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ARTICLE

Reluctant Rulers: Policy, Politics, and Assisted Reproduction Technology in Japan

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Abstract

This article puts the spotlight on the world's largest artificial reproduction technology (ART) industry—that of Japan, seeking to explain the exceptional tardiness of the government there to install a comprehensive legal framework that regulates these practices. By relying on minutes from a conversation with an influential parliamentarian active in this area, as well as official documents, media reports, and an interview conducted with key physicians, the article reconstructs the historical trajectory leading to the enactment in December 2020 of the *Assisted Reproduction Technology Act.* The author contends that it is only on the background of an overview of what happened in the two decades preceding the promulgation of this Act that a sense can be made of why the latter came to be as scant and evasive as it is in terms of provisions, *de facto* leaving unaltered the socially and ethically undesirable situation of self-regulation in ART application by the Japanese doctors. This article adds credence to the hypothesis with regard to the issue of regulatory governance of emerging technologies more broadly that the direction of travel is toward soft, as opposed to hard, law.

Keywords: Japan; assisted reproduction technology; self-regulation; Japan Society of Obstetrics and Gynecology; soft law

> He thought he saw an Albatross That fluttered round the lamp: He looked again, and found it was A Penny-Postage Stamp.
>
> *"The Mad Gardener's Song" — Lewis Carroll (1889)*

Introduction

Japan is no stranger to medically assisted reproduction. In fact, no country relies on assisted reproductive technology (ART) more than this one. As recent data by the International Committee for Monitoring Assisted Reproductive Technologies demonstrate, the volume of ART activity in Japan is unprecedented. According to the 2019 report of this Committee,[1] for example, as many as 424,151 ART cycles were initiated in Japan in 2015—a figure that is an order of magnitude larger than that of the second biggest utilizer of ART, the United States, which registered 174,040 ART cycles for the same 12-month period and which, it is worth noting, is three times more populous than Japan.

To break down these figures, in terms of oocyte-aspiration cycles, in particular, a whole digit of difference could be observed between Japan and the United States. During 2011, for instance, there were 81,378 such cycles in the United States and 169,169 in Japan.[2] A gap of this scale was also recorded for the preceding 3 years.[3] Beyond oocyte aspiration, the other major category of procedures in terms of which ART activity is typically measured is the oocyte-transfer frequency, and, in this respect as well, Japan holds the record by far. Specifically, it documented 92,719 such cycles for 2011, which is an order of magnitude larger than the corresponding figure for the United States—29,231.[4] It is precisely this striking volume of transfers that made the popular magazine, *The Economist,* recently publish a column

on Japanese ART, describing how "[n]estling among a plantation of high-rises in a business district of Tokyo, [Kato Ladies Clinic—one of an unparalleled national number of 600-plus], according to Sarah Franklin and Marcia Inhorn[5] implants fertilized eggs in an average of 75 women a day."[6] "That makes [this facility] one of the busiest [ones] in the world," the magazine heeded.[7]

As for the number of births resulting from the application of ART, Japan leads in this respect as well. Notwithstanding the notoriously low Japanese *in vitro* fertilization (IVF) success rate found here (of about 20%),[8,9] which could be said to be a function of the average age of Japanese women undergoing infertility treatment being higher than that of their counterparts in other developed nations,[10] the country's share of the global such births appears to be the highest, with 56,979 of the world's total IVF births of 918,400 in 2018, for example, having happened here.[11] What is more, the utilization in Japan of ART is only expected to grow further in the future, as a result of an ever-increasing number of couples marrying later in life and consequently turning to IVF for family-building. As a way of corroborating this claim, it seems befitting to note that the above-mentioned figure of IVF births for 2018 was higher with 5,978 than that of 2015, which was 51,001, and that an increase in the number of initiated cycles was also observed of 30,742.[12] Although the figures from year to year do not always exhibit an increase, as data gathered by Osamu Ishihara et al. demonstrate,[13] there certainly is an upward trend in the Japanese populace's reliance on ART, and almost every consecutive year a new record is established here for the number of cycles and/or IVF babies.

On the background of Japan having grown to be the world's most heavy-weight utilizer of ART, it is striking how the country was devoid of a law regulating this sector until very recently. Indeed, it was only in December 2020 that the Japanese parliament promulgated a law pertaining to ART (i.e., the *Act Concerning the Exception from the Civil Code Relating to the Child–Parent Relationship in Cases Where Children Are Born through Assisted Reproduction That Utilizes [Gamete] Donation* [*Seishoku Hojo Iryō no Teikyō nado Oyobi Kore ni Yori Shussei Shita Ko no Oyako Kankei ni Kan Suru Minpō no Tokurei ni Kan Suru Hōritsu*],[14] hereafter the *Assisted Reproduction Technology Act*). Furthermore, as the title of the said law suggests, even then, the government only engaged with one element of what assisted reproduction can entail—specifically, it made secure the parent–child relationship where donated eggs and sperm have been used, recognizing the birth mother and the contracting father as the legal parents. Admittedly, such provisions have long been considered outstanding, given that as many as over 10,000 individuals are thought to have been born in Japan through sperm donation in particular.[15] However, decisions on other questions, for example, whether a donor-conceived child has a right to know their genetic origin (or, in other words, how information about gamete donation would be treated), whether sperm and egg donations would be compensated monetarily, whether surrogacy is to be permitted, whether embryo-selection based on sex or other attributes is to be allowed, or even simply who is entitled to ART treatment, have also been outstanding and, as a cursory glance at the four articles comprising the law would reveal, nothing was provided to clarify the government's stance on these.

Admittedly, the law in the area of ART is generally slow to emerge. As medical lawyer Amel Alghrani aptly observes, ART law is reactive in nature, always playing a catch-up game vis-à-vis the medical and technological advancements, which change rapidly.[16] Even in the United Kingdom—the country most widely considered the pioneer in establishing a formal regulatory regime for ART[17]—the law came late. Louise Brown—the world's first so-called "test-tube baby" born in Oldham General Hospital—was a teenager by the time the *Human Fertilization and Embryology Act* came into being. Brown's birth in 1978 raised public concerns about the future of human reproduction and a committee was promptly formed, chaired by the moral philosopher Mary Warnock, to provide a pathway for guiding these new practices. However, it was not until 1990 that the aforementioned Act was promulgated on the basis of the report produced at the end of the deliberations of the Warnock Committee.

The tendency of ART law to lag notwithstanding Japan's tardiness in this area appears exceptional. Most countries with an appetite for ART (i.e., the wealthy, developed nations) moved to equip themselves with a law of such kind around the turn of the millennium, and many amongst these have by now even gone on to revise these initial laws once or twice in order to keep them fit for purpose and in line with the constant progress in medicine. To bring the example of the United Kingdom again, it amended its 1990 *Human Fertilization and Embryology Act* in 2008.[18] In France too, the Bioethics Law of 1994 controlling for medically assisted reproduction was revised in 2004 and then in 2011.[19]

Spain—another heavy-weight user of ART—enacted its first law on assisted reproduction in 1988, amending it in 2003, and then overhauling the entire legislation on assisted reproduction in 2006.[20] Germany, perhaps because of ART's link with eugenics and the country's Nazi past, was also a forerunner in introducing ART regulation, approving a law in 1990, which it then modified in 2011.[21] As for nations where the government has had a single legal intervention into the ART sector (which still puts them ahead of Japan in this respect), there are Austria, Belgium, Italy, Canada, New Zealand, and Australia, with their respective years of promulgating legislation being 1992, 2003, 2004, 2004, 2004, and 2007.[22]

So why has the Japanese government been so slow to step in to regulate for the country's enormous ART market? Why did such a big industry go uncontrolled and unsupervised for so long, and why were the rules that were introduced in December 2020 so scant? What exactly is holding the law in Japan to be such a long way behind the nation's fertility boom? The situation in Japan clearly cannot be explained simply by saying that the minefield of ethical dilemmas in this field—that is, tough questions such as "should gamete donation or surrogacy be allowed?", "who should have access to ART and to what extent?", "which inheritable conditions, if any, render it legitimate to perform life-selection?", "should life-selection for family-balancing purposes be permitted?", and "should tax-payers' money be spent on ART treatments?"—is too off-putting for policymakers. After all, as noted above, the political elite of so many other jurisdictions (which, it should be reiterated, use ART on a much smaller scale) has found it appropriate to interfere in a timely manner and produce more holistic formal guides as to what is to be permitted. What compounding factors are there in Japan that render it difficult for a more comprehensive and robust regime to emerge?

With regard to this indolence of Japan to legislate for ART, it ought to be noted that it is perplexing for one more reason than the international standard in this area being higher. Indeed, even on the background of Japan's own efforts to provide formal oversight over the application of biomedical technology, the case of ART stands out. To elaborate, the Japanese Government cannot be found to be lackadaisical when it comes to legislating for stem cell therapy and regenerative medicine, for example. In these areas, there has been a comprehensive regulatory framework in place since 2013, when three laws were promulgated simultaneously—the *Act Partially Amending the Pharmaceutical Affairs Law* (*Yakuzai-shi Hō*), the *Regenerative Medicine Promotion Act* (*Saisei Iryō wo Kokumin ga Jinsoku katsu Anzen ni Ukerareru yō ni Suru Tame no Shisaku no Sōgōteki na Suishin ni Kan Suru Hōritsu*), and the *Act on the Safety of Regenerative Medicine* (*Saisei Iryō nado no Anzensei no Kakuho nado ni Kan Suru Hōritsu*).[23] The framework provided by these three laws combined has guided both scientists and private companies involved in the delivery of such treatments. Why did the Japanese government legislate early on for these types of biomedical treatments whilst failing to do the same for ART?

On this divergence, it might be tempting to explain away the progress in regulation of stem cell therapies and regenerative medicine as a function of the Japanese Government's desire to capitalize on what could be construed as the country's comparative advantage (in that it was a Japanese national, Shinya Yamanaka, who discovered the precise mechanism for the creation of the material on which these treatments are largely envisioned to rely on in the future—the so-called induced pluripotent stem cells, obtaining also patents relating to this material's production). However, it is not as if Japan failed to revolutionize ART, too. At the turn of the century, Japanese biologist Masashige Kuwayama and his colleagues gave ART vitrification—the flash-freezing, glass-like solidification method for cryopreservation of gametes and embryos.[24] Vitrification, experts readily concede, was truly a game-changer for cryopreservation. It significantly reduced deoxyribonucleic acid damage, transforming the rates of survival and implantation from how they were for 20 years since 1986 with the slow-freezing (cooling) method. Indeed, a 2008 systematic analysis showed that the clinical pregnancy rates improved by over three times following vitrification compared to the slow-freezing protocol.[25] Today vitrification is employed as a standard in most fertility treatments globally and has been central to the rise in the number of babies born following IVF procedures in Japan, for which freezing plays an increasingly important role. So, how is it that Kuwayama's innovation did not spur a similar regulatory move as Yamanaka's? What accounts for the difference in outcome between the relevant regulatory regimes?

If we accept that the ethical dilemmas relating to ART are the same across societies and that there have been developments on the Japanese assisted reproduction scene comparable with those that led to timely

and robust regulatory regimes in other areas of biomedicine, then one of the inferences we are led to formulate to explain the regulatory ART stagnation in Japan is that there are certain aspects of the domestic policymaking landscape that impede progress. This article examines precisely whether there is any evidence to corroborate this hypothesis. As for the reason why ascertaining this is important, I argue that it is through understanding of the workings of the domestic ART policymaking landscape that a better insight could be gained as to what the revision of the *Assisted Reproduction Technology Act* currently scheduled for 2022, would look like—a development that would impact greatly Japanese patients, physicians, and donor-conceived people.

Entering the Key Players

Toward the goal of finding out what factors in the Japanese policymaking scene might be hampering the creation of a comprehensive formal ART oversight, this article zooms in on the actors with a significant potential to play a role in political decision-making. Concretely, I examine the stances hitherto taken toward this issue by two ministerial departments—the Ministry of Health, Labour and Welfare (MHLW) and the Ministry of Justice (MOJ), the political elite, the Japan Society of Obstetrics and Gynecology (JSOG), patients' groups, and the feminist and disability movements. What has their attitude been so far toward building a fully-fledged regulatory ART framework, and how much effort have they put in this direction?

To elucidate further, insofar as it is the case that most laws in Japan are drafted by the bureaucracy, it seems appropriate *a priori* to begin with an examination of the endeavors toward regulating for ART of the MHLW, as the governmental agency under whose jurisdiction the administration of medical interventions lies, and the MOJ, as the body that investigates issues of civil law, including family law. Prior to 2020, has the enactment of an ART law been on the agenda of these Ministries? And how might have their initiative been met by a political entity such as the Liberal Democratic Party (LDP), which has largely dominated Japan's politics? Indeed, beyond the bureaucratic departments, the role of the legislature cannot be overlooked.

In what follows, I trace the developments that led to the enactment in 2020 of the *Assisted Reproduction Technology Act.* To reconstruct this process, I rely on interviews with central players, ministerial documents, and media reports.

A Rebel's Provocation: Dr. Yahiro Nezu Spearheads the Bureaucracy into Action (1998–2003)

In October 1998, on the backdrop of a rapidly heightening public debate about third-party reproduction, the MHLW made the move to establish a committee to examine the ethics of using ART. What spurred the public debate was the revelation that egg donation had taken place despite the prohibitions imposed by the JSOG through their guidelines/recommendations for doctors. Particularly, it was announced by the director of Suwa Maternity Clinic in Nagano prefecture, doctor Yahiro Nezu, that multiple patients in his clinic had given birth using eggs donated by relatives (i.e., the sisters of the concerned women). Doctor Nezu's action was taken, as he explains,[26] in a bid to provoke a discussion about the restrictions imposed by the JSOG, which he thought had grown incongruous with the way society had evolved. The fact that it was permitted for Japanese couples to purchase eggs abroad was, for him, irreconcilable with the prohibition on altruistic egg donation within Japan between sisters. Furthermore, it did not stand to logic for him that one form of third-party reproduction—namely, sperm donation (known in Japan as Artificial Insemination by Donor ["AID"])—has been permitted since the 1940s, resulting in hundreds of children,[27] whilst the individuals who needed eggs to conceive a child, or a gestational carrier for that matter, were turned away. The upshot of this situation is that those amongst them who do not want to give up becoming a parent in this way encounter considerable burden being forced to seek help overseas. Indeed, it had been reported that between 1991 and 1998 more than 80 Japanese couples had sought third-party reproduction services solely in the United States, with more than 100 children having been born as a result.[28] Given that doctor Nezu's actions and the resultant revocation of his membership by the

JSOG received extensive media coverage, with a report of an internet survey conducted by an Osaka clinic having found a 73% support for third-party reproduction (albeit with many of those who approve expressing reluctance to undertake such procedures themselves),[29] the MHLW was spearheaded into action, setting up a committee to discuss the nature of reproductive treatment.

The Bureaucracy Produces a Draft Bill: 2003

Following 2 years of deliberation, the MHLW's so-called Special Committee on Medical Technology for Reproduction (*Seishoku Hojo Iryō Gijutsu ni Kan Suru Senmon Iinkai*) produced a report that would partly form the basis of a draft bill nearly presented in parliament in 2003. To give a flavor of what the deliberative process looked like, 29 meetings were convened between the five gynecologists, the nurse, the philosopher, and the three lawyers comprising the Committee. Furthermore, five hearings were undertaken to solicit the opinions of patients, members of religious organizations, and legal and medical experts, and views were exchanged with ART specialists from Britain (including with members of the Human Fertilization and Embryology Authority), Germany, and other European countries. The committee did not deliberate on ART in general and rather focused on third-party reproduction, with the conclusion that utilization of donor gametes and embryos by infertile married couples is permissible, although a clear position was not taken on surrogacy.[30] As a way of managing the third-party reproduction that was to be allowed, it was urged that a body is established, amongst other things, to keep donor information accessible for offspring when they turn 20. As for what is to follow next, the recommendation was made that a public council be created to draw concrete legal guidelines and regulations. This proposal was with the view to ensuring that reproductive technology is used within the appropriate limits, and that doctors who do not comply with these would face penal provisions.

In May 2001, 5 months after the issuance of these recommendations, and just 3 months into the deliberations of the newly established Sub-committee for Parent–Child Relating to Reproductive Medicine at the Legislative Council of the Justice Ministry (*Hōsei Shingi-kai Seishoku Hojo Iryō Kanren Oyako Hōsei Bukai*), doctor Nezu announced Japan's first case of surrogacy. This announcement served to push further the boundaries of the ongoing debate on third-party reproduction. Having debated the issue for two more years, the MOJ's own deliberative panel issued, in June 2003, a Mid-term Draft Report (*Seishi, Ranshi, Hai no Teikyō nado ni Yori Seishoku Hojo Iryō ni Yori Shussei Shita Ko no Oya-ko Kankei ni Kan Suru Minpō no Tokurei ni Kan Suru Yōkō Chūkan Shi-an*), according to which "the mother of a child should be the woman who gave birth to that child; that the father of a child born by AID should be the husband of the mother when there was his previous consent to the AID; and that the donor of the sperm would not be able to legally affiliate the child by their acknowledgement." This largely aligned with the outcome of further deliberations at the MHLW, where a *Seishoku Hojo Iryō Bukai* had recommended in April that year that surrogacy be banned and that penal punishment is imposed on non-complying doctors.[31] As the next section would illustrate, however, these perspectives would fail to become enshrined into a law and a legislative standstill will be the outcome for nearly two decades.

Legislative Stalemate: The All-Or-Nothing Approach of LDP's Seiko Noda

Whilst Japanese female politicians, whose number remains staggeringly low in comparison to that of other developed democracies, tend to be stereotyped as impotent, the present case of ART law-making demonstrates, in agreement with recent research on this subject,[32] that they are perfectly capable of exercising agency and making their voice heard on the policymaking arena. What specifically happened on the occasion of the two aforementioned Ministries pushing in 2003 for their draft bill to be sponsored in parliament by the LDP is that this party's member Seiko Noda was capable of single-handedly blocking it. In particular, holding the opinion, as she explains in an interview,[33] that no law is better than letting a "retrogressive" or "restrictive" law (toward infertility patients) be promulgated, Noda, upon hearing that an MHLW representative would be discussing the issue of ART at the party's cross-house Committee Investigating the Ethics Surrounding Brain Death and Life and Organ Transplant (*Nōshi/seimei rinri*

oyobi zōki ishoku ni kan suru chōsa-kai), felt a sense of crisis and made it her job to register attendance, despite not being a regular/official member of this committee, and argue vociferously against the bill proposal. The statement that the bureaucrats use to explain that draft bill being dropped—that is, that there were other important parliamentary matters to be decided at the time, is, Noda explains, just an excuse—they simply do not want to admit failure (*kanryo no make oshimi ni suginai*).[34]

Being a mother of a child conceived, after a long battle with infertility, through egg donation in the United States, Noda explains how strongly she felt about the proposed legislation, especially the prohibition of surrogacy. In her view, it was a draconian measure to try to prohibit the application of ART explicitly in the law, installing also legal provisions that would ensure penalization of doctors wanting to help their patients. It is important, she argued, that people are given choice: for those who want to use ART, they should be given the freedom to use it, domestically, safely, and cheaply, and for those who do not want to resort to it, they should be guaranteed the freedom to not do so.

However, even beyond the issue of surrogacy, the draft bill was, for her, full of problems (*mondai darake*). She explains that her issue starts with the skewed selection of members for the ministerial panels described above. Beginning with the academics, Noda contends, the criteria for choosing to invite them had been whether their views fit the bureaucrats' premeditated position—a type of people who she calls "kept-scholars" (*goyō gakusha*). As for the patients who had been panel members too, she protests that the group from where these were selected—*The Friends of Finrrage, Network for Infertile Women in Japan*[35]—does not at all act on behalf of the majority of women suffering with infertility. In contrast to the stance of this group, which, she maintains, aligns with the ministerial position that the application of ART ought to be restricted, the bulk of infertility patients cling to the idea that through the advances in medicine they would somehow be able to become mothers. To make the situation worse, Noda explains, the politicians whom the officials had been preparing to address were ignorant and indifferent with regard to questions relating to ART. "The politicians are even worse than the bureaucrats in terms of awareness about ART," she alleges, asking rhetorically "How many people within the LDP do you think have any knowledge about this and recognize it as an important issue?" She answers by saying "It is probably just me and my husband."[36] Unable to understand the issues involved, she continues, these politicians' tendency is to opt on the conservative side—that is, for prohibition.

In trying to explain her hesitancy to propose a draft bill herself for submission to parliament, Noda expressed the fear that a premature step, one which is taken whilst there is still wide-spread ignorance of the involved issues, might be counterproductive to the cause of easing patients. Arguing that such a course of action might end up being as troublesome as "waking up a sleeping lion (*neta ko wo okosu*)," she showed reluctance to go beyond opposing/blocking legislative attempts she deems inappropriate. Even though the ART law of December 2020 does not go beyond the very minimum in terms of provisions and scope, the fact that it was submitted as soon as Prime Minister Shinzo Abe resigned from office in the fall of that year belies the logic that familiarity with and interest in the issues at stake is pivotal to legislative success. The resolution of this deadlock in Japanese ART, if the 2020 law could indeed be viewed as a significant development, could perhaps be more appropriately explained in terms of a political windfall for Noda.

Concluding Discussion

Physicians' self-regulation in ART application is undesirable from both social and ethical perspectives. Amongst the arguments to be made on the social justice-side, there are (1) the need to ensure fairness and equality for patients through a nationwide standardization of treatments; (2) the necessity to secure legal protection (i.e., relief through the court system) in cases of medical mistreatment or negligence; and (3), not least importantly, the necessity to clarify, for the doctors' own sake, the gravity that only a statutory provision carries, the duties and obligations that the latter have toward patients. On social justice in ART, it is well-known that professional societies' guidelines seldom contain any attachments about potential sanctions if a doctor fails to comply, which is something that makes these rules less powerful than formal legal statutes. In the case of Japan and the JSOG regulations, the incidents of breach by Dr. Nezu showed

precisely that following these rules are only voluntary for member doctors and that failure to do so entails no punitive legal measures. Indeed, putting aside the issue of whether Dr. Nezu's actions were morally justified or not (and it should be said that his eventual re-admission in JSOG is perhaps a sign that many there recognized that his actions stemmed from a good place), the only measure taken against him for violating the JSOG rules was the Society's own disciplinary act of expulsion from its ranks. There was never a question of his medical license being revoked. In 2008, the Supreme Court dismissed the doctor's complaint about the disciplinary measure to which he had been subjected by confirming the Society's, right to impose its own sanction on him if it so chose, full stop.

As for why ethically it is wrong to leave doctors to self-regulate in ART, this is because, as bioethicists have widely argued,[37] doctors are not experts in ethics and many of the questions on ART applications concern ethics. There is no question that when it comes to choosing the best clinical practice (i.e., read safety and efficacy), the most qualified people to decide are doctors. However, when it comes to issues such as equity of and access to treatment, the welfare of children resulting from ART treatments and the justifiability of certain screening procedures or monetary remuneration for reproductive assistance by third parties, the doctors' judgment becomes one of no more value than that of a banker, a bus driver, or a farmer.

The undesirability of the doctors' self-regulation in ART still remains the *de facto* situation in Japan, even after a statutory regulation was introduced. Indeed, because the *Assisted Reproductive Technology Act* eschewed the vast majority of issues in ART where clear ethical decisions were needed, the *status quo* of the doctors' organization to, by default, decide on these matters remained unaltered. Although there is now a law, the regulatory gap in ART application has certainly not been filled, because that law says nothing about issues that are disputed and controversial. No matter what some proponents might say about this Act being a major step forward and a watershed moment for ART in Japan, the fact is that it is actually largely hollow, leaving as much room as there was before for those who implement ART on the ground to make their own decisions. It essentially continues to give free hand to the physicians' community, with the change being just in form and not in substance. Therefore, the regulatory change is only an illusion of progress. To those who insist the step of law installment does represent progress, it could be said that this is the progress of the Orwellian type—that is, "the progress is not an illusion, [it has happened,] but it is slow and … disappointing."[38]

After reaching the above realization, it is fair to ask the question: Does the doctors' community want to be in the ruling position of making political decisions on behalf of society and the political elite? The answer is: Not really. Even if they might have entertained the idea of becoming the sole entrepreneur of reproductive rights in Japan in the age of the first "test tube babies," time has taught JSOG that this is quite a heavy and unwelcome mantle to carry. Concretely, since the 1990s, finding themselves in an untenable position in the battle with patients against disability and feminist movements over Pre-implantation Genetic Diagnosis (particularly for both the heritable gene-mutation type, as opposed to the spontaneous chromosomal abnormality type), JSOG has been issuing repeated calls to politicians to step in, do their job, and take the ART ethics burden off them, with the expression of *seiji no taiman* ("political neglect") having become a common way to describe the existing situation in these circles. So, rather than perceiving the physicians as craving the authority to cast decisions in this highly consequential area, it seems more accurate to conclude that they are, in fact, loathe to be forced into this role of rulers, simply as a function of being at the site of ART implementation.

Is this outcome of the doctors still being forced to govern by default, anything of a surprise? For insiders of Japanese politics, it could be said that it is not. Japanese politics has long had the reputation of not being innovative in making laws that challenge the *status quo* and introduce novel and radical ways of dealing with issues. It is, indeed, understood amongst experts that in areas where there are ethical controversies, the Japanese political elite would only go as far as putting a stamp of approval on what is already accepted and widely practiced. The case of the promulgation of the *Assisted Reproduction Technology Act* certainly appears to be no exception. However much applause some might want to give to Noda for almost singlehandedly pushing the heavy rock of ART legislative provision up the steep hill of passage through a disinterested, aged male-dominated parliament, the truth is that the granting of the status of legal mother to a woman who gives birth to a child she has conceived through egg donation—the

only element of the Act that, to put it bluntly, could be construed, on its own and without a context, as remotely bold—is already the norm in Japan and has been so for a long time. Indeed, it was as far back as 1962 when the Supreme Court interpreted for the first time the Civil Code to mean that the woman who delivers the baby is its legal mother. And even though the possibility of birth after egg donation did not, of course, feature anywhere on the minds of those who devised the Japanese Civil Code during the post-war Occupation, the hard fact remains that no woman giving birth in Japan could have been considered, prior to the 2020 Act, not the legal mother of that child, whatever way she conceived it. This is, indeed, why Noda, the architect of this Act, has been recognized herself by the Japanese state as the legal mother of her child conceived through egg donation in the United States from the moment she gave birth to him in 2011.

A final question worth considering with regard to the Japanese ART regulatory situation is: Who is troubled or disturbed by this situation of there being a vacuum in terms of formal rules for ART in Japan? True, as partly mentioned in the discussion of Dr. Nezu's actions, there are patients who are forced to either go abroad or underground for the solutions that the Japanese JSOG framework does not permit. (And, yes, beyond Dr. Nezu's initially unpublicized actions, there can be found plenty of underground—read "unreported", "undetected", "unaccounted for"—activity in ART in Japan if one is determined to find it. For example, according to the admission of the director of a major maternity clinic, the so-called Percoll Method, which enables distinguishing sperm with an X chromosome from sperm with a Y chromosome, with far from reliable results, appears to have been used behind the scenes for sex selection long before JSOG lifted the ban on this in its guidelines in 2006, with one particular type of case where it had been utilized in order to enable Buddhist priests secure an heir for their temple.[39]) However, apart from these patients, where can those be found who are challenging the situation and shouting that the existing regime is intolerable or harmful? There certainly does not appear to be much of a clamor (sorry, this is the word I meant originally but had misspelled it—in the original manuscript it was "clammer") in this regard. It is perhaps for this reason that one JSOG member remarked that "[i]n Japan, what is in the best interest of everyone concerned with ART is that there is as little as possible in terms of regulation."[40] "As less rules and as loose rules as possible is what enables everyone to have their way," he commented.[41]

Insofar as the above is true, it seems unsurprising that the players in the Japanese ART scene are behaving the way they do. To paraphrase an old adage, if it is not broken, why fix it? Why would the doctors, to pick the stakeholder that shown earlier voiced repeated calls for formal ART governance, push more proactively and lobby for legal framework when, leaving aside the burden of becoming embroiled in ethical controversies, they have much to lose from a comprehensive legislation on ART? As Tokyo-based freelance journalist Philip Brazor recently observed gynecologists would see their income drop substantially, with some clinics even going out of business, if political stance is taken on issues such as the-morning-after-pill, abortions, and IVF.[42] "Gynecologists currently charge whatever they want for abortions and fertility treatments," he writes. They do not want, Brazor continues, the morning-after-pill to be mainstreamed and available over the counter. Nor do they want the oral pill for abortion to be made legal, as this would shrink the business they have with the clinic-based intervention known as Dilation and Curettage (which, to give an idea of its scale, stood at approximately 160,000 in 2018).[43] Providing further insurance coverage for IVF is also not something the doctors want, Brazor argues, for it would lead to national standardization of treatment that would no longer permit them to charge whatever they want for the infertility treatment courses they provide.

Lastly, as for the broader applicability of the finding that in Japan ART effectively remains governed by the informal, voluntary, and unenforceable JSOG guidelines, it serves to uphold, albeit in a modest way, the fledgling conjecture amongst scholars of emerging technologies that the tendency now internationally is toward these being governed more through soft law, not less. As Ryan Hagemann et al.[44] have recently contended, hard law, as in "state-promulgated formal statutes," is incapable of responding to the challenge of rapid technological progress. From this, it is only natural to conclude that the undergoing biotechnological revolution will be controlled, to the extent that this is possible at all, through "rules of conduct," "guidelines," or "recommendations" issued by professional associations, that is, soft law indeed. In the words of Hagemann et al.:

> The era of hard law governance appears to be fading and the age of soft law is firmly underway. Scholars and policy advocates of quite different ideological dispositions may have reservations about this development, but that is unlikely to keep it from happening. In that sense, much like Winston Churchill once famously said that democracy represented "the worst form of Government except for all those other forms that have been tried from time to time," it may be the case that soft law represents the worst form of technological governance except for all those others that have been tried before.[45]

This is precisely what the recent Japanese developments in ART regulation appear to showcase. The promulgation of the *Assisted Reproductive Technology Act* should not in the least distract from the reality that the world's largest ART industry remains essentially a soft law-governed one.

Conflict of interest. The author declares none.

Notes

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