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MEDICAL, PHARMACEUTICAL AND LIFE SCIENCES

Utilization of Medical Data and Act on the Protection of Personal Information

I. Introduction

Medical data has the potential to revolutionize healthcare by enabling more personalized and effective treatments, improving patient outcomes, and reducing healthcare costs. For example, medical data can be analyzed to improve patient care, discover new treatments, and advance medical research. More specifically, by analyzing medical records, researchers can identify trends and patterns in patient outcomes, and healthcare providers can use this information to improve patient care and clinical decision-making.

However, there are also concerns about patient privacy and data security, as medical data often contains sensitive personal information. In this regard, the Act on the Protection of Personal Information (the "**APPI**") imposes various restrictions on the utilization of medical data. For example, companies must not use personal information beyond the scope necessary to achieve purposes specified by such companies pursuant to the APPI without obtaining the prior consent of the subjects of such data. Also, in principle, companies are prohibited from disclosing personal data to third parties without obtaining the data subjects' prior consents. Furthermore, the APPI imposes heavy restrictions on the use of sensitive personal information. For example, sensitive personal information cannot be provided to third parties by using an opt-out mechanism.

In order to utilize medical data, companies must address how to abide by the APPI's restrictions on sharing such data with third parties. There are several ways to disclose personal data to third parties without obtaining the prior consent of the subjects thereof.

II. The "Public Hygiene" Exception

Companies can disclose personal data to third parties without obtaining the data subjects' prior consents in cases where there is a special need to enhance public hygiene, or to promote fostering healthy children, in both cases where it is also difficult to obtain a data subject's consent (the "**Public Hygiene Exception**").

Last year, the Personal Information Protection Commission (the "**Commission**") publicly represented their view on the Public Hygiene Exception in a Q&A regarding the Guidelines for the Act on the Protection of Personal Information. The Commission's view was that (i) use of personal data for the purpose of

observational study or improving medical technology meets the requirement of "a special need to enhance public hygiene" and (ii) not only cases where the companies do not have the contact information of the data subject, but also cases where there is a possibility that obtaining a data subject's consent would interfere with the relevant studies in terms of time and cost, etc., satisfy the requirement of "difficulty in obtaining a data subject's consent."

The Public Hygiene Exception may be helpful in utilizing medical data at research phases; it may, however, not work for companies intending to provide outcomes generated from medical data to third parties for business purposes, as this use does not fall within the scope of public hygiene.

III. The "Academic Studies" Exception

Companies can disclose personal data to third parties without obtaining the prior consent of the data subjects in the following cases (each of which excludes cases in which there is a possibility of unreasonable infringement upon an individual's rights or interests) (collectively, the "**Academic Studies Exception**"):

- Where the companies are academic research or similar institutions and there is a compelling interest in the provision of personal data for the publication or teaching of the results of academic research;
- Where the companies are academic research or similar institutions and there is a need to provide personal data for the purpose of academic research (limited to cases in which the companies and a third party jointly conduct academic research); or
- Where the companies are academic research or similar institutions and there is a need for the third party to deal with the personal data for the purpose of academic research (including where only a part of the purpose relates to such academic research).

The Academic Studies Exception is also attracting increased attention in the context of the utilization of medical data; like the Public Hygiene exception however, this exception may not work for companies intending to provide outcomes generated from medical data to third parties for business purposes, since such use would exceed the scope of this exception. In this regard, in the Commission's public expression of its view on the Academic Studies Exception in the Guidelines for the Act on the Protection of Personal Information, it stated that if companies deal with personal information for the purposes of product development, such activities do not fall within this exception.

IV. Anonymized Information

"Anonymized Information" (*tokumei kako joho*) means information relating to an individual that can be prepared in such a way that it is not possible, by taking any of the measures prescribed in the APPI, to (i) identify a specific individual by use of such information, or (ii) restore such personal information. Companies can use Anonymized Information for any purposes (i.e., beyond the scope necessary to achieve specific purposes) or provide Anonymized Information to third parties without obtaining the prior consent of the data subjects, since Anonymized Information is considered to not fall within the scope of Personal information.

There are drawbacks to Anonymized Information as well, however. First, the anonymization of information in accordance with the techniques and processes for anonymization stipulated by the APPI is burdensome. Furthermore, since such information is anonymized in a way that makes it impossible to restore it to personal information, it is difficult to prove reliability by returning to the original medical information.

V. Anonymized Medical Information

The Next Generation Medical Infrastructure Law (the "**NGMIL**"), which is a special law of the APPI, defines "Anonymized Medical Information" (*tokumei kako iryo joho*) in a way similar to the APPI's definition of Anonymized Information. Briefly, the NGMIL allows for the use and provision of Anonymized Medical

Information without obtaining patients' express consent. In other words, unless the patients expressly "opt-out", their medical information may be anonymized and used for various purposes, including medical research.

Last year, the NGMIL Studying Working Group pointed out that Anonymized Medical Information cannot meet the on-site needs of medical studies as to (i) data provision on rare cases, (ii) continuous and developmental data provision regarding same target group and (iii) proving reliability by returning to the original data in order for authenticity verification, which is a requisite for pharmaceutical applications.

VI. Pseudonymized Medical Information

On March 3, 2023, a bill of amendments to the Act to Revise the Next Generation Medical Infrastructure Law (the "**Bill of Amendments**") was introduced to the 211th ordinary session of the Diet. The Bill of Amendments intends to establish "Pseudonymized Medical Information" (*kamei kako iryo joho*) as a legal concept, covering medical information that is prepared in such a way that it cannot be used to identify a specific individual unless collated with other information.

As opposed to Anonymized Medical Information, the preparation of Pseudonymized Medical Information does not require deletion of singular values or data regarding rare diseases. Furthermore, companies can provide Pseudonymized Medical Information to the Pharmaceuticals and Medical Devices Agency ("**PMDA**") (PMDA is in charge of pharmaceutical licenses, including marketing authorizations for pharmaceutical products). In cases where PMDA conducts examinations to judge whether licenses should be granted, companies which applied for certain licenses using Pseudonymized Medical Information can re-identify specific individuals. The Bill of Amendments also purports to make it possible to conduct interlinked analysis between Pseudonymized Medical Information and the National Database of Health Insurance Claims and Specific Health Checkups of Japan (NDB), one of the most exhaustive healthcare database in Japan which includes health insurance claims every month and specific health checkup data every year. The Bill of Amendments also intends to impose certain obligations on medical institutions to make efforts to cooperate with governmental requests for the provision of medical data, in order that sufficient information can be collected and valuable outcomes generated under the NGMIL. Both the preparation and the use of Pseudonymized Medical Information, however, require governmental certification; the use of Anonymized Medical Information, by contrast, does not. This certification framework, if operated strictly, could constitute a barrier to entry.

VII. Conclusion

Although there are pros and cons for each framework, the utilization of medical data, which can lead to various nationwide benefits such as improved patient outcomes, more personalized medicine, new medical breakthroughs, cost savings, and better public health outcomes, is quite important. The government is therefore actively promoting the utilization of such data. Given that the medical data industry constantly undergoes radical improvement, it is important to remain open to the latest administrative and policy trends, and to keep up to date with emerging technologies and innovations.

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CORPORATE GOVERNANCE

Looking Back on Shareholder Activism in Japan in 2022

When it comes to the shareholder activism in Japan, 2021 was a dramatic year: after hostile takeover attempts by third parties, a variety of takeover defense plans (in this article, this type of takeover defense plans are referred to as "contingency poison pills") were contested in court, and several precedent rulings resulted. 2022 was a somewhat milder year in comparison, but shareholder activism was still one of the central topics in the legal / corporate scenes in Japan.

I. Judicial Decision (Mitsuboshi Case)

Adding a new page to the series of judicial decisions in 2022 was the Supreme Court ruling on the contingency poison pill which Mitsuboshi Co, Ltd. (TSE 5820) ("Mitsuboshi") introduced and exercised against a group of shareholders, including Adage Capital Management.

This is the first case in Japan where a contingency poison pill was introduced against so-called "wolfpack tactics", in which a group of shareholders (rather than a single shareholder) increase their shares with the joint purpose of making a proposal to the management, without disclosing they are acting in concert. As a result of the court battle, the Supreme Court and the lower courts all ruled in favor of the plaintiffs who sought an injunction of the poison pill defense. The court determined that the plan introduced by the company was unreasonable due to the wide discretion of the company in determining in what "concerted action" consists, and what actions the investors could take to withdraw from such concerted action. In this regard, the decision was largely determined by the specific language of the plan, and further decisions are necessary before a general principle can be drawn. However, this decision will inevitably have an impact on the scope of practical decisions available to Japanese companies under similar circumstances.

Another novelty of Mitsuboshi is that the court approved the injunction despite the fact that the company consulted the independent committee, received approval in a voluntary-held shareholders' meeting, and also provided a mechanism to mitigate the disadvantage of the investors suffering from exercise of the contingency poison pill. Traditionally, these three factors were considered to be important, if not decisive, in determining the validity of poison pills. Therefore, the new ruling in Mitsuboshi has complicated analysis of how Japanese companies can introduce a legally valid contingency poison pill.

II. Shareholders' Meeting

In the shareholders' meetings held in the period from September 2021 to June 2022, 96 listed companies received shareholder proposals, of which 47 companies (approximately 49%) received proposals submitted by activist shareholders. These figures are the highest ever with a steep rise from 2021, when 65 companies received shareholder proposals, 24 of which from activist shareholders. At present, the circumstances under which proposals by activist shareholders have been accepted in shareholders' meetings are very limited (although there are some cases where the company proposals were amended such that they substantially reflected the activist proposals), but their presence in the Japanese capital market has steadily increased over the years.

Japanese companies have long held the door firmly shut against approving directors dispatched from activist shareholders, but this robust door is gradually opening. A symbolic example is that Toshiba Corporation (TSE 6502), which is in the process of going private, approved two senior executives of Farallon Capital Management and Elliott Management as its external directors. In this case, the full texts of nomination agreements concluded with these investors have been publicly disclosed in English and Japanese. These events suggest that similar cases are likely to become more common in the future.

Following the increased presence of shareholder activists, poison pills introduced before commencement of hostile takeover attempts by third parties (hereinafter referred to as "non-contingency poison pills") have come back into the limelight. Indeed, eight companies newly introduced non-contingency poison pill at general shareholders' meetings in 2022, which is almost double the figure from the previous year. A majority of institutional investors, however, have negative views of or are strongly opposed to non-contingency poison pills, and accordingly, 14 companies discontinued or did not renew their incumbent non-contingency poison pills, so the overall number of companies introducing non-contingency poison pills remains on a slight downward trend.

III. Conclusion

As described above, 2022 may not have been as dramatic as 2021 with regard to the development of shareholder activism, but over the past few years a clear tendency has emerged. Meanwhile, administrative and legislative movements have also accelerated. In November, 2022, the Ministry of Economy, Trade and Industry (METI) launched a "Study Group on Fair M&A Practices" to examine, among other things, how takeover defense measures should be designed and to what extent they will be allowed. More recently, the Financial Services Agency (FSA) is reportedly contemplating a review of the rules on takeover bids. NO&T will keep a close eye on the future developments in the practice and legislation of this area and update accordingly.

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