Laws on Medicine

- Lecture No.2 (in Classroom 22, on Wednesday, October 8, 2008, at 15:00-16:40)

１）Peculiarities of the industrial physician and medical examiner for life-insurance examination

2) Contract-based thought —situations where contract forms barriers

3)One form of conflict of interest (if time permits)

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Laws on Medicine

Redefine the state of laws and jurists involved in medical care

Most standard textbook:
Yutaka Teshima, *Introduction to Laws on Medicine* (2nd ed., Yuhikaku, 2008)
Students are hopefully expected to read this book and give a further thought to the subject.

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)

Doctor-Patient Relation→Start from Contract

To redefine the starting point per se:

1) To rearrange merits and demerits in one's own way

2) Barrier in "doctor-patient relation" in U.S.

Barrier in "contract" in Japan

There are cases where doctors and "patients" are not involved in a doctor-patient relation or a contractual relation.

Doctors are already engaged in a contractual relation with other party concerned.

Example 1: Industrial Physician

A construction-equipment operator X underwent a physical examination prior to his employment. The construction company outsourced health-checkup affairs to a separate firm Y1 in medical care business. A doctor Y2 employed by Y1 conducted diagnostic examination including an X-ray diagnosis, and a radiologist Y3 detected mediastinal dilation that was possible to be Hodgkin's disease of malignant lymphoma, thus made a report of his finding to Y2, referring also to a need for detailed testing by a CAT scan. But, upon sending a report to Y1, just saying, "X-ray picture shows abnormality," Y2 did not touch upon mediastinal dilation in his statement. Y1 in turn sent a report to the construction company stating there was no problem about X's health condition, though its reason was unclear. X died 8 months later.

Reed v. Bojarski, 746 A.2d 433 (N.J. 2001)

Example 2

Let us suppose that, just now, you have been diagnosed with cancer of the prostate in an advanced stage. This type of cancer can be cured well if detected early, but is incurable otherwise. Well, thirteen months ago, when you made an application to take out life insurance, the result of blood test for diagnostic examination was provided to the insurance company, and you were not notified of the result. This has been found out now.

* Hannah E. Greenwald, *What You Don't Know Could Save Your Life: A Case for Federal Insurance Disclosure Legislation*, 102 Dick. L Rev. 131 (1997).

Industrial Physician

Industrial Safety and Health Law

(Industrial Physician, etc.)

- **Article 13** The employer shall, by each workplace of the scales prescribed by Cabinet Oder, appoint an industrial physician from among medical doctors as provided for by the Ordinance of the Ministry of Health, Labor and Welfare, and have said person carry out health care for workers and other matters prescribed by the Ordinance of the Ministry of Health, Labor and Welfare (hereinafter referred to as "health care for workers or the like").

Article 1 The purpose of this Law is, in conjunction with the Labor Standards Act, to ***secure the safety and health of workers in workplaces***, as well as to facilitate the establishment of comfortable working environment, by promoting comprehensive and systematic countermeasures concerning the prevention of industrial accidents, such as taking measures for the establishment of standards for hazard prevention, clarifying the safety and health management responsibility and the promotion of voluntary activities with a view to preventing industrial accidents.

Industrial Physician

Industrial Safety and Health Law

Article 66 The employer shall, as prescribed by the Ordinance of the Ministry of Health, Labor and Welfare, have medical examinations of workers conducted by a physician.

Article 66, paragraph (6) The employer shall notify workers who have undergone medical examinations conduced pursuant to the provisions in Article 66, paragraphs (1) to (4) of the results of said medical examinations as prescribed in the Ordinance of the Ministry of Health, Labor and Welfare.

Industrial Physician

Question 1: Is it true to say that Example 1 in the above can happen in the U.S., but not in Japan?

Question 2: Cite peculiarities of the industrial physician as a medical doctor.

Case of Medical Examiner for Life-Insurance Examination

Minoru Oya, *Medical Practice and Law* (2nd ed. of compensated new version), from p.165 on down (Kobundo, 1997)

①Diagnosis by the medical examiner does not aim at medical care as in physical examination.

②As to his diagnosis, the medical examiner assumes the duty of the diligence of a good manager to the insurer, not to the insured (i.e., the applicant of an insurance policy in the above example).

③While a standard of the examiner's duty of the diligence, according to the precedents and theories, equals the one for general practitioners, the duty level is considered to be lower due to the peculiarity of the life insurance examination (a situation such as those undergoing examinations not accurately responding to interviews with the doctor).

Medical Examiner for Life-Insurance Examination

Question 1: Is it true to say that Example 2 in the above can happen in the U.S., but not in Japan?

Question 2: Cite peculiarities of the examiner for life-insurance examination.

Scheme to Prevent Tragedy

To fulfill the duty to directly notify the doctor of the diagnostic outcome

Barrier of contract in our county

1) nonexistence of contractual relation

2)Additional barrier can be that the doctor has been already in a contractual relation with the employer and the insurance company.

Case of insurance→Kind of conceivable trade secret

Barrier exist in the U.S. as well.

Whether or not physician-patient relationship is deemed appropriate.

Changes in the ethical code of American Medical Association

Scheme in U.S.

1 Thin wall of the concept named relationship, not a contract

2 To change substance by the ethical code, not by law:
Soft law; responsibility of the specialists; an autonomous norm

There is the guideline for the industrial physician in our country, too…

One scene of Doctor's Conflict of Interest

(The following will be discussed if time permits.)

1 Authorization/propulsion for new drug development under a tie-up between industry and academia

2 Procedure for the approval of a new drug

A doctor X connected to a pharmaceutical company A becomes a committee member of the pharmaceutical council and gets engaged in approval of new drugs.

How should this problem of conflict of interest be resolved?

Measures Taken Now

Europe/U.S.

As for the problem of drugs, there is a precedent of the tripolar agreement.

In each case, the quantitative degree of monetary relationship is the base to distinguish the qualification for participation between deliberation and voting.

Example: When a new drug of a company A is an agenda item,

◎unable to participate in voting if in excess of ¥500,000 a year

◎unable to participate in deliberation if in excess of ¥5 million a year→Withdrawing regarding the relevant case

Solution to Conflict-of-Interest Rule

Prohibition rule: Rule to forcefully eliminate those concerned, i.e., to prohibit a state of conflict of interest

Consent rule: Rule to approve if the consent is obtained from those menaced with a harmful effect with conflict of interest

Disclosure rule: Rule to approve if it is disclosed that there is conflict of interest

Peculiarity of Case of New Drug Approval

Tie-up between industry and academia is a measure for propulsion.

It is important to guarantee scientific and specialized natures in the approval of new drugs.

Apprehension about conflict of interest to cause the negligence of scientific and specialized natures

Conflict of Interest in Moore Verdict

Moore v. Regents of the University of California, 51 Cal.3d 120 (1990)

Upon the removal of the spleen from a patient, a doctor extracts cell line, has it patented, and harvests huge profits.

Profit in medical care and another in medical research

California State's Supreme Court approved the application of the legal principles of informed consent , but denied the wrongful act of conversion (embezzlement of property, infringement of right of ownership).

Gist of Moore Verdict

Consent rule?

Case where the patient had no other choice but splenectomy

How about an alternative not to allow the use for research?

Consent rule if conceivable

①Could the doctor refuse a treatment of such patient?

→refusing the use of all data; the internal organ excepted?

②Could the patient collect the organ and dispose of it? At least, could it be stored? (Change of the patient's mind)

Informed Consent

What does it protect in this case?

1 Actual possibility of the surgery for the sake of research usage

(restraint on unnecessary surgeries)

2 Even if a research usage is secondary, cooperate for research should be up to one's self-determination/ voluntary decision.

Actually, Isn’t It Disclosure Rule?

Even after the disclosure, it is possible that the patient disapproves of the plan.

When the patient asks for the surgery but denies research usage.

Consent rule

→Danger of bringing about the same result as conversion

Resolution by negotiation→Compensation

Possibility for Research After Splenectomy

In this case, there is no possibility of informed consent before the fact.

Inspiration at the sight of the spleen removed

It is all right to have disclosure rule.

Transparency in medical research: danger of abuse

Case of Pharmaceutical Council

Presently, it is a kind of prohibition rule.

Isn’t there a possibility for consent rule?

Is it not more rational to resolve the subject matter with disclosure rue?

Isn’t disclosure rule a more rational solution to the subject matter?