to achieve the following objectives, including those which have not yet been realized.

(a) To obtain fundamental knowledge and findings in biology, embryology, cytology, gene engineering, embryological engineering, etc. {This is related to all of the above-listed technologies.}

(b) To promote advancement in regenerating medicine such as production of organs and tissues for transplantation which will not cause immunological rejection

(e.g. Production of organs for transplantation through the use of culture of stem cells in individual organs: using a technology of transplanting a nucleus derived from a somatic cell to an enucleated ovum and manipulating genes of a nucleus to be created by the technology with the aim at producing not an individual but a specific tissue only such as an organ)

{This is related to technologies involving "(E) Stem cells" in particular among the above-listed technologies, and also related to technology of nuclear transplantation and artificial change of the genetic characteristics of an embryo.}

(c) To accelerate progress in reproductive medicine

(c)-1. Diagnosis and complementation for malfunction of spermatogonia, sperm, etc.

(e.g. Introduce a human spermatogonia into a mouse testicle to allow them to grow sperm. Allow the sperm and an egg from a hamster or other animal to unite for the purpose of examining fertilization rates and if the sperm is normal. Destroy the formed embryos before they reach the two-celled state.)

{This is related to technologies involving "(A) Reproductive stem cells and spermatogonia" in particular among the above-listed technologies.}

(c)-2. Treatment of mitochondrial abnormality (When the mother suffers from mitochondrial abnormality, use technology of transplanting a nucleus derived from the fertilized egg to the other enucleated ovum to prevent the child from inheriting the abnormality from the mother.) {This is related to technology of nuclear transplantation in particular among the above-listed technologies.}

(c)-3. Diagnosis and treatment of other hereditary diseases
{This is related to technology of nuclear transplantation and artificial change in genetic characteristics in particular among the above-listed technologies.}

(c)-4. Diagnosis and treatment of infertility

(e.g. Use technology of dividing an embryo to produce several embryos from a single embryo, and transplant these embryos with the aim at compensating for low success rates of pregnancy.)

From the viewpoint that it is necessary to impose restrictions on implementation of the above-listed technologies, safety-related and several other types of problems may occur when implementation of a technology is associated with production of an individual, and brings about the creation of a cloned human baby in particular. The justification for regulation will be described in detail in Section 6.

In addition, surrogacy, fertilization between human gametes and animal gametes, transplantation of embryos produced by such fertilization into humans or animals, transplantation of human embryos into animals, and creation of human chimeras (i.e. acts and technologies marked with #) may raise ethical problems, which is a different issue from examining problems involved in application of cloning technology (note that artificial insemination, in vitro fertilization, examination of reproductive cells and other relevant technologies which have already been put into practice in Japan are excluded.)

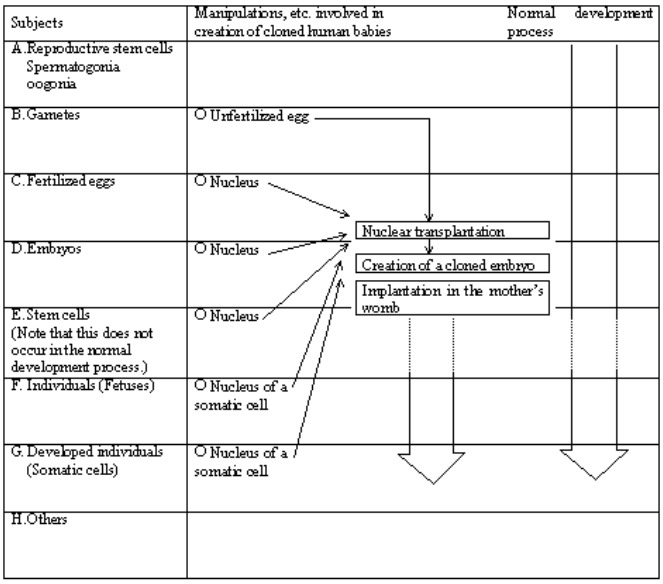
Regarding handling of these technologies, the subject of regulation will be decided after comparing advantages and drawbacks of accepting research and technology application on the basis of the currently available scientific knowledge and current status of technology as well as the sense of values that the society has, and such decision will be made on the basis of political and ethical judgment. Such decision-making will require exact identification of subjects and acts.

For the purpose of preventing creation of cloned human babies (as described at the beginning of this section, the conclusions to be stated in Section 6 are described here in advance), we have to look at several acts involving several subjects at the development and growth stage such as gametes, fertilized eggs, and embryos as shown in the figure (note that these acts are indicated by the mark * in the above list). Assuming that all of these acts be individually regulated, such regulation can be complicated and impractical. On the other hand, an attempt to regulate the acts of transplanting of embryos to the mother's body for the purpose of implantation may be relatively clear and surely effective in prohibiting creation of cloned human babies (refer to the table on the next page).

(If acts intended to create individuals are only regulated, how to handle experiments and research not intended to create individuals can be problematic. Even in the latter type of experiment and research, an individual may either willfully or negligently be created from embryos for research since the research itself directly connects to the process of producing an individual. It is therefore considered that also regulating activities not intended to create individuals is reasonable.

Furthermore, due to the remarkable pace of achievement in the life sciences, it is likely that new technologies not included in the above list may be put into practice in the near future. The social order and sense of values will change. Reexamination after a certain period will be required.)

Table : Manipulations, etc. involved in creation of cloned human babies

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## Section 6: Grounds for Justifying Regulation (with Primary Regard to Cloning Technology)

### 6A: Safety

1. Types of Hazards Caused by Application of Cloning Technology

In this Section, the authors will investigate the reasoning behind regulation. If we try to investigate grounds for regulation (e.g. assuming that a penal code be selected for regulation, we need to investigate which of the legally protected interests would then be violated), we have to identify dangers and harms caused by individual technologies and therefore, we cannot investigate merely by generalizing technologies under the headings of life sciences or reproductive medical technology, which so far has been done in this Report. Instead we have to investigate a strictly limited area. Accordingly, as described at the beginning of this Report, the authors will focus on cloning technology only in this Section and discuss the other technologies as far as such discussion is necessary for comparison with cloning technology.

(1) Hazards to Mothers who Deliver Babies

Transplanting a nucleus to an egg and implanting of the egg into the womb of the mother may cause hazards to the health of the mother. The mother's life and body should be protected. Hazards to the mother's health clearly violate the legally protected interests of the individual as well as negatively affects the benefits of the individual. It is therefore considered that protecting the mother's health raises no special problems. If cloning technology should affect the safety of the mother, there will be no problems caused by regulating and prohibiting application of cloning technology to such cases.

A report issued by Science Council points out the following safety-related issue as grounds for justifying regulation:

- Physiological compatibility between an implanted embryo and the mother's body (e.g. oversized fetus)

(2) Hazards to Babies Born

When a nucleus is transplanted to an egg to create an embryo and that embryo is then implanted into the womb of the mother, the baby to be delivered of the mother may suffer from many hazards to his/her life and body. Firstly, the egg in itself was not originally capable of bringing about the formation of an embryo, but as a result of the manipulation was later born as a baby; accordingly, it is understood that nuclear transplantation produced some change or damage to the egg as compared to its original status. Another reading of the situation is that if the egg is considered as an controllable object separate from the body, then the egg in itself was subjected to damage, and thus it can be considered as destruction of things. (The authors introduced in Section 3 that scholars in penal law point out the necessity of establishing new legislation, because under the currently effective laws, fertilized eggs can only be treated as things.) Secondly, even if due to incompleteness of technology or for any other relevant reasons a baby is not born or is born with abnormalities, the child (or the fertilized egg produced by normal pregnancy that is supposed to form an embryo which is later born as a baby) will not suffer from danger or harm. It is hardly considered, therefore, to establish a legal framework that punishes individuals who are engaged in nuclear transplantation, on the ground that the safety of life and body of fetuses is legally protected. At present this ground is applied to the crime of abortion.

Even assuming that an egg to which a nucleus is transplanted be regarded as identical at the time of nuclear transplantation as the fertilized egg produced by normal pregnancy, fetal death or abnormality caused by cloning technology cannot be regarded as damaging to the life and body of the child, i.e. violation of the legally protected interests of the child, since application of cloning technology is unavoidably associated with occurrence of such fetal death or abnormality.

On the other hand, the thought that hazards posed to the baby to be born are regarded as a violation of the legally protected interests of the child or of the benefits of the child can be based on the view that an act itself of bringing about the delivery of an abnormal child is a violation of the legally protected interests of the social order. According to this view, however, (i) when a baby is born dead, none of the legally protected interests are damaged, but (ii) an act of bringing about the birth of an abnormal baby corresponds to a violating act. These two may cause eugenic problems.

In light of the above-described points also, the safety of the baby to be born, together with genetic effects described in the next section,

has to be evaluated in connection with a higher and abstract level of social risk.

(3) Hazards in Connection with Genetic Effects on the Next Generation (i.e. Children) and Subsequent Generations

Since the somatic cells differ from the reproductive cells in function, genes of the somatic cells may be resistant to chromosomal alterations by external forces, e.g. radiation. It is therefore understood that a number of damaged (altered) genes exist in somatic cells, without affecting their function. However, when transplanting these somatic cells for the purpose of cloning, in theory, a damaged gene which may exist only in that single somatic cell out of all the cells of the body of the "parent" will ultimately be shared by all the cells of the entire body of the "child": the damaged gene in question may therefore have an enormous influence on the child. At present, it is considered difficult to identify such gene damage in advance among the multitude of genes within the somatic cell and it is therefore difficult to obtain the original (fully intact) genes as in the case of reproductive cells (note that reproductive cells are strongly sensitive and will die when their genes are damaged).

Genetic impact inherited by genes is expressed in terms of probability but it is difficult to foresee specific damage. In addition, genetic impact in many cases cannot be confirmed until knowledge and findings have been accumulated over many generations. In the human population, it is accepted that impairment caused by hereditary disease naturally occurs in approximately one of every 100 persons and that of having genetic predisposition for a disease (e.g. diabetes mellitus) is much higher, at approximately one of every 10 persons. Regarding hereditary diseases, there is a strong tendency in Japan to keep them confidential, which hinders gathering of relevant data, and responsive actions taken are passive. In contrast, European and North American countries have a very high interest in hereditary diseases, and the responsible agencies perform diagnosis of hereditary diseases and take responsive actions.

In Japan, the Japanese Association of Gynecology and Obstetrics issued the Association's recommendations entitled "Opinion on Fetal Diagnosis for Inborn Errors, with Special Regard to Early Examination of Villus" (in 1988) and "Opinion on Pre-Implantation Diagnosis" (in 1998). The Japan Association of Anthropology and Heredity established "Guidelines Concerning Genetic Counseling and Pre-Birth Diagnosis" (in 1994) and "Guidelines Concerning Gene Diagnosis for Hereditary Diseases" (in 1995). Regarding diagnosis of genes in fertilized eggs in particular, application for the first case of this diagnosis was recently made to the authorities in Japan.

It is necessary in Japan to deepen people's understanding to the same extent as in European and North American countries regarding actions to be taken to cope with hereditary disease. On the other hand, it is considered easier to obtain people's understanding regarding regulation of causes which bring about artificially induced hereditary effects. It is also considered reasonable to regulate such causes for the sake of preserving people's health since there is the possibility that such causes may result in large-scale, unforeseen damage. When evaluating the application of cloning technology, we cannot ignore these artificially induced hereditary effects since manipulation at the level of the gene is performed. In addition, as described above, unlike artificial insemination and in vitro fertilization which use highly sensitive reproductive cells (i.e. if a reproductive cell has damaged genes, then the reproductive cell will die, according to which adverse genetic effects are not likely to be inherited) or nuclei of the reproductive cells, cloning technology uses poorly sensitive somatic cells (i.e. even if a somatic cell undergoes gene damage due to ultraviolet light or radiation, it is most likely that the cell itself will survive and continue to play cellular roles) and transplants the nuclei of these somatic cells. Cloning technology may thus inadvertently pass on hereditary effects onto subsequent generations and thus extreme caution should be exercised in handling cloning technology. For example, a differentiated epidermal cell with gene damage, within the tissues of the human body surface, is unlikely to have any adverse effect on the rest of the body; in contrast, removal of the nucleus from this particular somatic cell with gene damage and transplantation of the nucleus for the purpose of creating a cloned human baby introduces the possibility that the cloned human baby thus created may have identical gene damage in all the cells of the body: as a result of this, extremely serious effects may occur both in the cloned individual and his/her descendants.

Despite the possibility of producing such serious effects, the risk of producing hereditary adverse effects is considered not as a specific danger but an abstract risk, which makes it difficult to set requirements or standards for regulations. In Japan, regulations were imposed on nuclear energy-related matters from the viewpoint of genetic effects. The authors would like to proceed with our investigation by referring to these regulations in the field of nuclear energy. Regulation of genetic effects is evaluated in connection with violation of the legally protected interests and benefits of society and from the viewpoint of probability, and therefore, hazards posed to the child to be born can be also taken into account.

As described above, the authors only introduced examples of easily understandable gene damage in this section. Science Council lists the following as important safety-related matters in connection with genetic effects in particular:

- Examination for fertility of the descendant (Even if it appears to be normal, infertility may occur in the subsequent generation.)
- Genome printing (Since reproductive cells are not used, genome printing may fail.)
- Compatibility of mitochondria (Compatibility with the somatic chromosome is unknown.)
- Telomere related problems (Telomerase lacking mice are apparently normal but may suffer from infertility after several generations have passed.)
- Somatic cell mutation (Accumulated or programmed mutation during somatic cell division)
- Extent of normality of gene expression of a frozen embryo (This is not identified even in animal experiments.)

The Committee additionally lists, among others, genetically consanguineous marriage due to use of frozen/stored eggs and a possibility of rapidly losing genetic diversity in the human population. These additional matters are excluded from our investigation since they are far away from the direct genetic risk.

2. Regulation from the Viewpoint of Genetic Effects Caused by Radiation

(1) In connection with research of genetics, research of genetic effects caused by radiation has been actively performed since many years ago as causes to be given can be identified quantitatively, and the field has produced substantial achievements. International organizations regarding research of radiation induced effects, the UN Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) and the International Commission on Radiological Protection (ICRP), also evaluated various types of physical impairments as well as genetic effects attributable to radiation and set standards. Among these standards, the ICRP set the standard citizen's genetic dose (this is currently referred to as collective dose) in PUB6 (Publication 6). This is based on the view that "appropriate projects regarding nuclear power plants and the other large-scale peaceful uses of nuclear energy will require limit exposure to the entire population firstly by limiting dose exposed to the individual and secondly by limiting the number of people to be exposed." By focusing on the 'maximal permissible genetic dose' and separating exposure attributable to natural background from medical exposure, they concluded that the genetic dose derived from all sources to the population should not exceed 5 rem and recommended 2 rem as an allocation after excluding the reserves (refer to Reference 2 for details).

(2) In Japan, the Nuclear Reactor Regulation Law prescribes that the Atomic Energy Commission shall examine application for installation of a reactor and grant a license for the installation. The guidelines for examination of reactor locations that is used upon examination of the safety of the reactor concerned stipulate that "the site for the reactor concerned shall be away by a required distance from dense population areas. The required distance from dense population areas means the distance far enough to reduce, in a hypothetical accident, an integrated whole body exposure dose to such an extent as fully acceptable from the viewpoint of the standard citizen's genetic dose" (decided by the Atomic Energy Commission on May 27, 1964). (Subsequent review of the atomic energy administration decided that the Nuclear Safety Commission will examine safety of reactors and accordingly, the guidelines for examination of reactor locations were handed over to the Nuclear Safety Commission.) Furthermore, according to a report issued by the Special Task Group on Reactor Safety Standards that established the above-described guidelines, the dose that should be reduced was set at $0.5 \times 10^8$ man.rem.

(3) As described above, despite the fact that none of the laws expressly and directly establish dose limitation, the currently available system is to limit population exposure dose not only for the purpose of preventing the individual from directly suffering from radiation damage but also inhibiting genetic effects.

Regarding limitation of population exposure, the ICRP states that "this limitation unavoidably implies compromise between harmful effects and social benefits" and that there would be no fixed standards. The ICRP continues to state that "factors influencing balance between dangers and benefits may vary depending on countries and each country should assume responsibilities to make the final decision regarding this issue" and accordingly, that the value indicated should be regarded as the "tentative upper limit."

(4) Finally, when limiting population exposure dose, the ICRP allocates the exposure dose as indicated in the table below. Reference 2 shows the underlying thoughts contained in the guidelines for examination of reactor locations.

| |
|---|
| <1> Natural background level |
| <2> Medical exposure |
| <3> Occupational exposure, etc. |
| <4> Exposure to the population as a whole |
| <5> Long-term reserves |

The recommendations recently issued by the ICRP contain no statements regarding the maximum permissible genetic dose. The Commission currently is based on the concept of collective dose and primarily focuses on limitation of carcinogenesis risk.

3. Methods of Regulating Cloning Technology

(1) On the basis of the above-described fact that genetic effects attributable to radiation were limited through the use of the standard citizen's genetic dose, it may be possible to restrict cloning technology for the purpose of preventing genetic effects related by implementation of cloning technology, e.g. transplantation of a somatic cell's nucleus to an unfertilized egg.

The point of such restriction is "what should function as the quantitative condition in restricting cloning technology?" In the case of radiation protection measures, the standard citizen's genetic dose is the quantitative condition. Some argue from the viewpoint of scientific technology that the genetic effects not only attributable to ovum manipulation but also to various chemical substances should correspond to the radiation equivalent. There exist many difficulties, however, since the phenomena related to cloning technology is not as simple as the physical phenomena related to radiation.

(2) Firstly, it is considered that when the ICRP issued the recommendations, they did not have clear knowledge or grounds for the genetic effects attributable to radiation but they evaluated the balance between benefits and risks resulting from utilization of nuclear energy and proposed that permissible dose. Accordingly, as far as specific advantages obtained from application of the technology concerned are not recognized by the society, it could be possible that no quantitative regulation be imposed on that technology but instead no application of that technology be approved (i.e. application of the technology concerned will as a rule be prohibited).

Special attention should be paid to the fact that when the ICRP issued the recommendations, radiation was the known cause of bringing about the greatest genetic effects. Since it was considered that new scientific findings would probably not be obtained for a while, it was significant for a nation to indicate the certain standard, even if that level was not a fully established one, and to ensure that people follow that standard because the nation takes responsibilities of protecting the life and health of its citizens.

(3) Secondly, evaluation of the structure of regulation built by the guidelines for examination of reactor locations (and the ICRP's recommendations) may indicate that {<1> natural background level} corresponds to damage of our genes which we unavoidably suffer from during our daily lives (it is considered that even if there exist no special causes, humans possess and accumulate harmful genes). What correspond to {<2> medical exposure} are in vitro fertilization and various technologies supporting pregnancy, the effects of which should be permissible as far as they are properly controlled, according to the same idea employed for the radiation protection: these technologies are therapies for infertility and we can accept their advantages. The authors will omit discussion about {<3> occupational exposure} since nothing corresponds to this. Cloning technology corresponds to {<4> exposure to the population as a whole}. At present, we cannot think of any direct and evident advantage resulting from cloning technology. In the case of nuclear power plants, the advantage that we can share is to secure good-quality energy in a stable manner. We therefore need to compare possible advantages with {<5> long-term reserves}, which should be held in reserve to cope with unforeseeable future effects on us and our descendants due to, for example, radiation, environmental changes and chemical substances contained in foods, in order to determine the extent of acceptance. The authors think it is possible that as a result of such comparison, application of cloning technology causing the genetic effects corresponding to <4> and <5> be totally prohibited.

(4) In light of the above-described points, it may be acceptable to regulate cloning technology from the viewpoint of its risks. Cloning technology is associated with impairments at higher probabilities as compared to in vitro fertilization, gene diagnosis, and gene therapy, which are considered similar types of technology as cloning technology. Even if the risk of such impairments at higher probabilities is compared with advantages from cloning technology, it is considered acceptable that cloning technology be differentiated from the other similar types of technology and be regulated accordingly.

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6B: Social Order

1. Formulating Social Order

(1) Regarding relations between married couples, parents and their children, and relatives, each country has its own ideal family model, based on which the country establishes laws and regulations. The ideal family model varies greatly depending on country. In addition, the family status in reality is substantially affected by religions, local manners and customs, morals, and sense of family bonds, and is considerably far from that prescribed by the state in actually established family acts (refer to "Historical Changes Over Time in Family Act" authored by Sumitaka Harada, Horitsu-Jiho Vol.69, No. 2). Even within a single country, great differences are noted among the people, e.g. some follow traditional views of the family while others adopt new views of the family. Changes in social circumstances also substantially affect the social order surrounding the family relationship, which functions as the foundation of public order.

In Japan, the family relationship experienced enormous changes after World War II. Great changes were noted in particular in the so-called "*ie*" system, the Japanese traditional family system in which the head of the household was the absolute center of the family. The prewar Civil Code, for example, allowed the head of the household, typically the father, to have absolute authority over the other family members: he had the rights to designate the place of living for the other family members; his approval was necessary before family members could marry or adopt a child; and he had the right to remove the name of any family member who did not follow his orders, from the official family

register. The head of the household also had the obligation of supporting the other family members. On the other hand, the Civil Code rewritten after World War II prescribes that both parents have parental rights over their child until that child reaches the age of consent, but the reform also indicates dramatic and fundamental changes according to the principles of respect for the individual's dignity and equality of the sexes. When looking at the relation between husband and wife, the wife was not entitled to have any legal capacity under the old Civil Code but is allowed to have legal capacities under the new Civil Code, according to which the wife is entitled to equal rights as the husband in terms of, among others, mutual consent of both sexes for marriage, rights and obligations between the husband and the wife, property-related matters, divorce, and parental power. Regarding inheritance, the old Civil Code prescribed that the head of the houseuld, i.e. the eldest son, inherited all the family's assets, whereas the new Civil Code establishes the basis of equal succession, irrespective of sex and age. With regard to a common-law marriage, although the related rules of the Civil Code were not rewritten, attempts have been made at providing the same extent of protection in reality for the common-law marriage as that given to officially approved marriage, e.g. the common-law marriage is treated in a more positive manner according to the view of legally protected interests. (Note that according to precedent cases, the individual against whom a common-law marriage relation is unreasonably canceled by the other, is allowed to demand compensation for damages from the other on the grounds of breaching the promise marriage, and at the same time, is allowed to claim damages on the grounds of an illegal act (Supreme Court judgment, April 1, 1958); when an individual who is not a common-law husband nor wife interferes unreasonably with and results in failure of the common-law marriage relation concerned, the individual shall have a responsibility for compensating damages as an illegal actor (Supreme Court judgment, February 1, 1963.)) Regarding the Penal Code, the Supreme Court adjudicated on April 4, 1973 that the rules regarding a person who kills his/her lineal ascendant (i.e. Article 200 of the Penal Code) were against Article 14-1 of the Constitution of Japan (which is an equality clause prescribing that all people are equal under the law). As described above, the sense of value itself has dramatically changed in connection with the relation between husbands and wives, parents and their children, and relatives.

It is expected that the family relation will change even more drastically in the future. These changes have been under active discussion from the viewpoints of social science, economics and ethics. From the viewpoint of the Family Act in particular, the issues to be addressed are how to relate the way a family should be and the individual's independence within the principles of self-assistance by family (i.e. the principles of private assistance and protection), and how to cope with related problems. Specifically, these problems are related to criticism of the current system for accepting divorce, the background of which is the increased divorce rate; law suits based on the claim that the legally prescribed length of period during which remarriage is prohibited is unconstitutional; request for free choice of different surnames by married couples; criticism of discrimination against children who are not born from the registered couple; and criticism of the fact that factual marriage or unmarried mothers are discriminated against (refer to the above-cited report by Sumitaka Harada). Under these circumstances, it is predicted that the prescribed way of reproduction and delivery will become a significant issue, particularly in connection with the discussion about right of autonomy. Upon such discussion, it is highly likely that although some of these matters are conventionally and currently regarded as unethical acts, they may in the future gradually be accepted. (Note that in this section, when we state that an act is "unethical," the authors do not only consider purely ethical issues but primarily focus on the areas controlled by the law, e.g. an act is invalid because it is contrary to public policy or good morals (according to Article 90 of the Civil Code) or the case concerned is a legal issue such as a responsibility for having performed a tort.)

(2) In addition to the social sense of ethics concerning the family relation as a whole, application of reproductive medical technology has serious effects on relations among relatives. What is considered unethical concerning the application of reproductive medical technology varies depending on countries and also has changed over time.

The authors would like to take artificial abortion as an example, since among reproductive-related matters, artificial abortion has been most seriously discussed, although this is not related to a foundation of any relative relation. In Japan, the Eugenic Protection Law was established in 1948. Japan was the first country in the world to enact an artificial abortion-related law. The Law was intended to protect the health and life of the mother and to prevent birth of eugenically poor descendants (note that the Eugenic Protection Law was reformed into the Mother's Body Protection Act in 1996 at which the provisions prescribed from the eugenic point of view were eliminated). One reason for protecting the health and life of the mother is an "economic reason" and it is therefore considered that the crime of artificial abortion stipulated by the Penal Code does not exist in reality but in name only (refer to "Comment on the Crime of Artificial Abortion" in the book "Basic Law: Commentary on the revised Penal Code" authored by Toshio Sawanobori).

In the UK, the Abortion Act was established in 1967. This was followed by the establishment of similar laws in France and Sweden in 1975, and in Italy in 1978.

West Germany amended their Penal Code in 1974, according to which artificial abortion under certain conditions was not to be punished. However, the Federal Constitutional Court adjudicated that this amendment was unconstitutional in 1975. In light of this judgment of unconstitutionality, the drafted Penal Code was separately examined and established in 1976. Along with the unification of Germany, the Pregnant Women and Family Support Act was established in 1992. Some members of the Federal Parliament filed a motion against the establishment of the Act and the Federal Constitutional Court again passed the judgment of unconstitutionality in 1993. Subsequent discussion between the ruling party and the opposition party about the bill has failed to lead to establishment of any new law (which was the situation as of 1995, according to "Overseas Information on Laws (in Germany)" authored by Junko Saitoh, Juristo No. 1067).

In the US, the Supreme Court of the United States adjudicated in 1973 that the provisions for the crime of artificial abortion in the state of Texas were against the constitution and accepted artificial abortion (Roe's judgment). Subsequently, there occurred in the US active discussions including possible amendments of the Constitution, although the Federal Congress did not call for legislation regarding artificial abortion. Under these circumstances, the Supreme Court of the United States has shown their stand that they will not change the basis of Roe's judgment in 1973, as indicated by Webster's judgment in 1989 and by Cathy's judgment in 1992, but made some judgments to accept regulation of artificial abortion according to state laws.

One of the issues attracting our attention in the future may be marriages between homosexuals, which is not related to reproductive medical technology but has already been a hot issue in European and North American countries. This is an example which cannot be handled according to traditional standards of ethics and represents the possibly of a changing social order in the near future, to which society will show different ways of acceptance from the current attitude. In Japan, the Civil Code uses terms indicating separation between the sexes, e.g. married couple, husband, and wife, and the Marriage Act and the Parent-and-Child Act are based on the assumption that a male husband and a female wife has a child (or children). Accordingly, it is considered in Japan that a marriage between homosexuals constitutes a hindrance to marriage according to the currently effective laws. Marriage of persons of the same sex is accepted, however, in Sweden where the Law Concerning Marriage of Persons of the Same Sex was established in 1995, and also in Denmark, Norway, and Iceland (refer to "The Way the Sexes should be" authored by Masayuki Tanamura, Jurisuto No. 1126). In Japan also, there was a precedent case indicating the necessity of protecting the rights and interests of homosexuals: the High Courts of Tokyo supported the judgment made by the Tokyo District Court that the act of Tokyo's Youth Hostel which forbade homosexuals to use the Hostel's institution by applying their rules of forbidding men and women to use the same room, was illegal. The judgment made by the High Courts of Tokyo further indicated that the disapproval by the Tokyo Municipal Education Commission was illegal since it unreasonably restricted the right of use by homosexuals and stated that the administrative authority is required to fully protect the rights and interests of homosexuals (refer to the same report above by Masayuki Tanamura).

On the other hand, Japan has also attained the stage where sex-change operations are performed in medical practice. We have to admit that there exist problems in handling marriage of such patients, i.e. individuals who become women after a sex-change operation, in connection with family registration.

The trends in regulations regarding advanced reproductive science and technology including in vitro fertilization between non-spouses and surrogacy have already been described in Section 2. Subtle differences are noted among countries in terms of the scope prohibited by laws

and the reasons for prohibition. It should be considered that this is because each country has its own standards, on the basis of which unethical judgment is made. From now on, the authors will discuss cloning technology and try to determine if problems caused by application of cloning technology are within the range of differences among countries in terms of ethical standards that we have already discussed in the previous sections, or are universal.

2. Framework for Changes in the Social Order (Legal Fiction for Genetic Relation and Family Relation)

(1) When evaluating changes over time in the family relation which require amendments or interpretation of the Family Act, we may consider that these changes in the family relation do not bring about totally new human relations but that these changes represent legal fiction based on traditional, or different, human relations, or equalization in power or transition in power. The family relation is basically conservative and when looking back on the history of family relation, there was no event of creating totally new human relations. The new family relation, which suffers from some confusions due to changes in social circumstances, however, is treated as legal fiction of the traditional family relation and human relations and therefore, has not experienced fundamental inconsistencies.

Adoption is evidently a legal fiction of the relation of parents and their own child. Common-law marriage is a legal fiction of registered or lawful marriage and is currently given almost the same protection as that given to registered or lawful marriage from the legal point of view. The above described marriage of persons of the same sex accepted in foreign countries is not a newly created family relation but is based on the argument that the marriage of persons of the same sex should be given similar rights to those accepted for the traditional way of marriage. In Japan, the postwar status of the wife is equal to that of the husband, which can be regarded as legal fiction of the husband's status (i.e. equalization in power). Considering the fact that in the modern society, people are more and more oriented toward contract-based relation but on the other hand, some aspects of the society still require the traditional relation among relatives under which the family members build up the sense of family bonds regarding reproduction, supporting, and family togetherness, we may be able to assume that at least currently, no drastic changes will occur in the family relation and it is not unreasonable to base a nation's policies and investigations of the social order on this assumption.

As the authors have already discussed in the previous sections, the social sense of values and the social order experience substantial changes, which makes it even harder to reach an absolute conclusion that an act is right or wrong, or ethical or unethical. On the other hand, we also have to admit the absolute fact that the order based on the family relation constitutes part of the currently accepted sense of ethical values (e.g. prohibition of consanguineous marriage which will be discussed later). For these reasons, it is necessary for us to regard separations from the social order not as merely abstract concepts but as specific social phenomena. In this section, the authors try to evaluate how substantially the traditional family relation would be affected by reproductive medical technology, a totally new technology to humankind, using one methodology, i.e. "To what extent does interpretation through the use of legal fiction help evaluation of this issue?" Unlike an ordinary type of new social order, reproductive medical technology will provide reproductive environments that humankind has never before experienced. This is the first experience associated with advancements in science and technology. Careful considerations are therefore necessary in light of problems which would not have occurred in human relations without such technology. The authors would like to evaluate in particular the extent of social confusion and risk caused by cloning technology, as compared to other reproductive technologies, by looking at relations based on legal fiction. We consider that such evaluation may enable us to establish grounds for regulating application of cloning technology.

(2) From the viewpoints described above, we can compare what would be associated with application of new reproductive technologies. As an example, the authors will evaluate a new parent-and-child relation created by application of new reproductive technologies both from the biological (genetic) viewpoint and from the viewpoint of family laws (for which we follow interpretation of Japan's Civil Code for the purpose of evaluation in this section).

(i) In the case of {artificial insemination by husband (AIH) and in vitro fertilization between spouses}, the husband and the wife have their own child and there exists no problem from the genetic viewpoint nor the viewpoint of family laws.

(ii) In the case of {artificial insemination by donor (AID) and in vitro fertilization between non-spouses}, the genetic relation is that the wife is the mother of the child and the third individual is the father of the child. From the viewpoint of family laws, the birth of the child makes the wife become the mother and her husband is presumed to be the father of the child (assuming that the husband has given his prior consent to implementation of artificial insemination by a donor or in vitro fertilization and therefore, will not deny the legitimacy of the child). There exist inconsistencies between the genetic relation and the relation based on family laws. In reality, however, the following case occurs: a child is born between a wife and a third individual and after she gets married to her husband, they adopt the child. When the parent-and-child relation in this case is regarded as legal fiction of adoption, we can consider that the parent-and-child relation in this case is similar to the case when the parents have their own child, from the viewpoints of both genetic relation and family laws-based relation.

(iii) In the case of {surrogacy}, the genetic relation is that the wife is the mother of the child and the husband is the father of the child. From the viewpoint of family laws, the donor of a womb becomes the mother after giving birth to the child, but there is no father and the child is a non-legitimate child. If this situation is left to stand, then the husband, the wife and the child will not have any relation from the viewpoint of family laws. However, if the individuals concerned have reached prior agreement that the child to be born will be the child of the husband and the wife, then the husband and the wife adopt the child and from the viewpoint of family laws, they thus become the parents of the child. As a result of such agreement, there are no inconsistencies between the genetic relation and the family laws-based relation, although the child is not their own child but the adopted child. At present, however, these circumstances are not always handled by established laws: if the donor of a womb refuses to hand over the child, it is predicted that extremely complicated legal relations would occur.

Even if evaluation through the use of legal fiction reveals no inconsistencies between the genetic relation and the family laws based relation, it is possible to give political considerations to this issue according to conditions or national sentiment in a country. For example, it could be possible for a national government to judge that a surrogacy agreement is contrary to public policy or good morals.

{Note} Surrogate mothering, i.e. implantation of a fertilized egg into the womb of the woman, who has no genetic relation with the egg, is a new experience for humankind. However, the biological relation created by the surrogacy, e.g. the relation of the child his/herself and his/her genetic father and mother, and the relation of the child his/herself and the surrogate mother (who has no genetic relation with the child and therefore is the third individual for the child), is in no way different from the conventional relation among the father, the mother, and the third individual. In addition, surrogacy is not as a rule different from the special method of in vitro fertilization between non-spouses: obtain a matured ovum from a donor who does not suffer from infertility, allow the ovum and sperm obtained from a man who does not suffer from infertility to form an embryo, and implant the embryo into the womb of an infertile women (i.e. the man's wife) (note that this is one of the methods of donating embryos). The authors will therefore have no intention to discuss to what extent surrogacy has been explored as a technique itself. For the reader's information, both technologies are already lawful in the UK and at present, many children may have been born by these technologies.

(3) Discussed below is Creation of a Cloned Baby by the Methodology Using Legal Fiction.

(i) Genetic relation

First of all, as is generally discussed, the authors have some doubts about the idea that the donor of a somatic nucleus can be the father of the cloned baby. Genetically, the relation between the donor of a somatic nucleus and the cloned baby is similar to the relation between monozygotic twins. If someone attempts at building up a genetic relation between monozygotic twins which is similar to the relation between the donor of a nucleus and the cloned baby, using currently available technology, the following method may help create such genetic relation: freeze and store one embryo of monozygotic twins at the time of fertilization and allow the other embryo to grow; when the latter embryo

develops and is born as a baby who further grows as a child, the frozen embryo is implanted back into the womb of the mother who gives birth to the baby; and there exist monozygotic twins who are different in age. In other words, their relation corresponds to one of biological siblings.

Secondly, the woman who gives birth to a baby takes a similar position to that of the donor of a womb in the above-described surrogacy and is not a genetic mother, since her ovum is used but she is not given a nucleus which has genetic information. Accordingly, the donor of a nucleus is not a genetic father and the donor of a womb is not a genetic mother. As is shown by the above-described example of monozygotic twins, the genetic father and mother are the father and mother of the donor of a nucleus.

Even though the relation between the donor of a nucleus and the cloned baby is considered similar to the relation between monozygotic twins, the requirements for monozygotic twins are that they are born simultaneously and exist as siblings. There is no such case, in reality however, of freezing and storing one embryo of monozygotic twins and implanting it again into the womb of the mother when the other embryo has developed, born as a baby and grows as a child, resulting in monozygotic twins who are different in age. Creation of a cloned baby will thus create a new biological relation which has never ever existed before.

(ii) Relation from the viewpoint of relatives laws

First of all, since creation of a cloned baby will create a new biological relation which has never existed before, there is no relation which represents legal fiction based on family laws. This is one conclusion.

Secondly, for the purpose of discussion, the authors will take it that the relation between the donor of a nucleus and the cloned baby is similar to the relation between monozygotic twins. In the case of monozygotic twins, their genetic father and mother decide on their own to have a child, although there are some accidental factors for them to have twins (note that for these accidental factors, we can consider that their father and mother decide on their own by selecting a negative option of not eliminating one of the embryos through the use of artificial abortion). Even if one of the embryos of monozygotic twins is to be frozen and stored, their genetic father and mother decides on their own to do so. On the other hand, when a cloned baby is produced using a somatic nucleus, the will of a genetically elder brother or sister who is born earlier determines the birth of his/her younger brother or sister (although this is conceptual). Creation of a child on the basis of the will of not his/her father and mother but a third individual may not be acceptable. (Usually, it is considered that having a child (i.e. the donor of a somatic nucleus) through conception belongs to the right of autonomy of father and mother.)

From the viewpoint of family laws, the donor of a womb who gives birth to a baby becomes the mother. If the donor of a somatic nucleus is the husband of the donor of a womb, he is presumed to be the father of the child, which constitutes the parent-and-child relation from the viewpoint of family laws. None of the family relations prescribed by the existing laws find any legal fiction which corresponds to the case in which genetic siblings constitute a parent-and-child relation from the viewpoint of family laws. (However, if the donor of a somatic nucleus is not the husband of the donor of a womb, he is not the father of the child and is not allowed to acknowledge paternity of the child, but he could adopt the child. In Japan, there can be a case in which a boy/girl is adopted as the child of his/her elder brother/sister.)

If the relation of siblings prescribed by the family laws applies to the relation between the donor of a nucleus and the cloned child, then it is possible that various rights and obligations may be retrospectively changed. For example, there may be an argument that for inheritance after death of the genetic father and mother, the cloned child could claim retrospectively the portion of assets he/she should inherit from what the donor of the nucleus has inherited. In any event, creation of a cloned baby will bring about totally new factors to the social order from the viewpoints of properties laws and family laws.

(4) As discussed in the previous section, creation of a cloned baby does not correspond to any of the legal fictions based on the currently existing family laws but will create totally new human relations, leading to dramatic changes in the existing social relation. Even as compared to in vitro fertilization between non-spouses and surrogacy, creation of a cloned baby will have a substantial impact on the social order. It is desirable as a matter of course that legal regulations on the entire reproductive medicine field be fully discussed in Japan. Nevertheless, the authors consider that we have reasonable grounds for regulating technologies or related matters involved in creation of a cloned baby in particular.

(5) In connection with the above-described issue of creating a cloned baby, special considerations should be given to the cases described below.

(i) A case in which a cloned baby is produced using the somatic cells derived from a child when his/her parents lost the child due to death

This case may occur in particular when one of the parents (e.g. father) has already died and the child who subsequently died was the only child: the remaining parent (e.g. mother) wants to have a cloned baby using her ovum and womb. This mother's desire is understandable when considering her feeling and no individual will exist who has the identical gene to the cloned baby to be born. For these reasons, the above-described confusions are less likely to occur. However, none of the parents have the right of manipulating the genes of their child who died, without consulting the child and in addition, another order, that is, the currently accepted social order regarding death, will be confused. Accordingly, the case is considered inappropriate. (The authors have described in the previous section (2) that "it is considered that having a child (i.e. the donor of a somatic nucleus) through conception belongs to the right of autonomy of father and mother." We also should consider that the holder of a somatic nucleus (i.e. the child who died) has the right of preventing creation of a cloned baby derived from him/herself as a variation of the autonomy which is involved in his/her personal exclusiveness.)

(ii) A case in which the father and mother of the donor of a nucleus agree to creation of a cloned baby

When the father and mother of the donor of a nucleus, who are genetic father and mother, agree to creation of a cloned baby, the above-described confusions may be avoided and it is therefore difficult to make an immediate judgment that this case is not appropriate from the viewpoint of social order. This case should be handled in a similar manner to that given to a case in which one embryo of monozygotic twins (or dizygotic twins) is frozen and stored (note that this case is more likely to occur than the previous case since substantial quantities of excess embryos are produced upon in vitro fertilization).

(iii) Creation of monozygotic twins using naturally fertilized eggs, embryos and fetuses

In this case, the wife who is pregnant and his husband manipulate a fertilized egg and subsequent embryo according to the natural process in order to create monozygotic twins by the use of nuclear transplantation or any other relevant techniques. In this case, it is evident that during its natural process to form an individual, the life and body of the fetus (i.e. the fetus which should be formed through development and growth of a fertilized egg and subsequent embryo) may be damaged. This act will not be beneficial to the embryo since the embryo may be damaged one-sidedly, and therefore, is not accepted. As described in case (i), the holder of a somatic nucleus (which is the fetus in this case) has the right of preventing creation of a cloned baby derived from him/herself as a variation of the autonomy which is involved in his/her personal exclusiveness. It should be considered that as far as no consent is obtained from the holder of a somatic nucleus, even his/her parents are not allowed to create monozygotic twins using the somatic nucleus.

3. Significance of Cloning Technology

Finally, the authors would like to investigate the significance of creating a cloned baby as a measure to cope with infertility. As described previously, there are other methods available for handling infertility, such as artificial insemination and in vitro fertilization. When pregnancy is regarded as an act to allow eggs and sperm to unite to form new genes, to allow these genes to divide and differentiate within the fertilized

eggs to form an embryo, and to bring about the birth of a baby, medical practices intended to eliminate obstacles to this act and help achieve its objective are therapies for infertility. Artificial insemination and in vitro fertilization mentioned above all satisfy these requirements for the infertility therapy. When creating a cloned baby, however, there is no fertilization between an egg and sperm. Creating cloned babies is therefore not an infertility therapy to eliminate obstacles in pregnancy but is an act of increasing individuals in number which, again, is a totally new experience for humankind. The authors consider that even if cloning technology is prohibited, such prohibition will not damage the right of undergoing medical practice. We also would like to mention here that in the filed of stock-breeding, cloning technology is understood as one of the technologies to develop new breeds of animals, improve the quality of animals, and increase the number of animals.

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6C: Conclusions Regarding Grounds for Regulation

1. Examination of the Other Grounds for Regulation

(1) Human Dignity

Article 13 of the Constitution of Japan stipulates as follows: "All of the people shall be respected as individuals. Their right to life, liberty, and the pursuit of happiness shall, to the extent that it does not interfere with the public welfare, be the supreme consideration in legislation and in other governmental affairs." The expression "respecting of the individual" in this Article is also referred to as "the dignity of the individual" or "human dignity" and is interpreted to constitute the base of human rights or the fundamental idea of human rights. It is controversial, however, if this provision is interpreted to cover specific rights (i.e. the fundamental human rights prescribed by the Constitution) or not. Regarding the right of own portraits, the Supreme Court adjudicated as follows: "It should be understood that every person has freedom of not being photographed for his/her looks or figure without giving his/her consent to do so. Whether this is called the right of portraits or not is another issue. However, at least an act by a policeman of taking pictures of individuals' looks, etc. without any justified reasons is contrary to the philosophy prescribed in Article 13 of the Constitution and therefore will not be acceptable (Supreme Court Judgment, December 24, 1969)." This judgment indicates a negative action toward creation of new rights but makes it possible to give protection directly based on the provisions of this Article.

Euthanasia and death with dignity are the issues involved in life sciences that are related to the "respect for the individual" prescribed in the Constitution. There is a view that "when it is impossible for a patient to recover from disease and the patient has suffered from severe pain, his/her "refusal to receive any treatment merely to prolong his/her life" can be acceptable if the patient him/herself expresses evidently the will to do so" (refer to a book "Constitution" authored by Koji Sato and other literature). In this view, the term "death with dignity" is used but not many scholars supporting this view focus on the individual's dignity or the human dignity as the direct ground for the acceptance. They instead understand the patient's will as the right of autonomy regarding how to handle his/her own life and body and argue that this autonomy is guaranteed by Article 13 of the Constitution.

As specific rights related to the provisions of Article 13 of the Constitution, rights involving the personality such as the right of one's portrait and the right of privacy as well as the right of autonomy are generally considered. The right of autonomy means the right, according to which the individual is entitled to decide on his/her own regarding certain personal affairs, without suffering from any intervention caused by exercise of public power (refer to the book mentioned above by Sato). It is understood that the right of autonomy involves matters regarding how to treat one's own life and body, as described above, matters related to formation and maintenance of family such as marriage and divorce, matters related to reproduction such as contraception and artificial abortion, and clothing/appearance (refer to "Development of Science and Technology, and the Right of Autonomy" Hogaku-Kyoshitsu No. 212).

Many technologies in the field of life sciences involve human dignity, e.g. artificial abortion, artificial insemination, in vitro fertilization, surrogacy, pre-birth diagnosis, intentional selection of having a baby boy or girl, gene therapy, gene diagnosis, and human genome analysis. Of these technologies, only human genome analysis is a technology for which necessity of regulation should be investigated from the viewpoint of respect for the individual, i.e. the right of autonomy. The other technologies starting with artificial abortion can be regarded as those supporting the woman's right of having or not having a baby (as the right of autonomy).

When considering possible application of Article 13 of the Constitution to creation of a cloned baby, we can look at this issue on the side of the donor of a nucleus who may be entitled to exercise the right of autonomy regarding how to treat his/her own body and reproduction. The point in this consideration is the details of reasons because of which restriction is to be imposed on the right of autonomy that the donor of a nucleus would have. Since Article 13 of the Constitution prescribes that "Their right to life, liberty, and the pursuit of happiness shall, to the extent that it dose not interfere with the public welfare, be the supreme consideration in legislation and in other governmental affairs," the right of creating a cloned baby that the donor of a nucleus would have (note that whether this can be regarded as a right or not is another issue) will be limited since it is contrary to the public welfare. Although several categories in the public welfare may restrict the right of autonomy, there are two key points requiring particular attention: <1> conflict with the dignity of the child as an individual who is to be born (e.g. the right of pursuing happiness) and <2> opposition against the public order such as public policy or good morals. As a result of taking these points into account, the right of autonomy regarding creation of cloned babies is to be restricted. When considering the point <1>, i.e. the right of the child who is to be born, the following issues may be addressed: <a> whether the child who is to be born in the future, can be regarded as the subject who exercise the individual's rights or not; and <b> comparison of the two rights, i.e. the right of creating a cloned baby that the donor of a nucleus would have and the right of a cloned child who is to be born, would surely make the former inferior to the latter or not. (The authors will later discuss point <2>.)

For the issue <a> in the previous paragraph, the right of autonomy that the child who may be born would have regarding the way of living his/her life has not yet been the focus of discussion in the filed of constitutional law studies. On the other hand, the child who will be born cannot make any such decision that it would be better if the birth did not take place, since such decision denies him/herself. We have to pay attention to the possibility that ultimately, the argument around point <a> may come back to the third individual's evaluation that for specific children, individual would be happier to prevent them from being born. The issue <b> in the previous paragraph, i.e. comparison of weights between the two rights, is extremely difficult to address as indicated by the conflict between the right of a fetus with hereditary disease to be born and the right of his/her mother to undergo artificial abortion (i.e. the right of having or not having a baby).

Regarding "human dignity," it is possible to separate it from the interpretation of Article 13 of the Constitution and to acknowledge it as the universal ethical principle to humankind. This acknowledgment is more appropriate to understand the ethical issues related to reproductive medical technology in Europe. When European countries regulate reproductive medical technology, they invoke the principles of respecting human dignity and at the same time, they introduce the principles of protecting embryos and respecting human body in a specific manner, which will be discussed in a later paragraph.

The authors attempt to consider if there is any legal concept involving "human dignity" and "the individual's dignity" in Japan, other than the philosophy prescribed in Article 13 of the Constitution. The Civil Code prohibits consanguineous marriage and prescribes the following elements required for marriage: "Marriage between persons of lineal kinship or relatives by affinity up to the third degree of relationship in the case of collateral kinship shall not be allowed" (Article 734-1); "Marriage between persons of the matrimonial relationship shall not be allowed" (Article 735). These elements may be introduced from the concept close to the above-described philosophy related to "human dignity." In the field of civil code studies, it is understood that consanguineous marriage is prohibited for not only eugenic reasons, e.g. for the purpose of preventing hereditary diseases caused by consanguineous conception, but also the following reasons: because it is "contrary to morality and human feelings" (refer to "Family Laws and Inheritance Laws" authored by Ryo Ariizumi); and because "social and ethical

considerations" are given (refer to "New Version: Comments to the Civil Code" authored by Masakazu Ueno). These additional reasons may be included in the wider concept of public policy or good morals and therefore are considered to represent point <2> described in the paragraph above: the right of autonomy for marriage is restricted when it is contrary to the public order.

Some academic views point out the problem of prohibiting consanguineous marriage between relatives by blood for the sole reason of a risk that the quantities of genes to be shared may be substantial, even if eugenic considerations are given to this matter, and criticize the necessity of maintaining the elements related to prohibition of marriage between persons of the matrimonial relationship since postwar Japanese society has been shifting toward the nuclear family, which typically consists of married couples with or without their children (refer to "New Version: Comments to the Civil Code"). As such, prohibition from the viewpoints of morality and human feelings or from the social ethical points of view are based on the relative standards of the society and therefore, influences caused by violation of such prohibition may be diverse. Just for the reader's information, if violation of the rules regarding consanguineous marriage should occur, such violation will not invalid the marriage concerned but constitute the reason for cancellation, and accordingly, there is no criminal punishment applicable to such violation. No such punishment is applicable to common-law marriage (factual marriage), either.

(2) Beginning of Human Life at the Time of Fertilization (at the Stage of Embryo)

There is no established theory regarding when a human life begins, although this issue has been discussed in many fields including biology, ethics, religion and philosophy. When looking at the Japanese laws, the Civil Code prescribes that "The enjoyment of private rights commences at birth (Article 1-3)," according to which it is interpreted that when the whole body of a fetus is exposed out of the mother's womb, his/her human life begins. Application of some of the Inheritance Laws indicate that "in connection with inheritance, a fetus is regarded as a baby which has already been born (Article 886-1)." The Penal Code prescribes that according to precedent cases, the crime of murder is applicable when part of the fetal body is exposed. In addition, the Penal Code prescribes the crime of artificial abortion (prescribed in Articles 212-216 of the Penal Code) in order to protect fetuses. Basically, when the body of a fetus, either as a whole or in part, is exposed out of the mother's womb, the fetus is regarded as a human individual. Although these provisions give some protection to fetuses, there is no established view regarding how to treat a fetus as the subject that is entitled to have the human rights. The Civil Code stipulates that "The provisions prescribed in the previous paragraph will not apply to a stillborn baby (Article 886-2)." The Penal Code prescribes the crime of artificial abortion, whereas the Mother's Body Protection Act (the old Eugenic Protection Law) prescribes that when it is judged that continuation of pregnancy may awfully damage the mother's health for physical or economic reasons, artificial abortion can be performed after obtaining consent from the mother herself and her spouse. From the legal point of view, no concept of a fetus is established. Usually, it is understood that fertilization brings about the formation of an embryo, which undergoes division and is simultaneously implanted in the uterus to form a morula and subsequently, develops into a fetus.

As discussed already, the Embryo Protection Act in Germany imposes regulations primarily on embryos: it prohibits abuse of embryos which have already existed under the natural process and also prohibits artificial creation of embryos. It is recognized that these views supporting the prohibition reflect ones of the Roman Catholic Church. "The Gospel of Life" in the well-known Encyclical Letter entitled "On the Value and Inviolability of Human Life" issued by the Pope John Paul II in 1995 states that "Right from fertilization the adventure of a human life begins. Christian Tradition is clear and unanimous in describing abortion as a particularly grave moral disorder, and the more recent Papal Magisterium has vigorously reaffirmed this common doctrine. In this doctrine, it is declared that abortion always constitutes a grave moral disorder since it is the deliberate killing of an innocent human being." "Moral evaluation of abortion also applies to intervention in a human embryo which becomes increasingly widespread in research fields of life sciences. Using human embryos or fetuses as subjects of experiments constitutes a crime of violating the dignity of their existence as human beings. Utilization for experimental purposes of embryos or fetuses provided by in vitro fertilization will never be permissible even if such utilization is intended to help the others." (quoted from the outlined summary of Encyclical in "Limits to Autonomy" in "Theory of Law: 17" authored by Etsuko Akiba)

These views are ethical and religious briefs and thus we cannot discuss whether they are appropriate or not. However, as the statements in "The Gospel of Life" clearly indicate, these views are based on the concept that a life begins at the moment when the ovum is fertilized, which inevitably leads to protection of embryos. The prohibition of abusing embryos is inseparable from the prohibition of abortion. It is a matter of course that unless justification of artificial abortion is investigated, the legal position of the embryo cannot be accepted. It seems to be difficult to legitimatize artificial abortion and to give reasonable explanations about prohibition of studies using embryos on the basis of the above described reasons, as performed in Japan. The research result report entitled "Legal Problems Surrounding the Right of Personality in Reproductive Medicine," the report of the research project concerning legal problems related to reproductive medical technology that was supported by subsidies for scientific research in the year 1993, made the following statements in their recommendations: "Reference to the cases in foreign countries, together with our investigation, made us consider it difficult to attempt at making a positive definition of the legal position of an embryo from the legislative point of view, and revealed a possibility that sticking to this attempt too much may put problem solving away. In the present recommendations, we therefore reached the minimum necessary agreement that the issue of defining the legal position of the embryo is to be avoided, while trying to be consistent with the existing laws." There may exist many difficulties in claiming that protection of an embryo is a legally protected interest.

(3) Respect for the Human Body

In France, the Civil Code expressly stipulates "the principles of respecting the human body": "The present Act shall secure the superiority of the individual, prohibit all invasions of the dignity of the individual, and secure respect for the individual from the very beginning of life (Article 16)." On the basis of these principles, the Civil Code prescribes as follows: <1> every individual shall have the rights according to which his/her own human body is given respect; <2> the human body shall be inviolable; and <3> the human body as well as the elements constituting the human body and the products of the human body shall not be treated as the subject of property rights. The Civil Code accepts the right of claiming injunction regarding the respect for the human body (Article 16-2) and stipulates that violation of the integrity of the human body shall only be permitted if such violation is necessary to administer therapy for the same individual concerned (Article 16-3).

The Civil Code in France, as a result of respecting the human body, prohibits adding any proprietary value to the human body (Article 16-5), confirms the principles of gratuitous donation of a human body (Article 16-6), reaffirms the principles of anonymous donation of a human body (Article 16-8), and prescribes that no surrogacy agreements shall be effective (Article 16-7). It further prohibits eugenic acts for the purpose of obtaining profit and changing genetic characteristics leading to any change in descendants of humans, for the purpose of protecting the integrity of human kind (Article 16-4).

The Bioethics Act in France is characterized by the provisions of extremely systematic protection to the human body as described above. The Constitutional Council in France made its judgment that the Act is constitutional. The grounds for this judgment of constitutionality for each of the above described provisions of the Bioethics Act were the Preamble to the Fourth Republic Constitution in 1946, Articles 1, 2 and 4 in the Declaration of Human Rights of the French Revolution, and Paragraphs 10 and 11 of the Preamble to the above mentioned Constitution.

Specific actions to be taken in connection with implementation of the Bioethics Act are defined in detail by the Public Health Code, the enforcement ordinances, and any other relevant regulations. For example, regarding removal, storage and use of tissues, cells and products derived from the human body, specific categories are defined, e.g. those outside the scope of regulation, those to which special rules are applicable, and those which should follow the general rules, and the regulation appears to be mostly reasonable (refer to "Summary of French legislation leading to the Bioethics Act" authored by Ichiro Kitamura, Jurisuto No. 1090).

However, in Japan, the currently effective legal systems on the private laws are built upon the basis that there exist the subject (human) and the object (thing) for the rights, and accept as a rule the absolute right to control things. Under these legal systems, if one attempts to treat

the human body in a special way, then extremely careful considerations are required. As indicated by what France did, it would be required to make drastic changes in the currently effective Japanese legal systems as a whole which are centered on the Japanese Civil Code. Accordingly, we may have to be ready to accept substantial review of the legal system if we try to define any legally protected interest or benefit for the human body and to establish laws in order to regulate related matters.

2. Positive Benefits Obtained from Application of Cloning Technology

Cloning technology is not to be considered as an 'evil' technology and as previously discussed, application of cloning technology may bring about many things useful for promoting the happiness of humankind in the future. For example, <1> it is not only indicated for the treatment of infertility but also contributes to improvement of future medical technologies, such as clarification of cancer development and advancement of regenerative medicine (e.g. artificial organs causing no rejection); and <2> it may facilitate accumulating knowledge which can be utilized if unforeseeable situation in the future should occur (e.g. it may function as a back-up if we face a crisis to the future of humankind's reproduction, as pointed out by the discussion related to endocrine disturbing chemicals, i.e. so-called hormone-disrupting substances). There are additional points: <3> since scientific wisdom, supported by researchers' curiosity and autonomous activities, has brought about the creation of magnificent systems for science and technology, it is therefore feared that introduction of inappropriate limitations, even in part, may result in withering or declining of research. <4> The right of autonomy in the medical care field has caused substantial changes recently in European and North American countries in particular, the flow of which has brought about the concepts of artificial abortion, informed consent, and death with dignity. We cannot say that the right of autonomy is almighty, but under these recent trends noted in medical policies, it is highly likely that many reproductive medical technologies may be regarded as a form of exercising the autonomy right (which corresponds to "the respect for the individual" prescribed in the constitution). The authors therefore consider it desirable to evaluate relative advantages and disadvantages of the above-described various points in order to determine an appropriate form of regulation.

3. Summary

Academic councils organized by the national government have also begun to investigate regulation regarding application of cloning technology, and some reports are already published. These reports individually analyzed problems pertaining to cloning technology.

The Bioscience Group, Subcommittee for Promotion of Research in Specific Fields, Academic Examination Committee issued a report entitled "Research on Cloning at Universities, etc." on July 3, 1998. This report listed the following two problems related to cloning technology: <1> a concern that cloning technology may have undesirable effects on the genetic characteristics of the cloned baby to be born; and <2> a concern that cloning technology may have undesirable effects on the way that the individual, the family, and the society should be. This report also pointed out the following matters to which special considerations should be given: research on cloning may cause new arguments regarding the parents' right of decision-making on their child or the individual's independence, and eugenic ideas may be abused. In addition, this report focused on the fact that there exist social anxiety about or misunderstanding of cloning technology, and emphasized the necessity of taking appropriate action to cope with this current situation. Regarding whether cloning technology is ethically acceptable or not, this report indicated that there are both points for and against the technology.

The Clone Subcommittee, Bioethics Committee, Council for Science and Technology issued an interim report entitled "Basic Ideas on Cloning Technology" on June 15, 1998. This report addressed two major issues.

<1> Securing the human dignity: violation of the right according to which the individual is given respect; and deviation from the social recognition regarding the way human's reproduction should be.

<2> Safety-related problems: disorders of a newborn baby or occurrence of disturbance during the growth process.

European and North American countries impose individual regulations on reproductive technology from their own viewpoints. The outcome of these regulations are similar among the countries. However, these regulations are not always based on the idea that a human's life is begun from the stage of an embryo. It is not always true, either, that the inseparability of the human body is becoming accepted as a new principle of the civil code in all countries.

Nevertheless, regulation of cloning technology has been standardized from the global point of view, predominantly in Europe, in particular, and Japan needs to take some actions for regulating cloning technology. If this global standardization can be regarded as external unification regarding regulation, then it is desirable for Japan to explore its own grounds for justifying regulation while referring to the legal systems and supporting opinions to the legal systems in each of the countries.

In this section, the authors have focused on the following two points as the grounds for justifying regulation, for the reasons as described above.

<1> Safety

<2> Social order

These do not merely serve as the grounds for legislation but also deserve to be addressed aggressively by the national government as legislative policies, since the national government takes responsibilities for maintaining a lively and developing society.

When, on the basis of these legally protected interests and benefits, we evaluate the modality of regulation that has already been discussed in Section 5 entitled "Investigation of Subjects in Regulating Technology," we may consider that neither the safety nor social disorder related problems discussed above will occur for a moment if a series of events from implantation of a cloned embryo into the mother's womb, growth of the embryo into an fetus and to birth as a human individual will not occur. Accordingly, from the viewpoint of not only scope of regulation but also grounds for justifying regulation, the authors consider it favorable to investigate the way regulation should be in the two stages described below. We consider it proper to evaluate, as appropriate, methods of regulation, details of regulation, and measures to secure regulation according to the categories listed below.

<1> Core regulations (implantation of a cloned embryo into the mother's womb)

<2> Surrounding regulations (all other cloning-related research activities)

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## Section 7: Supplementary Discussion: Legal Responsibilities of Researchers

### 7A: Aggravated Negligence

(1) The authors have investigated in the previous sections the modality of and grounds for regulation when regulations are imposed on advanced science and technology. This section is concerned with general discussion about legal liability of researchers since regulations to be imposed on advanced science and technology are applicable to researchers, although this discussion is not directly related to what we have discussed so far. Even researchers, when they commit a culpable and illegal act causing damage, may be liable for damages on the grounds of non-fulfillment of obligations or torts according to the civil code, may be penalized according to the civil code, and may be charged with a

disciplinary punishment according to the administrative law. Up to now, social duties and ethical responsibilities of researchers have been discussed by the Japan Academic Examination Committee and international organizations of scientists, but responsibilities of researchers have not yet been discussed as frequently within the legal framework. When looking at practical sites where research into life sciences is performed and life sciences related technology is applied, an individual frequently functions as both a medical doctor and a researcher. Both medical doctors and researchers are treated as professionals in the society. Responsibilities of the medical doctor in an individual who is also a researcher are relatively well defined and the same holds true for legal liability, whereas responsibilities of researchers are unclear.

If a researcher is blamed for any responsibility, cautious examination is required to determine if such blame can be based on the characteristics of the researcher him/herself or on other attributes that the researcher possesses, which may include not only the above-described combined functions as a medical doctor and a researcher but also their social positions such as researchers working at national testing & research institutions (national government employees), researchers working at national universities (educational public service personnel), researchers working at public testing & research institutions (local government employees), and researchers working at non-private research institutions (i.e. special positions based on applicable laws, by-laws, etc.). These attributes should be excluded when responsibilities of pure "researchers" are investigated.

In this section, the authors will investigate responsibilities of researchers firstly by focusing on a new concept of aggravated negligence which is recently discussed as "professional responsibility" in the field of civil law studies, and secondly by discussing negligence in general.

(2) At present, in the field of criminal law (including the administrative penal code), general systematic theories pertaining to responsibilities of researchers and individuals who are comparable to researchers have not yet been established. On the other hand, in the field of civil law, "theory of professional responsibility" is the focus of active discussion both inside and outside Japan. The authors will introduce the theory and evaluate the possibility of incorporating researchers into this theory to discuss responsibilities of researchers. We primarily referred to the literature listed below.

<1> Umeharu Nishijima "Basic problems related to professional liability insurance" in the book "Lecture on the currently effective laws concerning liability for damages" edited by Ryo Ariizumi

<2> Ken Kawai "Professional responsibility"

<3> "Feature: Legal principles of "professional responsibility" ? Issues to be addressed and future prospects" Horitsu-Jiho Vol. 67, No. 2

<4> "New lecture on the currently effective laws concerning liability for damages: No.3 (products liability, professional responsibility)" edited by Takuo Yamada

In the Civil Code, non-fulfillment of obligations and torts are elements constituting liability of professionals such as medical doctors. From the viewpoint of the Civil Code, professionals such as medical doctors and their clients make a contract for assignment and the professionals shall be liable for fulfilling the assignment entrusted by the contract giver under the contract concerned. According to the provisions in Article 644 of the Civil Code "the contract receiver shall bear the obligation of handling matters, with which the contract receiver is entrusted by the contract giver, with the care of a good manager according to the true aim of the contract concerned," the professionals shall have the duty accompanying with the care of a good manager. It is prescribed that the magnitude of this duty shall be determined on the basis of the ordinary citizen as the standard and may vary depending on the type of profession of the contract receiver concerned. As the society approaches one consisting of an increasing number of more specialized occupations, of having more and more accumulated knowledge, and of being highly industrial and information-oriented, many professionals and experts are born and work actively in accordance with requests made by their own clients. When, as a result of these activities, a client suffers from unexpected damage, there is a tendency towards accusing the professional concerned of strict liability. (For medical doctors, the Supreme Court adjudicated on February 16, 1961 that "the individuals who are engaged in professions involved in the management of life and health of humans shall have the obligation of taking the best care necessary from the experimental viewpoint to prevent risks, according to the nature of the profession concerned.") The theory of professional responsibility indicates that when the obligation mentioned in the judgment above is extended to jobs not involved in human life, this matter should be discussed as the liability common to all professionals. (With special regard to obligation of giving explanation and report (accountability), obligation of giving advice, and obligation of confirming investigation which lawyers, judicial scriveners, etc. should have, refer to "Analysis of key precedent cases in connection with professional responsibility" authored by Yugen Kudo (Horitsu Jiho Vol. 67, No. 2), which introduces recent precedent cases that accepted these obligations).

The idea of professional responsibility is relatively new, and no theoretical framework has yet been completed. It is generally understood that professionals have the duty of care and the duty of faithfulness. Elements required for the duty of care are divided into categories according to the types of individual professions. (Malpractice suits in particular have outlined that medical doctors shall have the duty of care.) Particular attention is paid to the duties and responsibilities that medical doctors should have: those of giving information such as informed consent and of giving advice. On the other hand, prior to establishment of professional responsibility, insurance systems for their responsibilities have already been set and have contributed to the society (although the professionals covered by these insurance systems do not always correspond to those discussed in connection with the theory of professional responsibility in this section). In addition, maintaining confidence of customers, fulfilling duties, information gap and over-concentration of information in certain sectors, and magnitude of providing public services by the profession concerned are listed as issues to be addressed. These matters are still controversial regarding whether they are incorporated into the theory of professional responsibility.

The professional responsibility substantially varies depending on country. In the UK, individuals engaged in the judicial professions and medical doctors are regarded as "professions" and they organize self-governing bodies to rule themselves. In the US, responsibilities of professionals have been long discussed and the negligence of professionals is stipulated by laws.

Regarding the definition of professionals, Nishijima's report <1> states that "the profession is a type of job that is supported by scientific or highly advanced knowledge and requires special education or training for an individual to acquire its special skills (which possess its own basic theories), and thus, the professional who has acquired the special skills is capable of taking specific activities in response to requests randomly made by individual clients among an unspecified number of ordinary citizens: the profession is therefore a job which contributes to the interests of society as a whole."

(3) Requirements for the professional are discussed inside and outside Japan, which indicates several common definitions (refer to Nishijima's report <1>).

(a) The profession for which the general principles have been established regarding its job duties and which requires long-term education and training for individuals to acquire skills based on the established theoretical knowledge;

(b) The profession for which official licenses, qualifications or certificates should be authorized;

(c) The profession for which associations of individuals engaged in the same occupation have been organized (i.e. professional bodies) and the association secures autonomy;

(d) The profession, the primary objective of which is not to gain profits but to contribute to promotion of public interests; and

(e) The profession which has autonomy and independence.

In the US, the definitions listed below are generally accepted and the requirements in these definitions are basically the same as those listed above (refer to Literature <2> "Responsibilities of professionals" according to US laws" authored by Osamu Kasai).

(a) The capabilities and skills of professionals are intellectual in nature and high-level abilities which require long-term training until one can acquire them, and the professionals use these abilities to fulfill their job duties.

(b) The contents of services provided by the professionals can be in many cases unevaluable by ordinary citizens, who are non-professionals and entrust the professionals with such matters. This gives the professionals a wider range of exercising their own discretion. On the other hand, a person who wants to entrust a specific professional with something tends to do so on the basis of not his/her own evaluation of the professional but his/her trust in the professional which precedes the evaluation.

(c) The professionals have the obligation of not only providing services for the sake of interests of the person who entrusts them with jobs but also making efforts to contributing to the social interests beyond the person's interests. The professionals are therefore requested to be highly moral. (Codes of practice issued by self-governing bodies for individual professions have greatly contributed to maintenance of high morals.)

(d) The social status of the professional has usually a long history.

In light of the above-described definitions, the representative examples of professionals in Japan are lawyers, appraisers, public notaries, certified public accountants, judicial scriveners, land and house investigators, housing land and building business managers, and registered architects. The legal principles of professionals' responsibilities are actively discussed in European and North American countries. The professionals in which these principles are considered are medical doctors in various fields, pharmacists, attorneys at law, certified public accountants, and engineers in the US; and architects, technical experts, surveyors (professionals who determine and evaluate land and houses), barristers (a type of judicial profession: lawyers who represent clients in courts), solicitors (a type of judicial profession: lawyers who represent clients in transactions), medical doctors, dentists, and chartered accountants in the UK.

(4) The professional responsibility is based on the following idea: "When you ask a layperson to do something and the layperson fails to achieve the objective, you may think that this was personally your fault since you asked the layperson. When you entrust a professional with a job and the professional fails to achieve the intended objective, however, you may feel that no excuse from the professional will be acceptable since he/she is a professional. Laypersons entrust professionals with jobs because they think that "the job concerned requires a high level of expertise and that laypersons are unable do it" or that "laypersons may do the job concerned but more satisfactory results will be obtained by the relevant professional." Accordingly, professionals are expected to display higher levels of capabilities and skills than laypersons." (Refer to Literature <4> "Basic structure of professional responsibility" authored by Kaoru Kamata.)

This concept regarding "professionals" was firstly born in European and North American countries, although this is not a totally established concept and each country has its own ideas. When looking at key foreign countries, in the US, the general ideas of professional responsibilities are being built according to the specificity of each profession through the use of precedent cases in relevant law suits and establishment of laws. It is said that the professional responsibilities are being defined in the form of standardized responsibilities in particular.

In the UK, the idea that professionals should be liable for damages is accepted on the basis of accumulated common-law cases. The UK is particularly characterized by the fact that the State will not intervene in any agreement made between the profession and the society. The principle of not controlling by the administration but of self-governing is widespread in the UK. Accordingly, the bodies of legal professions and the medical professionals have established strong self-governing frameworks, within which, in the case of the legal professions' bodies for example, systems of handling complaints, examining disciplinary acts, supervising laypersons, etc. have been set. The State has established the Law Services Act on the basis of these systems.

The professional responsibility is not only the focus of the above-described discussion regarding liability for damages but is also becoming an important issue at practical sites owing to the debut of professional liability insurance. The types of "profession" defined by the insurance are more diverse than the above-described professions. Specifically, in Japan, professional liability insurance for medical doctors was commercially available in 1963, followed by various types of professional liability insurance for architects, certified public accountant, professionals involved in the medical care field such as orthopedic care givers or *judo* experts, pharmacists, acupuncturists, *moxa* therapists, massage givers/acupressure therapists, druggists, midwives, nurses, physical therapists and paramedics, professionals involved in handling of official documentation such as patent attorneys, judicial scriveners, public notaries, land and house investigators, lawyers, licensed tax accountants, and in addition, consulting engineers, surveying engineers, travel agents, and tour conductors.

The intention of the professional liability insurance is as follows: when a professional, who is the insured, is liable for damages caused by his/her professional act, the insurance is used to help the insured cover the loss. Accordingly, the professional liability insurance performs functions of protecting the professionals and preventing the professionals' enthusiasm for research from being weakened (refer to Nishijima's report <1> above). At present, no professional liability insurance is available for researchers.

(5) In light of the above-discussed theory of professionals, the authors determined if researchers satisfy the above-listed requirements for professionals or not and found that researchers do not always satisfy these requirements. First of all, we examined the requirements listed in (3) above.

(a) Usually, researchers have received long-term education and training. This is because in reality, unless they have experienced such education and training, they will rarely be well-recognized in scientific associations or on any other relevant occasions. Accordingly, having long-term education and training is not an essential requirement for someone to become a researcher. In recent years, scientific associations of multidisciplinary fields have increased in number. In these fields, the general principles have not always been established for their job duties and researchers who have attained excellent achievements in these fields do not always have a history of research: many of those researchers have been engaged in business, which contribute to these excellent research achievements.

(b) No special licenses, qualifications or certificates are required for someone to become a researcher. The degree issued by universities is not considered to be a special qualification. Even if this degree is regarded as qualification, research can be performed without such a degree. In addition, it is not true that such degree is essential for evaluation of a researcher's work.

(c) There exist scientific associations to which relevant researchers belong. All researchers do not have to become a member of a scientific association, however. These scientific associations are not professional bodies but academic organizations providing the opportunities of communication and discussion among researchers.

(d) We can hardly say that researchers always set their objectives at promoting public interests. It is acknowledged that the driving force of researchers is curiosity and this is especially true for fundamental studies. These studies, of course, may be ultimately applied to various fields useful for society and thus contribute to expansion of human wisdom. It is true that evaluation of such indirect interests is a way of promoting fundamental studies. However, some fundamental studies do not bring about such indirect contribution to the society and considering the characteristics of research, it is hard to set such contribution as an objective of research. On the other hand, when looking at private enterprises and venture firms, we can find researchers whose objective is evidently to gain profits.

Secondly, we examined the US requirements listed in (3) above.

(e) In recent years, scientific associations involved in life sciences related fields have frequently proposed voluntary ethical rules. However, it is not always clear if the job responsibilities of researchers require high morality or not.

When examining the above-described requirements, the authors considered that the "researchers" are those who actually perform research. If the researchers are regarded as those who register themselves at scientific associations, then individual associations have own internal rules for registration. Regulating those registered individuals only for the purpose of regulating research does not have any real significance.

(6) When comparing the responsibilities and obligations of professionals with those of researchers in reality, the authors found fundamental and great differences between the two, although the magnitude of these differences very depending on the form of employment of researchers.

(i) Basically, the professionals such as medical doctors and their clients make a contract for assignment, according to which the clients entrust the professionals with jobs (sometimes they make a contract for work), whereas the researchers are employed by the national government, municipal governments, public bodies, private enterprises, and any other relevant entities. In the case of employment, the employer usually directs the employee regarding their job responsibilities. The researchers, however, in many cases have a wider range in which they are allowed to exercise their own discretion, and they frequently have the freedom of exercising own discretion to the same extent to the professionals such as medical doctors (refer to the examples described in connection with the autonomy of universities).

(ii) As described above, the researchers have the freedom of exercising their own discretion to the same extent as professionals such as medical doctors. On the other hand, the details of job responsibilities of the researchers are frequently undefined and unclear as compared to the contract for assignment which professionals such as medical doctors make with their clients. At universities and any other relevant institutions, researchers are free to choose what they study on the basis of the university's autonomy and accordingly, what they should present to the employer (which corresponds to study reports or patents if this means the obligation that should be given to the employer and which corresponds to study contents if this means the obligation that should be performed) is not set as an objective in advance and even if set, it may often be an abstract objective. At private laboratories also, study managers usually allow researchers to perform studies independently and give instructions to them as appropriate while considering the progress of their studies and their capabilities, and this is particularly true for fundamental studies. The objective of the researcher's job is therefore in many cases undefined, as compared to individuals who are engaged in ordinary jobs. (This way of management is extremely widely accepted as a study management method of allowing researchers to display their creativity.)

(iii) In the case of contract for assignment, the contract receiver has the obligation of handing over money and any other things which he/she has received for the purpose of handling the assignment, to the contract giver, and the contract receiver has the obligation of transferring any rights which he/she has obtained under his/her name for the sake of the contract giver, to the contract giver (Article 646 of the Civil Code). When the contract receiver bears expenses which are judged necessary for the purpose of handling the assignment, the contract receiver is entitled to ask the contract giver to pay back these expenses and interest incurred starting on the day of paying these expenses, to the contract giver (Article 650 of the Civil Code).

On the other hand, all results obtained by activities of a researcher within his/her working hours do not revert to the employer. Rights pertaining to patents are in many cases allocated between the employer and the researcher(s) concerned according to the method defined in advance. Study reports are contributed under the name of not the employer but the researcher(s) concerned. Names of prize winners are rarely the employer's name but mostly the researcher's name. For financing, the principles of bearing expenses are different from those applicable to the professionals such as medical doctors, as indicated by the following system: when a researcher working at a national institution attends at a scientific association's meeting to present his/her study report as an official duty, the researcher should bear expenses required for registration at the meeting, travel expenses and any other necessary expenses (note that in this case, accidents which occur in the course of executing his/her official duty are accepted but the national government still does not bear the expenses necessary for his/her enrollment at the meeting).

(7) Because of the difference in job responsibilities between the professionals and the researchers as discussed above, methods of evaluating achievements of researchers (e.g. if achievements are reflected on counter-performance or merit-rating results such as salaries, etc. or not) may substantially differ from those used for the professionals such as medical doctors. Since these methods are based on employment agreements, we cannot determine if one of the two is appropriate or not.

The researchers perform their duties on the basis of undefined job responsibilities, as described above. Accordingly, the researchers are not legally requested to have strict liability, the duty of high-level care, or the duty of faithfulness. The researchers are not legally requested to have the following obligations, either: the obligations of giving explanation and report, giving advice, and confirming investigation that are newly acknowledged as the obligations that lawyers should have; the obligations of exercising the best care, always studying hard, and recommending change of a doctor/hospital that medical doctors are expected to have.

Excellent study results are highly likely to obtain patents and to be put to practical use. Regarding the administration and the management of a private enterprise, the researchers are not aware, even if these fields are their specialty, that they are requested to have the duty of high-level care, the duty of faithfulness, the obligation of giving explanation, or the obligation of giving advice. Even if they are called for their opinion or give their advice, they do not realize that they have a legal responsibility of making such opinion or advice reflecting the administration or the management.

Nevertheless, researchers are generally considered as professionals like medical doctors and lawyers. This may be because the researchers have special characters, which result from, among others, the following facts: <1> in Japan, the researchers obtain high confidence and are neutral and public since those working at universities as well as national and public research institutions constitute the core of the researchers; <2> there exist academic associations which are self-governing bodies; <3> evaluation standards used for employment or interchange of personnel are considered to be relatively universal; and <4> since research is a special job responsibility, the special management method (i.e. the management method of allowing researchers to have an extremely wide range of exercising their own discretion, with the aim at drawing out their research abilities at maximum) is used. The authors therefore do not consider that there exist any special responsibility conditions that the researchers themselves should satisfy.

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7B: Negligence in General

(1) The authors have investigated the special negligence in the previous sections and in this section, will review negligence in general. In the Civil Code, negligence has been discussed as an element constituting liability for a tort. In the Penal Code, negligence has been discussed as an element constituting a crime. Since the Civil Code differs from the Penal Code in legal systems, handling of negligence is also different between the two, for example, in terms of what constitute negligence and relation to illegality. According to the Civil Code, negligence is applicable to all acts. According to the Penal Code, negligence is only applicable to the items for which the Criminal Code prescribes punishment against negligence. The two Codes follow their own logic in many other aspects: the effects resulting from negligence and the basic principles (i.e. in the Penal Code, the principle of "no crime nor punishment without law" works and penalties for negligence shall be expressly stipulated; in the Civil Code, differences between intention and negligence are not a major problem). On the other hand, when these codes are applied to handle social problems in reality, it is found that the two Codes share similar concepts regarding the duty of care. Accordingly, someone can raise enormous discussion about the homogeneity and differences between the Civil Code and the Penal Code in negligence. The authors intend to discuss the characteristics of negligence of researchers in this section: we will not deeply get into the theory of negligence in the Civil Code and the Penal Code individually but only introduce the rough structure of negligence within the

common concepts shared by the two Codes and then make a quick move to a discussion about researchers' responsibilities.

Negligence basically consists of the duty of foreseeing results and the duty of avoiding results. Both academic views and precedent cases regard either one or both of the two duties as key element(s) constituting negligence. The authors will review the traditional theory of negligence, the new theory of negligence, and the others.

(i) In the "traditional theory of negligence" (old theory of negligence) the duty of care constituting negligence is regarded as the duty of foreseeing results, according to which a person should exercise extreme caution to foresee specific results, and it is understood that the duty of foreseeing results is born of the foreseeability of results. This is accepted as the common view in both the Civil Code and the Penal Code (for the Penal Code, refer to "Multiple Revision: Penal Code of Japan" authored by Ei-ichi Makino, "New Version: Outlined Lecture on the Penal Code" authored by Sei-ichiro Ono, and "Introductory to the theory of crime" authored by Yukitatsu Takigawa; for the Civil code, refer to "Increased Version: Particulars of the Japanese Claim Law" authored by Hideo Hatoyama, "Voluntary administration of business, undue profit, and torts" authored by Sakae Wagatsuma, and "Torts" authored by Ichiro Kato). The traditional theory of negligence does not always eliminate the duty of avoiding results but interprets that violation of the duty of foreseeing will result in violation of the duty of avoidance, i.e. that these two are sequential.

(ii) On the other hand, the precedents in both civil and criminal cases tend to indicate that negligence is regarded as violation of the duty of avoiding results, which is contrary to the common view. In light of the tendency noted in these precedent cases, the "new theory of negligence" is born, which argues that negligence is violation of the duty of avoiding results, i.e. negligence is caused by a faulty act (an act which deviates from the standard act required for a person to live a social life). This new theory is based on the following idea: although acts with accompanying possible risks are foreseeable, e.g. when a medical doctor performs an operation, he/she can foresee a possibility of making a failure which may put a patient to death, or when a person drives a car, he/she can foresee a possibility of causing a traffic accident, the social life would be confused if none of those who perform such acts can be saved from negligence. For the acts useful for the society, the person of the act is not blamed for negligence as far as he/she has performed that act without any fault, i.e. he/she has observed the duty of avoiding results (the duty of objective carefulness). This concept is related to "the principles of reliance" or the theory of "permissible risks." (For the Penal Code, refer to "Structure of criminal negligence" authored by Masaharu Inoue, and "Total Revision: Outline of the Penal Code" authored by Taira Fukuda, and for the Civil Code, refer to "Theory of laws concerning liability for damage" authored by Norio Hirai, and "Civil Code VI" authored by Tatsuaki Maeda.)

(iii) In addition, several new theories of negligence have been proposed. In the Penal code, there is the "theory of apprehensive feeling" (i.e. the new version of new negligence theory). In the new negligence theory, the foreseeability of results is required as a precondition that results may be avoidable and this foreseeability of results should be considered not merely in an abstract manner but in connection to progress of specific causality. On the other hand, the theory of apprehensive feeling argues that feelings of apprehension or anxiety are sufficiently enough as elements which increase strictness of the duty of avoiding results in connection with unknown risks such as environmental pollution or scandals regarding drug regulation or production, and as a precondition which acknowledges the duty of avoiding results (for the Penal Code, refer to "Penal Code" authored by Hideo Fujiki). On the other hand, there are several opinions proposed in the area of Civil Code. One theory is as follows: the duty of care as a precondition of negligence should be based on the ordinary person as the standard as far as the duty is related to the ordinary citizens' lives, whereas a business entity which uses high-level expertise and complicated organization to perform a large-scale business should take the duty of conducting investigations and surveys in organized and continuous manners in order to explore a possibility of occurrence of risks and prevent such risks from occurring; and if the business entity fails to conduct such surveys, resulting in occurrence of damage or loss, then that entity is blamed for negligence on the ground of violation of the duty of care with which they had to foresee occurrence of risks (for the Civil Code, refer to "Study of environmental pollution from the viewpoint of private laws" authored by Hiroshi Sawai). The second theory is as follows: negligence is separated from the issue related to subjective mental state and is an objective issue, and in other words, negligence is the issue of whether or not the person concerned has taken reasonable actions to prevent damage or loss which exceeds acceptable levels; and if such damage or loss beyond the acceptable levels should be caused, the person should be blamed for negligence whether the results are foreseeable or not (for the Civil Code, refer to "Intention, negligence and illegality" in the book "Establishment and development of environmental pollution laws" edited by Ichiro Kato).

(2) Importantly, the background to the above-described changes over time in negligence theories, i.e. from the traditional theory of negligence to the new theory of negligence and further to the new version of new theory of negligence, is the progress in science and technology and their application to society. The new theory of negligence is intended to provide ease for users of technologies which are useful for society but also possesses potential risks such as automobiles and medical practices, for which the traditional theory of negligence may blame such users for negligence. The most recent theory of negligence is intended to impose strict liability on acts of business entities which, through the use of new technology, may cause damage to an unspecified number of the general public, e.g. environmental pollution, scandals regarding drug regulation or production, and adverse effects on safety of foods.

Negligence theories are closely related to the progress in science and technology and their application to the society, as described above. The debut and widespread use of life sciences related technology, i.e. totally novel technology, have raised the necessity of investigating negligence theories from the new points of view. For example, reproductive medical technology differs from the above-described technologies supporting the new negligence theory, such as automobiles and medical care technologies, because application of reproductive technology may cause abstract and extensive risks. Life sciences related technology differs from environmental pollution and scandals regarding drug regulation or production, which support the most recent theory of negligence, since reproductive technology is not a type of business performed by large enterprises having complicated organizations and large-scale facilities but may be a type of small-scale research and in some cases, as small as personal research. On the other hand, the recent progress in life sciences allows a certain technology to be applicable to not only a specific area but also every corner of the society, creating the situations in which we should not only focus on individual issues separately. This is also true for information technology, the field of science and technology that has also attained remarkable progress like life sciences related technology. The authors consider it necessary to keep these points in mind when investigating regulation of life sciences related technology in the future.

(3) Apart from the issue of whether violation of the duty of foreseeing results is directly regarded as negligence or violation of the duty of avoiding results is regarded as a precondition of negligence, foreseeability is an important element constituting negligence. For the foreseeability, there exist several opinions regarding what should work as the standard.

(a) Objective theory: The ordinary person's ability of exercising caution works as the standard. When results are foreseeable by the ordinary person, the duty of foreseeing results is valid even if the person who did the act concerned was not able to foresee the results.

(b) Subjective theory: The ability of exercising caution of the person who does the act concerned works as the standard.

(c) Compromise theory: The ability of exercising caution of the person who does the act concerned works as the standard, but if that ability exceeds the ordinary person's ability, then the ordinary person's ability works as the standard. Precedent cases are based on the objective theory and many of the conventional views agree with the objective theory. There are different opinions regarding laws: some claim that laws prescribe standardized duties irrespective of differences in abilities among individuals and force citizens to observe such duties, through which they try to function as rules and regulations; and others claim that laws are based on the idea that unlawful acts break confidence by the person receiving damage or the third individual, although such confidence is regarded as a precondition for ordinary community life. However, those following the subjective theory criticize that whether the act conducted is blamed or not, i.e. whether or not the person who conducted the act concerned is held responsible for negligence or not, should be based on the ability of exercising caution of the person him/herself who conducted the act, as indicated by the following case: when a person drives a car and causes an accident because of a disease which is not foreseeable by the person, it is not appropriate to blame that person for negligence.

(d) In criminal law studies, the following opinion regarding handling of the objective theory becomes predominant: the ordinary person works as the standard when violation of the duty of objective carefulness is evaluated as an element constituting negligence, and the person who did the act works as the standard when violation of the duty of subjective carefulness is evaluated as responsibility (when an individual injures another individual by negligence, the awareness that the subject to be injured was a human is evaluated according to the standard of the ordinary person, but legal causes for exclusion of responsibility such as the state of unsound mind are evaluated according to the standard of the person who did the act concerned).

In this section, the authors cannot complete discussion about whether these theories are right or wrong. We instead focus on matters which support these theories and also are extremely important when discussing responsibilities of researchers. First of all, we will focus on foreseeability. It seems to us that there has existed the assumption that what is foreseeable by the ordinary person is right, when discussing foreseeability by comparing the ordinary person with the person who did the act concerned in terms of the ability of exercising caution. The compromise theory assumes that in some cases, the person who did the act concerned is superior to the ordinary person in the ability of exercising caution. However, none of the theories regards the following as a proper assumption: irrespective of the ability of exercising caution, i.e. no matter what caution is exercised, the ordinary person is always wrong and the person who did the act concerned has always right understanding. Such reversal can frequently be noted in the field of science. In the area of life sciences in particular which is the subject of our discussion in this Report in connection with regulation of technology, we frequently encounter the following situation: what is believed right by not only the ordinary citizens but scientific associations is not considered by specific researchers to be correct, and these researchers perform their own studies according to their independent opinions. Results obtained by these researchers are highly appreciated since their studies and results have originality. Even if regulation of life sciences is imposed not by restricting research but by limiting application of technology, researchers are the subjects to be regulated and in most cases, application of technology in their studies may be restricted. Under such circumstances, although the common idea throughout the society is important, the yardstick of researchers' judgment is decisive. It is therefore likely that the general conditions accepted by researchers' groups such as scientific associations are always opposed to what researchers individually foresee.

In light of these points, the following cases are considered: <1> when the ordinary person (the ordinary citizens' views or average opinions of scientific associations or any other relevant bodies) foresees the presence of risk, but the person conducting an act foresees the absence of risk and performs an experiment, resulting in occurrence of harm; <2> when the ordinary person foresees the absence of risk and the person conducting an act foresees the presence of risk and performs an experiment, resulting in occurrence of harm; and <3> when the ordinary person cannot foresee the presence nor absence of risk and the person conducting an act foresees the presence of risk, and harm occurs. In the case of <1>, the person who conducted the act may be responsible for negligence according to the objective theory but excused for negligence according to the subjective theory. In cases <2> and <3>, the person who conducted the act may be excused for negligence according to the objective theory but may be responsible for negligence according to the objective theory. In cases <2> and <3> in particular, what is foreseeable agrees with what actually occurs. These cases may indicate that researchers have foresight, apart from whether it may constitute a crime or a tort. The authors will not move forward here regarding these issues. Considering the fact that researchers improve together through friendly rivalry every day, regulation of advanced science and technology on the basis of the subjective theory may prevent the purpose of such regulation from being achieved. On the other hand, it may be a problem if the person conducting the act is not responsible for negligence even in the case of <1>. The authors consider it necessary to review again opinions (a) through (d) regarding what should work as the standard, in connection with negligence of researchers.

{Note}

In 1989, it was reported that Professors Fleischman and Pons at Utah University in the US electrolyzed heavy water (more strictly speaking, deuterided lithium hydroxide and heavy water solution was electrolyzed at constant current with a cathode (palladium) and anode (platinum)), resulting in continuous generation of heat at 10 W/1 $cm^3$ for over 100 hours (which was sufficient heat generation to exceed that produced by the experimental measurement conditions). It was reported that at the time of this experiment, no one was present in the laboratory room and there was no personal loss. Calculation indicated that this quantity of heat required generation of $10^{11}$–$10^{14}$ neutrons, which is presumed to be lethal to humans. (However, the readings obtained from the gamma ray measuring unit in the laboratory room indicated that only $10^4$ neutrons were generated per second.) On the basis of the scientific knowledge and information available at the time, no one was able to foresee occurrence of nuclear fusion during electrolysis of heavy water. This experiment, known as "cold fusion," created a considerable sensation within society. Following this, in Japan also, universities and the Ministry of International Trade and Industry conducted similar experiments. Regarding the experiment conducted by Professors Fleischman and Pons, however, subsequently performed studies came to the same conclusions that "it was judged difficult to confirm their experiment because the reproducibility of neutron measurement was insufficient" and "it is not considered that theories supporting the presence of ordinary-temperature nuclear fusion have been investigated substantially enough to give convincing explanation to that presence" (JAERI Review "Nuclear fusion" by the Study Group of "Ordinary-Temperature Nuclear Fusion" of the Japan Atomic Energy Research Institute in 1995). Up to now, no convincing evidence has yet been obtained.

(4) Article 4-1 of the Products Liability Act prescribes that if the manufacturer of the product concerned proves that the manufacturer cannot discover a defect in the product, on the basis of the scientific and technological knowledge and information available at the time of delivery by the manufacturer, the manufacturer shall not be liable for damage stipulated in Article 3 (regarding products liability of manufacturers, etc.). This is interpreted as the defense of failure to discover risk during product development.

It is understood that the reasons why the scientific and technological knowledge and information is made the legal ground for exemption of responsibility is because "the Products Liability Act assumes that science and technology progresses, and accepts the defense of failure to discover risk during product development while trying to avoid hindrance to advances in science and technology which contribute to improvement of stability of national life and to growth of national economy." What the Act considers as a problem is impossibility of awareness of defective based on "the knowledge and information regarding science and technology." Accordingly, "the "knowledge and information" in the Products Liability Act means the whole knowledge established that may be affected when the presence or absence of defective is evaluated and that is not owned by any specific person or entity, and is therefore defined as the whole knowledge that exists in the society from the objective viewpoint. …In other words, since this means the knowledge established that may affect the others, this includes everything from a rudimentary knowledge to the state-of-the-art knowledge. A manufacturer who wants to be exempted from liability is required to prove that even on the basis of the state-of-the-art knowledge available that was necessary for them to determine if the product concerned was defective or not, they failed to be aware that the product was defective. …Accordingly, whether or not a defense of failure to discover risk during product development is accepted or ruled out in a case is determined by the level of state-of-the-art knowledge and information in science and technology available upon the relevant time." (Refer to "Explanation on individual articles of products liability" issued by the Consumer Administration Division 1, the National Life Bureau, the Economic Planning Agency.)

No specific cases have occurred, which are related to the defense of failure to discover risk during product development on the basis of products liability. Of the previous cases in which the legal issue was negligence in torts, we found out many precedent cases examined at lower courts in which the level of scientific and technological knowledge and information was examined in connection to foreseeability.

(i) In the Tokyo SMON (Subacute Myelo-Optico-Neuropathy) law suit, the Tokyo District Court adjudicated as follows on August 3, 1978: Since the drug concerned was a new drug, the defendant had the duty of foreseeing results and had to performed, prior to marketing the drug, in vitro experiments, animal experiments and clinical studies using the state-of-the-art knowledge and information. It was evident that Chapter 42 of the La Semana Medica Journal which carried the report authored by Gravietsu and Barosu (written in Spanish) was retained in the Annex of Tohoku Imperial University School of Medicine as of June 15, 1937, two years later. Considering this fact, together with the fact that Gravitsu wrote his statements in the Ciba Jiho Journal No. 62, it is not acceptable that the defendant had difficulties in obtaining information regarding case reports by Gravitsu, Barosu…as of 1935.

(ii) In the second law suit of the chloroquine case, the Tokyo District Court made the following judgment on May 18, 1987: Drugs are manufactured and improved on the basis of the state-of-the-art academic knowledge available at each relevant time. ….drug manufacturers are required, when developing and manufacturing drugs, to perform thorough literature survey, experiments and studies to confirm not only the efficacy but also the safety of the drug concerned. The occurrence of retinopathy caused by chloroquine preparations was evident by the Hobuz report published in the Lancet journal issued in October 1959 and the subsequent report by Furudo. It was possible for the defendant pharmaceutical manufacturer to obtain and examine the above-mentioned Lancet issue to discover the occurrence of retinopathy caused by chronic use of chloroquine preparations.

Specifically, it is understood that what these judgments required is as follows: nothing in the scientific and technological information, reports, etc. available indicated the existence of the defect concerned, on the basis of which the defendant performed a series of experiments and was not able to be aware of the existence of the defective. It is impossible to find direct evidence indicating the non-existence or unavailability of literature. There exist several systems for retrieval of scientific and technological information, reports, etc. available in Japan, e.g. retrieval systems by Chemical Abstract, Index Medica, and the Scientific and Technological Information Center. It is presumed that these systems would indicate the non-existence of information indicating risk at the time concerned. (Refer to ″Defense of failure to discover risk during product development″ authored by Hideyuki Kobayashi and Motoko Yoshida in the book ″New Modern Lecture on Damage Compensation Laws: No. 3: Products Liability″ edited by Takuo Yamada as representative editor).

This appears to be an extremely stringent element constituting liability. The Products Liability Act is interpreted as follows: ″When only a specific single scholar has pointed out risk, it is not interpreted that in such a case, the defense of failure to discover risk during product development becomes unacceptable immediately (refer to ″Explanation on individual articles of products liability″ mentioned above). There seem to exist subtle differences between the purport of the judgments and the issue of whether it is permissible to use the established academic knowledge as a basis or not (since another possible interpretation of the documented judgments can be that as far as the defendant just follows popular opinions of scientific associations, the defendant cannot be exempted from liability and that ultimately, the defendant is required to make confirmation by themselves).

It is a delicate issue how this standard is utilized in actual specific cases. However, investigation from the different viewpoint from that of product liability may be necessary: when regulating research itself, whether this standard based on the interpretation of Products Liability Act would be sufficiently significant and effective or not; and it might be a problem for a person to be blamed for liability regarding unrealizable prospects.

In the US, state laws and precedent cases indicate that product liability actions are generally grounded on theories of negligence, strict liability and breach of warranty. Strict liability is not always the issue. Advantages of individual defendants vary depending on awarded damages. Among these theories, the concept of technology standards is primarily based on strict liability in particular. There are four opinions for these technology standards, i.e. <1> traditional practices in an industry which have been commonly performed regarding manufacture of a similar type of products to the product concerned, <2> legal, administrative, or industrial voluntary quality and safety standards, <3> level of knowledge attainable in fields of science and technology, and <4> feasibility and availability from the factual and economic points of view. There are no uniform nor fixed definitions. (Refer to the report authored by Hideyuki Kobayashi and Motoko Yoshida mentioned above.)

(5) The authors have discussed regulation of cloning technology from the viewpoint of risk in the previous section. There are several points to be considered, which will be discussed here. When regulating cloning technology from the viewpoint of invasion into the legally protected interests for the reasons described above, that form of a crime is regarded as criminal endangerment (not criminal invasion) according to the Penal Code. The criminal endangerment in connection with cloning technology would constitute abstract types of criminal endangerment, in contrast to specific types of criminal endangerment such as endangerment of traffic, criminal attempt and crime of setting fire.

In Japan, the criminal endangerment has not frequently been discussed but the popular views indicate that this crime is based on the theory of formal requisite: a person who conducts an act is not accused because he/she merely violated the prescribed code of practice (this is the theory of non-observance) but because the act conducted by the person, i.e. an act prescribed in legal documents, has abstract risk of invading the legally protected interests. In addition, the abstract risk is determined by the extent of possibility of occurrence of such invasion and by the extent of abstraction upon evaluation of risk (e.g. as the subject to be damaged by invasion extends from a specific person to unspecified persons, causing social anxiety, the extent of abstraction is greater). (Refer to ″Study of criminal endangerment″ authored by Atsushi Yamaguchi.)

The above-described view is not wrong. If the abstract risk described in the above theories means effects caused by prohibited acts, effects caused by permissible acts, effects which occur naturally, etc. such as the genetic effects attributable to exposure to radiation, then it becomes possible to make evaluation from the viewpoint of probability along with progress in science and technology, and following this, evaluation standards may be investigated for risk or safety of whole matters including the above. In Japan, from the legal point of view, none of rules or regulations may currently incorporate this way of evaluation from the viewpoint of probability, into safety evaluation. We have heard, however, that some safety-related administration of the national government started to try to incorporate this way of probability-based evaluation when setting safety management objectives. The future issue to be addressed may be a relation between such administrative objectives and legal risk.

Specifically, persons driving cars cause traffic accidents at a certain probability. According to the old theory of negligence introduced above, car drivers can foresee that they might cause traffic accident and therefore, cannot escape negligence. Criticism against this created the new theory of negligence, according to which persons who invaded the legally protected interests (i.e. who caused a traffic accident) can escape negligence as far as they fulfill the duty of avoiding results (i.e. they observe the relevant rules and ordinances). However, if the method of probability-based evaluation becomes accepted by the society (or internationally), then the risk of facility or equipment concerned is evaluated by comparing the risk of the others and within such comparative evaluation results, duties for persons conducting acts to fulfill are defined. The debut of such new regulation may trigger reexamination of the existing theories of negligence or create new duties of avoiding results (new duties of care).

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## Part 2: Guidelines Established by Countries and Academic Associations

### Section 1: Guidelines

(Authored by Minoru Kuniya and Mami Oyama)

#### 1. Guidelines Regarding Life Sciences

(1) The authors have so far discussed regulation of life sciences, assuming that such regulation would be based on legislation. Some claim, however, that voluntary regulation by researchers is more appropriate since it is highly likely that this type of regulation may be imposed on research itself in reality. Voluntary regulation by researchers may comprise voluntary standards or guides for restriction issued by scientific associations or any other relevant bodies.

Regarding voluntary regulation by researchers, various guidelines have already been set out in a diverse range of research fields by scientific associations, etc. It is pointed out that these guidelines are not sufficient to cope with the issue of regulating cloning technology since these guidelines are basically effective only among those who participate in scientific associations and even if some researchers violate the guidelines, they are only expelled from the relevant association and no additional punishment is available.

Regarding guidelines for reproductive medical technology, the Japanese Association of Gynecology and Obstetrics announced the "Opinion about in vitro fertilization and embryo transplantation" (as an association's announcement in 1983), followed by the 11 association's announcements listed below. The members of the Association are all aware of these opinions.

<1> "Opinion about in vitro fertilization and embryo transplantation" (1983)

<2> "Opinion about studies handling human sperm, ova, and fertilized eggs" (1985)

<3> "On a system of registering and reporting clinical implementation of in vitro fertilization and embryo transplantation" (1986)

<4> "Opinion about whether or not organs, etc. from dead fetuses or newborns are used in research and about the range of permissibility" (1987)

<5> "Opinion about fetal diagnosis for any malformation, with special regard to chorionic villi sampling (CVS) during early period of pregnancy" (1988)

<6> "Opinion about freezing/storing and transplanting human embryos and ova" (1988)

<7> "Opinion about clinical implementation of microscopic fertilization method" (1992)

<8> "Opinion about safety of use of Percoll method in choosing a sperm having X-chromosome or one having Y-chromosome" (1994)

<9> "Opinion about multiple pregnancy" (1996)

<10> "Opinion about artificial insemination between non-spouses and sperm donation" (1997)

<11> "Opinion about the range of clinical application of in vitro fertilization and embryo transplantation in humans" (1998)

<12> "Opinion about pre-implantation diagnosis" (1998)

(2) On the other hand, the Ministry of Health and Welfare and the Ministry of Education have issued guidelines for life sciences. These guidelines function as standards at national universities, medical institutions under the jurisdiction of relevant authorities, and institutions supervised by the administrative office according to laws within the jurisdiction of relevant authorities. Unlike the guidelines issued by scientific associations, some of them are legally valid as an order of the administrative authority.

<1> Announcement by the Ministry of Education "Guidelines for Recombinant DNA Experiments at Universities, etc." (March 31, 1979)

<2> Announcement by the Ministry of Health and Welfare "Guidelines for Clinical Studies of Gene Therapy" (February 8, 1994)

<3> Announcement by the Ministry of Education "Guidelines for Clinical Studies of Gene Therapy at Universities, etc." (June 9, 1994)

Regarding regulation of studies of cloned humans which is currently the topical issue, the Bioscience Group, the Subcommittee for Promotion of Research in Specific Fields, Science Council issued a report entitled "Research on Cloning at Universities, etc." on July 3, 1998. In this report, "drafted guidelines for regulation to be imposed on research of creation of cloned human individuals at universities, etc." were shown and the following idea was stated: considering the point that regulation should be the same to all researchers at universities, it was considered appropriate that guidelines on research of cloning at universities, etc. be formulated by the Ministry of Education and be put to practical use according to professional investigation and examination by Science Council. On the basis of this view, the Ministry of Education announced the "Guidelines for Research of Creation of Cloned Human Individuals at Universities, etc." in August 1998.

(3) Regarding gene recombination, the Prime Minister decided the "Guidelines for Gene Recombination Experiments" on August 27 1979, in response to Advisory Opinion No. 8 of the Council for Science and Technology, an advisory commission of the Prime Minister, "On the Basis of Promoting Policies for Gene Recombination Studies." The authors will describe the details later again.

2. Effects of Guidelines

(1) It is acknowledged that the history of voluntary standards for life sciences (including medical practices and experiments) traces back to ancient Greek times and began with the "Hippocratic Oath." An epoch-making movement occurred after World War II, which was triggered by repentance following the experiments on humans conducted in Nazi Germany. The "Nurnberg Code" formulated through the progress of the Nurnberg War Tribunal had a great influence on subsequent moves. Along with subsequent events including the "Declaration of Helsinki" issued by the World Medical Association, the world's first successful heart transplantation in South Africa in 1967, and the discovery of the Tuskegee case in the US, various standards were born in countries over the world. In the "Encyclopedia of Bioethics" (published by the Kennedy Institute of Ethics, Georgetown University), the initial standards pertaining to medical practices are listed as described below (refer to the translation by the Planning Bureau, the Science and Technology Agency).

{General codes involving medical practices}

- "Declaration of Geneva" issued by the World Medical Association (1948)
- "International Code for Medical Ethics" issued by the World Medical Association (1949)
- "Principles, Written Reports and Statements Regarding Medical Ethics" issued by the American Medical Association (1957)
- "Oath of Soviet Union's Medical Doctors" (1971)
- "Ethical & Religious Directives for Catholic Health Care Institutions" issued by the American Catholic Council (1971)
- "Medical Ethics, Statements on Policy, Definitions, and Rules" issued by the British Medical Association (1974)

{Directives involving experiments on human bodies}

- "Nurnberg Code" (1946)
- "Responsibilities in Studies of Humans" issued by the British Medical Research Council (1963)
- "Experiments and Studies of Humans" issued by the British Medical Association (1963)
- "Declaration of Helsinki" issued by the World Medical Association (1964 and 1975)
- "Ethical Guidelines for Clinical Studies" issued by the American Medical Association (1966)
- "American Guidelines for Human Studies" (Institutional guidelines for the policy of the Department of Health & Human Services regarding protection of humans) (1971)

An event requiring particular attention is the establishment of the National Research Act in the US in 1974 which is intended to protect human subjects in scientific research. On the basis of this Act, the "Ethical Principles and Guidelines for Protection of Humans in Clinical

Studies" was formulated, which is applied to research involving human subjects subsidized by the Department of Health & Human Services. The Ethical Principles and Guidelines prescribe that a researcher who intends to perform a clinical study shall obtain approval from an institutional review board (IRB), the establishment of which shall be the duty of each relevant medical institution, prior to submitting an application for subsidies to the Department of Health & Human Services. Immediately following this, the Declaration of Helsinki was revised at the Tokyo Conference of the World Medical Association and the revision contains additional points, among others, as follows: a scientific experiment involving human subjects shall be discussed, reviewed and directed by an independent committee; and publication of reports which do not comply with the principles of the Declaration shall be refused. In Japan also, an institutional review board was first organized at the Medical Research Laboratory, Tokyo University in 1981.

In recent years, informed consent has been given particular importance in the field of medical practices. This is also the product of standardization in science & technology related areas such as experimental medical practices and clinical development of new drugs. The US President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research issued a report outlining informed consent in 1982. This report expands use of informed consent to therapies and made a proposal that the theory of informed consent is based on laws but has ethical characters and therefore, informed consent should be treated as an ethical issue.

In the field of gene technology research, Watson and Crick discovered the double-chained structure of genes as early as 1953. In the US, Cohen and Boyer first succeeded in gene recombination in 1973. According to a proposal made by the National Academy of Science (NAS), the Ashiroma Conference was held in the State of California in 1975. In light of the Conference results, the NIH prepared guidelines for gene recombination in 1976. The Guidelines formed the basis of subsequent guidelines for gene recombination experiments in Japan and other countries.

The various guidelines thus formulated function as standards in life sciences and medical practices, although many of them are not legislative but treated as autonomic ethics. Guidelines in Japan also follow this principle.

(2) Regarding guidelines for gene recombination, the Recommendation in response to Advisory Opinion No. 8 of the Council for Science and Technology was published, i.e. "On the Basis of Promoting Policies for Gene Recombination Studies." This Recommendation stated that potential risk which was predicted at the beginning of discussion remains still now within the range of hypothesis and accordingly, regulating gene recombination studies by laws may not be appropriate but instead voluntary observance of the guidelines by researchers is desirable. The report issued by the Life Sciences Committee of the Council for Science and Technology, which had been published prior to the Recommendation above, stated that regulations to be imposed on gene recombination experiments should follow the methodology accepted in foreign countries, reflect considerations given so as to agree with guidelines issued by the Ministry of Education, be reviewed as appropriate according to availability of new scientific knowledge and information, and be based on internal demands within life sciences related fields so that it is desirable to position research on the basis of proper understanding of the society. It seems to us that the report gave considerations to a possibility that these conditions may be damaged if guidelines are ruled by law.

The authors need to undertake further discussion to determine if the present guidelines have a legal effect or not, however. We would like to introduce the most recent two cases pertaining to the guidelines for gene recombination.

(i) Firstly, there were two law suits involving the guidelines for gene recombination experiments: in one case, an injunction was claimed against use of Experimental Room P4 at the Life Sciences Tsukuba Research Center of RIKEN (the Physical & Chemical Research Laboratories); in the other, a motion was filed that gene recombination research performed at the NIH (the National Institutes of Health) should be banned. In the former case, the motion was ruled out by the Court (the Tsuchiura Branch of the Mito District Court) on June 15, 1993. This judgment stated as follows: the Japanese guidelines for experiments are not special at all but it is understood that they are used since they are generally appropriate; on the other hand, the contents of the Japanese guidelines are more stringent as compared to guidelines or any other relevant rules in the US and accordingly, the safety is secured. Usually, in civil cases involving a motion of injunction or a claim for damages, the following principles are employed: <1> the plaintiff has the burden of proving that the act causing damage is illegal; and <2> the Court examines the case, on the basis of evidence, and establishes the facts by itself and makes its own judgment. However, prior to the case described above, the Supreme Court had adjudicated in the case of Ikata Nuclear Power Plant law suit that <1> when the Court examines the case and makes judgment, such examination and judgment should be made from the viewpoint of whether there exists any unreasonable points in the judgment made by the administrative office on the basis of professional and technological investigation, examination and judgment, e.g. those made by the Atomic Energy Commission and that <2> although the plaintiff as a rule should have the burden of proof, the defendant administrative office is required to prove on the basis of reasonable evidence and information that their judgment contains no unreasonable points, considering the fact that the relevant information is all retained by the defendant administrative office. This Supreme Court judgment indicates transfer of the burden of proof from the plaintiff to the defendant and movement from the judgment based on the Court's independent fact finding to the judgment based on results of examination for unreasonable points in the administrative office's judgment. In the above-described case involving gene recombination, the judgment stated that "irrespective of form of documented judgment, the true intention of examination and judgment agrees with the contents indicated by the Supreme Court's judgment made in the Ikata Nuclear Power Plant case as mentioned above" (Hanrei Jiho No. 1467). It is therefore considered that the national guidelines stating that voluntary observance of the guidelines by researchers is desirable, have similar effectiveness to that achieved by the standards based on the Nuclear Reactor Regulation Law (although there is a difference from "presumption of lawfulness" which "official power" has, we can see that in the guidelines also, some presumption is performed since the Court does not examine nor judge the contents of standards from the scientific viewpoint).

This of course follows the logic that what complies with guidelines (standards) does not need to be banned since its safety has been confirmed. This does not directly lead to a judgment that what does not comply with standards, which is the issue, can be banned since its safety has not been confirmed (injunction is applicable to the private person; in the case of administrative office, non-licensing is applicable). Nevertheless, the above introduced cases may worth referring to.

(ii) Secondly, for gene recombination guidelines, the municipal government of Suita City, Osaka Prefecture established the "Bylaw to Secure Environmental Safety in Facilities Involving Gene Recombination in Suita City" in October 1994. In Suita City, there exist 13 business units in 7 locations where gene recombination is performed. The Bylaw is intended to take all possible measures to prevent hazards caused by unforeseeable and unknown dangers, and prescribes the following as mandatory: submitting various notifications, consultation, making agreements, retaining records, reporting, and acceptance of on-the-spot inspection. Regarding safety, the Bylaw stipulates that "the person conducting business shall observe the guidelines for recombination experiments and the other guidelines prescribed by regulations and rules," according to which the Bylaw requires observance of the national guidelines in terms of safety (note that the expression "the other guidelines prescribed by regulations and rules" include the Announcements by the Ministry of Education described above). Regarding the necessity of establishing this type of by-law, some views claim that no additional regulations are necessary if they are substantially the same as existing ones. The other support the Suita City's action by arguing that we cannot deny the fact that the Bylaw gives legal binding power to the standards prescribed by the national guidelines, which enables us to make a legal judgment indicating opposition against some researchers who are not mindful of the national guidelines, ignore them, and make their own way in research (refer to "Legal issues in connection with the Suita City's Bylaw regulating gene recombination facilities" authored by Kaoru Inoue, Jurisuto No. 1064). Apart from whether or not the existence of these double-binding standards is a desirable situation for the people or not, we can consider that if there exist norms which should function as safety standards when they are incorporated into a bylaw, such norms, together with the above described precedent cases, are not legally meaningless but may have certain legal effects.

From now on, the authors will make further investigation on this matter.

{Note} Our discussion in next sections onwards will be primarily based on national guidelines. Before moving forward, we would like to discuss effects of guidelines issued by scientific associations, i.e. {legal effects of voluntary standards}.

Like a person who performs an act which is not contrary to ethics, business entities and individuals engaged in business set self-regulating standards (voluntary standards) as a code of practice when performing their business. These voluntary standards exist in various fields including, among others, production, business transaction, maintenance of environment, education, medical care, settlement of disputes. An extremely small number of reports have discussed legal effects of voluntary standards, however. Here, we will discuss this matter by referring to a report "Voluntary Standards and Laws" authored by Jisuke Nagao. Nagao's report focuses on acts involved in business transaction and his scope of discussion is not as wide as that in this Report. However, his report is primarily based on analysis of precedent cases and contains views which are applicable to general issues. The authors therefore would like to introduce his report.

Voluntary standards are prepared by an industry association, members of which are companies to the same industry, and are expected to be observed by those member companies. Voluntary standards therefore prescribe criteria for directing and handling the members and thus function as providing models in certain cases. The authors will not touch on this function here, though. Nagao's report pointed out that voluntary standards have the following four functions which are legally significant: (a) a function to contribute to clarification of legal concept contained in articles of laws (for which he referred to the judgment made by the Tokyo High Courts on July 18, 1980 that the State should, when making a judicial judgment, give importance to the examination criteria for obscenity issued by the Film Ethics Regulatory Committee as a piece of information which helps the State estimate the popular view on obscenity in the society); (b) a function to define the meaning of acts performed by the individuals involved in a dispute; (c) in the case in which the domestic written rules and regulations grant legal effects to voluntary standards formulated by industry associations, a function to constitute specific details of such laws of voluntary standard; and (d) a function to identify legal elements. In connection with the function to identify legal elements in particular, he examined unlawfulness and the duty of care.

When looking for precedent cases at lower levels of courts, he found out the view indicating that voluntary standards constitute the ground of judgment of unlawfulness or as the ground of violation of the duty of care. The judgment of unlawfulness can be divided into the following three categories: <1> unlawfulness is judged because the rules of faith are violated; <2> unlawfulness is judged and therefore, liability for damages on the basis of non-fulfillment of obligations or torts is accepted; and <3> unlawfulness is judged because the act concerned is contrary to public policy or good morals. In law suits, voluntary standards are treated as at least an important factor when unlawfulness is judged in <1> and <2> (refer to the judgment made by the Osaka High Courts on September 24, 1991 and one made by the Kyoto District Court on November 26, 1968; and also the judgment made by Yokohama District Court on December 18, 1987 in which voluntary standards were accepted as an element). On the other hand, when a contract is judged to be invalid because of the ground stated in <3>, it is understood that voluntary standards do not function as a sole factor leading to a judicial judgment that the act concerned is contrary to public policy or good morals (refer to the judgment made by the Osaka High Courts on September 24, 1991).

Regarding judgment of negligence, considering the feature that voluntary standards express what corporate activities should be in order to meet the demands of the society, when a violation occurs in relation to an item subject to regulation of voluntary standards and a person who suffers from damage caused by such violation makes a claim for compensation for the damage, voluntary standards have the significance that they provide a yardstick for evaluation of the duty of care. In specific cases, however, it is unavoidable to set limits to a scope in which this significance functions (refer to the judgment made by the Yokohama District Court on December 18, 1987 and one by the Tokyo District Court on December 25, 1989).

The precedent cases introduced above are related to commodity exchange and not a small portion of the voluntary standards discussed above are incorporated into the framework of administrative regulations and rules pertaining to the commodity exchange industry. Nagao's report pointed out that these voluntary standards do not always provide the immediate significance of the order between the parties concerned. In the judgments introduced above, unlawfulness was not only based on voluntary standards but also on the relevant laws. In addition, there was a judgment which is evidently contrary to the true aim of Nagao's report (i.e. the judgment made by the Hakodate District Court on October 24, 1975 that for an act which violates model-regulations and laws, we cannot say that this act constitutes a tort because of the violation; note that some scholars criticize this judgment). Accordingly, it may be dangerous to draw any universal conclusion on the basis of these limited judgments. Nevertheless, the above described points and cases may indicate that it may be inappropriate to consider that voluntary standards have no evident legal effects in all cases.

Considering the fact that the entity establishing standards under discussion of this Report is not industry associations which consist of companies doing business for the purpose of profit-making but scientific associations, the authors consider that there exist great differences between voluntary standards of the two types in terms of effects.

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## Section 2:Unwritten Legal Codes

### 1. Non-Licensing on the Ground of Violation of Public Policy or Good Morals, etc.

#### (1) Bars to Patentability According to the Patent Law: the Patent Law Expressly Bans Violation of Public Policy or Good Morals, etc.

The Patent Law prescribes bars to patentability as follows: "those which may damage the public order, good morals or public health" (Article 32-2). In Japan, since the establishment of "Patent Ordinance" in 1886, those which may disturb the order and good morals have consistently been barred to patentability. At present, the majority of the theories have no objections against the view that inventions which may damage the order or good morals should not be patented (refer to "Outline of the Patent Law: 8$^{th}$ version" authored by Kosaku Yoshifuji). Inventions which are contrary to public policy or good morals are defined as follows: <1> the original purpose of invention damages public policy or good morals (e.g. counterfeit money producing machine, opium inspirator); and <2> although the original purpose of invention may not damage public policy or good morals, owing to the purpose and elements of the invention concerned, anybody can easily find out a possibility of using it for an immoral purpose and in addition, such use is expected highly probably (according to precedent cases, libido-intensifying devices are included in this category <2> but bingo games are not). For example, any invented gene recombination technique producing microorganisms harmful to human bodies should be a bar to patentability according to the provision of the article described above.

Outside Japan, the Intellectual Property Right Code in France stipulates that "inventions, publication or embodiment of which is contrary to public policy and good morals" shall not be patented. The following form was added to this Code: "human bodies as well as their elements and products, and knowledge of human genes as a whole or in part cannot be a subject of patent." This is based on the philosophy in France that since acts of handling human bodies as goods are illegal, knowledge of gene sequence is regarded as common assets which the humankind share and therefore is made public, whereas in the US, the predominant idea was to try to obtain patents for every piece of knowledge obtained from analysis of gene sequence (refer to "Summary of French legislation leading to the Bioethics Act" authored by Ichiro Kitamura, Jurisuto No. 1090).

As illustrated above, the contents of public policy or good morals greatly differ among countries. In these countries, the provisions regarding public policy or good morals are expressly set forth in laws and they are treated as bars to patentability.

{Note} Regarding this matter, there is another view as follows: granting patent to an invention means only giving the exclusive right to the invention and does not mean that the invention will surely be put into practice; accordingly, granting patent does not always mean that practicing the patented invention is admitted; on the other hand, an invention which is not given patent can be practiced if such practice is not banned by the other laws or ordinances; and regarding the inventions included in the category <2> above, it is sufficient to regulate them

by the other laws and ordinances according to the form of the invention concerned and the Patent Law should not intervene in them (refer to "Industrial Property Rights Act" authored by Nobuhiro Nakayama).

(2) Possibility of Non-Licensing by Laws and Ordinances which do not Expressly Prescribe Provisions Regarding Public Policy or Good Morals

In the case of general administrative laws, the authors will discuss if an application for license can be ruled out or not, or acceptance of a notice can be refused or not according to general clauses regarding public policy or good morals, etc. even though laws or ordinances do not expressly prescribe specific provisions unlike the Patent Law. The reasons why inventions contrary to public policy or good morals will not be patented according to the Patent Law are not based on industrial policies but considered as a matter of fact (refer to Nakayama's report above). It is not clear, however, if violation of public policy or good morals can be a bar to patentability if the Patent Law would not have no expressly prescribed provisions.

Precedent cases and academic views indicate the following reasons of law as sources of law in the case of unwritten laws: principles of equality, principles of proportion, principles of estoppel, principles of good faith, and principles of procedural justice (refer to "Summary discussion about administrative laws" authored by Naohiko Harada); and abuse of rights and principles of faith and sincerity (refer to "Basic matters regarding administrative laws" edited by Takenori Murakami). When reviewing precedent cases with special regard to invalidity of administrative acts, administrative acts were often judged to be invalid on the ground of the following defects, among the categories of defects of administrative acts: because the act(s) concerned abused rights (which is frequently noted in judgments made by the lower level of courts); and because the act(s) concerned violated the principles of good faith (which was the judgment made by the Supreme Court on August 17, 1965, although the principles of good faith were not expressed).

No academic views expressly accept public policy or good morals, however. When looking at precedent cases, we found the judgment that Article 90 of the Civil Code prescribes acts or legal relation from the viewpoint of private laws and has never been applied to procedures of buying out farmland, which is the effect of exercise of public power (made by the Tokyo High Courts on January 29, 1954). In these cases, administrative acts conducted on the side of the administrative office had reasons for blaming. These judgments are therefore not applicable to the issue of whether the administrative office can rule out an application for license or refuse a notice or not when the individual who has made the application or has submitted the notice has such reasons for which his/her acts should be blamed. That is why it is stated that the principles of equality, proportion and good faith play important roles as binding principles for the discretion that the administrative power has (refer to "Outline of administrative laws" authored by Toshio Fujii). On the other hand, unlawfulness in the State Redress Law is judged not only when the acts(s) concerned violate the legislative laws but also when the act(s) concerned is contrary to the reasons of law (e.g. public policy or good morals, principles of faith, and abuse of rights), although some interpret this matter in a narrow sense and others, in a wider sense (refer to "Administrative Laws (Revised version)" authored by Toshi Takada). Accordingly, there are no grounds indicating that the administrative laws exclude the idea employed by the Civil Code that maintenance of public policy or good morals, etc. is given the supreme importance from the viewpoint of laws and regulations, but instead we should interpret that laws will not help realization of an immoral act (note that it is stated in "New version: Administrative Laws" authored by Jiro Tanaka that "the reasons or law or logical sequences which indicate what things should be according to the sense of justice in the general society have significant meanings as the basic principles for interpretation of laws and also as complementary sources of laws if some defects are noted in laws"; Tanaka thus stated the existence of legal grounds and pointed out, as one of the grounds, "Rules for the Conduct of Trial" announced by the Cabinet in 1876).

{Note} "All legal relations should be governed by public policy or good morals. Public policy or good morals is regarded as the philosophy to govern the whole systems of laws. In other words, the idea that exercise of rights and fulfillment of duties should follow the principles of good faith, setting limits to self-help, and the fact that the reasons of law are used for interpretation of legal acts represent nothing but specific application of the philosophy of maintaining public order and good morals." (refer to "General Rules of the Civil Code" authored by Sakae Wagatsuma).

The authors would like to take the Family Registration Law as an example. Regarding a notice on the child's name, Article 50 of this Law only prescribes that "the Chinese characters that are in common use in Japan and that are easy to read shall be used for children's names" (Article 50-1) and "the scope of the Chinese characters that are in common use in Japan and that are easy to read shall be defined by relevant orders" (Article 50-2). We can interpret that these provisions have nothing to do with the meaning of the child's name. Concerning this interpretation, so-called *"Akuma-chan"* case occurred as described below.

In 1993, a person submitted to a city hall a notice stating that his child's name will be *"Akuma* (in Japanese which translates as "devil" in English)." The notice was accepted and this name was entered on his family register document. Following this, the city hall gave instructions to the person who filed the notice that since naming his baby *"Akuma"* was an abuse of the parent's right of naming their child and the child's name stated in the notice was inadequate, the person was requested to submit a different name. The city hall then decided to regard this baby's name as "not named yet," stated "not named yet" in the column of birth in the family register document, and eliminated the name *"Akuma."* The person who had filed the original notice was dissatisfied with this decision and filed a motion for complaint to the Family Courts. It is said that the city hall's decision was in accordance with the Response by the Civil Affairs Bureau, the Ministry of Justice (dated September 14, 1993). In response to the motion for complaint, the Family Courts decided as follows: when the right of naming the child is abused and such abuse is evidently unreasonable from the viewpoint of the generally accepted idea by the society, the city, town and village mayors are allowed to refuse the notice regarding the child's name concerned; this is applicable to the name of *"Akuma"*; however, since the notice was once accepted by the city hall, the rules that the city hall should observe are that they try to persuade the parents to make an application for correction of their family register document even if the name submitted violates the rules of the Family Registration Law; the city hall did not do this and eliminated one-sidedly the entry *"Akuma"* from the register document; and this elimination was illegal and accordingly, the entry "not named yet" should be eliminated (refer to "A child named *"Akuma""* authored by Aiko Noda, Jurisuto No. 1042). The city hall was dissatisfied with this decision and immediately filed an appeal to the Court. However, the person who filed the original notice withdrew his motion for complaint and gave a different name to the child. The case thus ended.

The above-described case is not related to public policy or good morals but involved banning of abuse of rights. The point in this case is whether or not the administrative authorities can refuse acceptance of a notice on the basis of the idea employed by the Civil Code that banning of abuse of rights is given the supreme importance, even if the Family Registration Law, an administrative law, does not prescribe any relevant provisions. The side of the administrative authorities (which are, in this case above, the city hall and the Ministry of Justice) and the Court admitted that the name *"Akuma"* is evidently unreasonable from the viewpoint of the generally accepted idea by the society and accordingly, they were allowed to refuse acceptance of the notice concerned. Prior to the occurrence of this case, the circular concerning the Family Registration Law had been issued, which prescribes that when a notice on a name not conforming to the provisions of Article 50 of the Law is submitted, such notice should not be accepted. It is therefore considered that in the case above, the Court took a positive attitude toward abuse of the right of naming.

Article 37 of the Administrative Procedures Law established following the case above prescribes that "as far as a notice satisfies the following conditions: a documented notice has no inadequate entries; a documented notice contains required documents as attachment; and a documented notice meets the other requirements by laws and ordinances concerning the form of the notice, it shall be regarded that the procedural duty of completing the notice concerned is fulfilled at the time when the notice concerned is delivered to an office of an institution which is designated as the entity to which the notice concerned is submitted." In subsequent cases, the interpretation of the relevant articles of the Administrative Procedures Law may also be an issue to be addressed.

(3) Meaning of Public Policy or Good Morals

(i) Classification of public policy or good morals

Article 90 of the Civil Code stipulates "*contra bonos mores*" (violation of public policy or good morals). This Article and Article 1, which stipulates public welfare, banning abuse of rights and violation of the principles of good faith, are regarded as general clauses. Article 90 prescribes that a juristic act which is contrary to public policy or good morals shall be null and void and produces a wide range of legal effects: when a person causes damage to others because of his/her act is performed in such a manner as contrary to public policy or good morals, the act is regarded as a tort and the person shall be liable for compensation for damages; and when payment is contrary to public policy or good morals, the payment is illegal and no one shall be entitled to claim for return of unreasonable profits. The contents of this Article, like the other general clauses, represent extremely abstract concept, however. Accordingly, the idea of public policy or good morals should be determined by taking into account the customary practices of the society and the ethical thoughts of the relevant time.

{Note} When looking at foreign countries, Germany has a similar concept of public policy or good morals to Japan (although, there is no concept of public policy in Germany) and France has her own concept of public policy or good morals. Some of the political policies in France have recently been revised and the following revisions, among other, are made by legislation or courts' decision: life insurance shall be immoral and therefore null and void since it speculates on human life (by the Law in 1930); intermediation of marriage is immoral and contrary to public policy (by the judgment of the Court of Appeals in 1944); and transfer of customers between individuals who run their own business independently is contrary to vocational policy (by the judgment of the Court of Appeals In 1961).

It was considered at the beginning of legislation that public policy was different from good morals. At present, however, these two are considered as similar concepts having an identical objective, according to which the following seven categories of specific *contra bonos mores* (violation of public policy or good morals) were classified by Sakae Wagatsuma before the War on the basis of precedent cases are still now generally accepted: <1> those which are contrary to humanity or morality; <2> those which are contrary to the idea of justice; <3> acts which produce unreasonable profits or benefits by adversely utilizing another individual's unthoughtfulness and/or difficulties; <4> those which pose extreme restrictions to the individual's freedom; <5> limitation of freedom of business; <6> disposing property which is the base of living a life; and <7> those which are outstandingly speculative (refer to "General rules of the Civil Code" authored by Sakae Wagatsuma).

The classification of precedent cases by Wagatsuma focused on pre-war cases and it is extremely difficult to classify post-war precedent cases according to Wagatsuma's classification. Some claim that the contents of this classification have changed in character. In recent years, many proposals are made for new classifications in addition to Wagatsuma's classification. For example, one proposal is to classify legal interests that have been protected under Article 90 of the Civil Code, according to individual norms and orders as follows: <1> violation of the constitutional order; <2> violation of the order of laws and regulation under the public laws; <3> violation of the order under the trade laws; <4> violation of the order under the family laws; and <5> loss of legally protected interests which are under establishment. According to this new classification, the majority of the recent cases are included in the category of the violation of the order under trade laws, whereas there is a decreasing number of cases included in the category of the violation of the order under family laws. With special regard to "loss of legally protected interests which are under establishment," marriage between homosexuals, surrogacy, and selling & buying organs are included in this category, although no precedent cases in this category have yet occurred in Japan (refer to "Types of violation of the provision regarding public policy or good morals prescribed in Article 90 of the Civil Code" authored by Hiroki Nakaya, in a book "Study of violation of public policy or good morals" edited by Yoshio Tsubaki and Susumu Itoh). Matters regarded as ethical problems in the fields of life sciences and reproductive medical technology may mostly be included in this category of "loss of legally protected interests which are under establishment."

For relation between public policy or good morals and abuse of rights, both of which are regarded as general clauses, public policy or good morals are considered to be simple criteria for examination for abuse or rights or requirements for abuse of rights. On the other hand, public policy or good morals involve conclusion of a contract, i.e. a stage at which rights are generated, whereas abuse of rights involve exercise of the rights thus generated. When we follow this idea, the above-described abuse of the right of naming may be interpreted to be a violation of public policy or good morals if we focus on the name given to the baby. Recent academic views and precedent cases do not mention abuse of rights and this is because cases to which abuse of rights is applicable according to the conventional concept are handled by more specific and individual provisions owing to legislation and legal interpretation (refer to "Public policy or good morals and abuse of rights" introduced above).

(ii) Cases in which application of advanced science and technology to medical practices involves public policy or good morals

Both inside and outside Japan, there exist not many cases in which application of advanced medical technology is contrary to public policy or good morals. In France, the Court of Appeals adjudicated that an association to recruit and introduce surrogate mothers was null and void on the grounds of the laws or any other regulations according to which non-profiting associations are null and void if they are contrary to the public policy that the human status is inviolable and contrary to good morals (refer to "Public policy or good morals in precedent cases in France" authored by Joji Nanba introduced above). In Japan, some theories argue that surrogacy agreements are contrary to public policy or good morals and therefore null and void.

On the other hand, the Japanese Association of Gynecology and Obstetrics announced their opinions regarding in vitro fertilization and embryo transplantation (in October 1983), studies handling human sperm, ova and fertilized eggs (in March 1985), a system of registering and reporting clinical implementation of in vitro fertilization and embryo transplantation (in March 1986), selection of sperm (in August 1994), use of organs, etc. from dead fetuses or newborns in studies (January 1987), fetal diagnosis for any malformation (in January 1988), freezing/storing and transplanting human embryos and ova (in April 1988), clinical implementation of microscopic fertilization method (in January 1992), multiple pregnancy in the case of in vitro fertilization and embryo transplantation (in February 1996), artificial insemination between non-spouses and sperm donation (in May 1995), the range of clinical application of in vitro fertilization and embryo transplantation in humans (in October 1998), and pre-implantation diagnosis (in October 1988). The Association indicated their opinions that each of these medical practices should be performed under certain conditions. On the basis of these opinions, in vitro fertilization or embryo transplantation, for example, was performed in 17,992 women using fresh embryos, in 1,531 women by using frozen embryos, and in 6,559 women by microscopic fertilization (in the year of 1995 for each technology). We cannot deny the performance thus achieved. On the other hand, when application of reproductive technology is contrary to the conditions proposed in the announcements of the Japanese Association of Gynecology and Obstetrics, can we make an immediate judgment that such an act is contrary to public policy or good morals? This is a difficult issue.

Regarding cloning technology, the Japanese Association of Gynecology and Obstetrics stated in the announcement entitled "Opinion about in vitro fertilization and embryo transplantation" that "when implementing in vitro fertilization and embryo transplantation, gene manipulation shall not be performed." The announcement defines the "gene manipulation" here as artificial implementation of gene engineering, cloning, creation of heterogenous hybrids or chimeras, etc. and lists the following manipulations: biological manipulations such as viral implantation; physical manipulations such as irradiation and mechanical manipulations using micro-manipulators; and chemical manipulations such as administration of chemical substances which may affect humans. The Association stated in the announcement that these manipulations are contrary to the objectives of in vitro fertilization as medical practice and therefore are contrary to medical ethics.

2. Standards of the Duty of Care in Medical Care

(1) Relation between Medical Doctors and Researchers

The authors will discuss the relation between medical doctors and researchers by taking cloning technology as an example. As previously described, creation of a cloned baby requires removal of a human unfertilized egg or fertilized egg. According to the current technology, it is difficult to raise an ovum into which a human somatic nucleus is transplanted, outside the uterus. It is therefore necessary, when returning back the ovum into the womb for development and growth, to make a cloned embryo implanted in the uterus so that the embryo

subsequently follows the same process as in the case of in vitro fertilization.

The Medical Practitioners Law prescribes that "nobody but those officially qualified as medical doctors shall practice medicine" (Article 17). The Law further prescribes that a person who violates this rule shall be punished with imprisonment for at least two years or with a fine of at least twenty thousand Japanese yen (¥20,000). In this provision, practicing medicine is defined as performing medical acts continuously and repeatedly. The contents of medical acts are complicated and diverse, and also always change along with advancements of medicine. It is therefore difficult and inappropriate that laws define medical acts: the Medical Practitioners Law does not define medical acts. Under these circumstances, precedent cases and academic views indicate various ideas for the definition of medical acts. The idea generally accepted at present is "any act which may cause hazards to the human body if not performed under medical judgment and technology of medical doctors." Specifically, the following acts related to reproductions are regarded as the medical acts according to precedent cases: to a woman suffering from irregularity of menstruation, acts of hearing from her symptoms, making a diagnosis, and inserting a menstruation-inducing pill into the uterus by using uteroscope and forceps; and an act by a practitioner of moxibustion of inserting uteroscope into the uterus for internal examination. Academic views regard artificial insemination as a medical act (refer to "Medical Affairs Law" authored by Hiroshi Noda). The authors therefore consider that removal of unfertilized or fertilized eggs, introduction of cloned embryos into the uterus for implantation and any other necessary technologies for creation of cloned babies correspond to medical acts and nobody but medical doctors can perform these medical acts. The authors have regarded application of cloning technology as research and in this sense, the creation of a cloned baby (i.e. implantation of a cloned embryo into the mother's womb) that the authors has proposed to be regulated should be included in the category of core regulations in the previous section is advanced research activity and at the same time, is a medical act.

In reality, it is doubtful whether or not acts of transplanting a somatic nucleus to an unfertilized or fertilized egg and performing other similar levels of techniques required for creation of a cloned baby can be regarded as medical acts as far as these acts are performed for the sole purpose of research. We thus cannot deny the possibility that these acts may be performed by those other than medical doctors. However, some of the acts performed for the purpose of creating cloned babies cannot be nothing but medical acts and accordingly, medical doctors will take final responsibilities. As described in the previous section, it is possible to impose restrictions on creation of cloned babies only by regulating medical doctors even if there are no direct regulations on researchers, on whom it is difficult to impose regulations.

If a cloned egg grows in vitro, then of course it becomes necessary to impose direct regulations on researchers. However, considering the currently available technology level, we cannot foresee such possibility for a while.

(2) Restrictions on Medical Care Acts

The medical care act is an invasive act to a human body in nature. When individuals other than medical doctors perform medical care acts for purposes other than medical care, such conduct will constitute a criminal bodily injury according to the Penal Code and the person concerned will not escape liability for a tort according to the Civil Code. As far as medical doctors perform the medical care act that should be performed by medical doctors, those medical care acts are justifiable acts and illegality is excluded. In this section, the authors will make general investigation regarding to what extent medical care acts are regarded as legal causes of exemption of illegality, not getting into specific investigation regarding individual responsibilities such as criminal liability, civil liability and further, administrative liability according to the Medical Practitioners Law, etc.

A medical care act is required to satisfy the following three criteria in order to be regarded as a justifiable act: <1> an act which is medically appropriate; <2> an act which is valid as a medical technology; and <3> a patient has given his/her consent. When a medical act does not satisfy one of the three criteria, there may be no legal ground of exemption of illegality for that act. The authors will focus on criteria <1> and <2> in this section.

Acts having medical appropriateness are defined as those which are appropriate, from the objective viewpoint, for saving a patient's life and maintaining and promoting a patient's health, and which are valid when implementation of these acts is required. In this sense, cosmetic surgery, consented injury, eugenic surgery, sex-change operation, surgery for intentional artificial abortion, etc. become problematic. In the field of reproductive medical technology, artificial insemination and in vitro fertilization may also be problematic according to this definition. Regarding the validity of medical care technology, medical examinations which do not achieve the level of available medical care that the authors will describe later, experiments on live human bodies, and clinical studies for investigational purposes may cause problems in relation to this definition.

The contents of individual acts, however, are extremely affected by changes over time in the social conditions. For example, the medical affairs related law prescribes the requirements for obtaining certificate of medical doctors, etc., the duties of medical doctors, the standards of medical institutions, but contains an extremely small number of provisions pertaining to the details of medical care acts. Accordingly, medical doctors are allowed to have a greatly wide range for exercising their own discretion regarding medical care acts. This is because the administrative office has assumed the policy of not as a rule being involved in the details of medical care and health care related instructions and of allowing medical doctors, etc., who have acquired expertise and skills in medical care, to freely make their own judgment regarding these matters since medical care is a highly specialized area (refer to "Medical Affairs Law" authored by Hiroshi Noda). The major reasons why medical doctors are allowed to exercise their own discretion in this wide area are described below (refer to "Medical Care Acts and Laws (New Version)" authored by Ohtani):

(i) Since a pathological change, i.e. a lesion, is determined by a patient's own physical conditions and is affected by environmental conditions under which the patient exists, application of medical technology which is approved from the viewpoint of medicine will differ among individual patients and thus will be individualized.

(ii) In order for a therapeutic act by a medical doctor to produce benefit to the patient concerned, the medical doctor is allowed to be free to make full use of his/her academic learning, skills and experience.

The authors will review these requirements later in a specific manner. In any way, if it is judged from the viewpoints of medical acts described above that cloning technology lacks medical validity and appropriateness, then the act of performing cloning technology cannot be regarded as a justifiable medical act and is therefore an illegal act, without having any specific laws established regarding this technology.

Considering the characteristics of medical practice, the Japanese national government has avoided policies of imposing direct regulations on the contents of medical care by legislation. The Medical Practitioners Law was amended in 1949 and Article 24-2 of the amended Law prescribes that "when the Minister for Health and Welfare judges it necessary, in a case in which material harms to public health may be caused, to give relevant directions regarding medical care and health care related instructions, to the medical doctors in order to prevent such harm, the Minister for Health and Welfare shall be entitled to do so (Article 24-2-1)," and that "the Minister for Health and Welfare shall, when giving directions under the aforementioned provisions, consult with the Medical Ethics Council (Article 24-2-2)." The right that the Minister for Health and Welfare has for giving instructions is thus prescribed and he/she is entitled to exercise this right after consulting with the Medical Ethics Council. According to these provisions, the "Standards that Medical Doctors and Dentists shall Follow regarding Blood Transfusion" was already announced (Announcement by the Ministry of Health and Welfare in 1952). In addition, many administrative Circulars regarding the contents of medical care were issued, although the issuance of these Circulars was not directly related to the right to directions described above (refer to "Medical Affairs Law" authored by Hiroshi Noda). These Circulars may at least be based on the provisions of the Article introduced above.

Some claim that directions given by the Minister for Health and Welfare have no legal binding power but are merely regarded as instructions, while the others argue that the directions have a norm-like binding power. When reviewing judgments made at the lower level of courts, many of them follow the former theory.

{Note} The case that triggered the amendment of this law was as follows: blood taken from a donor infected with syphilis who was paid remuneration was transfused to a patient who subsequently contracted syphilis. The Supreme Court admitted negligence of the medical doctor concerned and adjudicated as follows: if the medical doctor had conducted reasonable medical interview, the medical doctor should have been able to foresee the occurrence of the results; the individuals who are engaged in professions involved in the management of life and health of humans (i.e. medical practices) shall have the obligation of taking the best care necessary from the experimental viewpoint to prevent risks, according to the nature of the profession concerned."

(3) Appropriateness of Medical Acts

Unlike discussions regarding the validity of medical care acts and the level of available medical care which the authors will describe later, discussions regarding the medical appropriateness of medical care acts are frequently related to the issue of public policy or good morals. We will investigate them by introducing specific cases.

(A) Cosmetic Surgery

The medical act should have the objective of eliminating harms caused by a disease and in addition, the elimination should overweigh the medical act which is an invasive act. Cosmetic surgery does not have this objective and it is therefore interpreted that cosmetic surgery is not a medical care act. The common view in the field of criminal laws follows this interpretation and indicates a negative stand to the opinion that cosmetic surgery is a medical care act (although it is explained that since a victim has given his/her consent, elements constituting a crime are incomplete or illegality is escaped). In the field of civil law, it is generally understood that cosmetic surgery is application of specialized medical technology and has nothing different from the usual medical examination. There is a precedent case, although made by a lower level of court: "eliminating mental dissatisfaction, e.g. admiration for beauty and worry about poor-looks, is also accepted as a positive objective" (Tokyo District Court on May 1, 1972). Subsequently, the Medical Service Law was amended and to the amendment, cosmetic surgery was added as a new department of medical examination. Cosmetic surgery is thus officially approved legally, although it is said that cosmetic surgery is still treated slightly differently from ordinary medical care.

(B) Consented Injury

As far as consented injury is not contrary to public policy or good morals nor social reasonableness, the injury is not regarded as a criminal bodily injury and not punished. There is an opinion that although no one is entitled to decide how to treat another's life, it is considered that every person has the right of making their own decision regarding how to treat his/her own body and this right of treating their own body can be exercised by the person that owns the body concerned: a person who tattoos on the body of a Japanese gangster (*yakuza*) or who helps a *yakuza* amputate the tip of a little finger either as a punishment or as a token of penitence is not punished (refer to "Medical Care Acts and Laws (New Version)" authored by Ohtani).

(C) Intentional Artificial Abortion

The Mother's Body Protection Act (and also the old Eugenic Protection Law) prescribes that when it is judged that continuation of pregnancy or delivery may awfully damage the mother's health for physical or economic reasons, a medical doctor is allowed to perform artificial abortion after obtaining consent from the mother herself and her spouse. The true aim of this provision is that intentional abortion performed from the social viewpoints shall only be accepted when continuation of pregnancy or delivery may gravely damage the mother's health. In reality, however, "it is impossible for medical doctors to investigate or confirm how the mother's health is affected by economic reasons, and medical doctors do not have such obligation. We can see that social political views are directly incorporated in the medical appropriateness of artificial abortion. An attending medical doctor can make his/her own judgment regarding whether an operation for intentional artificial abortion is reasonable or not and the legal regulation on artificial abortion has no substantial significance. The provisions regarding artificial abortion by the Penal Code are therefore meaningless" (refer to "Medical Care Acts and Laws (New Version)" authored by Ohtani).

(4) Level of Available Medical Care

The authors do not consider it necessary to discuss the validity of medical care in detail here and will only discuss the level of available medical care. In the medical affairs law, responsibilities of medical doctors (responsibilities of fulfilling obligation and not conducting torts) on the basis of accidents caused by malpractice are investigated and the idea of "level of available medical care" is employed as the medical doctor's duty of care: medical doctors have the duty of performing medical examination and therapy within the level of currently available medical care; and even if a medical doctor did not perform medical examination and therapy beyond the level of currently available medical care, he/she will not be liable for non-fulfillment of obligation nor a tort.

There are two specific levels of available medical care: "level of medicine as a study (i.e. the level of fundamental studies which are under progress with the objective that results of such studies will be standardized)" and "level of practical medical care (i.e. the current objectives to be achieved by medical care which is already standardized among professional health care individuals)." The level of available medical care employed by the medical affairs law is the latter one (refer to "Between Medicine and Laws" authored by Toyoharu Matsukura; and the judgment made by the Supreme Court on March 30, 1982). This level of available medical care is general and objective. Differences of medical care among hospitals are related to the actual state or circumstances and do not affect the level of available medical care. Accordingly, medical doctors should have the duty of recommending patients to change a hospital (i.e. when a medical doctor finds him/herself not to give appropriate medical examination and therapy, he/she shall have the duty of giving explanation to the patient and recommending that the patient should move to an appropriate medical institution). The level of available medical care should be based on publication at meetings of scientific associations or in journals, discussion, and additional studies (refer to Matsukura's report above). Precedent cases also indicated that a new therapy attains the level of available medical care only after the following process: many additional studies of the new therapy have been performed and the new therapy has been accepted by relevant scientific associations as a valid therapy; and subsequently, the new therapy has, through the use of education, been widely spread and planted its roots in clinical practice performed by specialized medical doctors (refer to the judgment made by Fukuoka High Courts on June 21, 1982).

As a specific example, the Supreme Court adjudicated on March 30, 1982 that as of the beginning of 1970, light coagulation method for the treatment of retinopathy of prematurity was at the trial stage where only researchers taking a leading part in this particular field began to perform this method on an experimental basis, and therefore, no duty of giving explanation & instructions nor duty of recommending change of hospital was recognized from the view point of the level of available medical care. The Courts judged that this therapeutic method attained the level of available medical care in 1975 when the Study Group of the Ministry of Health and Welfare published the "Study Report concerning Diagnosis and Therapeutic Standards for Retinopathy of Prematurity" (refer to the judgment made by the Fukuoka High Courts on June 21, 1982 and the judgment made by the Supreme Court on March 26, 1985). In this case also, we have to pay attention to the fact that reports presented at meetings of scientific associations or reports provided the yardstick for determining validity of medical care.

The discussion above is concerned with civil liability. Regarding criminal liability also, when determining whether or not criminal death caused by negligence in the conduct of business (under Article 211 of the Penal Code) is constituted, the level of available medical care is used as the criterion, on the basis of which is decided whether or not the medical doctor concerned has violated the duty of care that he/she should fulfill when performing the medical care act concerned (refer to "Criminal Liability for Medical Care-Related Accidents" authored by Osamu Sakuma in a book "Contemporary Medicine and Medical Affairs Law System" edited by Masayoshi Ohno). Regarding selection of operative procedures for surgical treatment, however, the fact that medical doctors are allowed to exercise their own discretion is considered as follows: since the medical doctor concerned selected the operative procedures concerned for surgical treatment on the basis

of his/her own expertise and experience, his/her legal responsibility cannot be called for, and the range within which medical doctors are allowed to exercise their discretion is determined by the level of available medical care (refer to Sakuma's report above). We do not find many such cases among precedents and the majority of the precedent cases are related to rudimentary errors.

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## Section 3: Violation of Standards

### 1. Influence of Violation of Public Policy or Good Morals

The authors have so far discussed possible guidelines for medical practices from the viewpoint of public policy or good morals. We would like to summarize the discussion in this section. First of all, there are two issues to be addressed with regard to public policy or good morals discussed in Section 2-1 as described below.

(1) Is application of cloning technology contrary to public policy or good morals?

(2) If application of cloning technology is contrary to public policy or good morals, which actions could the administrative office then take to cope with this violation?

(1) We consider it difficult to make a comprehensive judgment regarding whether or not application of all cloning technologies is a violation of public policy or good morals since there exists extremely diverse modalities of their application. However, as discussed in Sections 5 and 6 of Part 1 of this Report, investigation of individual cases for determining if the legally protected interests are violated by a certain status of research reveals specific findings regarding the contents of the technology concerned, distinguishes between what is to be regulated and the act concerned, identifies which specific aspect of the legally protected interests is to be violated, and provides any other relevant information, then such information meets the minimum necessary conditions for the administrative office to make its own judgment, which may enable establishment of a certain standard for regulation. In other words, as in the case of the above-described guidelines for gene recombination experiments, such standard thus established may have some social and disciplinary effects.

Public policy or good morals represents the ethical consciousness in the society and should ultimately be based on the agreement among the ordinary citizen and be a generally accepted idea by the society. However, under the circumstances in which science and technology providing a basis of ethical consciousness in the society or generally accepted idea by the society is extremely advanced and specialized and in addition, such science and technology itself is progressing, it is difficult or even impossible for the ordinary citizen to draw a definitive conclusion and foresee any accompanying effect. As such, if no agreement of the ordinary citizen is achieved or no common idea is born without any actions taken by anybody, then it is expected that scientific associations, an assembly of researchers, or the State that is responsible for administrative matters would take an initiative to formulate standards (guidelines) in such a manner as deemed acceptable by the society.

From the above-stated viewpoints, it is desirable that guidelines be formulated on the basis of opinions from relevant individuals involved in a variety of related areas through open hearing procedures, especially after due consultation with those who might be both advantaged and disadvantaged or damaged by such guidelines, by the authorities that will take ultimate responsibilities. Guidelines shall never be based on any arbitrary investigation. Accordingly, it is desirable that such guidelines be not those formulated by scientific associations which primarily outline and summarize opinions from specialists in areas of science and technology but those issued by the State which represent opinions from those engaged in a wider range of areas.

If guidelines are investigated and formulated in the manner described above, we have no doubt that such guidelines would effectively function as social discipline. In other words, they could be used as an internal discipline of a scientific association, according to which violators may be expelled from the association, could provide a basis for administrative guidance by the administrative office, or could be used as the standards for statutory actions such as licensing by the administrative office. The previously introduced Bylaw issued by the municipal government of Suita City can be regarded as an example indicating that the social norms having the above-described character are used as a standard of a bylaw which has legal enforcement power.

If it is accepted that such guidelines provide sufficient norms for the ordinary citizen (with regard to formulating procedures, regulating intensity, procedures of making changes to cope with advancement in science and technology, etc.), then it may not be impossible to directly employ such guidelines as norms for administrative disposition or law suits. Regarding an entity who would ultimately make a principal judgment regarding whether guidelines functioning as social norms provide an immediate yardstick according to which a certain act is judged to be contrary to public policy or good morals, for example, the administrative office plays that role when an administrative disposition is performed on the basis of the Medical Practitioners Law, etc. and the Court plays that role when compensation for damages is claimed (note that regarding the former, the authors introduced the judgment by the Mito District Court, in Section 1, as an example indicating how the Court made its judgment regarding the disposition made by the administrative office regarding specialized technology).

The authors would like to give some supplementary explanation to emphasize that such guidelines, even when formulated by the State, do not have any legislative character, but should be regarded as accepted social norms since they are formulated by referring to opinions from specialized professionals and resulting from review of awareness about public policy or good morals in the society. When looking at the future ways the administrative authorities should behave, the necessity of such operations of providing public services which can only be performed by the State may be increased. As a matter of course, we may find any problems with incorporation of such guidelines, which are formulated in the manner described above, into laws or ordinances when they become enacted as a law.

(2) Assuming that application of cloning technology constitutes a violation of public policy or good morals and that there exist related licenses (e.g. by the Medical Service Law or the Radiation Hazards Prevention Act) or notices, what types of actions could be taken by the administrative office? First of all, the two actions described below can be considered when an act is contrary to public policy or good morals.

<1> The administrative office decides not to grant a license in response to an application made for license or decides not to accept a notice on the ground that the act concerned is contrary to public policy or good morals.

<2> The administrative office decides to grant a license or accepts a notice on the ground that a violation of public policy or good morals is not a criterion for licensing nor a formal requisite of the notice concerned.

In response to the decision in the case of <1>, if the person who made the application for license or prepared the notice filed a motion to the Court that the decision of non-licensing should be canceled or the notice should be accepted and the Court accepted the motion, then the Court would accept that the act contrary to public policy or good morals was valid and assist the realization of the act contrary to public policy or good morals, which is unjust (note that some argue that in a law suit filed against the administrative office, the claim by the person who made the application or prepared the notice may be accepted, but in a case where the person who made the application or prepared the notice are those who are directly involved in the act contrary to public policy or good morals, the juristic act of the person who made the application or prepared the notice may be judged invalid, although this argument may merely complicate the case). The above-described concept is found in the case regarding the Family Registration Law, i.e. the *"Akuma-chan"* case in which it was judged that the person who submitted the notice abused his right of naming his child and the notice concerned was not accepted.

Against the license or the notification in the case of <2>, if someone tries to file a motion of complaint or file an administrative law suit, the competency of the individual(s) concerned or the area within which the administrative office is allowed to exercise its discretion would be an issue. In any case, it is required to make a judgment on a case-by-case basis. On the other hand, those who directly involve the act contrary to public policy or good morals could file a civil law suit against the person who was given the license or who submitted the notice to confirm that their juristic act is invalid and to call for injunction against the violating act. In this sense, a motion of complaint made against the administrative office or an administrative law suit may have no substantial significance.

In light of these points, the authors consider that if guidelines have criterion for disposition by the administrative office as indicated in <1> above and disposition is performed according to such criterion, then such guidelines may be actually effective even without having any legislative provisions.

2. Influence of Violation of Standards for Medical Care Acts

Next, the authors would like to see if cloning technology satisfies the criteria described in Section 2-2.

(1) Is cloning technology an act which is medically appropriate?

(2) Is cloning technology an act which is valid as a medical technology?

(1) The medical appropriateness is related to what objectives a certain medical care act is intended to achieve. Generally, the following are approved to have medical appropriateness: <1> treatment and improvement of disease; <2> prevention of disease; <3> correction of deformity; <4> delivery and medically required abortion; <5> studies using patients for therapeutic purpose; and <6> experiments contributing to advancements in medicine (refer to "Laws from the viewpoint of medical doctors" authored by Toyoharu Matsukura). Of course, subjects of medical care have changed over time. For example, it was once considered in the past, in accordance with the criteria above, that cosmetic surgery and sex-change operation did not have medical appropriateness. Among reproductive medical technologies, there still exist strong opinions raising doubts about artificial insemination, in vitro fertilization, and implantation of a fertilized egg in the womb of a surrogate mother. Considering the special character of medical care, medical doctors have more grave ethical responsibilities than professionals in other fields and the issues listed here are related to the ethical aspects involving medical doctors. However, the problems related to medical appropriateness should ultimately be resolved not from the viewpoints of medical ethics but from the legal and social viewpoints (refer to "Medical Care Acts and Laws (New Version)" authored by Minoru Ohtani). It was considered in the past that organ transplant did not have medical appropriateness. At present, however, legislation is put in place to support organ transplant, which is accepted as a medical care act. On the other hand, lobotomy was once used as a medical technology but its medical appropriateness is currently ruled out. At present, artificial insemination and in vitro fertilization between spouses are regarded as medical care actions complying with the announcements made by the Japanese Association of Gynecology and Obstetrics, whereas in vitro fertilization between non-spouses do not comply with them. We should be careful, however, in making an immediate judgment that this non-compliance indicates non-medical appropriateness of in vitro fertilization between non-spouses.

As previously described, artificial insemination and in vitro fertilization are measures to cope with infertility. On the other hand, creation of a cloned baby through the use of cloning technology does not result from fertilization and subsequent pregnancy process, which indicates evidently the remarkable heterogeneity of this technology. When creating a cloned baby, there is no fertilization between an egg and sperm. Creating cloned babies is therefore not an infertility therapy intended to eliminate obstacles in pregnancy. As cloning technology is understood as one of the technologies to develop new breeds of animals, improve the quality of animals, and increase the number of animals in the field of stock-breeding, cloning technology is an act of increasing individuals in number which is a totally new experience for humankind. We therefore can consider that cloning technology is totally different from medical care acts such as treatment of disease or correction of deformity.

Finally, the authors compare cloning technology with surrogacy, for which many individuals express a negative opinion against its appropriateness as a medical care act. We previously introduced the idea that surrogacy is contrary to public policy or good morals. A violation of public policy or good morals is the legal judgment. As in the case of narcotic drug use or the case where a Japanese gangster (*yakuza*) amputates the tip of a little finger either as a punishment or as a token of penitence, it is not undue that the medical care act concerned lacks medical appropriateness because it is contrary to public policy or good morals. As previously explained, surrogacy may confuse the social order but, on the other hand, the State can make its discretionary decision on surrogacy related matters. A new family relation created by cloning has no legal friction and will cause greater confusion. The idea that creation of a cloned baby is contrary to public policy or good morals is therefore not unreasonable, on the basis of the discussion made on surrogacy.

(2) Medical technology displays its effectiveness in many cases by invading in any way the body of the individual that undergoes the medical technology. When evaluating medical validity, the benefit and risk attributable to the invasion concerned should be compared in particular and a medical technology is valid only when the benefit outweighs the risk. This risk/benefit ratio is derived from medicine or medical ethics. It is understood, however, that drawing a standardized criterion is difficult in reality and legal evaluation is necessary to determine the validity of a medical technology to be approved (refer to the report above authored by Minoru Ohtani).

Regarding safety of cloning technology, the donor of a somatic nucleus has almost no risks and some risks are foreseeable in the donor of an egg and the women who receives implantation in her womb. Overwhelmingly greater risks and genetic effects are posed to children and descendants. On the other hand, only the donor of a somatic nucleus enjoys benefit. The usual forms of artificial insemination and in vitro fertilization have the same character of benefiting one-sidedly. When focusing on the beneficiary, an extreme one-sided benefit is noted in cloning technology as compared to artificial insemination or in vitro fertilization where at least the couple, both wife and husband, enjoy the benefit. When focusing on the risk, cloning technology has higher risk of causing greater genetic effects as compared to artificial insemination or in vitro fertilization where highly sensitive germ cells are used. From the viewpoint of safety, cloning technology greatly differs qualitatively from artificial insemination or in vitro fertilization.

(3) As discussed above, cloning technology has many problems in terms of appropriateness and validity. In any event, what is discussed here is that cloning technology is an act which is not medically appropriate nor valid. It may be necessary to make such judgment focusing on the character of a medical care act, in addition to a judgment focusing on the character of a science and technology. It may be required that this non-appropriateness and invalidity of cloning technology is confirmed by legislation. However, considering the fact that the medical affairs related laws have not defined any legal grounds for the level of medical care or the standards of operating medical care technology, if standards of medical care acts are established in a form of guidelines issued by a scientific association or by the State, then it may be highly likely that such guidelines can be used as a ground for non-licensing or punishment of an act according to the regulations of the currently effective Medical Practitioners Act, etc.

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## Section 4: Supplementary Discussion: Theory of Technical Standards

(1) At present, many technical standards are established for the purpose of enforcement of administration. These standards are in the form of laws and regulations but some of them are formulated as standards issued by a national committee. The forms of laws and regulations include statute, Cabinet Order, ministerial ordinance, announcement, and circular (note that the lower level regulations do not specify legal justification). An example of standards issued by a natioanl committee is the guidelines for examination of reactor locations (which provide the

criteria for individual examinations within the area in which the relevant national committee is allowed to exercise its discretion) that the Atomic Energy Commission uses for examination prior to expressing its opinion regarding granting license to installation of a nuclear reactor (which actually means investigation in response to request for advice regarding granting license to installation of a nuclear reactor which is to be given by the Prime Minister).

In scientific law suits in which the legal issue is the validity of specialized technical standards used for judgment for whether installation of a nuclear power plant is to be licensed, the idea of "uncertainty law" is often proposed when discussing to what extent the examination and judgment by the judicial power affects the discretion made by the administrative office. This idea originated in Germany: the principles of essential theory have functioned, according to which the Federal Parliament shall make its own decision regarding essential matters and shall not entrust the administrative power with the decision; under these circumstances, when the legislator is, regarding the comprehensive standards stipulated by the Atomic Energy Act, forced to an invalid law or to totally abandon discipline, it is difficult from the viewpoint of legislative procedures to dare to make such forced condition effective by a law; and as a result of this, the idea of uncertainty law becomes accepted. (Regarding the theory of technical standards, the great concern is what examination rights the Court is allowed to have under the idea of uncertainty law when the Court examines a discretion made by the administrative office for specialized technology. Takagi's report described later addresses its primary theme of introducing and reviewing several theories, e.g. "theory of accepting professionals' opinions which have been expressed in advance," which restrict the Court's right to overall examination of technical standards issued by the administrative bureau in Germany.)

Various discussions have been performed to determine, under the "idea of uncertainty law," if the Court's judgment can affect the discretion made by the administrative office for specialized technology. The following theories, among others, have been proposed: a "theory of substituting substantial judgment" according to which the Court is allowed to conduct a complete examination to such an extent as affecting or even substituting the administrative judgment; a "theory of accepting professionals' opinions which have been expressed in advance" which was proposed along with subsequent installation of scientific facilities; and a "theory of supporting the administrative judgment" which provides the basis that the administrative power has the authority of making a final judgment. When looking at academic views in Japan, there are two representative ones described below. A "theory of procedural examination of substantiality": "Licensing installation of a nuclear reactor is characterized by a comprehensive judgment by assuming that there may exist in the future uncertain and probability-oriented events which are based on inference from knowledge and findings in highly advanced and specialized areas of technology, by taking into account various factors such as the utility of a nuclear reactor, and by evaluating all of these elements to determine what is really necessary for the future. Licensing installation of a nuclear reactor is a highly specialized technical judgment and at the same time, is regarded as a "political decision" which will affect the formation of the future society. We have to accept that the licensing is not a purely legal judgment based on facts which are objectively established. …Accordingly, when considering these discretionary elements that licensing installation of a nuclear reactor has, we can consider it reasonable that the Court avoided thorough examination of substantiality according to the theory of substituting substantial judgment. …As a matter of course, if the juridical examination has these limitations, then strict considerations are necessary to prevent arbitrary judgment by the administrative power or self-righteous decision under the name of professional technology. … When looking at the safety examination for nuclear reactors, the current system is based on the absolute reliance on investigational examination and judgment from the viewpoint of specialized technology which is made by the Atomic Energy Commission and the Nuclear Reactor Safety Specialty Committee, and accordingly, whether or not actual examination performed was in accordance with the spirit of the law should be strictly examined by the juridical power." (Refer to "Ikata Nuclear Plant Case" authored by Naohiko Harada, Extra Issue of Jurisuto No. 126.) A "theory of supporting the administrative judgment": "The defendant shall be liable for positively proving the safety of the nuclear reactor and its proof of the reasonableness of exercising its discretionary power was not sufficiently enough. It is enough for the plaintiff to present doubts or anxiety about the nuclear reactor, and the defendant must present evidence or explanation sufficient to eliminate these doubts. However, since the Court is not in a position of making a final judgment regarding the safety of the nuclear reactor on the basis of its own findings, the Court should take a neutral position to examine if the defendant's explanation is sufficient to eliminate the plaintiff's doubts. If it is difficult to judge which is right, the defendant's claim is accepted according to the German theory of supporting the administrative judgment." (Refer to "Legal Issues Regarding Nuclear Power Plant Law Suits" authored by Yasutaka Abe, Jurisuto No. 668.) It is understood that the background behind these ideas is that if the Court is requested to make such judgment, it should be a great burden to the Court and that elements affecting such judgment are not only objective technical matters in specialized areas but also policy-related matters. (In addition, regarding the method of stepwise regulation on nuclear reactor facilities, the Supreme Court made its judgment regarding a law suit of Fukushima No. 2 Nuclear Power Plant on October 29, 1992.)

The basis of these ideas is the judgment made by the Supreme Court regarding a law suit of Ikata Nuclear Power Plant, which showed the following views: the safety of nuclear reactor facility should be evaluated from many different angles and in a comprehensive manner, by taking into account the engineering safety of the nuclear reactor concerned, any other relevant social conditions and engineering competency of the entity that intends to install the nuclear reactor concerned; when evaluating the safety, matters related to foreseeability of future events are also considered and it is therefore evident that the evaluation requires an overall judgment based on most recent and updated and highly advanced scientific and technological knowledge and findings in diverse areas; considering these features peculiar to the evaluation of the safety of nuclear reactors, it is reasonable that regarding determination if installation of a nuclear reactor conforms to specific standards, the Prime Minister's reasonable judgment is accepted since the judgment is made by respecting opinions of the Atomic Energy Commission, consisting of individuals of learning and experience in their own specialized areas, which result from scientific and technological knowledge and findings in specialized areas. The Supreme Court adjudicated as follows: "In the law suit which was filed to call for cancellation of the granted licensing of installation of the nuclear reactor and in which the legal issue is whether or not the judgment made regarding the safety of the nuclear reactor was correct, examination and judgment by the Court should be based on its determination if there is any unreasonable point in the judgment made by the administrative office, the defendant, on the basis of the investigational examination and judgment from the viewpoint of specialized technology which is made by the Atomic Energy Commission and the Nuclear Reactor Safety Specialty Committee. If, in light of the currently available level of science and technology, any unreasonable points are found in the examination standards used for the aforementioned investigational examination, or errors or shortcomings which cannot be looked over are found in the process leading to the investigational examination and judgment made by the Atomic Energy Commission and the Nuclear Reactor Safety Specialty Committee that the nuclear reactor facility concerned conforms to the aforementioned specific standards, and the judgment made by the defendant administrative office was based on these inappropriate situations, it should be judged that the aforementioned judgment by the defendant administrative office has unreasonable points and accordingly, it should be interpreted that the disposition of granting license to installation of the nuclear reactor concerned on the basis of the unreasonable judgment is illegal" (refer to the judgment made by the Supreme Court on October 29, 1992). In other words, if there were no such unreasonable points, the discretionary judgment by the administrative office should be respected. As such, both the Court's views and academic views are currently against the theory of substituting substantial judgment" according to which the Court is allowed to conduct a complete examination to such an extent as affecting the administrative judgment.

For the reasons why the idea of uncertainty law is employed, the Supreme Court explains that "as far as the evaluation or examination ….. should require an overall judgment based on most recent and updated and highly advanced scientific and technological knowledge and findings in diverse areas, and because of continuous and never-stopping progress and advancement in science and technology, stipulating by law specific and detailed standards for the safety of nuclear reactor facility is not only difficult but also inappropriate since such stipulation cannot immediately cope with any change in the level of updated science and technology." In Germany also, two situations are pointed out in which it is hard to stipulate technical standards by laws: <1> when the subject of regulation rapidly changes; and <2> when details matters of relevant technology are required (refer to "Technical Standards and Administrative Procedures" authored by Mitsuru Takagi). However, when regulating science and technology itself, as discussed in (2) below, it is possible that standards other than those established as knowledge and findings generally accepted by the society may be used and it is necessary to investigate to what extent the Court is allowed to examine the administrative discretion from new different angles.

(2) In recent years, there has emerged a new category of technical standards to which the laws or the orders entrusted by the laws are not applicable. Examples of this category are, as previously discussed, the available level of technology in connection with the Product Liability

Act and the level of available medical care in relation to the medical affairs law. These levels cover a wide scope of areas and in addition, each technology progresses so rapidly that a specific technology standard cannot be established. The standards regarding life sciences that the authors have discussed in the Report are a very good example of this category of standards. The life sciences related standards may contain undefined scientific knowledge and findings which cannot be regarded as those generally accepted by the society.

Takagi's report entitled "Technical Standards and Administrative Procedures" investigates in detail "technical standards" by looking at law suits regarding nuclear power plants and air pollution control standards. In this report, he states as follows: "the properties of specialized technology that the administrative power possesses, which is claimed as elements justifying administrative discretion or administrative legislation, have two different aspects, i.e. one is expertise and technical knowledge in specialized technology areas, and the other is expertise providing the basis of political and administrative judgment which will not be confined to application of individual laws or regulations. The former is non-legal expertise and technical knowledge, which is in nature accumulated in a private area and is not always monopolized by the administrative power. The latter is knowledge which functions as a social management technology to support the administrative power and represents the most remarkable characteristic of the administrative power in comparison with the Court." Takagi thus describes that the administrative office's "judgment from the viewpoint of specialized technology," which is a legal judgment incorporating the non-legal expertise, contains "political judgment" and "value judgment." The judgment should therefore be expressed as engineering judgment and is closer to a judgment by engineers than one by scientists. His point is similar to Harada & Abe's report introduced above since both the reports indicate the two characters of standards. However, differences in concept between engineering judgment and scientific judgment are not clear in his report and in addition, it seems to us that his view is based on the assumption that there are some knowledge and findings already established as those generally accepted by the society.

Even though the existing standards may be engineering standards, the standards, etc. related to life sciences that the authors have discussed in the Report surely have the nature that allows the name of scientific standards. For example, as previously discussed about the foreseeability in connection with the Product Liability Act, the duty of care is required to perform comprehensive retrieval of past literature prior to manufacturing of a drug and in reality, science and technology related information gathering systems are operated in such a manner as meeting the demands of researchers. Considering the fact that if a researcher failed to fulfill the duty of care and did not retrieve relevant literature, then he/she is liable for the negligence, and on the other hand, if a researcher retrieved relevant literature, then he/she can escape from liability, we should regard this as not an engineering judgment but a scientific judgment. Since there is a possibility that standards based on knowledge and findings established as the common ideas of society may not allow a person to escape from liability, such standards are not written ones but are affected by currently available science and technology related activities (e.g. research activities and published reports). Such standards substantially differ from the conventional standards. The concepts regarding the available level of technology in connection with the Product Liability Act and the available level of medica care in connection with the medical affairs law have already incorporated ideas close to scientific level. If regulation was imposed on research, it would be further closer to the academic areas and would correspond to the "level of medicine as a study" when comparing the "level of medicine as a study" and the "level of practical medical care" introduced in the section regarding the available level of medical care (as previously described, it is accepted by the common view and precedent cases that the validity of medical care is based on the "level of practical medical care").

In recent years, scientific standards are formulated by considering not only safety but also ethics and social validity. Under these circumstances, standards are prepared after listening to not only professionals specialized in specific areas but also the ordinary citizen. It is therefore predicted that without involvement by the administrative power (e.g. conducting surveys of public opinion, holding public hearings or symposiums, setting up opportunities to hear from the ordinary citizen prior to formulation of standards), an increasing number of standards could not be formulated. This is not the accumulation of expertise in private areas nor the monopolized expertise by the administrative power described by Takagi. The standards formulated in the manner above may be considered to be legally effective as social norms since the Court hardly presents these standards merely by collecting scientific reports and making own judgment from the collected information.

In any event, assuming that the conventional technology standards <1> have been expressly stated on the presumption that these standards are established as the common views of society (e.g. "already standardized medical care among professional care individuals" according to the concept of the available level of medical care), <2> contain elements constituting political judgment which incorporates expertise, and <3> have the nature that these standards are monopolized by the administrative power, new standards regarding life sciences, etc. which will be required in the future, e.g. those for application of cloning technology, should have the following aspects: <1> these standards are related to the whole science and technology activities involving uncertain and undefined scientific knowledge and findings (and therefore, are hardly documented); <2> these standards strongly indicate the existence of ethical judgment based on specialized knowledge; and <3> because of the characteristics described above, these standards can be formulated by the administrative power that mediates among professionals specialized in specific areas, researchers and the society to confirm the social order. In terms of character, the conventional standards contrasts strikingly with the new standards. These differences between the two types of standards in their contents will inevitably give new aspects to the social disciplinary character of standards.

In light of the concepts of limiting the range of examination and judgment by the Court on the basis of the idea of "uncertainty law" that are indicated by the judgments made by the Supreme Court and academic views, we found a similar concept of limiting examination by the Court in the judgment made by the Mito District Court regarding gene recombination guidelines described at the beginning of this section. We might learn from this judgment that behind the judgment, the Court considers the existence of some norms (e.g. public policy or good morals, standards for medical care acts) which should be taken into account during a trial, and these norms might correspond to legal norms containing the idea of uncertainty law.

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## Chapter 2 Consensus Development Effort for Regulations

### Section 1: Parties Involved in Consensus Development

#### 1. Consensus Development Effort

##### (1) Consensus Development Effort

As seen in Chapter 1, in the application of life science and technology, especially reproductive medicine and technology, all-out effort may be required in light of its substantial effect on the nation as a whole. Even in European countries, which are on the verge of establishing legal systems regarding the subject, complete consensus was impossible as opinions varied widely.

In Britain and Germany, diverse views were presented in the Warnock report and Benda report, respectively, which were to be the basis for legislation. In France, objections against legislation were raised and examined by the Constitution Court. In Europe, where Christianity prevails throughout the entire society and life of the people, obstacles are expected in forming a consensus about ethics on reproduction, as is so noted in the introduction in the Warnock report.

In the U.S., even a nationwide abortion law is yet to be established, with legislation left to each state, much less a consensus on legislation regarding these problems, indicating difficulty with the issue of life science and technology.

Nevertheless, substantial regulations have been passed regarding reproductive medicine and science in Europe. European countries are said

to be ready for applying these laws to cloning technology. Europe's regulatory systems for this problem are highly likely to be adopted as a standard by EU and the United Nations Educational, Scientific and Cultural Organization (UNESCO). Thus, Japan will have to make its stance clear on such regulations sooner or later.

In Japan, strong voices are being raised for regulation on cloning technology, while concerns are growing about excessive restrictions on advanced science and technology.

(2) Means of Consensus Development

Under these circumstances, it is essential at least to make decisions based on varying opinions. The decision making process aside, the following describes desired methods for organizing opinions from different layers of the population so that they can be used as the basis for decision making.

The first problem in collecting popular opinions is deciding <1> from whom, and <2> how, such opinions should be collected. The first point will be handled in later discussion. For the second point, it is important that such opinions should be gathered from as many layers of the population as possible and that active debate should be carried out over conflicting views, thus deepening the understanding of acceptable regulations.

To form a consensus, a number of requirements must be taken into consideration, including disclosure, accountability, education, and the role of nonprofit organizations. Legal restrictions have been discussed in Chapter 1. We will first review two items closely related to these restrictions. The other items will be considered in later sections.

The purpose of collection and discussion of opinions is to provide sufficient data and materials to enable decision makers to make adequate decisions and build a basis for reaching a consensus on relevant regulations by balancing complicated interests among concerned parties systematically and comprehensively. It is desired, therefore, to involve a wide range of parties with different interests in heated debate through symposiums, hearings and other means of exchanging opinions, thus allowing comprehensive judgments. To realize efficient discussion procedures, it is also important to organize and maintain records of past debates so that they can be utilized for later reviews.

This consensus development approached will be examined in Section 2. Instead, this section will focus on which parties opinions should be collected from.

2. Interested Parties

Let us focus in detail on whose opinions should be collected.

In selecting parties to be involved in consensus development efforts, it would be useful to examine a wide range of interests, including those of patients and ordinary citizens. Although it is impossible to include all concerned parties, debate should be based on clear identification of present and latent conflicts of interests.

In our discussion, such parties concerned are classified into three categories: Category 1, composed of those whose interests will be directly related to restriction on research, Category 2, comprising those with indirect interests, and Category 3, with those who are free from such interests but needed in carrying out debate on this issue.

Although, as pointed out in the discussion of Category 2, it is in reality not easy to determine the category to which each concerned party should belong, it would be useful to give typical examples for each category.

(1) Category 1 (Directly Interested Parties)

These parties are those who can lose their rights or interests as a direct result of regulations. As described in Chapter 1, these parties will be entitled to claim their rights or interests by initiating countermeasures such as legal actions. In our discussion, if we extend the definition beyond legal terms, typical interested parties in this category may include the following:

<1> Recipients of technology (Patients, their families, etc.)

These persons, generally including patients, their families and agents, have the results of life science and technology applied to themselves. They should be granted the right to make their own decisions regarding safety, health incentives, and the selection of applications as research results. To respect the rights of patients, declarations of patients' rights have been established. In Japan, informed consent has been discussed with an increasing number of physicians adopting the concept. However, there is no unified agreement among patients and their families with regard to the application of research results, making it necessary to analyze their varying views. In medical practice in our country, there are two types of patients who have or will receive research results.

- Patients who put their trust in their researchers (physicians) and leave the decision to them, and patients who make their own decisions after receiving explanations from researchers (physicians).

In selecting a technical application, conflicts can arise among concerned parties. This requires us to be well acquainted with such conflicts in carrying out debates. These conflicts involve:

- Patients in a coma who are unable to make choices on their own concerning decisions based on research results (medical treatment) vs. their family who are totally entrusted with these decisions.
- Mothers who make a decision (e.g., abortion) based on research results (pre-natal medical examination) vs. their babies (fetuses), who have no other choice than accept their decision. (Conventionally, in reproductive technology, fetuses have been considered to be part of their mother. With advancements in reproduction medicine and technology, however, it is becoming necessary to see the mother-fetus relations from a new perspective.)
- Patients who would like to make their own decisions based on explanations by their physician vs. their family who would ask that explanations not be given to the patients for fear of possible negative results.

In addition, conflicts of interests are probable between those who benefit and those who anticipate disadvantages as a result of the application of a new technical method. These conflicts will involve:

- Those who have had successful surgery vs. those whose surgery fails.
- Those who seek blood transfusion to sustain their life vs. those who reject transfusion for religious reasons, which represents conflict not over an outcome but over an act itself.

In discussing our issue, those positions will require consideration.

<2> Test subjects

These parties contribute to medical studies by volunteering to be tested with a research result before it is directly applied to patients.

Conflicts of interests are also possible between those who have received effective medication (beneficiaries) and those who have been given

ineffective drugs (victims), as in administration of drugs and placebos.

<3> Future generations

These parties are members of younger generations who will be affected by the application of research results activities that have been conducted on the present generations. These generations are deprived of opportunities to express their opinions. Thus, it is necessary to have someone speak on their behalf. Deepened discussion will have to be made, however, on whether their parents should be the only party to act for them.

<4> Researchers (Physicians)

Researchers are those who conduct studies on life science and technology and apply the results of such activities to patients and subjects. They are directly affected by legal regulation. Nonetheless, they should not be regarded as always in conflict with patients and subjects, because, as Hippocrates cited in his oath, "You shall be for the good of the sick to the utmost of your power," they are under an ethical obligation to integrate with those to whom science and technology are applied. ("In Britain, women succeeded in forcing the government to legalize abortion by drawing support from physicians," Bioethics Over Life Science, Kiyoko Kinjo.)

This category includes a wide variety of parties, from physicians to advanced medical scientists to researchers working at pharmaceutical businesses. They are guaranteed freedom to conduct research and development activities, including those for new drugs, as well as practicing medicine. At the same time, they are required to provide medical explanations to those concerned, including patients and subjects.

Even these researchers (physicians) will have conflicts of interests among them. For example:

- Differences in medical policy between the physician and assistants within the same medical group.
- Conflicts among involved medical departments in the same hospital over the application of a research result (e.g., over the selection between surgical and internal treatments).
- Conflicts between researchers who pursue their own studies and research managers who stress the overall policy of the hospital regarding research programs, budgets and safety of the their studies.

Further, if any researchers conduct studies (and treatment) for the sake of their beneficiaries at their request, conflicts between the beneficiaries and the victims may also be reflected in the relationships among researchers.

<5> Administrative bodies

These parties determine the framework of laws and guidelines for the benefit of the country as a whole, while adjusting differences among competing policies. In addition to safety regulations, they are under an obligation to promote life science and technology related to medicine and work out strategies and policies from a long-term perspective.

(2) Category 2 (Indirectly Interested Parties)

Unlike those falling under Category 2, these parties are not directly involved in social rights and interests. Instead, they are deeply interested in the state of society brought about by the application of technology and express their views, especially through political activities. They do not, however, play a secondary role due to the fact that they are involved only indirectly. Rather, depending on the issue and technology, they may play a far more important part than those in Category 1.

<1> Those who view the state of society from a specific perspective

Although they do not have special interests directly connected to research results and regulations, religious groups supported by a large portion of the population and social activity groups have substantial political influence. In addition, their opinions are frequently presented in a logical, systematic manner. In Europe and the U.S., the strong influence of Christianity is felt across reproductive technology. This is because religious groups, Catholic churches in particular, have a large internal legal system, such as canon law, equivalent to civil law, and a well organized philosophical system, which serve as a global standard. Some civil law systems are said to have been established under these influences. Thus, it is justifiable to involve these parties in our discussions.

<2> Ordinary citizens

When making decisions on our issue, it is necessary to collect opinions from a wide range of citizens. It is difficult to define citizens and the category they should belong to. They may fall under Category 2 or Category 3. Or they may require a different category. For convenience, they are classified into Category 2 in our discussion.

Generally, citizens are not directly concerned with life science and technology, that is, they are not researchers nor are research results applied to them. They are non-specialists without special knowledge. In establishing scientific and technological policies, there will arise more opportunities to ask for opinions of citizens. The requirements for a citizen are unclear, compared with those for the parties falling under <1> to <5> of Category 1. The problems include:

- If citizens are defined as those not falling under <1> to <5> of Category 1, what is their role? Are they expected to represent common sense and social norms and complement opinions of "other" parties, thus serving as a "judge" for each party?
- Citizens are required to be interested in the research field involved in the regulation and participate in debate with clear ideas of their own. Or, if any citizens are unwilling to participate in debate for some reason, how should we treat them? Who will speak on their behalf?
- If citizens are thought to express a wide variety of opinions, is it possible to select them in an impartial manner? Or, should we focus on unique opinions? Depending on the purpose of a discussion, it is possible to adopt a jury system, in which citizens are sampled.
- It is impossible to foresee the interests of a citizen in research restrictions. Therefore, if any interests are identified during the course of discussion, the relevant citizens may be transferred to another category.
- Are foreign governments and foreigners "citizens?"

As seen above, it is extremely difficult to define the scope of a citizen. There are varying views over measures for forming a consensus involving citizens. It is hoped that discussion on the definition of "citizen" will be deepened by examining these cases individually.

In debates on reproductive medicine and technology in Europe and the U.S., few parties seem to have been chosen as citizens by various committees. Depending on the subject, civil participation may be extremely difficult. (Citizens have two functions: participating in politics and administration, and presenting a wide variety of views not available from interested parties. Extensive studies have been conducted on the former function in connection with general problems including application of science and technology. Our discussion will focus on the latter function, especially with respect to application of results of life science studies.)

(3) Category 3 (Neutral Parties)

These parties, who are not classified into Categories 1 or 2, are experts who hold neutral positions free from interests, and thus should be asked for opinions.

〈1〉 Researchers without direct interests

These are parties who are exclusively engaged in a field of study including the type of studies which will come under regulation but whose studies themselves are not involved in such regulation. With their studies not restricted by the regulations, they are in a position that permits them to present their views based on their professional knowledge and experience.

〈2〉 Peripheral researchers

These are researchers and intellectuals capable of expressing their views based on their professional knowledge and experience with respect to the field of study that covers the studies to be restricted.

Such parties will include:

- Researchers who specialize in a field of study that is not to be regulated but related to the field to be restricted.
- Law experts who study the legal system regarding regulation.
- Life ethicists who study ethical aspects of reproductive technology.
- Journalists who are acquainted with a wide range of views and engaged in proliferating these problems through media.

〈3〉 Intermediary experts, etc.

Experts in consensus development who are capable of explaining advanced scientific knowledge to subjects and the public. With increasing demands for accountability on science and technology policies, diversifying opportunities for discussion are likely to appear in the future. More experts will be in demand in line with this trend.

3. Anticipated Problems with Interested Parties (Cloning Technology)

(1) Typical Interested Parties

Our discussion so far has been concerned with those who should provide us their opinions in reviewing regulation issues related to the application of scientific and technological results. The discussion has focused on conflict of interests among various parties, as well as categorization according to their admissibility. The section to follow provides practical examples to make clear the way selection of interested parties should be made.

As in Chapter 1, our discussion focuses on cloning technology in connection with legal restrictions. Our first concern is which parties desire regulation of research activities in cloning technology. Those who want to have a cloned baby by presenting their body nuclei and physicians and researchers are directly interested persons. Women who present their fertilized or unfertilized ovum to have it implanted in their uterus have also similar interests in regulations.

On the other hand, opposition to views of subjects, physicians and researchers, who would support cloning technology, would be raised by those who view the state of society from a specific perspective, who are in Category 2. In Europe and the U.S., these oppositions are clearly propagated by Christian-oriented religious groups, while, in Japan, no distinct groups are present as opposition parties. The absence of such parties may reflect the fact that, in Japan, no strong voice has been raised against the promotion of cloning technology, with little discussion carried out on the subject. Clear, logical opposition is essential not only to have supporters to clarify their justifications but also to balance both sides, although too much opposition may obstruct consensus development, as was seen in the U.S.

We should not rely simply on citizens for opposing views. Instead, it is desirable to absorb opinions of those in Category 2 (well organized public opinion polls are highly useful tools), and reconstruct them systematically so that they can be used in discussions on regulations.

(2) Example of Opinions on Cloning Technology

At the end of this section, we should list opinions, just for reference, which would be heard among interested parties described in the preceding paragraphs with regard to restrictions on reproductive technology.

(i) Category 1

a. Recipients of Technology (Patients)

Those who are willing to present their body nuclei would claim the following rights and interests:

〈1〉 Infertility treatment based on the decision of an individual as with artificial insemination and external fertilization.

(To the question, "What do you think about the application of cloning technology to enable childless couples to have babies with genes of either the husband or wife without normal fertilization?" in "Survey on intellectuals regarding cloning technology," conducted in September 1998 by the Cabinet Public Relations Office, 67.3% of the 2,114 subjects responded that the technology should not be applied, while 22.0% said they would approve such technology if there is no other means of having babies and if it is conducted on certain conditions, including authorization by an investigative organization.)

〈2〉 Opportunities for males with azoospermia and those without the ability to produce sperm to have babies.

〈3〉 Right of females to have babies without male interference.

〈4〉 Right to make one's own decision in preserving one's genes in a perfect form.

On the other hand, the interests of those who use body nuclei provided by other persons might include:

〈5〉 Reproducing babies from the body nuclei of their dead children.

b. Subjects

If those offering the use of their uterus are considered to be subjects, they would claim:

〈1〉 The right to bear babies as with a surrogate mother, even if the newborns do not belong to them.

〈2〉 Parental rights to newborns, as with a surrogate mother.

c. Researchers (Physicians)

Some researchers (physicians) desire the application of cloning technology on the basis of their belief in free academic activities, while at the same time being tempted to implement it at a strong request of patients. (The patients' position has been discussed above.) They would assert:

<1> Research activities not aimed at human cloning should be permitted for the sake of the welfare of mankind.

<2> With some scientifically advanced countries where no restrictions are established, Japan is likely to lag behind them in para-cloning technology, such as reproductive medical technology.

<3> Even if regulations are imposed domestically, some Japanese researchers would conduct such studies overseas so long as there is demand for the technology.

<4> Cloning technology is not against their ethical and religious beliefs.

According to the previously mentioned "Survey on intellectuals regarding cloning technology," four percent of the 2,114 subjects surveyed responded with an affirmative answer to the question, "Is it desirable to apply cloning technology to humans?." Their justifications included (Multiple answer):

<1> Even if they are produced by cloning, humans can change in characters, such as ability and appearance, according to circumstances where they are brought up, so that there are no grounds for seeing human cloning as a special evil. (58.8%)

<2> The characters of a cloned baby are largely predictable by judging its parents because it is produced through interaction between the sexes, so that there is no need to be concerned about cloning technology. (40.0%)

<3> The production of more superior humans would contribute to the advancement of human society. (22.4%)

<4> Human cloning is a result of the advancement of science and technology, a sort of thing that cannot be stopped. (29.4%)

<5> Others. (12.9%) Undecided. (2.4%)

(ii) Category 2

As formerly mentioned, the presence of groups who view the state of society from a specific perspective is not so conspicuous in Japan as in Europe and the U.S. In addition, the definition of "citizen" is unclear. These factors make it difficult to collect a sufficient amount of opinion.

In the same survey above, 1,976 respondents, or 93.5% of the 2,114 subjects, agreed to the notion that the application of cloning technology to humans is not adequate for ethical grounds. Their reasons in multiple answers included:

<1> The application of the technology to humans would impair human dignity because the production of humans should involve both sexes. (67.7%)

<2> Human cloning treats humans simply as a means of achieving predetermined purposes rather than creating free individuals. (43.6%)

<3> It should never permitted to predetermine the characters of a human. (29.8%)

<4> There is a possibility that a society might be created where a priority is placed on producing humans with superiors characters. (26.1%)

<5> There is a possibility that social discrimination might arise between naturally born humans and cloned humans. (14.9%)

<6> Cloned newborns are not guaranteed safe growth. (10.0%)

<7> Others. (4.6%) Not decided. (0.3%)

To the question, "How regulation on human cloning should be implemented in Japan as compared with foreign countries? Choose one answer," the 2,114 subjects surveyed answered

<1> Japan should keep pace with other countries. (42.8%)

<2> Stringent regulations must be imposed, independently of other countries, to prevent unrestrained development in the technology. (38.1%)

<3> Whether stringent or lukewarm, such regulations should reflect the real state of Japan. (13.7%)

<4> Regulations should be loose enough to encourage research activities. (1.9%)

<5> Others. (2.0%) No specific idea. (0.3%) Not decided. (1.1%)

The findings of this questionnaire suggest that those classified as Category 2 hold affirmative ideas about regulating cloning technology.

The opinions provided here represent typical opposing views prevalent at present. It is necessary to create more opportunities for exchanging opinions in an active manner, thus accumulating a substantial amount of concrete views.

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## Section 2: Approach to Consensus Development

### 1. Promoting Debate on Advanced Technology

As previously mentioned regarding the application of cloning technology, an interim report was submitted on June 15, 1998 by the Clone Subcommittee of the Bioethics Committee under the Council for Science and Technology. Another report was available on June 3, 1998 from Bioscience Group of the Subcommittee for Promotion of Special Fields under the Education Ministry's Academic Examination Committee. In addition, the Survey on Intellectuals regarding Cloning Technology was conducted in September 1998.

In response to these views, newspapers actively presented their opinions. The following summarizes their main ideas expressed in commentaries and editorials. These excerpts do not include all information provided. It should also be noted that they may not exactly convey what the papers meant, since they were compiled at the discretion of the authors of this report. The points of their comments are as follows:

<1> Some comments insist on considering legal regulations, while others assert that such considerations are too early.

<2> Some refer to regulations only on cloning technology, while others cover reproductive medical technology on the whole, as well as basic bioethics legislation.

<3> Diverse views are presented concerning how debate should be carried out (e.g., the necessity of public debate and preliminary assessments).

In view of high social credit given to newspapers in Japan, it would be necessary to pay considerable attention to their comments when considering regulations on cloning technology. (It is difficult to determine whether papers should belong to Category 2 for their "influence on society" or Category 3 for their "neutrality."

With regard to pros and cons on the introduction of legal restrictions described in <1> and the scope of restriction in <2> , legal and technological issues were examined in Chapter 1. Our discussion to follow will focus on the methods and procedures to be taken for debate on regulations mentioned in <3> . Methods for public debate have been examined in a number of studies and some have been applied to various administrative fields. Our discussion, therefore, will concentrate on the method for discussion over the application of life science and technology, especially cloning technology.

Discussion on life science and technology is, generally speaking, centered on the application of science and technology to society. In commenting on how science and technology, including cloning technology, should be applied, an increasing number of commentaries are referring to technology assessment (such as those in Asahi Shimbun on January 14, 1999 and Nihon Keizai Shimbun on November 7, 1999). It goes without saying that effects on society and other influences should require full scrutiny before the application of science and technology, such influences are extremely difficult to estimate. Under these circumstances, it is interesting to note that particular stress is made on technology assessment for the second time in Japanese history. As stated in the introduction of this report, it was technology assessment that was adopted first as part of realistic policies at a time when the importance of the relations of science and technology to humanity and society was recognized. There are some reasons for the failure of the technology assessment concept to settle in Japanese society. Thus, it does not suffice to apply technology assessment in just the same way as it was applied previously. Nonetheless, it would be useful in deepening our discussions to understand the background and limitations of technology assessment and recognize the fact that new movements for technology assessment are in progress in European countries (the Consensus Conference, which frequently comes up in conversation these days, is a variation of new technology assessment). We should also note that technology assessment will give us much to learn about consensus development methods (Europe's new technology assessment is drawing attention as a civil-oriented approach). On the other hand, Science Council of Japan has recently pointed out the importance of developing science and technology based on comprehensive, long-term perspectives. To realize such a goal, it is essential for researchers and scientists to cooperate with their counterparts in other fields, legislators and people in general, instead of confining themselves to their own domains, thus keeping themselves abreast of new trends in society. In this sense, problems and developments in technology assessment are worth keen attention.

Table: Summary of major paper editorials and commentaries on cloning technology.

<1> June 9 (Yomiuri Shimbun): Progress and ethics of reproductive technology
On in-vitro fertilization: It would not be right to deny the benefits of science and technology only from an ethical perspective; intellectuals and professionals should discuss this problem in relation to parental rights, inheritance rights and social standards; it is desired to examine the necessity of establishing guidelines and legal regulations and present them for public debate; the Ministry of Health and Welfare and the Japan Obstetrics and Gynecology Society should endeavor to build a system to cope with technological innovations.

<2> June 13 (Tokyo Shimbun): Full review necessary on medical technology
European countries which permit in-vitro fertilization also have related laws; before Japan faces the same problems as those in the U.S., it should discuss the necessity of setting up effective guidelines and laws; the important point is to develop public debate on a nation-wide basis, and not leave the initiative to the medical circle.

<3> June 16 (Yomiuri Shimbun): Rules should be established for reproductive technology
The first thing to do is to set up a national rule regarding reproductive technology as a whole, including cloning technology; the government is required to act promptly to work out a unified view and a control measure.

<4> June 21 (Mainichi Shimbun): Regulations are premature
Considering that guidelines were enough to deal with genetic treatment, there is no need to impose legal restriction on cloning technology.

<5> June 22 (Nikkan Shimbun): It is natural to curb cloning technology as
the application of cloning technology to humans will impair human dignity and cause safety problems. (The paper did not discuss the option between guidelines and laws.)

<6> July 7 (Asahi Shimbun): Reproductive technology, cows and man
Consistent rules should be provided for the entire range of reproductive technology, including guidelines and laws; the important thing is what discussions these regulations should be based on; it is essential that women and handicapped persons participate in discussion; all processes of discussion should be open to the public, but neither the Council for Health Sciences nor the Council for Science and Technology are yet to meet this requirement.

<7> July 8 (Nikkei Shimbun): What cloning technology means
The application of cloning technology to humans will not only cause ethical problems but also bring about many problems, including total destruction of cattle.

<8> July 10 (Tokyo Shimbun): Ethics tried by "cloning"
Cloning technology is not so difficult to apply; in light of this fact, self-imposed rules are not enough for the technology; legal regulations must be considered; it is essential to review restrictions on reproductive technology as a whole and establish well-balanced regulations.

<9> July 30 (Tokyo Shimbun): Never, human cloning
To establish effective restrictions, debate should be extended to involve the nation as a whole.

<10> December 18 (Sankei Shimbun): Establish basic bioethics legislation
Set up an extraordinary bioethics committee to enforce a comprehensive basic law.

<11> December 23 (Mainichi Shimbun): Conscience of scientists at stake
It is realistic to compile guidelines on condition that cloned embryos are forbidden at least for the time being.
[For reference] February 8, 1998 (Nikkei Shimbun): Fundamental discussion desired for bioethics
Bioethics legislation may be required; we should now start extensive debate to be ready for future developments related to this problem.

(1) Appearance and History of Technology Assessment

The term "technology assessment" was first used in a report submitted in 1966 at the Scientific Research and Development Subcommittee of the U.S. Congress. The concept of technology assessment was born as a countermeasure to deal with pollution and urban problems as well as criticism against advancing science. In this report, technology assessment was seen as an early warning system for dangers created by science and technology.

Technology assessment is regarded as part of policy science for science and technology ("Technology Assessment: Practice & Method," Reikichi Shirane). Policy science, said to have been started in the 1950s, is an interdisciplinary study of policy formation. Since engineering

and information engineering were introduced into this field during the 1960s, policy science has evolved to be applied to the solution of policy issues. One of its major developments is a systematic budgeting method called PPBS (Planning Programming Budgeting System). In the course of its evolution, policy science produced the concept of technology assessment. Technology assessment is an attempt to make comprehensive assessments on human society as a whole in connection with science and technology. Technology assessment is not simply a method but also offers attitudes and ways of thinking in evaluating science and technology.

In 1969, the National Environmental Policy Act was enacted in the U.S. This led to the establishment of an organization for conducting technology assessment with extensive authority. The term "technology assessment" involved effects of science and technology not only on the environment but also on economy and society.

A technology assessment bill was submitted for discussion by Representative Daddario, followed in 1971 by a report, "A Technology Assessment Methodology: Some Basic Propositions," by Mitre Corporation at the request of the White House. The Office of Technology Assessment (OTA) was set up in 1972 under the Technology Assessment Act. Technology assessment was conducted by the office 20 to 30 times a year, producing a total of about 750 reports.

In the medical field, movements were made toward implementing technology assessment on its own, independently of OTA's technology assessment activities. Under its plan, several measures were put into practice, including the implementation by the National Institutes of Health (NIH) of a standardization program for medical treatment and examination and the establishment of a state-run medical technical center. There was a strong need for evaluation concerning the effectiveness of medical activities, because medicine was being practiced just by custom in those years without sufficient data on the effectiveness of medical practice. A surge in medical costs during the 1980s prompted the society to review the medical payment system, involving medical technology assessment deeply in policy making activities for cost reduction and more effective medical techniques. In recent years, medical technology assessment is shifting its attention from subjects directly related to medical professionals to the quality of life and ethical issues. The results of assessment reports are drawing more attention from the general public as well as physicians ("Technology for Genes, Thoughts on Genes," Yoshinori Hiroi).

Globally, on the other hand, OECD stressed the importance of technology assessment in the 1970s, as seen in the Brooks Report, which emphasized the role of technological assessment in April 1971 under the title, "Science, Growth and Society" at an OECD council. In 1973, a report, "Society and the Assessment of Technology," was released by Francois Hetman, an OECD technology assessment member. Further, in 1975, methodological guidelines (OECD, Methodological Guidelines for Social Assessment of Technology) were compiled regarding technological aspects of social assessment.

With respect to technology assessment conducted in by OTA of the U.S., the quality of its assessment reports was reviewed internally (OTA, Policy Analysis at OTA: A Staff Assessment). According to the review, these reports ranged widely in quality. Stressing that it is essential for reports to make themselves readable, analyze objectively and make congressional views clear, OTA admitted that the OTA reports as a whole failed to propose a sufficient number of practical policy options. External criticisms, most of which were from the Congress, included poor readability of the reports and too much Chapter in addition to too much time taken in compilation of the reports. It was also pointed out that some reports lacked objectivity.

Amid calls for cuts in the government budget, OTA went out of operation in 1995.

(2) Technology Assessment in Japan

Technology assessment was first introduced to Japan when a special study team on industrial projections visited the U.S. in 1969. This concept was incorporated as part of governmental policies n 1971, as the Council for Science and Technology stated in its 5th report that it is becoming increasingly important for us to introspect negative effects science and technology has on us and to predict their positive and negative influences based on human dignity. As early as 1971, the Science and Technology Agency conducted technology assessment research on pesticides, high-rise buildings and computer-based education. In the same year, similar research was carried out by the Ministry of International Trade and Industry on nuclear steel making. One survey implemented by the Science and Technology Agency involved 14 researchers, with five of them specializing in architecture, three in law and economics, three in psychology, two in medicine and one in welfare. The study was designed to clarify problems with an increasing number of skyscrapers and examine possible solutions. The results produced such proposals as the development of a network system against disasters, the establishment of flexible measures that incorporate changing elements, the importance of countermeasures against mass consumption and waste disposal problems, and the necessity to review effects on population and the human mind. In 1974, the Science and Technology Agency started a practical program based on technology assessment. In the same year, the Ministry of International Trade and Industry introduced technology assessment into its technological development program for new energy.

Years later, a number of methodological studies for the implementation of technology assessment were carried out, resulting in a variety of assessment methods. The number of technology assessment studies implemented by the government increased from five in 1971 to 10 in 1974. Since this year, research activities have been declining, with only one carried out in 1984.

The following tables present state-sponsored technology assessment surveys, with surveyors, year of implementation and themes.

Table 1 Technology Assessment by the Science and Technology Agency (STA)

| Surveyor | Year | Theme |
|---|---|---|
| STA | 1971 | Pesticides |
| STA | 1971 | High-rise buildings |
| STA | 1971 | Computer-based education |
| STA | 1972 | Vertical take-off and landing aircraft |
| STA | 1972 | Technological systems in newly developed towns |
| Power Reactor & Nuclear Development Corporation | 1974 | Technology assessment of atomic power plants based on system dynamics |
| STA | 1974 | Pipeline waste transport systems |
| STA | 1974 | Image telecommunications systems |
| STA | 1975 | Spread of synthetic paper |
| STA | 1975 | Marine ranches |

| | | |
|---|---|---|
| STA | 1975 | Artificial rain |
| STA | 1976 | Integrated use of laser systems |
| STA | 1977 | Technical problems closely associated with national life |

Table 2 Technology Assessment by Ministry of International Commerce and Industry (MITI)

| Sponsor | Year | Theme |
|---|---|---|
| MITI | 1971, 1972 | Nuclear steel making |
| MITI | 1973 | ME technology (medical systems for isolated districts) |
| MITI | 1973 | Electronic desk calculators |
| MITI | 1973 | Microwave cookers |
| MITI | 1973 | Synthetic paper |
| MITI | 1974 | Plastic material technology |
| MITI | 1974 | New packaging technology |
| MITI | 1974 | Preliminary assessment of a large-scale project |
| MITI | 1974 | Fuel-cell vehicles |
| JEMA | 1974 | Direct cycle helium turbine power system |
| MITI | 1975 | Microcomputers |
| MITI | 1975 | Large-scale utilization of methanol |
| KEIC | 1975 | Digital watches |
| KEIC | 1975 | Home video tape recorders |
| MITI | 1976 | Energy storage systems |
| MITI | 1976 | Vinyl chloride resin |
| JITA | 1976 | Thin-wall stainless lining steel tubes |
| JITA | 1976 | Cable fire preventives |
| MITI | 1976 | Preliminary assessment of a large-scale project |
| MITI | 1977 | LTA aircraft systems |
| MITI | 1977 | In-place leaching |
| JITA | 1977,1978 | Large conductive equipment cooling systems |
| JITA | 1977 | Hot-melt type glues |
| JITA | 1977 | Energy exchange technology |
| MITI | 1978 | Rust preventive technology |
| MITI | 1978 | Sulfur paving technology |
| JITA | 1978, 1979 | Industrial robots |
| JITA | 1978 | Corrugated pipes |
| JITA | 1979 | Fast rust-proofing methods for zinc |
| MITI | 1979 | Fine ceramics |
| MITI | 1979 | Long-life vehicles |
| JII | 1979 | Goal of advanced technology and economic effect analysis |
| MITI | 1980 | Hydrogen-fueled aircraft systems |
| MITI | 1980 | Biotechnology |
| JITA | 1980 | Very low temperature metallic materials |
| JITA | 1980 | Desalination using solar heat |
| MITI | 1980 | |

| | | |
|---|---|---|
| MITI | 1981 | New metal deoxidization processes |
| JITA | 1981 | Home video information systems |
| MITI | 1981 | Revolutionary function fibers |
| MITI | 1982 | Flying boat transport systems |
| JITA | 1982 | Effects of technological revolutions (ME) on employment |
| MITI | 1982 | Development of sensor technology and extension of applications |
| JITA | 1983 | Technological development for construction of an advanced information society |
| MITI | 1983 | Technological development for fiber industry |
| MITI | 1983 | Social impact of degeneration of urban facilities |
| | 1984 | Analysis of impacts of the material revolution and the next-generation and technology |

JEMA: Japan Electrical Manufacturers' Association. KEIC: Kansai Electronic Industry Center. JITA: Japan Industrial Technology Association. JII: Japan Industry Institute.

Source: JITA, Study on Conditions for Effective TA.

According to the "Survey Report on Actual State of Technology Assessment in Businesses," released by the Japan Industrial Technology Association, the most popular technology assessment methods employed in Japan are brain storming, the checklist, investigation of actual conditions, and the relevance tree.

A number of evaluation reports are available concerning the technology assessment activities during the 1970s. The Technology Assessment Concurrent Session working for the General Meeting of the Science and Technology Council summarizes in its 1975 report "Basic Concept and Promotion Policy for the Introduction of Technology Assessment": Technology assessment is not adopted in society as extensively as initially expected; factors in this slow proliferation include unfulfilled establishment of refined predication and evaluation methods required for technology assessment, difficulty with collection of widely ranging information, unfinished establishment of a reliable assessment base, and incomplete understanding by the society of the concept of technology assessment. With respect to the implementation of technology assessment, the report stressed the necessity of voluntary implementation in each stage of the assessment process and the need for sponsors, who are largely developers of the technology to be assessed, to take an impartial stance in the implementation of technology assessment. According to the report, social values play an essential role in the evaluation of the results of technology assessment, while such values are rapidly diversifying nowadays, making it extremely difficult to identify common values of the population. This means that the key to success in technology assessment is to accurately identify trends in changing values. Admitting the presence of barriers to the implementation of technology assessment and at the same time encouraging its promotion, the report cited, as requirements for successful technology assessment, the recognition by the society of technologies, the development of methods and personnel necessary for implementation of technology assessment, and the establishment of social systems, such as a society evaluation system, technology monitoring system and the insurance system.

Later, in 1979, a survey was conducted using a questionnaire aimed at large businesses ("Survey on Actual State of Technology Assessment in Japan," conducted by the Future Engineering Institute under the sponsorship of the Science and Technology Agency). The results of the survey showed that most businesses recognized the significance of technology assessment but that little effort had been made to implement it, indicating that they were just on the verge of the implementation stage. The survey pointed out that, in practical application of technology assessment, they were faced with the necessity to clarify basic goals for technology assessment activities, in addition to cost problems and incomplete implementation systems. The report also said that the real objectives of technology assessment are not fully understood by businesses, stressing the importance of clarifying such objectives and educating business people. According a report in 1980 related to technology assessment outside Japan ("Survey on Actual State of Technology Assessment in Foreign Countries," by the Future Engineering Institute), governmental organizations in the U.S., such as OTA and NSF, were conducting large-scale technology assessment activities, while they were faced with several problems, including the shortage of information, the shortage of professionals well versed in multiple areas of study, and too much time taken in an activity. Revealing that most respondents were not satisfied with the level of the technology assessment methods employed, the survey concluded that Japan was not lagging behind foreign countries in technology assessment efforts and urged the country to clarify the goals of technology assessment and improve its methods.

The point common to these surveys was that it was not so easy to comprehend the concept of technology assessment and that the implementation of the technique will face such problems as acquisition and disclosure of technical information, implementation methods, and manpower.

The aforementioned 1979 survey pointed out the fact that technology assessment in Japan drew keen attention because it was introduced at a time when pollution problems were growing into social issues. Although the original purpose of technology assessment is to identify real technical needs, the government and public found hope in technology assessment as a means of predicting negative effects of science and technology. As Japan's economic growth slowed after the oil crisis, however, the country expected technology assessment to be applied to technology development. At the same time, the report said that, interest in technology assessment lost momentum as more environmental measures were taken by the government. Some businesses had the wrong impression that technology assessment is intended to curb technological development. A 1977 research by the Policy Science Institute maintained that it was wrong to regard technology assessment as a hindrance to technology. Instead it asserted that technology assessment should be considered as a method for forming a consensus on the way we see technology and build a society which would find new values through involvement of the government, businesses, social groups and public ("Survey on Technology Assessment Methodology," sponsored by MITI and conducted by the Policy Science Institute"). The government was making efforts to promote technology assessment in those years. Later developments, however, demonstrate that its efforts bore little fruit.

2. New Trends in Technology Assessment

(1) New Technology Assessment in Europe

In the 1970s, heated political debate in European countries over the construction of nuclear plants and other industrial facilities gave rise to popular movements, involving general citizens in scientific and technological issues (Nelkin, Technological Decisions and Democracy). In 1979, OECD compiled a report concerning decision making on science and technology through public participation (OECD, Technology On

Trial). Almost at the same time, the Battel Research Institute of the U.S. proposed a new technology assessment method called "Social Learning," which embodied citizen-based processes (Future Engineering Institute, 1980).

Globally, the 1970s saw intensifying technology assessment activities, which declined in the 1980s (Rathenau Institute, Technology Assessment through Interaction).

By comparison, no conspicuous development was seen in technology assessment across Europe. It was during the 1980s that technology assessment activities gained momentum.

Technology assessment was based on "reactive" movements in the 1970s, during which a focus was directed to predicting potential dangers in science and technology. During the 1980s, on the other hand, attention was drawn to the "proactive" side of it.

Looking at this issue by country, OPECST (Office Oarlementaire d'Evaluation des Choix Scientifiques et Technologique) was set up in France in 1983. In Germany, the parliament established the Technology Assessment Bureau to be dedicated to conducting technical evaluations; in this country as a whole, which is characterized by decentralized policy making, scientific autonomy and growing environmental groups, a wide variety of technology assessment activities have been carried out.

In the Netherlands, NOTA (National Organization of Technology Assessment) was established (later renamed Rathenau Institute).

In the case of Denmark, technology assessment was conducted in 1980 on a trial basis for various interested parties to participate in debate. In 1986, the Technology Council was founded under the Danish Parliament to perform technical evaluation as well as offering the public opportunities to join discussion. Its activities include a consensus conference to promote democratic debate over science and technology.

During the 1980s and 1990s, evaluation systems were created for science and technology in Belgium, Austria, Greece, Finland and Italy. With EU support, alliances are being formed to discuss common technology assessment problems for Europe as a whole. The EU itself offers a program called TSER (Targeted Socio Economic Research), which aims at incorporating opinions of end users.

(2) New Attempt at Technology Assessment for Consensus Development

Technology assessment activities have so far involved only a small number of intellectuals consisting mainly of technological professionals on the relevant subject and experts in cultural sciences who specialize in the subject. In technology assessment, the participation of scientific professionals is essential because of their deep understanding of the nature of science and technology required. Technology assessment also needs experts in assessment methodology as more complex methods are required. These participants are represented in the previous paragraphs by "researchers" under "directly interested parties" (Category 1) and "peripheral researchers," who are neutral (Category 3).

As mentioned previously, in the evaluation of technology assessment, it was pointed out that no values of the society have been clearly identified. It is impossible to know what is valued by the public, if discussions are carried out only by professionals. In Europe, there are some cases in which scientific and technological problems grew into political issues, as reported by OECD in 1976. Since then, many countries have attempted to incorporate popular opinion in technology assessment. In other words, the participation of "indirectly interested parties" (Category 2), such as ordinary citizens and those expressing specific views on society, will have to be sought. At the same time, more importance will have to be placed on journalists and intermediary experts. (There were cases in which debate was shared by recipients and subjects, who fall under Category 1, and administrative organs.) The paragraphs to follow will focus on consensus conferences, which aim at involving such new participants in debate to reach a consensus. In consensus conferences, ordinary citizens take the initiative in conducting an exchange of opinions through direct or indirect contact with concerned professionals. Debate at consensus conferences involves a wide range of participants. Nonetheless, they do not include all parties. Opportunities for participation of those in the next generations and the socially disadvantaged are extremely limited. How to reflect opinions of these parties remains an open problem.

(i) Consensus conference

One new feature of technology assessment is the consensus conference. The consensus conference is defined, for example, by Grundahl as "a method for technology assessment, which is organized in the form of a meeting between a professional panel and a lay panel where the latter evaluates the development of a technology considered to potentially give rise to social controversy." In a consensus conference, a scientific or technological theme is selected first. Those citizens who have no interests in the problem are asked to join the conference. More than ten citizens are chosen from applicants and grouped as the "lay panel." For the "professional panel," more than ten experts capable of handling questions from the lay panel are selected, including university professors, company officials, public servants and private group leaders. The professional panel explains about the state of the technology in question in terms understandable to the citizens, and answers questions asked by the lay panel. Next, the citizens hold discussions among themselves within their panels until they reach a conclusion concerning the technology. Their final agreement is called a "consensus." The opinions of the lay panel are disclosed to the public and publicized in papers and by other media. The report on the civil discussion is circulated among administrative organs for reference. In this way, these opinions are utilized to form public opinions and governmental policies. Such opinions impose no legal restrictions.

Consensus conferences are required to be neutral with regard to the problem in question. To ensure this requirement, fully deliberate arrangements are made, including the selection of a conference theme and participants.

The consensus conference is said to have derived from the medical technology evaluation system of the U.S. Under the U.S. system, it was professionals that conducted technological evaluations. By contrast, the technological evaluation system in Denmark was quite different from the U.S. system in that assessments were carried out by citizens. The first consensus conference in history was held in Denmark in 1987 to discuss genetic engineering as a subject. Since then, such conferences have been implemented once or twice a year in the country. In the Netherlands, the first consensus conference was held in 1993 with genetic engineering as a theme, followed by Britain in 1994, which organized a similar conference on the application of biotechnology to plants. Such conferences have been organized on a trial basis in New Zealand, Norway, the U.S. and Switzerland. Besides, in France, similar conferences were held under the name "the parliament of citizens." In Korea, a conference was held to discuss genetically modified crops in 1998. This type of discussion is gaining momentum in recent years, including one in Britain, where one was held in 1999 to discuss nuclear waste problems.

(ii) Consensus conference in Denmark on infertility

In Denmark, more than ten consensus conferences have been organized. Our study which follows concerns infertility, which is closely associated with life science. (As shown in the list of consensus conferences in Reference 3, few of them focus on reproductive technology, suggesting a limitation of the consensus conference.)

Advancements in reproductive science and technology have changed the nature of "infertility." To be more specific, in the past if one was unable to create a baby, there was no other way than give up the hope to have one; nowadays, an option is available to allow one to receive artificial fertilization. This changed the way people see infertility. At the same time, there are concerns about artificial fertilization because of the fact that the artificial fertilization technique is still incomplete, without satisfactory studies available on the technology. Thus, society is faced with the problems of what is required by people and what social system should be built to handle these problems. It was under these circumstances that the Danish consensus conference was held. The application of cloning technology was not discussed in the conference at that time, since the technology was still at the initial developmental stage. The significance of this conference should not be overlooked amid growing development in recent years of reproductive technology. Our summary is based on the material available from the Danish Board of

Technology (www.tekno.dk). The material contains descriptions of key questions and responses to them exchanged at the conference.

The Danish consensus conference was conducted at the parliament building in Copenhagen, in October and November 1993 with the lay panel consisting of 13 citizens and the professional panel of 15 experts. The professional panel comprised physicians, infertility patients, public officers (lawyers), medical ethicists, Christian clergymen, clinical psychologists, social physicians, social medical researchers, jurists, Adoption Society members, and state health committee members.

A wide range of views were exchanged at the discussion. Along with opinions on science and research for infertility patients, proposals were made in connection with a social system for solving the problem. These proposals included the promotion of checkup services and knowledge for precautions against infertility, while an opinion expressed ethical concerns about the progress of the fertility techniques (reproductive technology).

The following eight key problems were presented. These were responded to with varying views (Reference 3) from professionals.

<1> Infertility and adoption.

<2> Identification of the cause of infertility and promotion of knowledge of infertility.

<3> Prevention of infertility.

<4> Costs of infertility treatment.

<5> Provision of eggs and sperm.

<6> Problems resulting from infertility treatment.

<7> Effects of new fertilization techniques on humans.

<8> Advantages and disadvantages of authorizing private infertility treatment.

At this conference, it was pointed out that the progress of fertility technology will cause ethical issues. The topics covered cloning technology and genetic engineering, with an opinion asserting that interference in genes should be banned and that the ban on cloning of human eggs should be maintained.

Although this Danish conference did not reach a consensus, a wide diversity of opinions were made clear as regards technical, institutional, social, ethical and legal problems with infertility treatment. Life science involves diverse problems to solve, such as conventional human perspective, doctor-patient relationships, future influences and genetic inheritance. The organizers of this conference concluded that many of these problems would require judgement on the part of citizens.

(iii) Attempt of Consensus Conference in Japan

Japan's first consensus conference was organized by a study group on civil participation in science and technology, which was led by Tokyo Denki University professor Masao Wakamatsu. Under the name "The Conference of Citizens on Genetic Treatment, " this conference met three times in three months, starting in January 1998, with the study group serving as the bureau. The results were released at an open symposium on March 21. The professional panel consisted of nine experts ? five physicians specializing in genetic treatment at medical colleges, two ethics experts, a medical economics researcher and a journalist. A total of 19 citizens were chosen for the lay panel from the Kansai district by publicizing the project and through personal connections. No special limitations were imposed on the scope of citizens.

Both the lay panel and the professional panel ardently participated in briefings and exchange of questions and answers. At the end of the conference, the lay panel submitted its opinions, which included minority views. The lay panel was characterized by orientation toward public interests as well as by the assumption that they stood by patients receiving genetic treatment. In its conclusion, the panel stressed the necessity to disclose the results of general treatment and establish a third-party organization which would check the safety of such treatment. The report also pointed out the need to systematically consolidate the current guidelines to curb excessive development of technology that would lead to unrestrained manipulation of reproductive cells. One participant expressed the fear of genetic treatment technologies being monopolized by the U.S. Some lay panelists were concerned about informed consent, which involves genetically treated patients: Informed-consent forms use too much technical jargon, frequently confusing and misleading patients; heavy emotional pressure would be placed on patients in critical condition if they were made aware that genetic treatment was given as the final option; for this reason, options should be widened to include hospice and death in dignity.

At the conference, one opinion argued that to reach a better consensus, the conference should comprise interested parties as well as ordinary citizens. Another comment pointed out that the conference was different in style from those in Europe in that it was carried out by the initiative of the conference bureau. Discussion was also made over the effect of consensus conferences on governmental policies and the types of themes that match the style of such conferences.

3. Points in Development of Consensus Development Methods

Technology assessment was employed in Japan on a trial basis in the 1970s. It failed, however, to gain wide social support, due to the ambiguity of its concept, the limited amount of information available, the incomplete development of methodology and the shortage of experts. The situation is changing in recent years as information disclosure systems are constructed, accompanied by remarkable developments in information infrastructures. At the same time, civil-based technology assessment is drawing more attention in Europe and the U.S. Domestically, a stronger voice is being raised for the participation of the general public in the governmental decision making process concerning complex problems like science and technology. In response to such public demand, new attempts are being made, including a round-table conference on nuclear policies and the use of the Internet and other means to collect opinions from wide layers of the population. In implementing technology assessment, it is essential to carefully keep up with these changing trends.

The consensus conference is one of such attempts to involve citizens as the major players in carrying out technology assessment in an effective manner. Nonetheless, it is extremely difficult to encompass all parties with interests in science and technology. In this respect, technology assessment methodology requires further improvements. One proposal for extending the range of opinions is to divide the opinion collection process into several phases for the three groups of interested parties, professionals and citizens (Renn et alternative, Public Participation in Decision Making: A Three-Step Procedure, Policy Sciences, Vol. 26). This approach is highly similar to the one discussed in Section 1 of this Chapter. To be more specific, interested parties will be asked to present opinions on their interest in science and technology; professionals will provide technical knowledge and suggest a number of solutions; citizens will express their values based on common sense and knowledge. This process appears to require a large amount of complex labor. Nevertheless, the approach is considered a measure to make the best use of the strengths of each group.

A number of methods and concepts have been proposed for consensus development. The majority of them, however, are new and untested for their feasibility. Our discussion so far has been focusing on technology assessment, which, actively undertaken by the government, is a typical consensus development method already corroborated with a sufficient amount of test data and evaluation results. To build a new consensus development method, it is desired to more deliberately analyze technology assessment policies implemented in the past.

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.

Acknowledgment

A large number of people have very generously helped in the preparation of this report. The way in which so many people have given of their time, expertise and advice has been a real revelation. Especially, the following experts provided us with detailed information and guidance:

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Shotaro Kohzuki: Advisor to Mitsui Information Development Co, Ltd. (Visiting researcher at the National Institute of Science and Technology Policy).

Hirohiko Tsujii: Treatment and Diagnosis Department manager at Heavy Particle Treatment Center, National Institute of Radiological Sciences.

Massaki Hori: Special researcher at Heavy Particle Treatment Center, National Institute of Radiological Sciences.

Toshimitsu Homma: Vice chief researcher at the Reactor Safety Engineering Department, Tokai Research Center, Japan Atomic Energy Research Institute.

We would like to thank those who gave generously of their precious time in cooperating with us.

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.

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〈Reference〉

Reference 1 Outline of the Legal System by Country Regarding Bioengineering and Reproductive Technology, including Cloning

| | Britain | Germany | France | U.S. |
|---|---|---|---|---|
| Law | Human Fertilization and Embryology Act (1990) | The Embryo Protection Law (1990) | The Bioethics Laws (1994): the Human Body Respect Act, the Transplant and Reproduction Act, and the Named Data Act. | No Federal laws established.<br><br>Presidential ordinance (1997) and presidential bill (1997, not passed) |
| Legal form | Covers the handling of human embryos and gametes.<br><br>Some studies and reproductive treatment using embryos and gametes are permitted subject to authorization by administrate bodies.<br><br>Administrative regulations with punishments. | Provides punishable prohibitive regulations for each reproductive technology using embryos and gametes. | Advanced medical technology in general is regulated by the above three acts, including organ transplants and reproductive technology.<br><br>The Human Body Respect Act added basic regulations to the Civil Code and criminal provisions to the Criminal Code.<br><br>The Transplant and Reproduction Act added regulations on organ transplants and reproductive treatment to | |

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| | | | the Health and Medical Code.<br><br>The Named Data Act added the procedures for using personal medical data to the Information Protection Law. | |
| Backgrounds, purpose, etc. | Legalized based on the Warnock Report (1984).<br><br>Intended for adequate administration of reproductive technology. | Legalized based on the Benda Report (1985) Aims to protect human life and dignity. | Legalized after a number of professional reports, including the Renoir Report. Ideal include respect for and inviolability of the human body and prohibition of infringement on the integrity of human races. | Recommendations and answers were provided by the National Bioethics Advisory Committee concerning embryonic stem cells in humans and other species. |
| Storage and use of gametes | [Storage and use of gametes are possible subject to authorization.]<br><br>Unauthorized storage or use (Article 4, Paragraph 1, a and b)<br><br>Detention up to 2 years, penalties or both. Under summary prosecution, detention up to 6 months, penalties or both (excluding use between a male and female as part of medical treatment).<br><br>Subject to permission, human sperm may be hybridized with eggs of special species, such as hamsters, for the purpose of checking the sperm rate or sperm normality tests. After testing, fertilized eggs must be destroyed not later than the first cell division. (Appendix 2, 1-(1)(f)) | | | |
| Sex selection<br><br>(identification of gametes and insemination) | | [Prohibited]<br><br>Insemination of eggs with sperm identified by sex chromosome.<br><br>Freedom restricting punishment up to 1 year or penalties (Article 3), except for authorization by a state law to prevent serious cases of sex-linked inheritance. | | |
| Post-mortem artificial insemination using stored gametes | | [Prohibited]<br><br>Artificial insemination using from dead males.<br><br>Freedom restricting punishment up to 3 years or penalties (Article 4). | [Prohibited]<br><br>Applies to a couple alive in reproductive years. (The Health and Medical Act, Article L152 (2)) | |
| Modification of reproductive cells | [Permitted subject to authorization except for partial modification of the embryo]<br><br>Storage or use of gametes (Article 4, Paragraph 1)<br><br>Detention up to 2 years, penalties or both. Under summary prosecution, detention up to 6 months, penalties or both.<br><br>Modification of the | [Prohibited with some exceptions, including a case in which reproductive cells are not used for insemination]<br><br>Artificial modification of genetic characters of human reproductive cells.<br><br>Application to insemination of reproductive cells containing artificially modified genetic | [Presumably prohibited under the following provisions]<br><br>Prohibition of infringement on the integrity of human races. Prohibition of eugenic acts intended for human selection. (The Civil law 16(4))<br><br>Eugenic acts intended for human selection.<br><br>20-year imprisonment | |

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| | general structure is not approved if the reproductive cell constitutes part of the embryo. (Appendix 2, 3-(4)) | characters.<br><br>Freedom restricting punishment up to 5 years or penalties. Also applies to abortive attempts. (Article 5)<br><br>As exceptions:<br><br>Artificial modification of in-vitro reproductive cells, which are not to be used for insemination.<br><br>Artificial modification of genetic characters of reproductive cells taken from dead fetuses or dead humans, which are not to be used in transplants to embryos, fetuses or humans, or which are not to develop into new reproductive cells.<br><br>Application to vaccinations, or radioactive, chemical or other types of treatment not intended for modification of genetic characters of reproductive cells. | with forced labor (The Criminal Law, Article 511(2)) | |
| Artificial in-vitro creation of human embryos, isolation of embryos from females, and artificial insemination | [Permitted subject to authorization for medical treatment and research]<br><br>Creation, storage or use of embryos without permission. (Article 3(1))<br><br>Detention up to 2 years, penalties or both. Under summary prosecution, detention up to 6 months, penalties or both. | [Prohibited]<br><br>Isolation of embryos before imbedding from females for the purpose of transplants to other females or use not intended for embryonic preservation.<br><br>Artificial invasion human spermatids into human egg cells.<br><br>Freedom-restricting punishment up to 3 years. Aborted attempts also punished (Article 1) | [Prohibited]<br><br>Prohibits in-vitro creation or use of human embryos for commercial or industrial purposes.<br><br>Detention up to 7 years and fine of Fr700,000. (The Health and Medical Law, Article L152(7), and the Criminal Law, Article 511(7))<br><br>Prohibits in-vitro creation of human embryos for the purpose of research or experiment.<br><br>Detention up to 7 years and fine of Fr700,000. (The Criminal Law, Article 511(18)) | |
| Storage or use of embryos and inspection or experiment using embryos | [Permitted subject to authorization]<br><br>Creation, storage or use of embryos without permission. (Article 3(1))<br><br>Detention up to 2 years, penalties or both. Under summary prosecution, detention up to 6 months, penalties or both.<br><br>Prohibits use or storage of embryos after appearance of the primitive streak. (Article 3(3a)<br><br>(the primitive streak is considered to appear within 14 days of gametic mixture.<br><br>Detention up to 10 years, penalties or both. | [Prohibited except for purpose of conception]<br><br>Sales of human embryos created in vitro or isolated from females before imbedding in the womb.<br><br>Transfer, acquisition or utilization of such embryos for purposes not intended for embryonic preservation.<br><br>In-vitro embryonic development for other purposes than conception.<br><br>Freedom-restricting punishment up to 3 years. Aborted attempts also punished. (Article 2) | [Prohibits use of embryos for commercial purposes or for inspection, with some exceptions]<br><br>Prohibits in-vitro creation or use of human embryos for commercial or industrial purposes.<br><br>Detention up to 7 years or fine of Fr700,000.<br><br>(The Health and Medical Law, Article L152(7), and the Criminal Law, Article 511(7))<br><br>Prohibits inspection or experiments regarding human embryos except inspection for couples.<br><br>Detention up to 7 years and fine of Fr700,000.<br><br>The Health and Medical Law, Article L152(8), and | |

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| | | | the Criminal Law, Article 511(19)) | |
| Human cloning<br><br>(embryonic manipulation) | [Partially prohibited. Practically prohibits by not giving permission.]<br><br>Prohibits substitution of the nucleus of an embryo with the nucleus taken from human cells, embryos or developed embryos. (Article 3(3d))<br><br>Detention up to 10 years, penalties or both.<br><br>Prohibits creation, storage or use of embryos except for the purpose of medical treatment subject to authorization. (Article 3(1))<br><br>Detention up to 2 years, penalties or both.<br><br>The authorizing agency made public its intention not to approve human cloning. | [Prohibited]<br><br>Artificial creation of embryos having the same genetic information as in other embryos, fetuses and humans.<br><br>Transplants of such embryos to females.<br><br>Freedom-restricting punishment up to 5 years or penalties. Abortive attempts also punished. (Article 6) | [Prohibited by presidential discretion under the following provisions]<br><br>Prohibits infringement on the integrity of human species. Prohibits eugenic acts for the purpose of human selection. (The Civil Law, Article 16(4))<br><br>Implementation of eugenic measures for the purpose of human selection.<br><br>Detention with hard labor up to 20 years. (The Criminal Law, Article 511(1))<br><br>In-vitro creation of embryos for the purpose of research or experiment.<br><br>Detention up to 7 years and fine of Fr700,000. (The Criminal Law, Article 511(18)) | No federal regulations<br><br>Suspension of governmental financial support of human cloning using body cell nuclei (Presidential Decree, 1997)<br><br>A Presidential Draft (1997) prohibits human cloning using body cells (to be reviewed in 5 years)<br><br>The NBAC recommendations cited ethical concerns and scientific uncertainties while admitting the usefulness of body cell transplant. |
| Chimeras and hybrids<br><br>(between humans and animals)<br><br>(Manipulation of gametes and embryos) | [Permitted subject to authorization]<br><br>Mixture of human gametes with animal gametes without permission. (Article 4(1c))<br><br>Placement of embryos in the animal body. (Article 3(3b))<br><br>Detention up to 2 years, penalties or both. | [Prohibited]<br><br>Cell junction of more than one embryo having different genetic characters using at least one human embryo.<br><br>Junction of human embryos with other cells that have different genetic characters and are capable of dividing after joint with the human embryos.<br><br>Creation of divisible embryos by insemination of animal sperm into human egg cells or insemination of human sperm into animal eggs.<br><br>Transplant of such embryos into females or animals.<br><br>Freedom-restricting punishment up to 5 years or penalties. (Article 7) | | The NBAC answers (1998):<br><br>It should not be permitted to maintain conception through fusion of human cells with animal eggs.<br><br>There are ethical concerns about embryonic development through fusion of human cells with animal eggs. However, human embryonic stem cells will not develop by themselves, causing no direct concerns.<br><br>No ethical problems will be caused if fusion of human cells with animal eggs do not produce embryos with development potential. |
| Artificial insemination and transplant of gametes or embryos to females | [Permits transplant of gametes and embryos subject to authorization.]<br><br>Prohibits the placement of sperm or eggs in the female body without permission. (Article 4(3))<br><br>Detention up to 2 years, penalties or both. Under summary prosecution, detention up to 6 months, penalties or both.<br><br>Permits the placement of embryos in the female body subject to authorization. (Appendix 2, 1-(1)(e)) | [Prohibits transplant to other humans than gamete donors. Limits the number of gametes and embryos to be transplanted.]<br><br>Transplant of unfertilized eggs from other females.<br><br>Artificial insemination of egg cells for other purposes than for conception.<br><br>Transplant to females of more than three embryos during the same menstruation period.<br><br>Fertilization of more than three egg cells during the same menstruation period by transplanting gametes | [Permits embryonic transplant as part of reproductive treatment]<br><br>Permits in-vitro creation of embryos intended only for medical intermediation in reproduction. These embryos require insemination with gametes from at least one partner of the couple. (Heath and Medical Law, Article L152(3))<br><br>As an exception, couples are permitted to receive embryos after unsuccessful effort in medical intermediation without the help of any third party. (Heath and Medical Law, Article L152(5)) | |

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| | | to the fallopian tube.<br><br>Insemination during the same menstruation period of more egg cells than should be transplanted.<br><br>Artificial insemination or transplant of human embryos to surrogate mothers.<br><br>Freedom-restricting punishment up to 3 years or penalties. (Article 1) | | |
| Transfer and trading of embryos | | [Prohibited]<br><br>Sales of human embryos created in vitro or isolated from females before imbedding in the womb. Transfer, acquisition or use of such embryos for purposes other than for maintaining them.<br><br>Freedom-restricting punishment up to 3 years or penalties. Also punishes aborted attempts. (Article 2) | [Prohibited except for reproductive treatment.]<br><br>Prohibits acquisition of human embryos to receive compensation, intermediation for such acquisitions, and offering of human embryos to receive compensation.<br><br>Detention up to 7 years and fine of Fr700,000. (The Criminal Law, Article 511(15))<br><br>Prohibits acquisition of human embryos except for reception of embryos by couples as part of reproductive treatment.<br><br>Detention up to 7 years and fine of Fr700,000. (The Criminal Law, Article 511(16)) | |
| Conditions for application of reproductive technology (including consent of donors of sperm and eggs) | [Consent required]<br><br>Requires consent on use of gametes or embryos. (Appendix 3) | [Consent required.]<br><br>Artificial insemination without consent of donors of eggs or sperm.<br><br>Transplant of embryos to females without their consent.<br><br>Freedom-restricting punishment up to 3 years or penalties. (Article 4) | [Consent required]<br><br>Prior consent required regarding artificial insemination or embryonic transplant of living couple who are married or have lived together at least 2 years and are in reproductive years. (The Health and Medical Law, Article L152(2))<br><br>Donors and recipients of embryos shall not be identifiable. (However, information available to physicians when necessary in treatment.) Donors shall not be paid. (The Health and Medical Law, Article L152(5)) | |
| Surrogate motherhood | [Prohibits commercial surrogate motherhood.]<br><br>The Surrogate Mother Contract Law (1985) | [Prohibited]<br><br>Artificial insemination of surrogate mothers or transplant of human embryos to them.<br><br>Freedom-restricting punishment up to 3 years or penalties. (Article 1) | [Prohibited]<br><br>Contract on reproduction and conception for the sake of others is invalid. (The Civil Law, Article 16(7)) | |

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Reference 2 Regarding Genetic Effects of Radiation on the Ordinary Citizen

Review of the Ideas about the standard citizen's genetic dose in the Guidelines for Examination of Reactor Locations in relation to the Nuclear Reactors Regulation Law

- "Guidelines for Examination of Reactor Locations" (decided by the Atomic Energy Commission on May 27, 1964)

These Guidelines are used by the Task Force for Reactor Safety for its safety examination prior to installation of a nuclear reactor to determine if the conditions of location are appropriate should an accident occur.

These Guidelines stipulate in "Section 2: Guidelines for examination of location" as follows: "2.3 The site for the reactor concerned shall be away by a required distance from dense population areas. The required distance from dense population areas here means the distance far enough to reduce, in a hypothetical accident, an integrated whole body exposure dose to such an extent as fully acceptable from the viewpoint of the standard citizen's genetic dose."

- Report issued by the Special Task Group on Reactor Safety Standards (on November 2, 1963)
  This Report gives the explanation by the Special Task Group on Reactor Safety Standards which established the above-described Guidelines, regarding the Guidelines.

  The Group considered that the standard citizen's genetic dose is equivalent to 0.5 $x10^8$ manrem on the basis of the yardstick given by the ICRP (International Commission on Radiological Protection), and thus drew the conclusion that "the integrated whole body exposure dose in a hypothetical accident should be much smaller than the value of 0.5 $x10^8$ manrem."

  In other words, this explanatory Report accepts the pre-condition that "the standard citizen's genetic dose in a hypothetical accident should account for only a small portion of the allocation to the genetic dose for the standard citizen according to the idea of allocation of exposure dose proposed by the ICRP" and refers to the ICRP's recommendation (in 1958) regarding the allocation to the category of exposure to the population as a whole, which is 2 rem (consisting of 1.5 rem for exposure inside the body and 0.5 rem for exposure outside the body), of the maximal permissible genetic dose of 5 rem (excluding exposure attributable to natural background and medical exposure). The Report then explains that the 0.5 rem for exposure outside the body is equivalent to 0.5 $x10^8$ manrem assuming that the total population in Japan be approximately 100 million people and that in the idea of exposure to the population as whole, the proportion of people in reproductive age groups in the total population be the same as that in the population suffering from exposure.

  One of the foreign cases which the Commission referred to when leading to the specific number upon establishment of guidelines was the Guidance for Sailing of "Savanna," a US nuclear-powered ship, within the Harbor (issued on August 1, 1962), according to which the standard level is 2 million manrem.

- ICRP Publication 6 (Recommendation in 1958)
  It is described as shown below in the section of "exposure to the population."
  As "general views," it is stated that "appropriate projects regarding nuclear power plants and other large-scale peaceful uses of nuclear energy will require limit of exposure to the entire population firstly by limiting dose exposed to the individual and secondly by limiting the number of people to be exposed." It continues to state that "this limitation unavoidably implies a compromise between harmful effects and social benefits." In addition, they admit that "the Commission is not yet able to make a proper judgment regarding the balance between dangers and benefits" and state that "factors influencing balance between dangers and benefits may vary depending on countries and each country should assume responsibilities to make the final decision regarding this issue." It is then described that "the Commission suggested the tentative upper limit for exposure to the entire population in its Recommendation in 1958."
  Regarding "genetic dose," the "genetic dose to the population" is defined as follows: "assuming that each individual within a population is exposed to a dose for a period from the time of fertilization to the time when he/she reaches an average age of reproduction, they suffer from genetic burden caused by the dose to that which they are actually exposed; and a dose which will cause the same extent of genetic burden to the entire population as that in the case above is defined as a genetic dose to the population." The "permissible genetic dose" is defined as follows: "assuming that each individual within a population is exposed to the genetic dose for a period from the time of fertilization to the time when he/she reaches an average age of reproduction, a dose which will cause acceptable burden to the entire population is defined as a permissible genetic dose."
  Regarding the "maximal permissible genetic dose," it is concluded that excluding exposure attributable to natural background and medical exposure, the genetic dose derived from all sources that the population is to be exposed to should not exceed 5 rem and the recommendation is that of the 5 rem, an allocation to the category of exposure to the population as a whole be 2 rem.

Regarding this "2 rem allocated to the category of exposure to the population as whole," it is explained that "this level was intended for development of nuclear energy plans (including related problems of disposal of wastes) and for plans for more wider utilization of radiation resources."

- Foreign Case: The Guidance for Sailing of "Savanna," a US nuclear-powered ship, within the Harbor (on August 1, 1962)
  The Commission referred to, in addition to the ICRP's Recommendation, the Recommendation by the NCRP (National Council on Radiation Protection and Measurements), and indicated the value of 2 $x10^6$ manrem (2 millionrem) for genetic exposure due to an accident. They understand that this value "is still valid for the objectives of plans."
  In other words, this Guideline is based on the following estimation made by the former chairman of the ACRS (Advisory Committee on Research Safeguards): assuming that an MCR (maximal conjecture accident) occurs once annually, the collective dose for 30 years is 2 $x10^7$ manrem (assuming that the total population in the US is 200 million) and the genetic dose contribution per person for 30 years is 0.1 rem.
  Then, the selection of 0.3 rem as a genetic dose for 30 years is slightly conservative as compared to the value of 2 rem which is allocated by the ICRP to the category of exposure to the population as a whole or the value of 1.5 rem which is allocated by the ICRP to the category of reserves, but provides benefits. (Note that the value of 0.3 rem corresponds to 2 million manrem.)

- The currently effective "On Yardsticks for Making Judgment Regarding the Guidelines for Examination of Reactor Locations and their Application" (partially amended on March 27, 1989)
  One of the three basic objectives is stated as follows: "c. To minimize substantial influences on the collective dose in the case of a hypothetical accident."

  It is stipulated in "Section 2: Guidelines for examination of location" as follows: "2.3 The site for the reactor concerned shall be away by a certain distance from dense population areas. The "certain distance" here means the distance far enough to reduce, in a hypothetical accident, an integrated whole body exposure dose to such an extent as fully acceptable from the viewpoint of the collective dose."

  (Note: The term "standard citizen's genetic dose" used before the amendment was replaced with "collective dose.")

As a yardstick on which the site for the reactor concerned is "away by a certain distance" or not as stipulated in Section 2.3 of the Guidelines, it is recommended to refer to overseas cases (e.g. 2 million Sv = 2 million manrem: derived from the Guidance for Sailing of "Savanna" within the Harbor mentioned above).

Note: The post-amendment Guidelines have taken over the idea of "collective dose." As the ICRP indicates its view that each country should assume responsibilities for decision-making regarding which factors should be ultimately incorporated her national standards, only Japan and Canada use this concept of collective dose as a standard for examination of nuclear reactor locations.

- The Kingdom of the Netherlands has proposed policies regarding risk management (in connection with environmental policies) including

areas other than that of atomic energy. Her policies provide reference to methods of handling risks with accompanying unknown effects.

In the Netherlands, under the recognition that introduction of systemic risk management policies is essential, the "1986-1990 Plan for Environmental Management" determined permissible risk levels for 3 key hazards, i.e. large-scale accidents, chemical substances and radiation exposure.
In this documented Plan, "individual risk" and "group risk" are introduced for humankind and "collective risk", for the ecological system.

When formulating a policy which focuses on the environment, the national government is responsible for identifying a risk and establishing the maximal permissible level, beyond which risk is not acceptable, and the level, below which risk is negligible. For humans, the maximal permissible lethal risks attributable to large-scale accidents, chemical substances and radiation exposure are individually determined so that the total mortality due to each of these hazards will not exceed $10^{-5}$/year. The maximal permissible level for individual activities or individual chemical substances is set at $10^{-6}$/year.

For both humankind and the ecological system, the risk level below which risk is negligible is set whenever possible in any case at 1% of the maximal permissible level.

If an existing activity brings about hazardous situations exceeding a specific limit, then social considerations may often be important to set up a length of period during which the hazard(s) concerned will be suppressed. In the case of a new activity, however, it will immediately be necessary to observe a specific limit.

It is generally understood that evaluation of proper risk level is extremely difficult. However, efforts must be made to minimize uncertainty which has a significant influence on policy formulation. It becomes important to incorporate this uncertainty into policy-formulating process in a clearly identifiable manner

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## Reference 3 Materials on Consensus Conferences

The following provides supplementary materials related to our discussion in Section 2 of Part 2.

Consensus conferences have been held in a number of contries, as follows:

Reference 3-1 List of Consensus Conferences

| Country | Year | Subject |
|---|---|---|
| Denmark | 1987 | Bioengineering in industry and agriculture |
| | 1989 | Radiation on food |
| | 1989 | Genetic mapping of humans |
| | 1990 | Air pollution |
| | 1991 | Education engineering (technology) |
| | 1992 | Genetically modified animals |
| | 1993 | Future of personal automobiles |
| | 1993 | Infertility |
| | 1994 | Technical traffic information |
| | 1994 | Integrated agriculture |
| | 1995 | Environmental thresholds |
| | 1995 | Genetic medical treatment |
| | 1997 | Tele Work |
| Britain | 1994 | Biotechnology applied to plants |
| Netherlands | 1993 | Bioengineering on animals |
| | 1995 | Biotechnology |
| New Zealand | 1995 | Biotechnology |
| U.S.<br>(Massachusetts areas) | 1997 | Information system |
| Switzerland | 1998 | Radiation on food |
| Norway | 1996 | Bioengineering |
| | 1997 | Energy |

Reference 3-2 Points in Consensus Conference

A variety of measures have been devised to facilitate the implementation of consensus conferences. The following provides several points for

understanding consensus conferences:

- election of themes: It is essential to select themes that would allow smooth progress of debate. Many subjects concern new technologies, including biotechnology, partly because they offer open problems and also because interests are still to be established.
- election of panelists: To accurately represent the nation as a whole, it is important to make a well balanced selection in terms of age, sex, and educational background.
- Cooperation of experts: It is necessary to encourage the participation of a
- large number of experts in the subject.
- Briefing by experts: The lay panel is strongly influenced by the way expert
- briefings are carried out. Thus, such briefings must ensure impartial and sufficient quality and quantity of the coverage of the subject.

Function of consensus conferences

Even in Denmark, where consensus conferences are held frequently, the results of a consensus conference are not legally binding. Nonetheless, they exert strong influence on the public as they are covered widely by the press. Because of this, some congressmen show a keen interest in what is discussed in such conferences. In this manner, these results have indirect influence on policy formation.

Reference 3-3 Consensus Conference on Infertility

In 2) of Section 2 (2) of Part 2, we presented an outline of the consensus conference held in Denmark on infertility. The following presents the results, released by the Denmark Technology Committee on the opinions of the lay panel, of the 1993 conference on infertility. (This information was collected from the Internet.)

<1> Infertility and adoption

Regarding the presence of people suffering infertility, the panel discussed the way the adoption system and rules should be revised. The lay panel opted for a more lenient adoption system. Some panelists argued that infertile couples should be made aware that they may consider adoption instead of infertility treatment and that sufficient medical and mental support should be given to these couples.

<2> Identification of the cause of infertility and diffusion of knowledge

The panel discussed whether a higher priority should be given to research on causes of infertility. The lay panel asserted: In research, a higher priority should be given to identification of causes than to treatment; to promote causal research on infertility, it is recommended to construct a research plan that involves fundamental studies, environmental research and epidemiological survey; with anticipated degeneration of human sperm, efforts should stepped up in research on sperm; there is no organized sperm research system; a sperm research system should be established to accumulate experience and knowledge; businesses should endeavor to improve working environments.

<3> Prevention of infertility

In the discussion on infertility prevention, the lay panel argued: Infertility prevention should be promoted; regular inspection should be implemented on 15- to 25-year-old males and females for chlamydia, which is thought to cause infertility; although such inspection requires large amounts of money, benefits would exceed costs; it is essential to provide the young with official information about the disease; it is required to establish a more flexible maternity absence system for working mothers and improve the management of public health centers in order to counteract the declining conception rate as the result of more females receiving higher education; daily prevention measures are also important, including giving up smoking and drinking.

<4> Infertility treatment expenses

The discussion also covered the amount of public money to be spent on infertility treatment. Various opinions were presented: Infertility is not a disease; beneficiaries of infertility treatment should bear part of the medical costs; government subsidiaries should be provided for adoption, depending on the income level of adopters; in infertility research, the government should focus on the identification of causes as well as prevention of infertility.

<5> Provision of sperm and eggs

The panel discussed potential problems with the provision of sperm and eggs. The debate mainly centered on a contradiction between the desire of children to know their parents and the legal protection of anonymity of donors. The lay panel argued: To maintain the public health system and offer genetic treatment, recipients and donors of sperm and eggs should be identifiable; therefore, anonymity of donors should be abolished to allow children to know their genetic origin.

The lay panel further maintained: In receiving hormone treatment, egg donors should be warned of risks accompanying the treatment; sperm and eggs should be provided free of charge; compensation to sperm donors should be prohibited; recipients of sperm and eggs should be adults under 40; at least one of the parents should be a genetic parent of the child. The lay panel demanded the abolition of the current law, which permits the provision of eggs that have been used for research purposes, because the quality of such eggs is not guaranteed.

<6> Problems arising from infertility treatment

The lay panel discussed social problems that would potentially arise as infertility treatment is practiced more widely. The panel questioned the low priority given to the review of the results of infertility treatment. It claimed: Infertility and its treatment are a cause of mental problems; wider practice of infertility treatment is causing stress on an increasing number of patients; sociological studies should be conducted before and after infertility treatment to determine how much mental assistance will be needed for infertility patients; the artificial reduction in the number of fetuses should be banned to avoid multiple birth, treatment techniques should be improved; in order to identify long-term effects of hormone treatment, infertility patients should be registered to facilitate descendant tracking; with opinions varying among specialists on the effects of hormone treatment, a higher priority should be given to research on such effects; infertility research and treatment should be concentrated in a limited number of centers.

<7> Effects of infertility treatment technology on human existence

The panel discussed whether there might be changes in the conventional way we view humans. A wide range of opinions were presented: Advancements in infertility technology should not lead to the belief that all humans have the right to have children; it should not be left to physicians to decide the extent to which abnormal conception should be permitted; the quality of our life, including the decision whether to have children or not, seems to be determined by infertility technology; infertility treatment might pose grave ethical problems; there is the danger that technological advancements will dissolve ethical standards.

The discussion covered cloning and genetic engineering: Genetic interference should be prohibited in infertility treatment; the ban on human egg cloning should be maintained.

<8> Advantages and disadvantages of private treatment of infertility

The panel discussed whether private hospitals should be authorized to conduct infertility treatment. Some panelist stressed the importance

of guaranteeing treatment quality and follow-up survey on long-term effects of treatment: Regulations are required to ensure a minimum level of quality of infertility treatment; treatment should be conducted by physicians with sufficient knowledge and experience; those who offer infertility treatment should not compete only in terms of price; a transparent and homogeneous market should be guaranteed; the results of infertility treatment should be maintained at a central registration office; registration procedures should be controlled by the sanitation committee; registration data should include the frequency of treatment, method applied, number of eggs collected, treatment applied to eggs, results of treatment, conception frequency, number of children born, number of fetuses aborted, and delivery method; a registration system for infertility patients is desired for the sake of openness; the registration will allow the government to control private clinics and hospitals; under the registration system, treatment information will be centralized to make it easily available to infertile couples; registration is also necessary to prevent the application of treatment methods still under development.

Reference 3-4 Categorization of Technology Assessment

A wide variety of methods are available for technology assessment. It is difficult to precisely classify them. On the basis of different types of technology assessment practiced in Europe, it might be categorized as follows:

* Scope

In a narrow sense, technology assessment in businesses aims at only technological and economical potential of new technologies and products, although in a wider sense, it means a comprehensive system designed to analyze effects of new technologies on the internal and external environments of a business.

* Characteristics

According to Cronberg, the characteristics of technology assessment can be classified on the basis of the relation of the technology to society.

a. Technology Prediction: If it is assumed that society in the future will be defined by technology and that it is possible to foresee technologies, it is essential to endeavor to predict such technologies (Tarja Cronberg, Technology assessment in the Danish socio-political context, *Technology Management*, Vol. 11, No. 5/6)

b. Passive Technological Evaluation: Based on the assumption that we are capable of knowing the effects of technology on society, such effects are analyzed in a passive manner.

c. Positive Technological Evaluation: Technology assessment is organized also as part of learning new technologies. Under the assumption that we are capable of controlling technological changes, a wide array of methods are employed, such as conversations, scenario workshops and consensus conferences.

d. Society-based Technological Evaluation: On the assumption that technology in a society is determined by interested parties, efforts are made to solve problems through negotiation between those parties.

* For whom?

Technology assessment was originated with the aim of protecting those who are placed in a disadvantageous position as the result of scientific advancement. In the 1970s, particular stress was laid on the prediction of negative effects of technology and science, focusing on consumers and victims of environmental issues. In recent years, however, many experts maintain that, in order to predict negative effects it is essential to involve as many interested parties as possible, such as scientists, engineers, businessmen and government officials, who have a considerable influence on technological advancement (Rathenau Institute, *Technology Assessment through Interaction*).

* Methodology

A large number of methods have been developed for technology assessment, including brainstorming, checklist, field survey, cost benefit analysis, relevance tree, KJ method, multi-step assessment method, correlational loop diagram, scenario writing, impact matrix method, multi-step filter method, multivariate analysis, delphi technique, random sampling, and system dynamics (The Japan Industrial Technology Association, *Survey on Conditions for Effective TA*.). These methods are widely employed by experts. A variety of other methods have been invented and tried to encourage civil participation.

Reference 3-5 Environmental Assessment

Environmental assessment is a life-cycle assessment method, having much to share with technology assessment. An environmental assessment system was first established in the U.S. in 1969. In the U.S., environment assessment was conducted earlier than technology assessment. Technology assessment was presumably a result of environment assessment. If Japan conducts environment assessment, all 29 OECD members will have completed some form of legal system that provides general rules for environment assessment. Environment assessment involves preliminary survey, prediction and evaluation to determine effects on the surroundings of large-scale developments that would accompany a change in the natural environment. Previously, environmental assessment was carried out through voluntary cooperation of developers under administrative guidance. As discussed later, the legislation of environment assessment made it mandatory for developers. In Japan, environment assessment is conducted for each development project, while in the U.S. and Europe, attention is centered on the introduction of a more strategic assessment system based on a long-term perspective. This is intended to apply assessment to entire long-term plans of the government, with an understanding that assessment on individual development project is not sufficient to protect the local and national environments.

In Japan, cabinet agreement was made in 1972 on the Environmental Protection Measures for Public Works. Since then, laws, administrative guidance, and local ordinances have been instituted in accordance with the agreement. The Environmental Effect Assessment Law was drafted by the cabinet in 1981, but was rejected by the Congress. The bill was presented to the Congress for the second time and was passed in June 1997 to be enforced in 1999.

The Environmental Effect Assessment Law is applied to 14 categories of large projects implemented or authorized by the government which are expected to cause grave adverse effects on the environment. These projects include the construction of power stations, conventional railroads and forestry roads. The law is intended to facilitate environmental measures at an early stage of construction by having builders scope evaluation items though consultation with the community and local government before starting assessment. The builders are required to compile and publicize preliminary environmental assessment plans before implementation of their projects to collect opinions regarding environmental protection. Then, they prepare environmental assessment schedules. These schedules are adjusted through consultation with the authorities.

The Environmental Effect Assessment Law, however, simply permits the community and the local government to express their opinions, leaving the whole decision to the builders with respect to how much such opinions should be reflected in their projects.

Environmental assessment is different from technology assessment in that legislation is established for the former and that, in implementing it, local characteristics must be taken into consideration.

Reference 3-6 Life-cycle Assessment

Life-cycle assessment is a method of evaluating overall effects of a product on the environment by analyzing each of the life stages of a products, starting from manufacture to use to disposal or reuse of the product. The product is measured at each stage in terms of energy, material and the amount of carbon dioxide emitted. The life-cycle method is useful in devising countermeasures against environmental pollution.

In automobiles, the life-cycle method demonstrates that, through the processes of manufacture, use and disposal of vehicles, about 70% of carbon dioxide is produced when the product is being used. This indicates that focus must be drawn to fuel when designing automobiles. In housing, it is known by life-cycle analysis that, although insulation or air-tight work during construction generates a greater amount carbon dioxide, the disadvantage is compensated in one year, with a further decline in carbon dioxide emissions in later years.

In material engineering, it is noted that, in estimating the life of a product, it is essential not only to measure durability of materials but also to take into consideration the cost and effects of the product on the environment.