(Study Notes)

iPS Technology and Political Science in Japan

— Have ethical issues been discussed in a political context? —

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Backgrounds and goals

In ten years, stem cell research and surrounding technologies have rapidly developed. iPS is a new type of pluripotent stem cells which is considered potentially an important resource for applications in regenerative medicine. The new technology is giving a hope to those who suffer irreversible damage to nerves, skin cells and organs. Although it is hard for us to see total medical application of the technology, stem cell, ES cell, and iPS research draw significant attention around the world. When a Japanese professor Shinya Yamanaka of Kyoto University won the Nobel Prize in 2012, bright future of application of the iPS technology was anticipated especially in Japan, where scientific breakthrough was long awaited for.

Despite the enormous expectation on the technology, certain moral issues have to be discussed urgently. Recreating human cells could develop into cloned humans. Although comparing experiments on reproducing mice's skin and creating a human cloning seems pointless, it must be recognized that the basic idea of new way of reproduction of two far different examples showed above is common.

When the birth of the first cloned sheep Dolly was reported to the world in 1997, many countries swiftly banned the application of the technology to human being. Many among developed countries including Japan have special laws which ban human cloning. Those are the days when no one actually expects scientists to develop the technologies so quickly. No country drew the line between the 'act of God' and astonishing treatments for incurable illness. New laws on banning human cloning never ban reproduction of organs (partial cloning).

I would like to point out the moral issues regarding this new technology. Then, like the other new medical improvements, new guidelines or regulation should be set before starting experimenting on humans. In the field of bioethics, heart transplants, drug experiments raised some of the first moral issues, followed by brain death arguments, reproductive technologies, ES cells technology, human cloning and so on.

My attention on ethical issues is about how and who decides the guidelines and regulations (laws). Government and some ministries often lead the arguments, but in Japan, government hardly decided themselves. What they call 'group of specialists on the area' (Yuushikisya) were the key to the decision making. Do you remember the

great divide in conclusions on brain death issues in late 1980's to 1990's? The legal committee could not give the green light for setting a new brain death standard because the 'specialists' never agreed on what death was. After this committee on brain death in Diet (Noushi-Rincho), ministries became cautious choosing decision making persons. This means, they tend to choose a group of specialists who are predicted to achieve unanimous conclusion. So far, no bigger issue on bioethics had become the main topic of political decision making, but it is easily foreseeable that people would start doubting the fairness of selection of members of committees.

In this study note, I would like to show some characteristics I discovered regarding decision making process on bioethical issues in Japan. Some are just theories yet, but still I am sure I would prove those in mere time.

1. Moral issues surrounding iPS studies

So far, there has been no objection to recreate (pluripotent) tissues of human being. Though researchers' goals are far closer to create cloned humans (without intentions), these days, human cloning is not the hottest issues on bioethics any more. As cloning human tissues seems to be welcomed by the world, the argument against human cloning seems almost antique. But where have the 'slippery slope arguments' gone? Once we admit one small change, someday, somebody would develop the exception into undesirable social change. Bioethists often quote Nazi in the case of euthanasia. Once people admitted it is no problem terminating mentally challenged and ill people's lives earlier, the same theory was applied to the Holocaust, saying 'there are some people who are not worth living'.

I am not the one who is willing to show a big STOP sign to iPS studies. Rather, my heart is with the sufferings. My argument here is to show a danger deciding guidelines and laws without apparent boundary and deliberation on this matter.

2. What is special about iPS?

There are many differences between human cloning arguments and iPS moral issues' arguments. First is the hope. In iPS case, there is a hope curing many people suffering incurable diseases. Compare to that, creating human cloning seems unnecessary and selfish. Second difference is the market values. Regenerative medicine is a billion-dollers projects for many countries and companies. Third difference is a 'Japan factor'. Before Professor Yamanaka, few Japanese researchers have involved in the debated fields. But this time, Japan has a Nobel prize winner. Hope described above is off the chart in Japan. I started to worry the excitement would mask the importance of the ethical issues on this matter.

3. How Japan handled bioethical issues in politics?

In Japan, decision making process over issues (guidelines, laws) regarding

bioethical problems have characteristics as follows;

- A. tendency to have no religious aspects
- B. procrastination, (Band-Aid solutions)
- C. treated as B-class issues which are not important in political agenda settings

A. Tendency to have no religious aspects

Most Japanese regard their religions as Buddhism or Shinto. Although few attend religious weekly or daily meetings. Enormous number of people think themselves as no-religion (a little different from atheism). In the process of decision making process on brain death debate, Buddhists groups attended legal meetings in the Diet. Some Buddhists consider heart beating human as a living person, others stressed on the importance of saving another peoples' lives.

As Christians (both Catholics and Protestants) are only below 5 % of population in Japan, the argument which appeals organ donation as an act of Charity doesn't fly. From these aspects, Japan is quite different from European countries and the U. S.

Do they make decisions based on pure pragmatism? Are they logically consistent? I don't think so. The basis of Japanese people's decision making has not been revealed in any study field yet.

B. Procrastination (Band-Aid solutions)

When the committee faced a great divide on what death is, Japanese Diet offered a mediate solutions not stating brain death as legal human death, but allowing surgeons to perform transplants based on written agreement by brain-dead person. This might have been a smart way not to hurt both sides, but hard for recipients and surgeons. Finding a written agreement was extremely difficult in cases of traffic accidents which are most of the cases. Then in 2009, the law was amended in order to allow family member's decision of substitute written consent of the brain-dead person. This way of incrementalism is often seen in Japanese law making process. Looking back, the first Organ Transplant Law was just a Band-Aid solution for less than 30 cases of transplants in a decade.

This was a typical case of the Japanese political culture of procrastination.

C. Treated as B-class issues which are not important in political agenda

Japan has a parliamentary diet system. As in the U.K., the Diet closes two or three times a year. At the end of each session, bills have to be voted to stay ongoing issues at sub-committees in the Diet. Those which were not agreed to be continued to discuss have to be submitted all over again at the beginning of next session. This means a long delay of legislations. Usually, bills regarded as less important tend to be postponed or ignored. Bioethical issues are one of these B-class bills because they don't have anything to do with elections. Unlike the U. S., abortion is not a big issue in Japan.

In Japan, there is almost no barrier exercising abortion nor strong opposition against it. There is no religious debate, people can have abortion by 'economical' reason under the Motherhood Protection Law.

As of brain death laws, it took over ten years until approval, three years on banning human cloning. Bioethical matters are difficult but irrelevant to the next election for every law making personnel. When it comes to iPS, people seem to welcome the application of the technology. The government is so glad to encourage the applications of iPS. It is possible that ethical aspect regarding the iPS would never be discussed in the Diet to avoid a long argument, like the precedents above.

4. Pros and Cons on iPS studies

Pros over iPS studies are obvious. The technology helps patients who are waiting for organ transplants, tissue transplant. The economic influence on applying it all over the world is enormous. Applying the technology to reproductive medicine, brain recovery, regenerate skin cells, it would change the concept of medical treatment. It could bring a big change in medical history.

The issue here, is about cons, theories against the application of the technology. There are several oppositions against it. Persuasive or not, I will categorize cons into four theories.

- a. Cloning is a cloning. It is impossible to draw the line between cloning of organs and whole body.
- b. Cloning tissue is logically the same as cloning a whole brain, or body.
- c. Cloned tissue will eventually influence functions of a brain. There is no use drawing a line between cloning a tissue and a whole body.
- d. The technology will be applied on the reproductive medicine. Then, there will be the whole copy of a person's DNA, leading to human cloning.

Conclusions - What do we need now?

What can we do to make bioethical issues regarded as important, A-class bills, then? I recommend two ways to improve the situation.

First is to have an independent research center or committees with enough budgets. Researchers on bioethics are not enough for various issues in Japan. The 'specialists' assigned by government ministries are not trusted by people these days, for they are regarded as scholars and doctors who have government-favored conclusions already. This distrust was widely revealed after the great earthquake in 2011. The 'specialists' have to be trusted by people.

Secondly, people need proper education on bioethics. Ideally, bioethics should be taught in school system from young age. Realistically speaking, at least news papers should explain about the issues and break down difficult ethical problems into daily life issues. As over 20 millions copies of newspaper are usually home-delivered in Japan, the

role of newspapers and TV broadcast is huge. They are responsible for explaining the philosophical, scientific myth to the people.

iPS studies' hope sure should not be damaged. On the other hand, we cannot neglect the fact that there are moral and ethical issues in this particular field. Without facing these problems, procreative science should never to be encouraged. We have to remember the tragedies from the past which we could have prevented with wisdom. That is why I suggest a deliberation before applying the technologies. If there is a slight chance that human dignity is to be harmed, a life to be regarded worthless, we, researchers along with policy makers have to stand in a way saying 'over my dead body'.

-Abstract-

iPS, a new type of pluripotent stem cells technology is developed by Japanese Nobel Prize winner, Prof. Yamanaka. Despite the enormous expectation on the technology, certain moral issues have to be discussed urgently. Recreating human cells could develop into cloned humans. My attention on ethical issues is about how and who decides the guidelines and regulations (laws).

In this study note, I would like to show some characteristics I discovered regarding decision making process on bioethical issues in Japan.

In Japan, decision making process over issues (guidelines, laws) regarding bioethical problems have characteristics as follows;

A. tendency to have no religious aspects

B. procrastination, (Band-Aid solutions)

C. treated as B-class issues which are not important in political agenda settings

Thus, I suggest a deliberation before applying the technologies to procreative medicine.