

Laws on Medicine

- Lecture No.1 (in Classroom 22, on Wednesday, October 1, 2008, at 15:00-16:40)
 - 1) Perspective on laws on medicine
 - 2) Contract-based thought
- Faculty of Law, University of Tokyo
- Norio Higuchi and Yasuji Kodama

A faint, light blue map of the Asian continent is visible in the background of the slide, centered behind the text.

Project of University of Tokyo:
“Law and Policy on Biotechnology and Bioethics ”

Progress in 2 Years and Future Prospects

Norio Higuchi
Representative Researcher of Above Project
Graduate Schools for Law and Politics, University of Tokyo

July 13, 2004

Original Research Objectives

① Construction of interdisciplinary research network

To bridge over medical science and jurisprudence, and further over other specialists

② Fostering of new specialist groups

What is specialization in biotechnology and bioethics?

③ In terms of concrete target

To offer a new course “Life Science and Law” in the newly established Law School

Original Research Objectives: Bioethics/Biotechnology

● Fields of Bioethics and Law ●

Specialization to discuss bioethics

① Ethics and law: Rulemaking for bioethics

E.g.: Cloning technology law, a movement to enact law in artificial reproduction
What are roles of laws in bioethical field?

② Ethics and medicine: New ethical issues in medical field

Progress in technology of recent years and formation of new problems go beyond conventional borders .

③ Need for building networking

Necessity for joint studies by an interdisciplinary/international research team

● Fields of Biotechnology and Law ●

Specialization to discuss biotechnology

① Status quo and issues of Intellectual Property Law for biotechnology

② Status quo and issues regarding inter-relation between bioethics and competition policy

Members of Research Team

Norio Higuchi:	Tokyo U; Law; Anglo-American law
Makoto Ito:	Tokyo U; Law; Civil Procedure Law
Hitoshi Saeki:	Tokyo U; Law; Criminal Law
Yoshiaki Morozumi:	Tokyo U; Law; Islamic law
Nobuhiro Nakayama:	Tokyo U; Law; Law for Intellectual Property Right
Masato Dogauchi:	Tokyo U (currently attorney, Waseda U); Law; International civil procedure law
Tadashi Shiraishi:	Tokyo U; Law; Competition law
Yasuyoshi Ouchi:	Tokyo U; Medicine; Prof. at advanced age dep't; Chairman of ethics committee
Shigeo Mori:	Tokyo U (currently Teikyo U); Pathology
Shinobu Gamou:	Kyorin U; Medicine; Chairman of ethics committee
Hidetaka Aizawa:	Waseda U (currently Hitotsubashi U); Law; Law for Intellectual Property Right
Veronica Taylor:	Washington U; Law; Asian law; Overseas advisor

Additional participation of young jurists and medical doctors by forming working groups

Activities During Past 2 Years

Activities During Past 2 Years

- 1) Full sessions and societies for study: 16 times
- 2) Discussion on bioethical case studies: 13 times
- 3) Societies for study on “Law and Policy on Biotechnology”: 2 times
- 4) Intensive series of lectures on “American Law on Bioethics ”:
13 times
- 5) Participation in activities of other domestic groups: 14 times
- 6) Dispatches to international conferences/seminars: 5 times/5 nations,
total of 11 people
- 7) Symposiums/workshops by inviting specialists from overseas:
8 times

Example of Symposium/Workshop

● “Symposium: Ethics and Law in Contemporary Society”

March 13, 2003 at Maru-biru Hall on 7th Fl., Marunouchi Bldg.

MC: Makoto Ito (Tokyo U)

“Corporate Ethics” by Noboru Kashiwagi (Tokyo U)

Comment by Kenichi Osugi (Metropolitan U)

“Bioethics” by Norman Fost (Prof. , Faculty of
Medicine, Wisconsin U)

Comment by Yasuyoshi Ouchi (Faculty of Medicine, Tokyo U)

“Intellectual Property Rights and Ethics” by Nobuhiro Nakayama (Tokyo U)

Comment by Hidetaka Aizawa (Waseda U)

Comment “What Links Three Ethics” by Noboru Kashiwagi and Norio Higuchi



Example of Symposium/Workshop (2)

● Workshop

“Law and Ethics on Artificial Reproduction—U.K., Australia, and Japan”

September 16, 2003 at main conference room on 8th Fl., Faculty of Law, Tokyo U.

<Section 1>

“Artificial Reproduction in U.K.” by Derek Morgan (Prof. of Law School, Cardiff U.)

“Artificial Reproduction in Australia” by Loane

Skene (Prof. of Law School, Melbourne U.)

“Artificial Reproduction in Japan” by Noboru

Ienaga (Senshu U.)

<Section 2>

Q & A Session

- Right to know one's origin
- Donor eggs from sisters, and so forth



Intensive Series of Lectures on “American Law on Bioethics ”

- Intensive series of lectures during May through July in 2003 through the use of case-study books employed in American law schools by inviting jurists in charge of editing these publications

Their brief outline being released in <http://www.j.u-tokyo.ac.jp/biolaw/>

◎Example

Lecturer: Rebecca Dresser (prof. of Washington U.; member of the Presidential commission on bioethics; giving lectures in law schools and medical schools)

Teaching material: Shapiro, Spece, Dresser & Clayton, *Bioethics and Law: Cases, Materials, and Problems* (West Group, 2d ed. 2003)

- ◆ Development of American ethics on medical research: Appearance of the Belmont Report

Basic Ethical Principles: meanings of the three principles

- ① Respect for persons; dignity of individuals
- ② Beneficence; good deed=Do no harm
- ③ Justice; righteousness

◆Deliberation in IRB(Institutional Review Board=Research Ethics Committee)

Study on how the three basic principles of Belmont actually work

Exercise: Clinical test of a new drug for Alzheimer's disease

While this new medicine has a potential to be efficacious to an improvement of memory capability and cognitive faculty of Alzheimer's patients, it also possesses an element of risk to cause a rise in blood pressure and severe kidney disorder. A test subject is paid \$300. Investigative studies so far have found it efficacious for early and intermediate Alzheimer's.

Case Studies on Bioethics

● Discussion by the three persons of jurists and medical doctors on interim exercises regarding bioethics and law

- ◆ 13 sessions in total; discussions joined by some 10 people in addition to these three
- ◆ Three persons wrote manuscripts that were serialized in *Jurist*.
The serial appeared 13 times from April 2003 through May 2004.
- ◆ Further, these writings, with notes and questions appended to each exercise, are scheduled to be publicized as teaching materials for graduate schools for law in the fall of 2004 from Yuhikaku.

● Two examples

① Case study on bioethics: Case 1

“Disclosing of Huntington's hereditary disease”: A 45-year-old woman is diagnosed with Huntington's disease. She asks the doctor not to notify her family and relatives including her children of the disease. What should the doctor do?

Shoji Tsuji: Faculty of Medicine, Tokyo U; leading authority on Huntington's disease

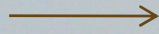
Kaori Muto: Faculty of Medicine, Shinshu U; sociologist

Norio Higuchi: Faculty of Law, Tokyo U

Issues on
Reproductive
Assistance
Medicine



Case Study:
Bioethics
and Law



Relation Between Medicine and Law

I Introduction

Common features between doctor and jurist→←Gap between the two
Phenomenon to legislate medical care

Six points as its reason: Yutaka Teshima, *Introduction to Medical Law*, (Yuhikaku, 2005)

II Image of Law

【Interim Exercise】 75-year-old man dies of an operation on the aortic aneurysm; the hospital admits a medical error.

Consultation with an attorney, who says, “We’d better report it to the police, just in case.”

【Question】 In consequence, what will happen ?
Why did one consult with an attorney?

Image of Law

Derived from 【Interim Exercises】

1 Laws for doctors and distrust of attorneys

2 In case of relying on guidelines

3 Out of dialogues between doctors and jurists

【Question】 Incurable hereditary disease.→Patient's wish
not to reveal it to family

What should the doctor do?

Example of CASE 1 →Ms. Kaori Muto's talking in the third
session

Presented problems regarding the rulemaking there

Distrust of jurists by participating doctors

Case Study: Bioethics and Law, Q1 & 2 in p.16

○Image of Law

- ① Absence of senses of job sites
- ② Abstract, uniformed, perfunctory, plain, alternative
- ③ Definite conclusion
- ④ Criminal law, speaking of laws

Laws on Medicine

Redefine the state of laws and jurists involved in medical care

Norio Higuchi, *Consideration of Medical Care and Law—
Ambulance and Righteousness* (Yuhikaku, 2007)

Id., *Sequel to Consideration of Medical Care and Law —
Medical-Care Guidelines for Terminal Phase of Disease*
(Yuhikaku, 2008)

Yutaka Teshima, *Introduction to Medical Law* (Yuhikaku, 2005)

Laws on Medicine

- Two perspectives to redefine the state of Japanese laws
 - 1 Perspective from foreign nations (U.S. primarily)
 - 2 Perspective from the specialist of medical doctor

International and interdisciplinary perspective

→ “*Consideration of Medical Care and Law*”

In reality, to consider the state of laws

Way to View Doctor-Patient Relation

Doctor-patient relation viewed by jurists

1) Law to be applied?

2) Why do jurists like a contract? How do doctors and patients grasp a doctor-patient relation?

Few descriptions defining a doctor-patient relation to be contractual in an American textbook *Health Law, Law & Medicine*

Reasons for Japanese Jurists' Preference for Contract

- 1 There is no other suitable concept (tool).
- 2 Law constitutes a platform anything can be loaded on as long as there is a concept.

Convenience of contracts

- 3 Law perfectly fits the latest fashion purported as a patient's right to self-determination and an equal doctor-patient relation.

Refutation of Contract Theory

1 Patients' voice

Doctors' voice

2 Survey on a model with respect to the doctor-patient relation

3 Ethical code of American Medical Association

Questions About Contract Theory

Question as to a theory of quasi-mandate contract (common view):

- ① So few regulations, i.e., 13 clauses
- ② Entry to contract
- ③ Reasons for terminating contract; terminable(cancelable) anytime
- ④ Appointee's duty to report occurs at the mandator's demand.
- ⑤ Regulations on the mandate contract fundamentally assume the trust of administrative works related to properties.
- ⑥ Appointee's remuneration and demand for expenses
- ⑦ Appointee, during the course of disposing of entrusted administrative tasks, when damaged without self-negligence, can demand its compensation from the mandator (Article 650, paragraph (3))

Based on these observations, even with the use of an instrumental conception of a quasi-mandate contract, there are only 13 clauses of provisions in Civil Law Act, the majority of which causes uncertainty as to its adaptability to the doctor-patient relation.

Questions About Contract Theory

- 1) Nature of equality between those concerned, plus information disparity; one side being handicapped in the first place
- 2) Medical care within an organization, not reflecting reality
In reality, it's a contract with the hospital. Doctor?

Doctor-patient relation→Toward a model of mandate
Approach of fiduciary relationship

Norio Higuchi, *Epoch of Fiduciary* (Yuhikaku, 1999)

This enables doctors and jurists to take the same standpoint.

Questions About Contract Theory

- ① A doctor found an unconscious person and a five-year old child remaining conscious fallen on the street.
- ② A doctor was facing patients behind their payments of medical expenses. Could he reject to provide any more medical treatments?
- ③ In the wake of a surgical removal of a certain organ, the doctor gave the patient a very kind and meticulous explanation regarding risks and the possibility of alternative measures (informed consent). The patient in his consent underwent an operation and came to recover, and later found out that the doctor obtained a patent through the use of the very organ he extracted.
- ④ Upon getting hospitalized, a jurist of the patient's acquaintance said to him, "Your counterparty is either a corporation or a person who set up this hospital, and doctors and nurses are merely execution supporters (or proxies) of the hospital."
- ⑤ A patient died after a surgery in a hospital. Explanation to the surviving members of the family?
- ⑥ Information that a patient being a company's president was seized with terminal cancer.

What sort of other examples can one think of?

Aren't there any better instruments among Japanese laws?