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What is Bioethics and Law? – From the Korean Perspective

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Abstract

Law and Bioethics is a relatively new academic area of dealing with a broad range of legal issues relevant to the biomedical ethics. This article first reviews the unique features of the Law and Bioethics as a special field of law. Legal topics in the Law and Bioethics are not limited to one specific area of a traditional field of law, such as criminal law, but cover almost all spheres of the legal phenomena. In addition, since the Law and Bioethics treats ethical issues raised in a very technical and highly specialized areas - life science and the medical science, legal reasoning in this area requires a certain level of knowledge on the scientific subjects as well as reflexive attitude towards legal and ethical conclusions. Considering these unique features of the Law and Bioethics, this article investigates the three regulation models: the model centered around regulations by law and rules, the model centered around administrative regulations, and the model centered around self-regulation. With specific examples, each model will be examined in the context of the Law and Bioethics.

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I. Introduction

Law and Bioethics is an area of dealing with a broad range of legal issues relevant to the biomedical ethics. In the United States, when bring other academic areas' methodologies or themes into the area of law, there is a tendency to create new areas and to name these interdisciplinary studies as Law and Society, Law and Economics, Law and Literature, etc. Law and Bioethics is one of such studies.

In addition, many of the biomedical ethics issues appear as the form of legal disputes. For example, the issue of whether the discontinuance of the medical treatment to terminal cancer patients is ethical becomes a social issue through the legal dispute in Quinlan Case. Many areas of handling biomedical ethics often come into the picture as a legal form. In this sense, the law and biomedical ethics are profoundly interrelated to each other. In Korea, although the frequency is not very often, such social issues become legal dispute, as represented by the so-called Boramae Medical Center case (Supreme Court 2004. 6. 24.Sentenced, 2002DO995).

II. Law and Bioethics as a Special Field of Law

The area of Law and Bioethics can be reviewed from the traditional view of the legal academia. In Korea, traditionally, the legal academia is divided into two sub-areas: the study of public law and the study of private law.

The third area, or the study of social law, is commonly added into these two sub-areas. The area of public law includes the studies of constitutional law, criminal law, and administrative law, while the area of private law covers the studies of civil law, business law, etc. In addition, the area of the social law contains studies of laws relevant to labor relations and other economic issues. Such classification is very useful for educating laws in the legal education institutes, but this classification does not fully satisfy the many actual legal demands in society. As a result, recently, considering the specifics in the legal phenomena and the needs in the legal demands, further professional and practical legal areas are getting more specifically divided as in the form of "the special field of law." In this category, a number of various types of laws are captured such as bank law, bankruptcy law, consumer law, and securities act, as well as intellectual property law and tax law.

The necessity of this special field of law comes from the fact that both the traditional public law principles and the private law principles can be applied to this field when appropriate. Because of that reason, the Law and Bioethics can be placed within the special field of law. Many cases handled in the Law and Bioethics have closely related to the national legal regulations. Currently, in Korea, the 'Bioethics and Safety Act' was enacted and recently became effective, and the 'Mother and Child Health Act' or the 'Internal Organs, etc. Transplant Act' etc. were enacted and have been in force for a relatively long period of time. These acts can be included into either the study of the criminal law or the study of the administrative law. In addition, because several issues in the biomedical ethics come before the public as a medical malpractice dispute, which can become claims for damages based on torts, principles of the private law are also often applied to these acts. However, if these acts are treated solely

within one aspect of laws, for example, the criminal law, there is a risk of neglecting the other aspects of acts, such as the aspects of the administrative law or the civil law. As a result, such a special field of law must be treated as one independent area of law, based on its similarities in the legal phenomena and its necessity of legal demands.

III. Two Specific Consideration Points for the Law and Bioethics

In order to understand the Law and Bioethics deeply, two specifics should be considered. In particular, the Law and Bioethics has special circumstances in establishing the methodologies for the Law and Bioethics, which are quite different from the other general legal areas.

First, the Law and Bioethics must take into account the fact that the subject of the study is the life science and the medical science - very technical and highly specialized areas. These areas require a large amount of knowledge over the boundary of the general public's sensible solutions. Thus, if the legal reasoning in this area is reached based on the sensible solutions, there is a risk of producing misunderstandings. Therefore, in order to deal with issues in the Law and Bioethics, the acquirement of relevant knowledge on life science and medical science becomes a prerequisite for the development of law and regulations.

Second, since the Law and Bioethics treats issues in ethics, it should maintain some level of carefulness. The law and ethics are related in some parts of their contents, but basically they flow throughout very different ways of thoughts. For example, the legal positivists argue that the law and ethics should be separated entirely and treated as two different norms. Of

course, the Korean Civil Law contains a provision which reflects the ethical judgment directly into the legal judgment, such as the Civil Act §103 Jurist Acts Contrary to Social Order. Furthermore, in criminal law, it becomes very hard to exclude the ethical consideration from the law when, for example, defining obscenity in the law punishing obscene behaviors. However, for the enhancement of the freedom, I believe, the reflection of ethical consideration into the law should be minimized. As a result, an interdisciplinary area of the Law and Bioethics must not accept ethical conclusions uncritically as legal conclusions but must reach legal conclusions after conducting a reflective review of the ethical conclusions.

IV. The Subjects of the Law and Bioethics

Let's look at the subjects dealt by the Law and Bioethics. Generally, the Law and Bioethics is a type of legal phenomena related to the area of the biomedical ethics. However, such legal phenomena can be grouped into several categories.

First, in a broad sense, the area dealt by the Law and Bioethics is the area of legal regulation. Legal regulation is sometimes taken as a form of the criminal law, i.e., the imposition of the punishment and sometimes taken as a form of the administrative law, such as the imposition of administrative punishment or other dispositions. The principle of *nullapoena sine lege* must be applied in the imposition of the punishment, while in the case of the administrative punishment, the principle of administration governed by law must be considered as a primary principle. Regardless of the form of regulations, either the criminal punishment or the administrative punishment, the legal regulation is not

specifically applied to the case-by-case basis, rather applied to all cases as a general and universal form. In other words, this characteristic of generality in the law is the major feature of the legal regulation.

Second, this generality of the law cannot solve all issues produced in the Law and Bioethics. As a result, either institutes or persons who have the power to make individual decisions according to the law must perform the role of reviewing individual cases in order to figure out whether the given cases are suitable for the legal regulation. This role can be conducted by the administrative agency which holds the delegated legal authority. Or, the court can conduct this role, when the case goes into the court as a lawsuit. In the United States, the litigation process in the court has historically played more meaningful role than administrative agencies. In particular, a series of cases conferred by the federal Supreme Court has estimated legislations and the administrative decisions done by the state and the federal governments from the constitutional point of view. As a result, in the United States, the federal Supreme Court has performed the leading role in making polices for bioethics. In Korea, many legal issues in this area will become a legal dispute and will be presented in the Supreme Court or the Constitutional Court. Thus, I expect that many specialized principles in this area will be confirmed by the Supreme Court or the Constitutional Court and will be settled in Korea.

Third, there is an area where issues have yet been legal matters, but still relevant to the law, especially holding close relationship with the constitutionally-guaranteed basic human rights. That is the area of self-regulation in the biomedical ethics. According to the view of the traditional legal studies, the area of self-regulation is included in the private area, in which the law is reluctant to interrupt. Without any special

reason, the law has tended not to interrupt into the private area for the protection of the freedom in society. In addition, the application of the public law into the area of private affairs has been considered as very awkward and uncomfortable, because the area of private affairs has been thought as the exclusive area for the private law. However, one perspective of the modern legal studies has justified this application of the public law to the private area within the boundary of the constitution. Consequently, principles of the constitutional law, which has been traditionally categorized in the public law, should not be excluded but be actively employed in their applications to the private affairs. Therefore, even when the self-regulation solves the ethical issues within the research community, that self-regulation should continue to be the subject of monitoring in order to guarantee the dignity of human beings, the right to pursue one's happiness, and the right to equality. Furthermore, when reviewing the self-regulation, the self-regulation's invasion of the researchers' freedom must be one issue. In other words, even though the self-regulation is not the legal regulation, it should exit within the boundary of the constitutionally-guaranteed human rights. In this sense, from the time when laws for the self-regulation are drafted, the constitutional issues for the self-regulation should be regarded in great account.

As such, the Law and Bioethics covers both legal regulations and self-regulations, as well as handling specific cases where detailed legal and bioethical issues are brought up. Therefore, the subjects of the Law and Bioethics are very broad, in fact, including almost all areas of the biomedical ethics.

V. Regulation Models in the Law and Bioethics

Historically, the research in the Law and Bioethics often lost its ethics. Even though hugely tremendous expectations on the research result exist, there is a study that must not be conducted. Moreover, as the research in the life science creates the new biological environment, the research in the life science holds a risk to create a new virus which has never existed in the earth. In this sense, the community has a reasonable motivation to regulate the research in the life science both from the ethical aspect and the safety aspect.

On the other hand, such regulation should not destroy the essential nature of the research protected by the Korean constitutional law. The Korean Constitution §22① says that "all citizens shall enjoy freedom of learning and the arts." This provision indeed implies that the scientists have the freedom to conduct their own research. The Korean Constitution §22① has been interpreted as the basic human rights of guaranteeing all people's intellectual freedom, not limited to but including professors in universities and researchers in research institutes. This freedom consists of the freedom of research, the freedom of announcing results of the research, the freedom of lecturing, and the freedom of academic assemblies. Among those, the freedom of research has been highly protected given the same level of protections to the freedom of worship or the freedom of conscience. However, the academic freedom has been understood as prohibited when the academic freedom violates the national security, the basic principle of the liberal democracy, the basic human dignity, or other people's basic rights.

In particular, the Korean Constitution §37② indicates that "the

freedoms and rights of citizens may be restricted by Act only when necessary for national security, the maintenance of law and order or for public welfare. Even when such restriction is imposed, no essential aspect of the freedom or right shall be violated." According to this provision, there must be the 'legal' grounds for regulating the freedom of research. In Korea, the laws of regulating the freedom of research are as follows: 'Bioethics and Safety Act,' 'Pharmaceutical Affairs Act,' 'Medical Service Act,' etc. The 'Pharmaceutical Affairs Act' becomes the ground law for regulating the clinical trial research, and the details of the regulation are articulated in the Pharmaceutical Affairs Act, its enforcement decree, its enforcement rule, and the Korea Good Clinical Practice of FDA. In this area's foundation studies other than the clinical trial research, the freedom of research is basically guaranteed except for the embryo research and the genetic research which has been applied by the 'Bioethics and Safety Act.'

The restriction on the freedom of research in the area of life science can be viewed as the regulation to the life science. The regulation model to the life science can be divided into three: the model centered around regulations by law and rules, the model centered around administrative regulations, and the model centered around self-regulation.

First, the model centered around regulations by laws and rules specifically articulate the details of the regulation as a form of laws and rules. Generally, the law provides the basis of the legal regulations first, and the specifics are then explained in the enforcement decree or the enforcement rule. Regulations by laws and rules are performed by the laws that have specific provisions regarding which bioethical behaviors are not allowed and how these behaviors should be punished. In other words, the subjects of the regulation are usually specific research

behaviors, and either the criminal punishment or administrative punishment is imposed in the case of the violation of the law and rules. Since this model prescribes the type of behaviors which are prohibited, it guarantees the trust of individuals and predictability resulting from the consistent application. However, this model fails to deal with newly-raised issues based on the advancement of the scientific technologies flexibly. It is because lots of time and efforts are required for the amendment of the law and rules. The example of this model is the German legislation of the 'Embryo Protection Act,' the strongest model of legal regulation which legally prohibited all research using embryos.

In the case of the 'Bioethics and Safety Act,' two separate rules were enacted for specifically articulating the details of the Act: the 'Enforcement Decree of Bioethics and Safety Act' and the 'Enforcement Rule of Bioethics and Safety Act.' The enforcement decree takes the form of a Presidential decree, while the enforcement rule takes the form of a decree of the Korean Ministry of Health and Welfare. As in this case, the model centered around regulations by laws and rules is ultimately grounded in the law, which comes from the idea that the national assembly holds the democratic justification for the regulations based on the people's support in the general election. Again, since the basic human right of the freedom of study has to be protected, the regulation on this right should be conducted by the law legislated by the representatives of the people, i.e., the national assembly.

The 'Bioethics and Safety Act' holds the characteristic of the general law which applies generally to most regulations. More specifically, the Bioethics and Safety Act §3 states that "unless there are other provisions from other laws concerning bioethics and the safety of life sciences and

biotechnologies, this act will be relied upon solely." As a result, other low rank rules or guidelines, which contain details contradicted to this act regarding the ethics and safety of the life science, must follow the contents of this act. However, since this act is the general law, special laws hold the priority when applied if special laws articulate the different details for specific contents.

The 'Bioethics and Safety Act' is composed of 9 chapters, 55 articles, and 4 additional provisions. In the Bioethics and Safety Act, the purpose, definitions, and other general contents are articulated in the General Provisions, and the contents include National Bioethics Committee, Institutional Bioethics Committees, Embryo Production and Research, SCNT Embryos, Genetic Test, Protection and Use of Genetic Information, Gene Therapy, and Supervision, Supplementary Rules, and Penal Clause. According to §1 of the Act, "this act aims to enhance the health of human beings and the quality of human life by creating conditions that allows for the development of life sciences and biotechnologies that can be used to prevent or cure human diseases. Additionally, this act aims to protect human dignity and to prevent harm to human beings by ensuring that these life sciences and biotechnologies are developed safely and in accordance with the principles of bioethics." Here, "life sciences and biotechnologies refers to the sciences and technologies that study and utilize human embryos, cells, and genes (Act §2)." Generally, this act stresses not only the bioethical aspect but also the technological preparation for the other life science. In this sense, this act has been criticized because of its narrow range of regulations considering the broad range of purpose of the act.

The model centered around administrative regulations can be

divided into two cases: one based on a uniform law of the grounded act and the other based on not-uniformly grounded laws. Both cases find the ground of regulations in the professionals' pursuit of the professionalism for national interests. Administrative regulations first stipulate the composition of the administrative institute and its functions in the laws and then allow that institute to regulate specific behaviors. This model can handle new issues arising from the rapid changes in scientific technologies easily and consider expert opinions from advisory committees which are composed of professionals. However, the considerable amount of discretion given to the administrative institute can be abused in some legal cultures. The HFEA of the United Kingdom are determined to be similar to this model. Holding a wide level of discretions for the embryo research and the stem cell research, the HFEA decide the approval of a research professionally.

In the Korean legal system, the guideline can be developed based on the forms of the order or an established regulation. The 'Biotechnology Support Act' §15(Preparation and Implementation of Experimental Guidelines) ② states that "the experimental guidelines as referred to in paragraph ① shall include measures necessary to prevent biological hazards, negative influences upon the environment and any ethical problems that may arise in the course of research on biotechnology and its industrialization, and shall also include safety standards for the transfer, handling and use of a genetically converted organism." This provision functions as a ground article for the administrative regulations in the Korean legal system.

The 'Enforcement Decree of the Biotechnology Support Act' §14(Formulation of Guidelines for Clinical Test and Inspection) provides

that ① "in order to establish a system of clinical testing and inspection for biotechnology-related products under the provisions of Article 14 of the Act, the Minister of Agriculture and Forestry, the Minister of Industry, Commerce and Energy, the Minister of Information and Communication, the Minister of Health and Welfare, the Minister of Environment and the Minister of Maritime Affairs and Fisheries shall formulate and implement guidelines for clinical testing and inspection after undergoing the deliberation of the Council: *Provided*, That this shall not apply if it is otherwise prescribed by other Acts and subordinate statutes." ② "Guidelines for clinical testing and inspection as referred to in ① shall include the matters falling under each of the following subparagraph: *Provided*, That if there are matters which cannot be covered by such matters may not be included in the guidelines." The examples are as follows: "1. animal tests of commodities produced or manufactured by using genetically modified organisms; 2. clinical tests of pharmaceuticals produced or manufactured by using genetically modified organisms; 3. analysis of components, degree of purity and degree of activity of commodities produced or manufactured by using genetically modified organisms; and 4. other necessary matters for clinical tests and inspection of biotechnological products."

In spite of these ground provisions of these guidelines, the guidelines for the ethics and safety are not successfully composed yet. In particular, the government must prepare guidelines for new areas of the life science such as the stem cell research, the genome research, and the xenograft research in the near future.

The model centered around self-regulation indicates that the individual institute or school develop their own standards and regulate

their own organizations. This type of regulation finds the validity of the regulation in securing the freedom of research. This will be the most desirable type of regulations in which the group of scientists who have the freedom of research regulates by themselves through their own decisions. However, the self-regulation, whoever the subject of the regulation will be, is a very difficult task, because the self-regulation is easy to adopt permissive or noninterference policies. As a result, countries adopt the self-regulations as a basic model but, in fact, only allow institutions' self-regulations when they follow the governmental guidelines with some level of latitude. In particular, in the United States, self-regulations are executed by the Institutional Review Boards (IRB or IEC) which are organized by civil research institutes - i.e., non-governmental officials. The IRB regulates individual studies, including the decision of whether to approve a certain research in the life science area, whereas the role of government is to supervise this IRB's performance. This model can enjoy the advantage of employing professional knowledge, but there is a risk of losing the consideration of the public interests because the review board is located in the private area. In particular, when the IRB is established inside of research institutes, it has been concerned whether that IRB can maintain its independency from that institutes. In Korea, the self-regulation is limited by the regulation by law and rules and the administrative regulations. Thus, the self-regulation is only permitted when no laws, rules, and administrative regulations are applied. In particular, the Institutional Bioethics Committees in the 'Bioethics and Safety Act' and the 'Institutional Review Board' in the 'Pharmaceutical Affairs Act' become the major institutional strategy for this self-regulation.

The three models explained above - the model centered around regulations by law and rules, the model centered around administrative

regulations, and the model centered around self-regulation - consist of the entire regulation model based on their mutual relationships. If the model centered around regulations by law and rules contains the provision of imposing the punishment type of sanctions, this provision must be interpreted as a criminal provision, although this provision is not included in the criminal law. Since the punishment publicly restricts the freedom of human beings, there is a necessity to prevent the abuse of the power of the punishment. In this case, therefore, the application of the punishment provision based by inference should be prohibited following the principle of *nullapoena sine lege*.

In addition, if the sanction does not appear in the form of the punishment, or no sanction is provided, the general principles of the administrative law should be applied. Thus, for example, the principle of the protection of the trust or the principle of the proportionality can restrict the sanction provisions. The protection of the trust is the general principle of protecting people who are deserved to be protected because their trust on the government is based on the government's previous actions or legal grounds. The proportionality is the general principle for balancing both the purpose and means of regulations; that is, it has been generally accepted not to regulate a person harshly considering the purpose of the regulation.

Administrative regulations should not exceed the boundary of the authority delegated by the law, which becomes the ground of constitutional basic rights or administrative regulations. Thus, if the freedom of a researcher is excessively intruded by the administrative regulations or if the ground rule of the administrative regulations is ambiguous, these administrative regulations should be questioned and

treated through the administrative litigations, or sometimes the constitutional appeals.

In conclusion, these three models have both advantages and disadvantages. Therefore, in practice, the issue is which model will be placed in the middle and which model will serve as a supplementary device for the selected model. Because the research areas in the life science are highly specialized, even life scientists could not understand other life scientists' areas of research. As a result, in order to achieve the policy goal of making bioethics, it is necessary that researchers be aware of the importance of self-regulations and change their research culture into taking self-regulations seriously. I believe, therefore, the self-regulations should become the foundation of the regulation. As a supplement of this model, it is desirable to have legal provisions regarding prohibitions of certain behaviors and authorization of an administrative institute for the supervision of that self-regulation.