Chapter 2 - IV

Medical Choice in the Era of Digital platforms

: What we believe and the way we choose our medical care

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On New Year's Day, 2024, the morning after my TV night watching Sayuri Ishikawa's "Tsugaru Kaikyo Fuyugeshiki" and YOASOBI's "Idol" on the Year-end music program (*the 74th NHK Kouhaku*), I started writing this paper as the "first calligraphy" of the year. (I must apologize to all those concerned — deadline had already passed at that time.) But at 4:10 p.m. that same day, a major earthquake with a seismic intensity 7 on the Japanese scale, struck Ishikawa Prefecture, and information about the severe damage was coming in every minute. Praying to God that the damage would be minimal, I kept the TV on to learn about the tsunami, fires, collapsed buildings, clutching my smartphone and endlessly scrolling through Twitter (now X), Yahoo! News updates, and more. Needless to say, my writing made no progress that day.

Despite my poor excuses, I would like to say that many of us living today tend to rush to open our laptops or smartphones to get information from Twitter (X), browse Facebook, Instagram, or YouTube, or search Google or Yahoo! when we need some quick information or when we have nothing to do. This reflex seems to be the case not only for information on natural disasters, which requires a rapid response but also for "medical care decisions" (medical care here is broadly defined as health-related activities, including public health administration, such as vaccination, etc.).

For patients and their families (in short, all citizens) who wish to access necessary medical care when they need it, it is desirable to have an environment that allows appropriate access to essential information as a prerequisite. It is true that "appropriate medical care cannot be chosen without appropriate information", and the Japanese Medical Care Act regulates "medical advertising" as well as "provision of information on medical care" as part of "assistance in choosing medical care". However, whether these measures provide sufficient assistance in that regard remains unclear, given that there are issues before the advertising regulations (see the following section for the issue of self-funded medical care).

On top of that, there also seems to be a problem with whether or not any patient or citizen can properly evaluate the medical information they receive from digital platforms. If there is a trap for dangerous information from digital platforms that could lead to health problems, will someone be able to expose and eliminate

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it? Is it something we cannot and should not expect, leaving it entirely to individual responsibility? In dealing with information related to medical care, while fully understanding the impact of digital platforms, I would like to consider how appropriate information should flow and be disposed of so that patients themselves can make better-informed choices about their medical care.

Here, digital platforms refer to GAFA and various big and small search sites (in Japan, there exists platforms such as Hospital Navi, Doctors File, EPARK, etc.) that are the starting point for obtaining medical information, although there are many other applications available. I'd assume that some of you may have had the experience of searching for emergency medical care by Google search when your companion fell ill while traveling in an unfamiliar place. As specific examples, please consider the following two situations.

a. I have been interested in cosmetic slimming, but was afraid of dubious products and didn't dare to try them. But then I saw a link to a YouTube video advertisement with magic words like "dream diet!" I figured that a beauty clinic with a medical license would be safe, so I decided to try the GLP-1 diet.

b. The government had suspended active vaccination recommendations for the HPV (human papillomavirus) vaccine, which is intended to prevent cervical cancer, but resumed it in April 2022. A "catch-up vaccination" program was implemented to allow women who had missed the opportunity to be vaccinated during the suspension period to receive the HPV vaccine free of charge. My daughter also received a vaccination voucher from the local government. However, I have heard that there have been some lawsuits regarding the side effects of the HPV vaccine, so I am wondering if I should have her vaccinated.

The family physician function reporting system established by the 2023 revision of the Medical Care Act requires hospitals and clinics to report to the prefectural governor whether or not they are implementing family physician functions. Based on this information, specific methods to support medical institutions and promote cooperation will be discussed at prefectural and local conferences to strengthen the family physician function on a regional basis. This is a system in which prefectures widely provide and publish such information[1]. Although the details of the system are being finalized with a view to implementation in April 2025, it is also a matter of concern whether this can be a new platform that contributes to future medical decisions. From the perspective of "informational administrative approaches" [2] it is important that the information provided at each stage of the reporting, consultation, and publication is substantive and accurate, and that it truly contributes to patient and public choice of medical care. In addition, appropriate support must be provided for those who are unable to access such information on health care (this could include children, the

1　The revision of the law in the same year also reformed the system of providing information on medical functions (centralizing and standardizing nationwide information and improving accuracy and convenience) to enhance "support for choice in medical care" (Chapter 2 of the Medical Care Act), and promoted the flow and differentiation of outpatient medical care by making it mandatory to provide written documents and explanations to patients with chronic diseases, etc., and by creating an environment in which citizens and patients can easily have a family doctor.

2　See, Tetsu Isobe "Disclosure and Publication of Government Information and Informational Administration Approaches (行政保有情報の開示・公表と情報的行政手法)" in Tsutomu Isobe, Mitsuro Kobayakawa and Yoshikazu Shibaike, eds. *New Concepts in Administrative Law II* (Yuhikaku, 2008), 343-367 pages.

elderly, people with disabilities, and people with low information literacy who are unable to make full use of information and communication technologies). In an age where everyone has access to a wide range of medical information, the key issue is, after all, how to ensure dialogue and trust with one's family physician. While I had originally intended to discuss a rage of related issues, such as whether the very structure of the medical profession is in question, I left most of them out due to space limitations.

1 Medical Advertising Regulations[3]

(1) Overview of Medical Advertising Regulations

Websites and social networking services operated by the medical institutions such as doctors, dentists, hospitals, and clinics are places where information on medical services and on pharmaceuticals and medical devices intersect. The laws governing the display of information on those media are also in a state of parallel development. The Medical Care Act regulates the advertising of medical practices, hospitals, and clinics, and the Pharmaceutical and Medical Devices Act frames the advertising of pharmaceuticals[4]. Since space is limited, let us focus on the advertising regulations for medical practices and related matters, as set forth in the Medical Care Act[5].

In determining whether an advertisement falls within the scope of regulation under Chapter 2, Section 2 of the Medical Care Act, "Advertising of Medical, Dental or Midwifery Services" (hereinafter referred to as "Medical Advertising"), the Guidelines for Advertising of Medical or Dental Practices as well as Hospitals or Clinics (Medical Advertising Guidelines. Hereinafter referred to as "GL") state that the following two requirements must be met: there must be an intention to induce patients to seek medical treatment (inducibility), and the name of the person providing the medical or dental practices, or the name of the hospital or clinic must be identifiable (identifiability) (GL 21)[6]. Not only physicians, dentists, or medical institutions such as hospitals, but also the mass media, advertising agencies, affiliates, patients, or the general public are subject to advertising regulations[7].

3 This section is discussed in detail in Tetsu Isobe "A Preliminary Consideration of Advertising Regulations Concerning Medical Care (医療に関する広告規制についての予備的一考察)" in *Essays in honor of the 70th Anniversary of Professor Katsunori Kai* (Seibundo, 2024).

4 Other important issues include the status of regulations, including those related to health foods, and the Health Promotion Act, but I do not consider them in this paper.

5 See, e.g., Hidenori Akabane, Keiko Inoue, "Q & A: Laws and Practices Concerning Advertising Displays of Health, Drugs, and Medical Care (Q & A: 健康・医薬品・医療の広告表示に関する法律と実務)" (Nihon Kayo Shuppan, 2020). The Ministry of Health, Labor and Welfare's website, "Regulations on Advertising of Hospitals, etc. under the Medical Care Act (医療法における病院等の広告規制について)" contains related laws, guidelines, and questions and answers. https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/iryou/ kokokukisei/index.html (Last reviewed on June 10, 2024. The same applies to the URLs in this paper.)

6 Examples of items not normally considered to be medical advertisements include: academic papers and presentations, articles in newspapers and magazines, testimonials and memoirs written by patients, etc., pamphlets posted in hospitals and distributed within hospitals, and advertisements for the recruitment of staff for medical institutions (Guideline No. 2-5).

7 Article 6-5, Paragraph 1 of the Medical Care Act provides that "No party shall make false advertisements when making advertisements or other indications by any means (hereinafter referred to in this section simply as "advertisements"), including documents, regarding medical or dental practices or hospitals or clinics as a means of soliciting patients for medical treatment".

The first pillar of medical advertising regulation is to prohibit certain advertisements in accordance with the law. Article 6-5, Paragraph 1 of the Medical Care Act prohibits false advertising because it may provide patients and others with materially incorrect information, resulting in lost opportunity to receive appropriate medical care or leading them to receive inappropriate medical care. In addition, the law prohibits comparative quality advertising (Article 6-5, Paragraph 2, Item 1 of the Medical Care Act), exaggerated advertising (Item 2 of the same), advertising of content offensive to public order and morality (Item 3 of the same), advertising of testimonials based on subjectivity and hearsay (Article 1-9, Item 1 of the Enforcement Regulations of the Medical Care Act, delegated by Item 4 of the same), before-and-after photographs and the like that may mislead patients and others (Item 2 of the same).

The second pillar aims to protect patients and other users by limiting the scope of advertising the names of departments and medical institutions, and advertising of other things is generally prohibited. However, there is an important exception to this second pillar. When certain requirements are met, it is to publish on the websites of medical institutions information that goes beyond the scope of those regulations. This is a so-called "lifting of restrictions" mechanism. When the law was amended in 2009 to expand the scope of the advertising regulations to include websites, medical and patient groups pointed out that the blanket prohibition on posting on websites of medical institutions, may lead to concerns that patients with intractable diseases or malignant tumors, for example, may not be able to obtain necessary information about treatments they want to know about, such as therapeutic agents approved overseas but not yet approved in Japan.

In the event of a violation of the above regulations, the GL envisages various responses, including (a) investigation and administrative guidance, (b) reporting order or on-site inspection (Article 6-8, Paragraph 1 of the Medical Care Act), (c) suspension or correction order (Article 6-8, Paragraph 2), (d) criminal prosecution, and (e) administrative disposition (Article 28 [order to change management] and Article 29 [revocation of opening license and closure order]). Also, when administrative guidance is not followed and the suspension or correction order is issued, or if criminal prosecution is filed, the case will generally be made public to alert patients about the offending advertisement.

In addition, the Ministry of Health, Labor and Welfare has been conducting the Internet Patrols (a commissioned project) under the "Proposal on Websites and Prior Explanation/Consent for Cosmetic Medicine Services" (July 2015) issued by the Consumer Affairs Commission in response to repeated consumer troubles related to cosmetic medicine services related to information provided on the website of medical institution. The Internet Patrol receives reports, conducts active monitoring and screening, and notifies medical institutions of any violations, and approximately 85% of these cases are corrected. Although it is a de facto initiative, the Internet Patrols have achieved some results. However, when improvement is not attained through alerts from the Internet Patrol operators, the case is shared with the local government. Still, some cases require a long time for the medical institution to respond. Most of these cases are corrected or the advertising is withdrawn, a certain number of long-term unimproved cases exist. Even in such cases, there are few cases where legal measures, such as reporting orders, on-site inspections, and suspension/correction orders, are implemented.

(2) Advertisements regarding treatment with unapproved drugs -----GLP-1 as material

Although advertisements for treatment with unapproved drugs are generally prohibited, they are permitted if all of the following conditions for lifting restrictions are met.

1 The information has to be posted on a website that contributes to appropriate medical choices, and such information must be sought out and accessed by patients themselves, and other advertisements of a similar nature;

2 Contact details should be provided so that patients can easily inquire about the content of the information. It should also be indicated by other means;

3 Clear information must be provided regarding the content and cost of treatments usually required for self-funded medical treatment;

4 Information must be provided about the major risks, side effects and other relevant matter the treatment related to self-funded medical treatment (3 and 4 are only relevant if information about self-funded medical treatment is provided).

When unapproved drugs are used in unrestricted medical care, in addition to (i) stating that the drug is an unapproved drug, (ii) stating the route of acquisition, (iii) stating whether the drug is approved in Japan, and (iv) clearly stating information on safety in other countries, it is necessary to (v) state that the unapproved drug is not subject to the relief under the Adverse Reaction Relief System for Drugs and the Biologic Product Infection Relief System.

The GLP-1 diet case involves an improper use of GLP-1 receptor agonists and GIP/GLP-1 receptor agonists, which are drugs for type 2 diabetes, as "slimming pills" by private importers and some beauty clinics. Although they are approved overseas for obese patients at high risk of health problems, we must keep in mind that they are approved for obese "patients," not just obese "individuals ," and their safety and efficacy without type 2 diabetes is not, in Japan, scientifically confirmed.

The increase in the number of GLP-1 dieters can be largely attributed to the partial revision of the Ministry of Health, Labor and Welfare's "Guidelines for the Appropriate Implementation of Online Medical Treatment" (March 2018), which now allows online treatment from the initial consultation. Although the guidelines apply to both self-funded and insured treatments, the removal of the principle of an initial face-to-face consultation principle has probably lowered the hurdle for both medical institutions and users of the GLP-1 diet. Another factor is the launch of an oral drug in February 2021, whereas initially, only an injectable drug was available. This trend was further accelerated by advertisements, which are now widespread on social networking sites promoting the off-label use of the drug for beauty, slimming, weight loss. If you search for "GLP-1 diet" on YouTube, you will find doctors in white coats advertising it at a price of 3,300 yen for 10 pills. As a result of this inappropriate distribution of drugs that should be used for treatment but are being misused by healthy people, nearly 1,000 cases are confirmed in which inpatient or outpatient prescriptions had difficulties to obtein or prescribe GLP-1 drugs[8].

8 https://www.med.or.jp/nichiionline/article/011391.html

(3) Medicine without scientific evidence: what to do

The situation in which medical advertisements promoting the off-label use of prescription drugs for dietary purposes and self-funded medical treatment have developed extensively, and even limited supply, suggests that the above-mentioned advertising regulation system is not working effectively enough. The current situation can be described as almost lawless.

However, an even more serious problem is that, in addition to the ineffective advertising regulations, there is a critical situation in Japan where medical care or pharmaceutical with little evidence are provided as a "self-funded medical treatment", and there is no control over this. It has long been pointed out that there is a problem with the lack of adequate regulation of the content of medical treatments outside of insured treatments[9]. However, the various problems of self-funded medical treatments have been discussed at the Japan Medical Law Association from time to time in recent years[10], and medical jurisprudence research is currently in progress[11]. In this context, the question of the self-discipline of professional associations in dealing with such issues is one of the most important issues to be considered (Kawashima's article in Chapter 3 is written with the same awareness).

The efforts of academic societies have a certain significance[12], but what about the Japan Medical Association? At the press conference held by the association's executive director on October 25, 2023[13], it was stated that "the use of GLP-1 receptor agonists for non-prescription purposes such as weight loss does not constitute a 'prescription'". He also expressed concern that "some of the valuable pharmaceuticals that should be used for the treatment of diabetes are inappropriately used as 'weight loss drugs' by personal importers and beauty clinics." He further pointed out the problem by saying, "I believe that such actions should be prohibited from the perspective of the risks of using pharmaceuticals on healthy people and the proper use of pharmaceuticals, as they are advertised as 'GLP-1 diets' and used for self-funded medical treatment.". Nevertheless, he

9 See, e.g., Shigeto Yonemura, *Lectures on Medical Law 2nd ed.* (医事法講義 第 2 版), Nihon Hyoronsha, 2023, p. 75 et seq.

10 Tsunakuni Ikka, Tatsuo Onishi, and Yuichiro Sato, "The Actual Situation and Legal System of Regenerative Medicine Practiced as Self-Funded Medical Treatment after the Enforcement of Regenerative Medicine Therapy (再生医療法施行後に自由診療として行われる再生医療の実態と法制度) in *Journal of Medical Law*, vol. 38, 2023, pp. 86-98. The record of the workshop of the 53rd Annual Meeting of the Japanese Association of Medical Law "Advertising Regulation and Medical Contracts as a Means of Regulation of Medical Services for Profit (営利目的の医療に対する規制手段としての広告規制と診療契約)" (Directed by Tsunakuni Ikka) will be published in the Annual Report of Medical Law No. 39 (to be published in 2024).

11 See, e.g., Masako Kotani, "Necessity of Prior Regulation for Medical Treatment with Poor Scientific Basis (科学的根拠に乏しい診療に対する事前規制の必要性)" *Kanagawa Hogaku*, vol. 55, no. 1, 2022, pp. 53-92; Tsunakuni Ikka, "Current Status of Cancer Treatment Based on Regenerative Medicine Law: Problem of Legal System Enabling Medical Practice with Unproven Safety and Efficacy to be Called *Treatment* (再生医療法に基づくがん治療の現状―安全性・有効性が未確立な医療行為を〝治療〟と称することを可能にする法制度の問題)", *Oncology*, vol. 31-5, 2023, pp. 580-585.

12 For example, the Japan Diabetes Society urges, "Physicians, especially members of the Society, should always be aware of the danger to patients' health posed by inappropriate drug therapy, strictly avoid inappropriate advertising that may lead to misunderstanding, and prescribe drugs appropriately based on the status of approval in Japan. In addition, we warn you that inappropriate drug use recommendations, especially by Society specialists, will damage the public's trust in diabetologists and will not be accepted by the Society". See, "Position of the Japan Diabetes Society on the Off-label Use of GLP-1 Receptor Agonists and GIP/GLP-1 Receptor Agonists (GLP–1 受容体作動薬および GIP/GLP–1 受容体作動薬の適応外使用に関する日本糖尿病学会の見解)" (April 12, 2023, https://www.pmda.go.jp/files/000252782.pdf and "Position of the Japan Diabetes Society on the Off-label) ; "Use of GLP-1 Receptor Agonists and GIP/GLP-1 Receptor Agonists/ GLP–1(受容体作動薬および GIP/GLP–1 受容体作動薬の適応外使用に関する日本糖尿病学会の見解)" (November 28, 2023. https://www.pmda.go.jp/files/000265856.pdf).

13 https://www.med.or.jp/dl-med/teireikaiken/20231025_4.pdf

concludes, “as a fellow physician, I very much regret that physicians are involved in this type of business under the name of a ‘medical institution.’ He also emphasizes that “drugs should be administered to those who need treatment and are expected to be effective, and it is against medical ethics for doctors, who are supposed to safeguard public health, to use them for purposes other than their intended treatment.

Even when it is clear that there are doctors who violate medical ethics by prescribing such drugs (which should not be called “prescribing”), the association merely expresses regret and does not take any effective actions. Of course, the association as a voluntary organization, it cannot be expected to impose effective sanctions. Still, it seems necessary to question once again whether such a legal situation in Japan is appropriate in terms of the design of the licensing system. Should such advertising not be subject to removal for reasons even more fundamental than merely being classified as “medically inaccurate information (see below)”?

2 Medical Information and Digital platforms

The above discussion focused only on the problems of ineffective advertising regulations, including those on digital platforms, and the implementation of medical care with little evidence in the name of self-funded medical cares. Next, with the above “Case b” in mind, let us consider the relationship between medical information and digital platforms.

(1) Voluntary Efforts by Digital platforms

There are countless cases of people who have been told that there is nothing can be done for their family member’s terminal cancer, who have tried everything from chemotherapy to radiation therapy, and who are looking for hospice care while desperately searching for the latest treatments. Then, they see the advertisements and words like “cancer cured!” and “few side effects, gentle on the body”, they quickly believe them based on the case pictures and testimonials, and end up paying several millions of yen in treatment fees[14]. Such advertisements can be found on YouTube and other sites, but as we saw in the previous section, the advertising regulations in the Medical Services Law are not very effective.

Data platform operators have been monitoring inappropriate information for some time, and YouTube has also established “community guidelines” that prohibit illegal information, including illegal drugs, fraud, threats, identity theft, and other content that violates the law, as well as harmful information that may offend human dignity, such as images of sex, violence, and corpses. Traditionally, YouTube has attempted to maintain appropriate conditions by deleting or issuing warnings. This practice is known as “content moderation,” and it has become a necessary part of digital platforms’ work as a socially influential organization. In August 2023, YouTube updated its materially harmful content policy and published three guidelines

14 Recent court decisions include the Utsunomiya District Court decision of November 25, 2021, LEX/DB 25591436, and the Tokyo High Court decision of July 6, 2022, No. 2553, p. 12, in which an autologous cancer vaccine was disputed.

regarding false or misleading information. One of these, the "Medical Misinformation Policy" [15], includes the following prohibitions on posting.

> Don't post content on YouTube if it includes any of the following:
>
> Prevention misinformation: We do not allow content that promotes information that contradicts the health authority (author's note*) guidance on the prevention or transmission of specific health conditions, or on the safety, efficacy or ingredients of currently approved and administered vaccines.
>
> Treatment misinformation: We do not allow content that promotes information that contradicts the health authority guidance on treatments for specific health conditions, including promotion of specific harmful substances or practices that have not been approved by local health authorities or the World Health Organization as safe or effective, or that have been confirmed to cause severe harm.
>
> Denial misinformation: We do not allow content that denies the existence of specific health conditions.

In the specific "Examples" column, "Health Authority and World Health Organization" is added, and in the "Additional Resources" column, a link to the Ministry of Health, Labor and Welfare's vaccination information [16] is provided, along with resources from the World Health Organization (WHO) or Centers for Disease Control and Prevention of the United States.

In recent years, the digital platforms have also been monitoring medical disinformation. Here "disinformation" or "misinformation" refers to information with little scientific evidence to support it. For example, in the "Outline of the National Action Plan for Novel Influenza" (July 2, 2024), "so-called fake news and false information of unknown authenticity" are referred to as "disinformation and misinformation[17]. In the past, they were not subject to any special regulation. They were left alone and not actively deleted from social networking sites. This was due to the concerns over freedom of speech and expression, and because there are cases where the sender of misinformation has no malicious intent, such as when it is simply an assumption

15　https://support.google.com/youtube/answer/13813322?hl=ja&ref_topic=10833358

16　https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/kenkou/kekkaku-kansenshou/yobou-sesshu/index.html?sjid=523668684639436944-AP

17　In the Government Action Plan for Pandemic Influenza, etc. Countermeasures (July 2, 2024), "Chapter 4: Information Provision and Sharing, Risk Communication," states that "In an infectious disease crisis, there is a risk of information confusion, prejudice and discrimination, and the spread of so-called fake news and false information of unknown authenticity (hereinafter referred to as "false information and misinformation"). Therefore, in order to effectively implement countermeasures against infectious diseases, it is important to promote the sharing of risk information and perspectives through two-way communication as much as possible, so that the public can make appropriate judgments and take appropriate actions. In addition, during the response phase, "the government will make necessary requests and cooperate with the efforts of social networking sites and other platform operators as countermeasures against prejudice, discrimination, etc., and false information and misinformation (3-1-3. Measures Against Prejudice, Discrimination, etc. and False Information and Misinformation). This action plan is a legal plan based on Article 6 of the Act on Special Measures against Novel Influenza. Previously, there was no specific legal basis for government agencies to monitor disinformation and misinformation and require digital platform operators to take action. However, by being clearly stated in this revision proposal, it became a legal basis for the government to monitor and implement requests to deal with false and misleading information. Although there are no direct penalties, there is an undeniable risk that freedom of speech and expression will be violated or atrophied, depending on how the measures are implemented. In promoting measures against misinformation, it is necessary to ensure transparency of the implementation status so that the actual situation can be understood and verified by a third party after the fact.

or misunderstanding on the part of the sender. During COVID-19, however, there were various movements through the public discourse surrounding the new coronavirus vaccine (see Russet's article and Kawashima's article for more information on the COVID-19 movement). Misinformation was regarded as a threat to public health, and the government and experts began to consider this as a problem.

(2) What is "medical misinformation"? ----- Regarding the HPV vaccine

However, is it appropriate for YouTube's policy to define "medical misinformation" regarding prevention, treatment as information that is inconsistent with guidelines issued by health authorities and the World Health Organization?

Let us refer to the opinion letter titled "Request for Review of YouTube Community Guidelines - Problematic nature of deleting videos that contradict MHLW's opinion as 'medical misinformation'" submitted to the Ministry of Health, Labor and Welfare on May 8, 2024, and published by the Council of Ombudspersons for Drug Harms. The Council is "an NGO that was established in June 1997 at the call of the lawyers of the contaminated blood scandal lawsuit and the National Citizens' Ombudsman Liaison Conference with the aim of preventing drug-related harm" (quoted from the conference's website) and it has continued to make proactive proposals on issues such as drug safety and the alleviation of health harm. This opinion letter is a call for the problematic practice of targeting videos that contradict the views of the Ministry of Health, Labor and Welfare for deletion as containing medical misinformation.

The following discussion is based on the HPV vaccine case study (above b). The basic information provided by the Ministry of Health, Labor and Welfare website regarding human papillomavirus infection, cervical cancer (uterine cervical cancer) and HPV vaccine is as follows[18]:

- Human papillomavirus (HPV) is a common virus that infects more than 50% of sexually active women at least once in their lifetime. It has been implicated in the development of many diseases, including cervical cancer, anal cancer, vaginal cancer, and condyloma acuminatum. In particular, the incidence of cervical cancer among young women has increased in recent years.
- The vaccine to prevent HPV infection (HPV vaccine) is routinely given to girls from the sixth grade of elementary school through the first year of high school.
- Active recommendations for the HPV vaccine were temporarily suspended in June 2013. However, in November 2021, an expert evaluation concluded that "it is appropriate to end the suspension of active HPV vaccine recommendations," and from April 2022, individual HPV vaccine recommendations have been made in the same manner as other routine vaccinations.

18 See, Ministry of Health, Labor and Welfare, "Human Papillomavirus Infection - Cervical Cancer (Uterine Cervical Cancer) and HPV Vaccine (ヒトパピローマウイルス感染症～子宮頸がん（子宮けいがん）と HPV ワクチン～)" https://www.mhlw.go.jp/bunya/kenkou/kekkaku-kansenshou28/index.html

According to the opinion letter, some videos of the international symposium held by the Council in 2018, in which representatives of foreign HPV vaccine side effect victim groups were invited as guests, as well as videos uploaded to YouTube by patients with side effects, their families, and supporters, were removed because they were deemed to be inaccurate medical information.

The HPV vaccine is available at public expense to girls between 6 and 12 years old. When the routine vaccination began in April 2013, various symptoms, mainly pain and movement disorders, were reported after the vaccination. Three months later in June of the same year, the Ministry of Health, Labor and Welfare decided to suspend active recommendations of the vaccine. Suspension of active recommendations means that local governments refrain from actively encouraging vaccination by sending out vaccination voucher to every household, although the legal status of the vaccine as a routine immunization, such as payment at public expense, remains unchanged. In April 2020, the Ministry of Health, Labor, and Welfare decided to resume active recommendation of the vaccine (while also starting catch-up vaccinations) after new data was collected showing the vaccine's safety and efficacy, in response to criticism by the WHO for Japan's low vaccination rate.

Meanwhile, women claiming health problems following HPV vaccination filed a class-action lawsuit in July 2016 seeking damages from the government and two pharmaceutical companies. At that time, while others complained of health problems caused by the vaccine, the government and the WHO recognized the safety of the HPV vaccine. According to the Ombudsperson Conference on Drug Harms, "According to a leaflet from the Ministry of Health, Labor and Welfare, the number of reports of suspected serious adverse reactions to the HPV vaccine is 5 to 7 per 10,000 vaccine recipients (about 1 in 1,500 to 2,000 people). This is approximately eight times higher than the average for other routine vaccine adverse reactions. In addition, the number of people who have received disability certification under the Adverse Reaction Relief System is about 20 times higher than the average for other routine vaccinations." [19] If this is true, it can be said that the frequency of suspected adverse reactions to the HPV vaccine is considerably higher than that of other vaccines such as the Japanese encephalitis vaccine or BCG. However, since "suspected adverse reaction" here is a concept in which the causal relationship between the vaccine and the symptoms has not been legally established, the Ministry of Health, Labor and Welfare has evaluated the various symptoms that have occurred after vaccination as not having a proven causal relationship to the vaccination and has thus far determined that no serious concerns can be found. Thus, the two sides present very different ideas: that there is a possibility of a causal relationship and while the other argues that a causal relationship has not been proven. Should one of these perspectives be immediately removed as "medically incorrect" merely because it contradicts the guidance issued by the health authority? Although I do not share the same views as the plaintiff and have been a proponent of catch-up vaccination, I still believe that it is necessary to maintain the viewpoint that the government narrative is not always correct[20].

19 Ombudsman Conference on Drug Harms, "Problems with HPV Catch-Up Vaccine - Do You Still Want to Get the Catch-Up Vaccine? -(November 23, 2023) https://www.yakugai.gr.jp/topics/file/20231123%20HPV_catchup_vaccination_problems.pdf

20 The Ministry of Health, Labor and Welfare maintains its own evaluation criteria, which differ from international standards, and has declared more than 99% of fatal cases of suspected corona vaccine side effects reported under the Immunization Act as "not

(3) Characteristics of medical information related to life and health

By the way, it is necessary to prevent the cervical cancer, and the low cervical cancer screening rate, which is less than 50% in Japan, should be taken into consideration. If precancerous lesions can be detected through screening, the onset of cancer can be prevented in many cases, and such information is important for cancer prevention. However, the term "screening" does not appear on the Ministry of Health, Labor and Welfare website for information about the HPV vaccine, and there is a bias in the information (is there a vertical fragmentation of the information, as the term appears on a different page?) Nowhere is it indicated that vaccines may not be the only important thing. In a rush to jump to conclusions about whether or not vaccines should be administered, I wonder if the information about what can and should be expected from vaccines, and what is known and not known about vaccines, has been sufficiently considered. While there are ongoing discussions on potential health risks, I believe that the social infrastructure is not sufficiently developed to organize and share professional information in an accessible way[21].

Except in cases where something is clearly wrong with the scientific methodology, it is not a reasonable attitude to assume that only one side of a scientific argument is correct and that all information on the other side should be limited in areas where judgments tend to be divided, such as the safety and risk-benefit balance of a particular pharmaceutical product. More importantly, when dealing with medical information related to human life and health, it is necessary to collect and analyze materials that contribute to the examination of right and wrong, and to develop an information infrastructure that allows third parties to verify the information provided to ensure its reliability.

This is because it is impossible to ignore the fact that, in the past, drug-related accidents have been caused by government-approved drugs. In the thalidomide case, the government ignored Dr. Lenz's warning that thalidomide caused fetal deformities and continued to market the drug, which was a remote cause of the spread of damage unique to Japan. The Solivudine case, which resulted in 15 deaths due to delays in emergency safety information among all other factors, taught the lesson that drugs must be properly controlled from approval to post-marketing. The safety of pharmaceutical products cannot be fully confirmed only by the information obtained from clinical trials conducted under strict conditions with a limited number of patients, and it is generally recognized that unexpected side effects are inevitable after approval and marketing. For this reason, various initiatives based on the Pharmaceutical Affairs Law are being implemented. The safety of medicines can only be ensured through the continuous collection and analysis of post-marketing safety information and through the review and evaluation of such information not only by the government, which

evaluable due to insufficient information," and there has been insufficient post-event verification of cases equivalent to "possible". It is reported that the public is neither convinced nor confident, and it is criticized that it is difficult to receive vaccinations with peace of mind (for details, see Tetsu Isobe, "Memorandum on Reports of Suspected Adverse Reactions to the New Type Corona Vaccine (新型コロナワクチン副反応疑い報告に関する覚書)" *Keio Law Journal*, No. 50, 2023, pp. 37-52.

21 For the similar observation, see, Koshiro Owaki (physician and translator), Weekly Toyo Keizai, July 6, 2024, p. 43. He stated that the HPV vaccine has been confirmed to reduce precancerous lesions, which are the stage before cancer, in a relatively reliable randomized controlled trial, while there has been no study showing that the vaccine reduces deaths from cancer, and that the risk of premature birth, etc., increases when precancerous lesions are removed. Although the vaccine is recommended to reduce precancerous lesions, the effect of reducing cancer has only been confirmed in observational studies, and it is a leap to link this to a reduction in mortality.

has the authority to approve medicines but also by a wide range of experts and researchers (similar concerns have been raised by the Ombudsperson Conference on Drug Injury, "Opinion letter"). The system in which only the views of the Ministry of Health, Labor and Welfare and other health authorities are correct, and any contrary or contradictory views are uniformly deleted as "medical misinformation," seems to be fraught with serious problems that disregard historical empirical knowledge of ensuring drug safety[22].

Conclusion

The present article, along with its accompanying series of books, aim to examine how preset and future society will or should resist transformation amid the battle of two monsters, Leviathan-State and Behemoth digital platforms. In her article on "Proposal 2" in this book, Kawashima portrays the medical profession as an "old monster" that stands alongside or rivals the giant monster Leviathan (which representing the state) in its influence. She explores strategies to combat infodemics together with the digital platforms, likened to a new monster Behemoth. In this way, the medical profession is important in the context of health and medical care.

In the Old Testament book of Job describes Behemoth, often portrayed as a large hippopotamus, stating, "Behold now, Behemoth, which I created as well as you; He eats grass like an ox" (Job 40:15 (1955 Revised Standard Bible)) [23]. From a Christian standpoint, it is difficult not to sympathize with Behemoth if he is excessively demonized, considering he is also described as "the first of God's works" (v. 19 of the same). Medicine should have been viewed as a natural part of human beings birth, survival and life, not to mention its connection to "Asclepius", the Greek god of healing, whose ancient temple was renowned for medical practices. While the monster metaphor might be more suitable for other volumes in this series, which treat individual rights, power or democracy, the status of medicine and its profession could be depicted using alternative representations.

The Constitution of Japan stipulates that the Leviathan (the state) "shall endeavor to improve and promote social welfare, social security, and public health." (Article 25, Paragraph 2). Still, it is unclear exactly how the healthcare system should be structured to fulfill this responsibility. Undoubtedly, it is imperative to establish a system to eliminate any attempt of bypass the monopoly of medicine by doctors (Medical Practitioners Act) and to ensure that medical facilities and pharmaceuticals have a minimum level of safety and quality

22 It is undeniable that there is medically incorrect and obviously inferior information about pharmaceutical products that should not be disseminated, and there may be cases where such information should be removed before harm is done. In such cases, it is necessary to have a full exchange of views and to explain what kind of information has been judged to be erroneous, based on what kind of evidence. The literacy of the recipient of the information is also a question that needs to be answered.

23 The word "Behemoth" in English can be pronounced and written in many ways in Japanese, but in this series of papers "Behemoth (ビヒモス)" is used primarily in the context of the Hobbesian style. Regardless of which kana notation is preferred by constitutional and political scholars, I believe that the way the notation is used here is related to the understanding of the meaning of Behemoth in the Bible in the first place. The New Common Translation of the Old Testament and the Encyclopedia of the Old and New Testaments (Kyobunkan) use different kana notations for Behemoth. As a Catholic, I would like to use the term "Behemoth (ベヒモス)" that I am personally familiar with.

assurance (Medical Care Act and Pharmaceuticals and Medical Devices Act). Failure to build any of these would clearly violate the spirit of the Constitution, but how should the new monster Behemoth deal with medical and healthcare information? While the legal framework has not fully adapted, it is hard to accept that it is enough that the new and old monsters collude to eliminate the dissenting information.

In Osamu Tezuka's comic series *Black Jack*, "Sometimes Like a Pearl" is one of the most memorable episodes for me. When Dr. Jotaro Honma, the surgeon who saved the protagonist, Black Jack's life, was on his deathbed, Black Jack performed a perfect operation, but Honma did not revive. While Black Jack was devastated, Homma (or his spirit?) placed his hand on his back and said, "Don't you think it's arrogant for humans to think they can control the life and death of a living thing?.....". The Hippocratic Oath, which has been handed down in Western medical education around the world to the present day as a written oath of professional ethics for physicians[24]. It an oath sworn to the medical gods Apollo and Asclepius, along with all the other gods, to fulfill the best of one's ability and judgment the duty of master and disciple and the precepts and confidentiality. Apollo, the god of medicine, was the greatest medical god of ancient Greece, who had the gift of prophecy and foresight and was "in charge of human life and death"[25].

In other words, before the mystery of life and death, there are limits to the power of medicine and man, and it is impossible to say that even drugs now considered safe are always safe, or that all side effects are known.

This is not to say that medicine is nothing compared to a force of nature and should be abandoned as soon as possible. The Chinese poetry "Gift to Medicine," which Professor Yukichi Fukuzawa, founder of Keio University, is said to have given to Dr. Shibasaburo Kitasato, who devoted himself to the establishment of the Research Institute for Infectious Diseases. It sums up that medicine is like the record of an endless battle of wits between nature and man, that doctors should not say that they are no more than servants of nature, and that only by recognizing disease and treating it appropriately with all possible means can the true essence of medicine be born (無限輸贏天又人　医師休道自然臣　離婁明視麻姑手　手段達辺唯是真[26]). The essence of civilization lies in efforts to harness nature through human intellect and apply it to human life, and the development of civilization and learning lies in the continuous struggle to do so. This manifests Fukuzawa's philosophy, and I believe many people still share this view. While keeping Professor Fukuzawa's very positive view of civilization that, eventually, all causes of diseases will be understood and cures will be found (see "Tendou Hito ni Kanari" ("The Way of Heaven is Possible for Man") in "Fukuō Hyakuwa" ("One Hundred Discourses of Fukuzawa")) as the ultimate goal, we need to carefully handle health-related information, while at the same time accurately assessing the achievements and limitations of modern science

24　Hideto Emoto, "Hippocrates and Medical Ethics (ヒポクラテスと医の倫理)", in Japan Medical Association, *Fundamentals of Medical Ethics*, 2018 Edition. https://www.med.or.jp/doctor/rinri/i_rinri/a06.html

25　For the translation and position of the medical god Apollo, see Mamitaro Otsuki (translation), "Oath (誓い)" in Shinichiro Otsuki, *New Revised Complete Works of Hippocrates*, Vol. 1 (Enterprises, 1997), pp. 579-582.

26　Keio University Hospital Medical and Health Information Site (KOMPAS) https://kompas.hosp.keio.ac.jp/sp/contents/medical_info/scholarship/

for the time being.

When “old monter”, medical experts, are enlisted by government agencies to influence policy formation or to participate in the decision to remove online content deemed “inconsistent with health agency guidelines,” they may act as if they were gods who know the truth about everything, unilaterally restrict the dissemination of various types of information. This is not a desirable and appropriate attitude, both from the standpoint of the history of drug abuse and the oath sworn to the gods such as Apollo. Neither closed discussions among experts alone nor closed discussions among the government, digital platforms, experts, and others can eliminate the risk of collective error, concealment of mistakes, and further harm, and it is essential that the information process be open to outside observers so that the adequacy of the collection, analysis, and evaluation of information can be properly monitored. The unrestricted spread of false and misleading information is undesirable, and while it is important to establish a monitoring system to prevent health hazards, it is expected that digital platforms will find their unique role and play it appropriately, taking into account the reflection of history that the views of experts and government authorities are not always correct.

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