Model of Regulation on Medical Innovation/ Medical Research from the Perspective of Comparative Law

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1.Introduction

The area of life science is very dynamic and flexible. For example, Aldous Huxley had already such a symbolic novel "Brave New World" in connection with in-vitro-fertilization in 1932, and recently, we have just known a new symbolic invention of "induced pluripotent stem cell(= iPS Cell)" by Prof. Shinya Yamanaka of Kyoto University in Japan in 2007, by which we have had just possibilities to use "regenerative medicine" or "tissue engineering" without breaking human embryos like in case of using "embryonic stem cell(=ES Cell)" . And then many efforts are tried to overcome the risk of cancer which will derive from the technique of iPS Cell.

In the post genome era, it may be disadvantages for mankind that the law regulates too strongly scientific and medical activities of this field because it can obstruct the progress of life science or medicine. Therefore it is true that the freedom of study and research is guaranteed by the Art.23 of the Constitution in Japan) on the one hand. But on the other hand, we must examine carefully whether this freedom is unlimited or not. Prof. Koichi Bai, who is the founder of medical law in Japan, had already pointed out some important fundamental perspectives on this aspect in 1974.

1)Awareness of the margin of legal intervention into natural facts and progresses of natural science,

2)role of law in adjusting conflict between one interest and the other interest, and

3)awareness of positive meaning of legal approach, or guarantee and establishment of fundamental rights(1).

These perspectives seem to me very useful also today. We must consider the balance between promotion of life science or medical science and protection of human right in this field. Thus we must rethink how we should regulate illegal misconducts in this field. On this point, also Prof. Dr. Albin Eser, who is one of the most famous scholar of medical law in Germany,

had presentated similar opinions in 1984, and recently proposes a global theory. In his theory, he insists that we should change our paradigm from "Sektorales Medizinrecht" (Sectary Medical Law) into "Integratives Medizinrecht" (Integrative Medical Law including bioethics) in 2006(2). I agree with his opinion.

In connection with these perspectives, in this paper, I will show a model of regulation on medical innovation/ medical research from the perspective of comparative law (3).

2.Objects of Regulation

We can classify objects of regulation into three categories. The first is Objects to regulate clearly; e.g. crimes, social harmful conducts (trafficking), abuse of eugenics, genetic discrimination, and human cloning (not including therapeutic cloning). We should legally prohibit these conducts due to such harmful to our society, and therefore impose criminal sanction on these conducts.

The second is objects to promote; e.g. genome research. Naturally, it needs due process in going on the study plan, but it is not necessary to regulate legally.

The third is objects to permit with conditions; e.g. therapeutic cloning, use of ES-cell, stem cell and iPS-cell. As we cannot foresee concretely any risks, we should watch these researches with certain conditions. We can hope that they may bring about possibilities to cure some curable diseases in near future. I think it appropriate that the UK Report of House of Lord (2002) has already decorated this direction. Also in Japan recently, this direction has been officially confirmed. Naturally, also it needs due process in going on the study plan, but it is not necessary to regulate legally.

3.Grounds of Regulation

How can we think about the ground of regulation ? According to my opinion, firstly "Human Dignity" (Menschenwürde in German), which derives from German philosopher Immanuel Kant, should be based on it. "Human Dignity" is "Sein mit Menschen-Dasein" and should be behind human being, human tissues, corpse, human embryo.

However the problem of ownership or property on his/her body conflicts with "Human Dignity" . Generally speaking, libertalianism is affirmative to ownership or property on his/her body(4). But it seems strange to me to grasp human body as property. We should consider rather human body in connection with "Human Dignity" .

Then how should we think about criminal regulation ? Anyway, criminal regulation is the last measure (ultima ratio). There are some fundamental principles in applying criminal law. Incidentally, Japanese criminal law has been strongly influenced from German criminal law.

The first principle is "Tatprinzip" (Conduct-principle in English). According to this

principle, we cannot punish a conduct without certifying an external harmful conduct. It includes causation. In Anglo-American jurisdiction, it is concerned with actus reus.

The second principle is "Nulla poena sine lege, nullum crimen sine lege" (No penalty without law, no crime without law). According to this principle, we cannot punish a conduct without a clear provision of law.

The third principle is "Schuldprinzip " (Nulla poena sine culpa; No penalty without culpability). According to this principle, we cannot punish a conduct without intention or negligence, and criminal responsibility). In Anglo-American jurisdiction, it is concerned with mens rea.

These three principles should be considerated into also in the field of medical or life science. At least, we should use criminal sanction such cases in people feel or have vague and slight misgivings alone in this field.

4.Model of Regulation

Then how should we think about model of regulation ? We can classify it into three categories. The first is the hard law style like in Germany. The German "Embryonen Schutzgesetz (Protection of Embryo Act) 1990) is typical of it, because it is a special criminal law. I think, however, that German legal system is not suitable for regulation to medical and scientific field, because it is too hard to keep up flexibly with the trend of life science. Indeed in Germany, "Gesetz zur Sicherstellung des Embryonenschutzes im Zusammenhang mit Einfur und Verwendung menschlicher embryonaler Stammzellen =Stammzellgesetz－StZG) has been enacted in 2002 (revised in 2008), and by this law, they have been able to use human stem cell for research in Germany. However it seems strange for me to use only stem cell which is imported from foreign countries.

The second is the soft law style like in Japan. We have many official guidelines in this field in Japan; for example, Ethics-Guideline for Human-Genome/ Gene Analysis Research (2001, revised 2004 by Ministry of Education, Culture, Sports, Science and Technology; Ministry of Health, Labour and Welfare; Ministry of Economy, Trade and Industry), the Guideline for the Protect of Personal Information for Business Operations Handling Personal Genetic Information (2004; Ministry of Economy, Trade and Industry). The last is to enterprises (excepting use for research), which includes 1)informed consent by documents, 2)genetic counseling, 3)setting up committee, 4)specifying strictly the aim of use, 5)prohibition of getting sensitive information, 6)safe risk management including anonymity of materials, 7)general prohibition of providing it to the third party,8)withdrawal of consent, 9)setting up the window for consultations.

However, these guidelines have no legal sanctions, therefore they cannot ensure more effectiveness to exclude remarkable abuses. And as they are so-called a kind of patch work,

we cannot understand the fundamental viewpoint. Thus this model is not enough suitable in this field although they are flexible.

The third is the hard and soft law mixed style like in UK and Australia etc.. The Human Fertilisation and Embryology Act 1990(=HFEA1990) and the Human Tissue Act 2004 are typical of it, and furthermore they are supplemented by some guidelines. According to this model, we can normally correspond with various new medical and scientific technologies and problems.

Thus as a result of comparative study, in Japan, we should aim at this mixed type between hard law and soft law. And yet, we should consider into " the Doctrine of Medical Due Process" (5) . This is the legal theory which I have insisted for a long time. According to this theory, as a rule, medical innovation/medical research without due process is unlawful. And Medical Due Process contains (1) informed Consent, (2) balancing between risks and benefits, (3) due review by appropriate ethical committee, and (4) compensation to human subjects system because we cannot foresee concrete risks. And furthermore (5) it contains some exceptional legal sanctions to extreme abuses. Due to this doctrine, we can build a bridge between law, bioethics and medical and scientific research and practice. I think that we can realize it by enacting the Fundamental Law of Bioethics in Japan.

5.Conclusion

Nowadays we are confronted with some concrete problems in this field. For example, problems of genetic information are very important. Recently, the Genetic Information Nondiscrimination Act of 2008 (=GINA) has been enacted in USA. It contains the prohibition of genetic information discrimination in health, insurance and employment. And in Switzerland, Budesgesetz über Genetische Untersuchung beim Menschen has been enacted in 2004 (2007 enforcement) . Also it contains very important and very stimulating provisions in Art.1, 2, 4, 5, 6 etc.. In the Netherlands, Wet op de medische keuningen has been already enacted in 1997 which contains a very important provision of Art.3. Also in Austria , Gentechnik-Gesetz has been already enacted in 1994, which contains a very important provision of Art.67.

To the contrary, in Germany, a suggestion of legislation concerning protection of genetic information was made by Deutscher Bundes Referat in 2002 (6), but such legislation has not yet realized. Also in Australia, there are only Guidelines on it (7).

Nowadays we should consider trans-nationally on the problems of genetic information, because biobank system has become more and more important in the world (8). And the first thing we should have to do is to make the Fundamental Law of Bioethics in Japan in harmonization with foreign countries. We are now preparing this draft with Prof. Ryuichi Ida (Kyoto University). Concerning to important points in bioethics, we should make a fundamental legal system. The Fundamental Law of Bioethics will be in the center of bioethics. Thus I think

it better that the model of regulation on medical innovation/ medical research should be the mixed type of hard law and soft law, that is to say, four steps which consist of public guideline(=soft law), civil regulation, administrative regulation, and lastly criminal regulation(=hard law).

(Note)

(1) Koichi Bai, Kagaku to Ho to Seimei to (Science, Law and Life), in Takamine Matsuo (Ed.), Seimeikagaku Noto (Life Science Note), 1974, Tokyo University Press, p.197ff. especially pp.200-201.

(2) Albin Eser, Perspektiven des Medizin(straf)rechts. In: Wolfgang Frisch (ed.), Gegenwartsfragen des Medizinstrafrechts, 2006, pp. 9-31.

(3)See in detail Katsunori Kai, Life Science and Legal Rule, in Waichiro Iwashi/Toru Masui/ Yasuko Shirai/ Tomoko Hasegawa/ Katsunori Kai,Kogi: Seimeikagaku to Ho (Lecture: Life Science and Law),

(4) So also Jean- Pierre Baud, L' affaire de la main volée. Une histoire juridique du corps, Paris, Édition du Seuil, 1993, but he is not a libertarian.

(5)See Katsunori Kai, Hikenshahogo to Keiho (Protection of Human Subjects and Criminal Law), 2005, Seibudo, Tokyo, p.7f. and 30ff.

(6) Deutscher Bundes Referat Öffentlichkeit(Hrsg.), Enquete-Kommission. Recht und Ethik der Modernen Medizin. Schlussbericht, 2002.

(7) Don Chalmers, The Governance of Biobanks and Databases for Research－Towards an International Consensus on Ethical Principles, Taiwan Journal of Law and Technology Policy, Vol.4 No.1(2007),p.5ff.

(8) To legal system of biobank in detail, see Jasper A. Bouvenberg, Property Rights in Blood, Genes and Data, the Netherlands, 2006.

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