

# Nanotechnology and Medical Robotics; Legal and Ethical Responsibility

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## **1. Introduction**

Nowadays nanotechnology and medical robotics become more and more important in our society. Especially, Japan is one of the most advanced countries in the field of nanotechnology and robotics in the world. However, legal and ethical problems on the meaning of nanotechnology and robotics have not been enough discussed in Japan. Generally speaking, lawyers have not paid attentions to them and we don't have any clear legal and ethical rules in this country. If this situation continues, we must be confronted with some legal and ethical troubles in near future. So, in this paper, I try to suggest a thinking scheme of regulation including legal and ethical responsibility on nanotechnology and robotics in Japan<sup>1</sup>. Especially, I will clarify some aspects of legal problems which nanotechnology and robotics will cause to human body or human life. But the range of these problems is too wide to treat them in this short paper. Therefore I will point out some fundamental issues which nanotechnology

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<sup>1</sup> To these points I have already reported under the title “Legal Approach to Nanotechnologies in Japan” in the IV JAPANESE-FRENCH SYMPOSIUM on BIOETICS and ETHICS of SCIENCE— THE CHALLENGE OF NANOTECHNOLOGIES:HEALTH AND ENVIORONMENTAL ISSUES (17-19<sup>th</sup> April 2009, Seinan Gakuin University, Fukuoka, Japan), and under the title “Medical Robotics and Legal Responsibility” in the V JAPANESE-FRENCH SYMPOSIUM on BIOETICS and ETHICS of SCIENCE—ROBOTICS AND MEDICINE (24-26<sup>th</sup> March 2011, Toulouse University, Toulouse, France). This article includes these contents of two presentations. And I have just published a new article on this theme. See Katsunori Kai, Sentan Iryo Gijutu no Kenkyu Kaihatsu to Tekisei Ruru no Kakuritsu – Ijiho/Seimeirinri no Kanten kara (Research and Development of Advanced Medical Technologies and Establishment of Due Rules – From the Viewpoint of Medical Lw and Bioethics –) (in Japanese), Law and Technology, N0.52, 2011, p.31ff.

and medical robotics will bring about to our society from the viewpoint of Japanese law.

## 2. Legal Approach to Nanotechnology in Japan

(1) The word of “nanotechnology” was firstly used by Norio Taniguchi in 1974. Since then, various nanotechnologies have been developed in Japan. For example, the discovery of carbon nanotube (=CNT) by Sumio Iijima is very famous in the world. However legal and ethical problems on nanotechnology have not been discussed in Japan. The main reason is that we cannot concretely understand and foresee the dangers and results which nanotechnology can bring about to human body or human life.

(2) However, for several years, we have become to get some knowledge of influences or risks of nanotechnology, which the Report of United Nations Educational, Scientific and Cultural Organization (=UNESCO) “The Ethics and Politics of Nanotechnology” (2006) has shown. The Report has already pointed out not only some merits of nanotechnology (e.g. removing pollution particles in water and air, finding cancer cells quickly, alleviating world hunger, cleaning the environment, curing cancer, spurring economic development, etc.), but also the danger created by excessive patenting in nanotechnologies, and some risks of them<sup>2</sup>. These risks are, however, abstract and not clear.

The newest knowledge, however, shows that carbon nano-tube (=CNT) can cause a kind of cancer according to the circumstances. Recently also in Japan, ethical discussion has begun in 2004, and a political proposal on social acceptance of nanotechnologies has been made public by a project team in 2006<sup>3</sup>. This proposal includes the direction of necessity of legal regulation to nanotechnology. I think that this proposal is very important. Also the Ministry of Economy, Trade and Industry begins to examine the assessment to nano-materials.

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<sup>2</sup> See UNESCO, *The Ethics and Politics of Nanotechnology*, 2006, p.3ff., 13ff.

<sup>3</sup> The National Institute of Advanced Industrial Science and Technology (AIST), *A Political Proposal*, 2006.

(3) What are legal issues on nanotechnology then? What are legal problems in Japanese law? I try to classify these issues into three categories.

The first category is the case with high risk for health or human body. For example, a kind of medical instruments or drugs with nanotechnology can be highly risky for patients. And a kind of dust (toxicity) or instruments with nanotechnology can be highly risky for labor and citizen. The second category is the case with high risk for environment. The third category is the case with high risk for personal information. In these cases we can set the issue as a legal dimension beyond ethical one. If so, what can we consider legal sanctions?

Firstly, we can consider civil sanction on this issue, if he (conductor or manager) could foresee the harmful result on condition that the causation to the harmful result had been proved. At the present time, however, damage law is not suitable to resolve issues on nanotechnology, because it is very difficult to prove the causation between the nano-products and the damage, except a little cases. And so we can consider product liability (PL Act) as more effective legal sanction in Japan.

Secondly, if civil sanction is not enough, we must consider administrative sanctions. On that occasion, we must consider administrative legislation to prevent risky conducts in advance. And we can consider the prohibition of publication of the results, freeze of research expenses, and announcing the project-name officially etc..

Thirdly, if also administrative sanction is not enough, we consider criminal (penal) sanctions as a last measure (ultima ratio). Of course in case he (conductor or manager) could concretely foresee the harmful result on condition that the causation and criminal negligence had been proved. In my opinion, however, criminal sanction is not a good measure in this field, because it may be difficult to prove this causation and foreseeability in this field. If so, lastly, we must consider the compensation system without legal sanctions in order to save victims. Of course, it needs legislation.

(4) What can we think of the range of permitted risks? In my opinion, it depends on the nanotechnology assessment.

(5) Thus we should consider the more effective legal policy before using

easy legal sanction. What is it then?

Firstly, we should establish the system of assessment to nanotechnology. Secondly, we should make the system of opening the results of the assessment to the public. In my opinion, it is better to make a public guideline without legal sanction than a law. Therefore, nanoethics is very important. And lastly, we should consider legal sanction after making grade of risks more clear.

### **3. Medical Robotics and Legal and Ethical Responsibility in Japan**

(1) Nowadays, robotics is developing in the various fields, and yet is increasing the role of application also in the field of medical clinics. Especially in Japan, robotics is remarkably developing in this field. Our Waseda University is one of footholds on researches in this field.

In medical practice, we know e.g. the nursing care robots and health robotics which are playing active parts in some hospitals. More concretely speaking, the cytocare robot in reconstitution of cytotoxics is very useful in clinics. Recently androids just like women appear in medical clinics<sup>4</sup>. In near future, medical robotics maybe have some important roles in health care.

Here I will clarify some aspects of legal and ethical problems which robotics will cause to human body or human health. But the range of these problems is too wide to show them for this short paper. Therefore, I will point out some fundamental issues which medical robotics will bring about to our society from the viewpoint of Japanese law.

(2) Here I analyze legal and ethical issues on medical robotics. Medical robotics can have some benefits but at the same time some risks.

On the one hand, these benefits can be in overcoming the shortage of manpower in the field of health care. Especially in our aging society, robotics can play an important role in nursing care for the elderly. The

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<sup>4</sup> See Hiroshi Ishiguro, *Robotto toha Nanika—Hito no Kokoro wo Utsusu Kagami* (What is a Robot? —Mirror which reflects human mind) (in Japanese), 2009, Kodansha.

cytocare robot in reconstitution of cytotoxics can be very useful in clinics due to the accuracy like as clockwork. On the other hand, these risks can include both foreseeable and unforeseeable ones.

Firstly, medical robotics can cause concrete danger or harm to the human body when it is used as a medical instrument to the patient. It can be connected with the Pharmaceutical Affairs Law, Tort Law and Product Liability Act (PL Act).

Secondly, medical robotics can bring about a kind of abstract or concrete danger to the human mind when it is used to intervene in it. In this case, it is very difficult for us to judge which legal responsibility should be imposed to it.

Thirdly, we must consider the problem whether we should legally regulate the area of medical robotics where it is developing to promote the welfare, or not. If so, we should consider the problem how we should legally regulate it, because roboethics is not enough effective to keep security of human daily life.

(3) How can we make any rules on medical robotics? What can we consider legal sanctions?

Firstly, we can consider civil sanction on this issue, if he (conductor or manager) could foresee the harmful result on condition that the causation to the harmful result had been proved. At the present time, damage law is an option to resolve issues on robotics, if it is possible to prove the causation between the medical robotics and the damage. We can consider also product liability by PL Act as more effective legal sanction in Japan.

Secondly, if civil sanction is not enough, we must consider administrative sanctions. On that occasion, we must consider administrative legislation to prevent risky conducts in advance. And we can consider the prohibition of publication of the results, freeze of research expenses, and announcing the project-name officially etc..

Thirdly, if also administrative sanction is not enough, we consider criminal (penal) sanctions as a last measure (ultima ratio). Of course in case he (conductor or manager) could concretely foresee the harmful result on condition that the causation and criminal negligence had been proved. In my opinion, however, criminal sanction should be the minimum measure in this field. Therefore lastly we must consider the compensation

system without legal sanctions in order to save victims. Of course, it needs legislation like as “Robolaw”<sup>5</sup>.

(4) What can we think of the range of permitted risks? In my opinion, it also depends on the robotics assessment.

(5) Lastly, we should consider the more effective legal policy before easy legal sanctions. What is it then?

Firstly, we should establish the system of assessment to robotics. Secondly, we should make the system of opening the results of the assessment to the public. In my opinion, it is better to make a legal rule than a guideline, because roboethics is not so effective.

#### 4. Conclusion

It is very important that each company should make a compliance program in order to ensure the security of products by itself, and the business world can trans-nationally share the information of risks about which nanotechnology and robotics can bring. We need to make Fundamental Law of nanotechnology and robotics in Japan in harmonization with foreign countries. In my opinion, we should make a developing legal regulation system by mixing nanoethics or roboethics (soft law), fundamental law, and hard law (Tort or Damage Law→Administrative Law→Criminal Law (ultima ratio))

Nevertheless, it remains more complicated ethical issue whether we should make a robot (remember the super cat “Doraemon”) like human who has an ability to think and a emotion. In such robotics, we must have responsibility to manage it as mankind.

Lastly, it is very useful for mankind to develop a type of rescue robot for catastrophe such as big earthquake, tsunami and the nuclear power plant etc. in Japan.

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<sup>5</sup> The word of “Robolaw” has been just used by Prof. Tsuyoshi Aways in the V JAPANESE-FRENCH SYMPOSIUM on BIOETHICS and ETHICS of SCIENCE—ROBOTICS AND MEDICINE (24-26<sup>th</sup> March 2011, Toulouse University, Toulouse, France).