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Short Curriculum Vitae - Chiaki Sato

Special competence in the area of legal policy in the medical field; research of trust legislation as a related domain. Awarded a Master of Laws (LL.M.) degree at the University of Washington School of Law in 2008, and Doctor of Philosophy Law at the University of Tokyo in 2010. Service as Project Researcher at the University of Tokyo Graduate School for Law and Politics from April to August 2009, and as Assistant Professor at the University of Tokyo since September 2009 and as Associate Professor at the Aoyama Gakuin University Faculty of Law since April 2015. Concurrent service as Visiting Scholar at the Brookings Institution since August 2012. Author of "U.S. Product Liability Law" (published by Koubundou Publishers Inc. in 2011) and major papers appearing in publications such as PLOS Medicine.

Toward the use of genetic information

At present, studies on the handling of genetic information in law are rapidly moving ahead in Japan. For a long time, discussion on this subject has been avoided in Japan. The mainstream current continued to shun discussion on not only the question of whether or not genetic information was a type of personal information in law regarding the protection of personal information, but also on bills for the prevention of genetic discrimination. Recently, however, the tide has been turning.

The tide has turned because of two chains of events. In Japan, these two chains occasioned the ongoing solidification of the trend toward granting certain genetic information protection in the context of law pertaining to protection of personal

information, through legal interpretations. The first chain of events began with the institution of the Council for the Promotion of Genome Medicine in the Cabinet Secretariat Headquarters for Healthcare Policy on January 21, 2015. After four meetings, the Council released its interim report on July 30 of the same year. Based on the healthcare strategy (determined by the Cabinet on July 22, 2014) and the plan for promotion of medical research and development (determined by the Headquarters for Healthcare Policy on the same day), the Council for the Promotion of Genome Medicine was instituted under the Headquarters for Healthcare Policy for the purpose of pursuing the emergence of genome medicine in coordination with the concerned ministries and organizations. In connection with genomic analysis, the Council asserted the need to reinforce comprehensive measures on the national level, in light of the fact that genetic information was already entering the stage of actual use in medicine.

The second chain of events started with passage of the amendment of the Act on the Protection of Personal Information on September 3, 2015 and the promulgation of the same on September 9 of the same year. Although it has not yet been fully effected, the amended Act on the Protection of Personal Information contains the new ideas of "personal identification codes" and "personal information requiring special consideration." The appearance of these new concepts led to examinations on the question of whether or not genetic information could be equated with personal identification codes and personal information requiring special consideration.

Trends appearing in movements in Europe and the United States

Comparison in the three aspects of the handling of genetic information in the context of law concerning protection of personal information, the handling of genetic discrimination, and legislation for assurance of precision and quality in genetic inspections reveals that legal policies in Europe and the United States are not always the same.

For example, while European and the United States legislation affords a certain level of protection to genetic information, there is considerable variation as regards perspectives on methodology for sufficient anonymization. In Europe and the United States, there is no classification of genetic information into the categories of "genome data" and "genome information," as there is in Japan. In Japan, careful discussion is

under way toward the end of clearly defining genome data corresponding to personal identification codes. In contrast, in Europe and the United States, although a certain level of protection is accorded to genetic information in law for the protection of personal information, there does not seem to be much careful consideration about clearly delineating the scope of genetic information to be protected. In the United States, attempts are being made to limit the definition of genetic information in consideration of the presence or absence of diagnosis by a physician etc. as well as the precision of genetic testing and the test results.

Differences in legislation in Europe and the United States become more pronounced in the area of methodology for sufficient anonymization. While genetic information is afforded a certain level of protection in law for the protection of personal information, such protection is naturally not accorded to even genome and other genetic information in Europe and the United States if this information does not enable personal identification. The problem is the prerequisites for eliminating the ability for personal identification from a piece of information. Without clear methodology for sufficient anonymization, processing to eliminate the personal identity element of certain information will be useless for compliance with laws and regulations. In short, the prerequisites for anonymization in Europe could become stricter than those in the United States. This is because the European rules for data protection do not contain any stipulations regarding the definition of anonymization or methodology for sufficient anonymization.

There are also differences in respect of prohibition of discrimination in insurance, employment, and other areas based on genetic information. While some countries in the West are taking legislative action to prohibit such discrimination, exceptions have been made, and attempts are not always being made to enact new ad-hoc legislation. In the case of Europe, while consideration of action on the level of individual countries must view insurance separately from employment etc., it must be noted that there are also many countries which have not enacted ad-hoc legislation to prohibit discrimination.

In the United States, federal law prohibits discrimination in insurance, employment, and other areas based on genetic information, but also provides for a wide range of exclusion from application. For example, the law allows use of genetic information for determination of prices for medical insurance. It also exempts life insurance, disability insurance, nursing-care insurance, and certain other types of insurance from

application. In the aspect of employment, it permits employers to use information (including genetic information) disclosed by potential employees of their own accord in hiring decisions.

There is a difference of opinion between the United States and Europe on the legality of provision of data from genetic testing without going through a physician. The questions of who should conduct the testing and what level of quality the testing should have are separate issues. There is a strong possibility that they will involve both the equivalents of the Japanese Medical Practitioners' Act and the Pharmaceutical and Medical Device Act. For this reason, it is difficult to analyze the problem in terms lumping European and U.S. legislation together in the first place. For example, in the United States, law concerning medical practitioners is enacted by individual state governments, and that concerning pharmaceutical and medical devices, by the federal government. It would consequently be hard to identify trends in the United States as a whole to begin with. The same thing applies to Europe. There, law concerning medical practitioners is under the jurisdiction of national governments, and that concerning pharmaceuticals and medical devices, under EU jurisdiction.

Nevertheless, in both Europe and the United States, there is a trend toward having certain types of genetic testing kits (including laboratory-developed test methods) subject to regulations on medical products, along the lines of Japan’s Pharmaceutical and Medical Device Act.

Options for Japan

As noted above, in Europe and the United States, there is not necessarily a congruence of opinion on legislation governing genetic information, or even a single clear trend in this regard. Under these circumstances, it would not be advisable for Japan to select and try to execute a single option from the variety of legal policy options. This is because there is a range of options to begin with, and not necessarily only one can be selected.

This very juncture, when there are clearly differences in the European and U.S. legislative arrangements related to genetic information, presents Japan with a golden opportunity to adopt its own policy on the matter, but also poses related risks. Depending on the future trend, Japan could even find that it has taken a step that distances itself from the worldwide mainstream. It is, therefore, probably necessary

for Japan, too, to further deepen its discussion on the subject, based on the subtle legislative differences in Europe and the United States.

Discussion from the perspective not of "regulation first" but of the advisable shape of tomorrow's medicine

Discussion on legislation governing genetic information is also related to the larger question of how to handle the goods and services to newly emerge in the future in the healthcare and medical fields. As such, it could be regarded as a touchstone for future orientations. This is because its conclusions could very well determine the target shape of tomorrow's medicine and, to go further, the actual future of personalized medicine. Discussion on the question of whether arrangements can simply be fit into the existing legislative framework or it would be possible to take a different approach must be fully based on the characteristics of products and services. There is likewise a need for consideration of the same factors in discussion on regulations to be imposed on mobile services and the like. In light of the advances in personalized medicine, I have earnest expectations for even more careful studies from the perspective of the advisable shape of medicine, on not only the possibilities for application of regulations to medical devices but also a wide range of other issues including assurance of the quality of test methods, procedure for obtaining informed consent, protection of privacy, incentives for development of new test methods, and access to genetic counseling.