

Laws on Medicine

Lecture No.3 (in Classroom 22, on Wednesday, October 15, 2008, at 15:00-16:40)

- 1) Ethics committee: What is jurists' role in there?
- 2) In clinical research, how is a drug trial different from an autonomous clinical test?
- 3) Why is informed consent necessary in clinical research? What is the function of an ethics committee?

Faculty of Law, University of Tokyo

nhiguchi@j.u-tokyo.ac.jp Norio Higuchi and Yasuji Kodama

Three Examples

1 “At 4:30 p.m. on a certain Friday, there was an incoming call to you being a legal advisor to a 300-bed hospital. The call was from Dr. Smith looking for your advice. This doctor examined a 37-year-old patient named Johns who was in the terminal stage of lung cancer that was already metastasizing to the bones. The status quo was that the remnant of his life was one month at best, and that the treatment was wholly focused on chemotherapy to delay disease progression and on an easing of throbbing pain. Besides, Johns had a pacemaker implanted.

Well, Johns said to the doctor to please discontinue chemotherapy and bring the pacemaker to an end. The same request was made repeatedly, and it was the doctor’s judgment that the patient expressed his consistent intent under the clear consciousness. Accordingly, the doctor made a consultation as to what he should do.”

3rd Social Page of Morning News of Asahi Shimbun Dated 10/8/08, Reporter Shinoda in NHK News Program of 10/7/08

“No problem from an ethical standpoint” as to removing respirator from the patient of an intractable disease: Opinion of a hospital ethics committee in Chiba

The ethics-issue exploratory committee of Kameda General Hospital (director Nobusuke Kameda) located in Kamogawa-city, Chiba-pref. established an opinion that “there is no ethical problem” regarding a patient of amyotrophic lateral sclerosis (ALS) who makes a request to remove an artificial respirator when the patient becomes disabled to communicate with those around him. Removing a respirator from progressed cases of ALS might have a decisive impact on life. According to a self-help patient group, it is rare that a medical institution’s ethics committee expresses an opinion on such a request of a case of ALS.

But the ethics committee does not make a definite statement as to how to respond to the request as “there is a possibility of criminal prosecution against any personnel who has removed respiratory apparatus.”

This patient is a male (68) from the same prefecture, who was diagnosed with an intractable disease ALS in 1991, and the following year got into respiratory difficulties requiring tracheotomy and wearing a respiratory apparatus. While bedridden, he communicates with his family by writing sentences with PC by the use of his right cheek that can move a few millimeters.

According to the family, this man considers that he “lives a human life only while there are communications with the family, friends, and medical staff,” and wishes to “have a respirator removed” when he becomes incapable to do that.

NHK news reported: “Discussion and research are necessary,” and “no law approves the removal of respiratory apparatus,” and Prof. Itakura’s opinion of “a possibility of the equivalent of murder by contract.”

Three Examples

- 2 Doctor A is a neurosurgeon in the department of neurosurgery of a certain university hospital. In his clinical experience, he came up with the following idea: Drug B, already approved as a new medicine and covered by health insurance, was likely to have a good effect on some critical cases of cerebral infarction. To verify this was quite meaningful, and the doctor considered to implement a clinical test.

To do that, he was told, it was important to obtain informed consent and an approval of the ethics committee. But he could not understand what these meant. So he asked an attorney of his acquaintance, but who responded that he knew little of such matters. An instruction on a fundamental thought is requested as to how the subject ought to be considered.

- 3 Doctor R is a family physician in a small provincial town. There came an approach from a contract research organization (CRO) for the doctor to participate in clinical testing for new nonsteroidal anti-inflammatory drugs (NSAID) against osteoarthopathy. She was to receive money in proportion to the number of patients she would register for clinical researches. The CRO guaranteed that it had obtained all approval for this testing, as well as the one by the ethics committee. Having no experience of participating in a drug trial, Dr. R felt good about it particularly for a special compensation to be provided for. Thus she accepted to take part in it without any further inquiry about scientific and ethical aspects of this testing.

Course of Actions on Three Issues

Problem No.1: Case book of U.S.

In this example, the attorney advises the doctor to present the problem to the ethics committee. Dr. Smith is considered to be lucky in that he is in a circumstance where the ethics committee and the legal advisor are willing to spend time standing face to face with this kind of ethical issue. The book concludes that even if the discussion arrived at the same conclusion as Dr. Smith reached by himself, this sort of process per se makes a meaningful difference from an ethical point of view (*make a moral difference*).

Course of Actions on Three Examples

Course of actions on the 2nd question for an examination

Two approaches:

1) Meaning of an autonomous clinical test; to explain about the meanings of informed consent and an ethics committee

2) What kind of advice would the attorney being requested for a consultation give to Dr. A?

→ Function/role of a legal advice

Apt to be excessively inhibitory (threatening)

→ “Not rocking the boat”

Distinction Between Autonomous Clinical Test and Drug Trial

Why are there distinctions?

Should distinctions continue to be there?

What sort of distinctions are there?

Role of Informed Consent in Clinical Test (Research)

What is informed consent?

Why is it necessary?

What should be explained?

In the light of the four principles of bioethics...

Ethics Committee

Who are its members?

What sort of role is the committee expected to play?

Ethical review on a clinical test

Ethical review on a clinical research

In the light of the four principles of bioethics...

What role can the jurist fulfill?

Course of Action on 3rd Example

© On the one side, an encouragement of private practitioners' participation in a clinical research

© On the other, “concerns expressed in the manual of World Medical Association”

Why? What are they concerned about?