AMERICAN UNIVERSITY | WASHINGTON COLLEGE OF LAW

# HEALTH LAW & POLICY BRIEF

VOLUME 16 • ISSUE 1 • FALL 2021

## ARTICLES

LIVING AGREEMENTS IN HEALTHCARE MERGERS AND ACQUISITIONS
*Emma Contino* ..... 1

COVID-19 AND THE LAW: HOW CAN GOVERNMENTS ENSURE THAT CITIZENS FULFILL THEIR OBLIGATIONS? A LOOK INTO JAPANESE LAW
*Dr. Yuichiro Tsuji* ..... 20

COVID-19 VACCINATION IN JAPAN: REMEDIES FOR INJURED PATIENTS
*Dr. Yuichiro Tsuji* ..... 40

AMERICAN UNIVERSITY
WASHINGTON
COLLEGE OF LAW

*Acknowledgements:*
We would like to thank our advisor, Lindsay F. Wiley for her support. We are also grateful to the American University Washington College of Law for providing a legal education that empowers us to champion what matters.

* * *

AMERICAN UNIVERSITY | WASHINGTON COLLEGE OF LAW

# HEALTH LAW & POLICY BRIEF

VOLUME 16 • ISSUE 1 • FALL 2021

## ARTICLES

LIVING AGREEMENTS IN HEALTHCARE MERGERS AND ACQUISITIONS

*Emma Contino* ..... 1

COVID-19 AND THE LAW: HOW CAN GOVERNMENTS ENSURE THAT CITIZENS FULFILL THEIR OBLIGATIONS? A LOOK INTO JAPANESE LAW

*Dr. Yuichiro Tsuji* ..... 20

COVID-19 VACCINATION IN JAPAN: REMEDIES FOR INJURED PATIENTS

*Dr. Yuichiro Tsuji* ..... 40

* * *

* * *

# LETTER FROM THE EDITORS

Dear Reader:

On behalf of the Editorial Board and Staff, we proudly present Volume 16, Issue 1 of the *Health Law & Policy Brief.* Since its formation in 2007, the Brief has published articles on an array of topics in health law, food and drug law, and emerging health technologies. Nearing year two of the COVID-19 pandemic, this is the fourth publication of the *Health Law & Policy Brief,* where we can see our authors grappling with issues in law, public policy, and justice that have emerged during or been illuminated by this pandemic. To that end, Volume 16.1 features three articles: one examining the insufficiencies of merger clauses in healthcare contracts and COVID-19's effects on these arrangements, and two articles exploring how Japanese law has contended with citizen enforcement and vaccination schemes during the pandemic.

Our first article, by Emma Contino, examines the implications that merger clauses have in healthcare mergers and acquisitions as the industry continues to grow and evolve. Ms. Contino discusses how, by their nature, merger clauses inhibit the business goals of healthcare companies and how they ultimately impact patient care. She addresses how the pandemic has further complicated this reality, and lastly, advocates for a prohibition on merger clauses in healthcare mergers and acquisitions. Our last two articles, by Dr. Yuichiro Tsuji, explore how Japan, like many countries, has approached key pandemic-related issues under its law and healthcare system. His first article discusses how Japan derives its authority to encourage or compel citizens to comply with COVID-19 protections and regulations, and the ramifications of such measures. His second article reviews the COVID-19 vaccination scheme in Japan and evaluates compensations rights under Japanese law for those who experience adverse reactions to vaccination.

We would like to thank the authors for their diligence, insight, and cooperation in producing these pieces. We would also like to thank the *Health Law & Policy Brief's* article editors and staff members who worked diligently on this issue.

To all our readers, we hope you enjoy this issue, that the never-ending complexities of this area of law inspire your own scholarship, and that you continue to anticipate and scrutinize the inevitable challenges that our healthcare system continues to withstand.

Sincerely,

Katherine Freitas
*Editor-in-Chief*

Allison Bock
*Executive Editor*

* * *

# LIVING AGREEMENTS IN HEALTHCARE MERGERS AND ACQUISITIONS

*Emma Contino**

## TABLE OF CONTENTS

INTRODUCTION ..... 2
I. MISUNDERSTOOD MERGER CLAUSES AND THE CONSEQUENTIAL PAROL EVIDENCE RULE ..... 5
*A. The Merger Clause and Contract Ambiguity* ..... 5
*B. The Parol Evidence Rule* ..... 8
II. A VERY PRICEY BREAKUP ..... 9
*A. Letter of Intent* ..... 10
*B. Consequences of Failed Mergers* ..... 11
III. TRADITIONAL MERGER CLAUSE LANGUAGE AND INHERENT TENSIONS ..... 12
IV. WHO'S MERGING, ANYWAYS? ..... 14
V. THE EFFECT OF COVID-19 ..... 16
CONCLUSION ..... 18

*"Often, the best ideas don't come from one institution; they are created when dedicated people from two or more institutions decide to work together to solve tough problems."*
Sylvia Romm, CIO of Atlantic Health System

* *Emma Contino is a J.D. Candidate, expected May 2022, at the University of Wisconsin Law School.*

## INTRODUCTION

Contracts have evolved significantly, in both complexity and importance, from the original offer, acceptance, and consideration framework.[1] Contracts are now exceptionally long documents with dense, perplexing language.[2] While the original offer and acceptance principles still lie at the foundation of these contracts, modern agreements require a close look at the language and, even more so, the implications of such language to help parties attain their goals with minimal conflict.[3] Admittedly, this objective is easier said than done. However, as the past has guided us before, it can do so again.

Mergers and acquisitions hold a dominant place in the corporate world.[4] A merger is when two bodies combine under the law, resulting in one surviving business.[5] Despite the magnitude of these agreements contract drafters insert a clause, hidden among the pages, that has the power to alter the entire agreement.[6] This sentences is referred to as the "merger clause."[7] The merger clause is viewed as a generic, standardized template until it becomes a point of contention.[8] If prepared and accepted improperly, contracts with merger clauses can result in unwelcome surprises and abuse emanating from power imbalances.[9] Merger clauses root themselves in the letter of intent (LoI), a document that is the product of initial negotiations between the parties.[10] The LoI contains both binding as well as non-

---

[1] Eric A. Posner, Karen Eggleston & Richard Zeckhauser, *The Design and Interpretation of Contracts: Why Complexity Matters*, 95 NW. UNIV. L. REV. 91, 127 (2000).
[2] *Id.*
[3] *Id* at 92.
[4] Anderson, D. Scott, et al., *M&A Trends in the Opportunity Economy*, THE NAT'L L. REV. 309 (2021).
[5] Eric Tower, *Top Considerations for Structuring Health Care Mergers and Acquisitions*, THOMPSON COBURN LLP (Jan. 7, 2020), https://www.thompsoncoburn.com/insights/blogs/health-law-checkup/post/2020-01-07/top-considerations-for-structuring-health-care-mergers-and-acquisitions. (last visited Nov. 3, 2021).
[6] *See* Timothy Murray, *The Misunderstood but Critically Important Merger Clause*, LEXISNEXIS (Feb. 21, 2019), https://www.lexisnexis.com/lexis-practical-guidance/the-journal/b/pa/posts/the-misunderstood-but-critically-important-merger-clause; *see also Merger Clause Sample Clauses,* LAW INSIDER, https://www.lawinsider.com/clause/merger-clause (last visited Nov. 3, 2021).
[7] *Id.*
[8] Roy Banerjee, *What is a Merger Clause?*, KPPB LAW (Aug. 12, 2019), https://www.kppblaw.com/what-is-a-merger-clause/ (last visited Nov. 3, 2021)..
[9] *Merger Clause Found Sufficient to Bar Fraud Claim by Sophisticated Plaintiff,* FREIBERGER HABER LLP (Aug. 16, 2017), https://fhnylaw.com/merger-clause-found-sufficient-bar-fraud-claim-sophisticated-plaintiff/(last visited Nov. 3, 2021).
[10] John A. Fisher, *Integration Clauses and Letters of Intent,* HARV. L. SCH. F. ON CORP. GOVERNANCE (Jun. 15, 2015), https://corpgov.law.harvard.edu/2015/06/15/integration-clauses-and-letters-of-intent/ (last visited Nov. 3, 2021).

binding provisions and has important implications for the final agreement.[11] Contracts typically serve as a manifestation of the parties' interests and rights, but what happens when those interests change?

Mergers and acquisitions in healthcare are dramatically increasing.[12] In 2019, transactions in the healthcare industry reached $533 billion.[13] In 2020, there were 642 mergers announced.[14] 192 of those announcements were in the healthcare information technology sector, 261 were in the post-acute sector, 65 were in the behavioral health sector, 26 were in labs, and 15 were in the managed care sector.[15] As new technologies develop, new entities join the industry, and as our understanding of healthcare increases, the demand for multi-faceted industries will increase alongside.[16]

Mergers and acquisitions of healthcare systems are complex and can be prone to conflict if either party does not fully understand the agreement, or if it demands quick modifications.[17] An example of this "but he said..." merger clause issue can be seen in *IBM v. Medlantic Healthcare*.[18] A healthcare provider purchased a multi-million-dollar computer system from IBM with a 15% discount as reflected in the contract.[19] However, during the negotiations, the IBM salesman assured Medlantic that it would actually be a 25% discount.[20] Despite the numerous reassurances, the final contract stated that there was a 15% discount and had a merger clause which stated that the text of the contract was irrefutable despite any previous agreements or promises.[21] Because Medlantic relied on the assurances made by IBM salesman,

---

[11] Jan Wenzel, *Healthcare M&A: Negotiating and Papering Key Aspects of a Deal,* BUCHANAN INGERSOLL & ROONEY (Jun. 8, 2020), https://www.bipc.com/healthcare-m-and-a-negotiating-and-papering-key-aspects-of-a-deal (last visited Nov. 15, 2021).
[12] Jeff Lagasse, *Hospital Merger and Acquisition Activity Will Remain Robust Throughout the Year, Moody's Finds*, HEALTHCARE FIN. (Apr. 22, 2020), https://www.healthcarefinancenews.com/news/hospital-merger-and-acquisition-activity-will-remain-robust-throughout-year-moodys-finds (last visited Nov. 3, 2021).
[13] Erica Garvin, *3 Trends Driving Healthcare Mergers & Acquisitions (M&A) Activity in 2020,* HIT CONSULTANT (Jan. 22, 2020), https://hitconsultant.net/2020/01/22/healthcare-ma-trends-2020-livingstone/#.YXwFuJ5KhQI (last visited Nov. 3, 2021).
[14] *2020 Healthcare M&A Activity Recovers, Edging Past 2019*, HAMMOND HANLON CAMP LLC (Jan. 19, 2021), https://www.h2c.com/2020-healthcare-ma-transactions (last visited Nov. 3, 2021).
[15] *Id.*
[16] Wenzel, *supra* note 11.
[17] Stephanie Winer Schreiber & John R. Washlick, *Healthcare M&A: What Decision Makers Need to Know Before Partnering*, BUCHANAN (Jan. 31, 2020), https://www.bipc.com/healthcare-m-and-a-what-decision-makers-need-to-know-before-partnering (last visited Nov. 3, 2021).
[18] *IBM v. Medlantic Healthcare*, 708 F. Supp. 417, 418 (D.D.C. 1989).
[19] *Id.*
[20] *Id* at 420.
[21] *Id* at 420-1.

it attempted to sue.[22] The court held for IBM because the text of the contract stated that there was to be a 15% discount.[23] The court reasoned that enforcing a 25% discount based on previous agreements would contradict the plain language of the written contract and invalidate the merger clause.[24]

There are two takeaways from this case that are relevant to this article. First, even the most sophisticated commercial entities fall into the merger clause trap.[25] Second, courts abide by a very strict "plain meaning of the contract" ruling, regardless of what you may have been promised.[26] *IBM v. Medlantic Healthcare* emphasizes the harsh implications and consequences of merger clauses and why they should be prohibited in the field of healthcare.[27]

Taking a step back, or rather, zooming in, the effect that healthcare mergers and acquisitions have on patients cannot be overstated. The care a patient receives, what medications they have access to, the treatments available, the financial strain placed on them, and their quality of life are all dependent on these enormous agreements.[28] Because of the money involved, the anti-competitive issues, and the heavy governmental regulation, it becomes far too easy to overlook the micro-scale impact on the patient.[29]

The first section will address misconceptions surrounding merger clauses and implications of the parol evidence rule. The second section will address failed mergers and the subsequent consequences. Next, the third section will introduce traditional language used in merger clauses and will discuss the inherent conflict between the clauses' stagnant nature and the progressive aspirations of the healthcare system. Following will be a fourth section, which will d the role of healthcare acquisitions along with example agreements, and how they affect the industry, research developments, and patient care. The fifth section discusses the COVID-19 pandemic and its predicted effects on the merger and acquisition

[22] *Id* at 421-2.
[23] *IBM*, 708 F. Supp. at 424-5.
[24] Paul Humbert, *Why the Integration Clause* Matters, LINKEDIN (Aug. 24, 2015), https://www.linkedin.com/pulse/avoid-integration-clause-trap-paul-humbert/ (last visited Nov. 3, 2021).
[25] *Id.*
[26] *Id.*
[27] *Id.*
[28] *Lilly Completes Acquisition of Prevail Therapeutics*, ELI LILLY (Jan. 22, 2021), https://investor.lilly.com/ news-releases/news-release-details/lilly-completes-acquisition-prevail-therapeutics (last visited Nov. 3, 2021).
[29] *A Guide to Healthcare Compliance Regulations*, MICH. STATE UNIV. (Aug. 12, 2019), https://www.michiganstateuniversityonline.com/resources/healthcare-management/a-guide-to-healthcare-compliance-regulations/ (last visited Nov. 3, 2021).

market. The final section proposes a systemic prohibition on merger clauses in healthcare mergers and acquisitions.

## I. MISUNDERSTOOD MERGER CLAUSES AND THE CONSEQUENTIAL PAROL EVIDENCE RULE

The healthcare system in America is a multi-trillion-dollar industry.[30] It is the largest U.S. employer, with over 20 million employees and a payroll of $7.1 trillion in 2018.[31] The estimated revenue of the healthcare industry in 2019 was $303.2 billion.[32] With the larger picture in mind, we can look to individual patients. In 2019, the United States spent $11,582 per person.[33] How much an individual spends is dependent on a number of factors, but on average, an American household spent nearly $5,000 per person on healthcare in 2018.[34] The purpose of these statistics is not to make you second guess your insurance policy or career path, but rather to illustrate the sheer enormity that is the healthcare industry in America. It is unfathomably expensive and staggeringly complex.[35]

### *A. The Merger Clause and Contract Ambiguity*

The healthcare industry is unique because, unless a person has pristine genes and an all-star immunity, nearly everyone, at some point, will seek medical attention.[36] To illustrate, in 2019, 84.9% of adults and 95.6% of children visited a doctor or other health care administrator.[37] Six in ten adults in the United States have a

[30] *U.S. Healthcare Industry in 2021: Analysis of the Health Sector, Healthcare Trends, & Future of Digital Health*, INSIDER INTELL. (Aug. 11. 2021), https://www.insiderintelligence.com/ insights/ healthcare-industry/ (last visited Nov. 3, 2021).
[31] Earlene K.P. Dowell, *Health Care Still Largest U.S. Employer*, U.S. CENSUS BUREAU (Oct. 14, 2020), https://www.census.gov/library/stories/2020/10/health-care-still-largest-united-states-employer.html#:~:text=Total%20employment%20increased%202.3%20million,to%20%247.1%20trillion%20in%202018 (last visited Nov. 3, 2021).
[32] *Health Care & Social Assistance in the U.S. 2020*, STATISTICA, https://www.statista.com/study/15826/health-care-and-social-assistance-in-the-us/, (last visited Dec. 3, 2020).
[33] *National Health Expenditure Data*, CTRS FOR MEDICARE & MEDICAID SERVICES, https://www.cmw.gov/Research-Statsitics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendDatea/natoinalHealthAccountsHistorical (last visited Nov. 9, 2021).
[34] Megan Leonhardt, *Americans Now Spend Twice as Much on Health Care as They Did in the 1980s*, CNBC (Oct. 9, 2019), https://www.cnbc.com/2019/10/09/americans-spend-twice-as-much-on-health-care-today-as-in-the-1980s.html.
[35] *Id.*
[36] *Ambulatory Care Use and Physician Office Visits,* CTRS. FOR DISEASE CONTROL & PREVENTION (Oct. 8, 2021), https://www.cdc.gov/nchs/fastats/physician-visits.htm (last visited Nov. 9, 2021).
[37] *Id.*

chronic disease, while four in ten adults have two or more.[38] Over 131 million people utilize prescription drugs.[39] There are 328.2 million people (and growing) in the United States.[40] This means that there are billions of dollars at stake and millions of lives affected when healthcare giants seek to merge. Kudos to the lawyers writing these contracts because each word and phrase must be perfect, or they risk the deal falling through, losing millions of dollars, or experiencing misunderstandings between the parties, which can lead to a messy public breakup. Why can't they edit the contract later? Within the final pages of the contract, there is a one to two sentence clause, the "merger clause," which prevents the parties from doing so.[41] This clause functions under a number of different aliases, including the "integration clause," or the "zipper clause," but they ultimately have the same effect: nullifying any previous agreements or representations not explicitly stated in the contract.[42] A merger clause states that every intention and interest that each party has is written in that document and that no prior deals, conversations, or documents can be used to alter, modify, or explain those final written terms.[43] Therefore, extrinsic evidence is precluded unless the terms in the contract are found to be ambiguous.[44]

Contracts are ambiguous when a term or phrase in the contract is reasonably susceptible to more than one meaning.[45] Therefore, when a case comes before the court, they will first try to ascertain the parties' intent based on the language present in the agreement.[46] When this happens, each party has definitions and interpretations they urge the court to adopt because it better serves their interest.[47]

---

[38] *Chronic Diseases in America,* CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/chronicdisease/resources/infographic/chronic-diseases.htm (last visited Nov. 3, 2021).
[39] *Prescription Drugs,* HEALTH POL'Y INST., https://hpi.georgetown.edu/rxdrugs/ (last visited Nov. 3, 2021).
[40] *United States of America*, DATA COMMONS PLACE EXPLORER, https://datacommons.org/place/country/USA?utm_medium=explore&mprop=count&popt=Person&hl=en, (last visited May 5, 2021).
[41] Stephen F. Ross and Daniel Trannen, *The Modern Parol Evidence Rule and Its Implications for New Textualist Statutory Interpretation*, 87 Geo. L.J. 195, 240-1 (1998).
[42] Murray, *supra* note 6.
[43] Ross & Trannen, *supra* note 41.
[44] *Id.*
[45] Lewis H. Lazarus, *Court Gives Great Weight to Pre-Merger Negotiations in Interpreting an Ambiguous Contract*, MORRIS JAMES DEL. (Apr. 5, 2019), https://www.morrisjames.com/newsroom-articles-Court-Gives-Weight-Pre-Merger-Negotiations-Interpreting-Ambiguous-Contract.html (last visited Nov. 23, 2021).
[46] *Id*.
[47] *Ambiguity In Contracts- What Do The Courts Do?*, L. OFFS. OF STIMMEL, STIMMEL & ROESER (2021), https://www.stimmel-law.com/en/articles/ambiguity-contracts-what-do-courts-do (last visited Nov. 23, 2021).

If the language is susceptible to multiple meanings, the court will consider extrinsic evidence.[48] Extrinsic evidence includes the parties' conduct prior to the dispute, previous agreement documents, and negotiations leading up to the transaction.[49]

This process can be seen in *Shareholders Representatives Services v. Gilead*.[50] In this case, the Delaware court was forced to uncover the meaning of the word "indication."[51] Gilead acquired Calistoga Pharmaceuticals in 2011, and the parties agreed to milestone payments based on the specified triggers in their contract.[52] At the time of the transaction, the drug CAL-101 was in development.[53] Their agreement stated that a trigger for a milestone payment for $50 million would be, "the receipt of Regulatory approval of CAL-101 in the United States or European Union, whichever occurs first, as a first-line drug treatment [. . .] for a Hematologic Cancer Indication."[54] The European Commission approved CAL-101 in September of 2014 for patients with chronic lymphocytic leukemia in the presence of genetic abnormality.[55] The issue presented was whether that approval triggered the $50 million milestone payment.[56] This $50 million transaction fell upon the single word of "indication."[57] Gilead and Calistoga argued for conflicting definitions, and the court found the word to be ambiguous.[58] In determining so, the court turned to various sources of extrinsic evidence.[59]

To begin, the court took judicial notice of how different peer-reviewed journals used the phrase "hematologic cancer diseases," and also noted how the medical experts who testified used it.[60] The court then turned to the parties' communications and the exchange of draft agreements that culminated in the merger agreement.[61] After taking a detailed look at these documents, the court held that the European Union approval of CAL-101 did not trigger the milestone payment.[62] The court based its reasoning on the absence of any discussion by the parties during their negotiations regarding a milestone payment for approved uses for sub-populations,

---

[48] *Id.*
[49] *Id.*
[50] S'holder Representative Servs. LLC v. Gilead Scis., Inc., 2017 Del. Ch. LEXIS 44.
[51] *Id.* at *1.
[52] *Id.*
[53] *Id.* at *6.
[54] *Id.* at *27.
[55] *Id.* at *1.
[56] *Id.* at *2.
[57] *Id.* at *1.
[58] *See id.* at *2–*3.
[59] *Id.* at *50.
[60] *Id.* at *47–*48.
[61] *See id.* at *51.
[62] *See id.*at *77.

the inconsistency of Calistoga's position regarding other milestone payments, and the commercial unreasonableness of Gilead agreeing to a payment of $50 million for an approved usage that might only benefit a minute portion of the disease population.[63]

### *B. The Parol Evidence Rule*

The merger clause can be thought of as a manifestation of the parol evidence rule.[64] The parol evidence rule governs the extent to which parties to a case may introduce evidence of prior agreements to explain, modify, or supplement the contract at issue.[65] There are several states that no longer use the parol evidence rule, and it continues to be a point of contention amongst judges and scholars.[66] Scholars, including Judge Arthur Corbin and Judge Samuel Williston, have expressed differing views.[67] Professor Williston found value in the parol evidence rule because it provides finality.[68] The parol evidence rule works to prevent constant and endless litigation, thus allowing the law to respect a final integration of terms in a contract.[69] The only evidence that Professor Williston considers admissible is the text in the final agreement.[70]

On the contrary, Professor Corbin found that the complex and ever-changing relationship between parties cannot be completely and accurately expressed in a single written document.[71] By allowing all relevant information to come before the court, contract interpretation would be able to move beyond generally applicable definitions.[72] Judges would be able to look to the meaning of the text, as well as understand the manifestations of each party and facilitate a continuing relationship.[73] Negotiations, modifications, and developments are necessary for agreements as complex and expensive as those in healthcare mergers.

The views expressed in this article reflect those of Professor Corbin, as adopted by the Restatement (Second) of Contracts and the Uniform Commercial Code

[63] *See id.* at *59, *48, *67.
[64] Murray, *supra* note 6.
[65] Ross & Trannen, *supra* note 41.
[66] *Parol Evidence Rule*, LEGAL INFO. INST., https://www.law.cornell.edu/wex/parol_evidence_rule (last visited May 5, 2020).
[67] *Id.*
[68] *Parol Evidence Rule, supra* note 66.
[69] *Id.*
[70] *Id.*
[71] *Id.*
[72] *Id.*
[73] *Id.*

(UCC).[74] Mergers in the healthcare field are complex transactions; the relationships between the parties are ever-changing because the demands placed on the industry are ever-changing. The UCC makes extrinsic evidence more readily accessible because it allows the introduction of oral and written agreements unless the written contract is proved to be a complete integration.[75] A contract is completely integrated when the written word constitutes an exclusive expression of the terms of the agreement.[76] This article argues that healthcare merger agreements are never completely integrated because of the unpredictable, yet unavoidable, changes present in healthcare. To illustrate using the drug example, imagine that the European Union's approval of CAL-101 was not for hematologic cancer but for another disease where it showed massive breakthroughs. Would Gilead deny the milestone payment? Perhaps they would because that was not the goal of their research, or perhaps the text of their agreement would deny the opportunity. Regardless, this article contends that healthcare merger agreements can never be fully integrated because it is impossible to account for the changeable nature of the industry and the potential public health ramifications.

## II. A VERY PRICEY BREAKUP

Healthcare mergers are a strategic business move but often do not result in the idealistic patient-centered outcomes that we hope for.[77] Hospital mergers thus far have resulted in increased healthcare prices, little to no improvement in patient care, and monopolization among the healthcare giants.[78] By no means is this article meant to disparage all healthcare mergers, but because they will undoubtedly continue, it aims to align public policy concerns with healthcare business initiatives. The anti-competitive implications of healthcare mergers will not be addressed in this paper.[79]

A vast majority of failed healthcare acquisitions settle and never make it in front of a court. However, the most telling insights come from acquisitions that fail before

[74] *Parol Evidence Rule, supra* note 66.
[75] Eric E. Johnson, *Chapter 8: Parol Evidence Rule* (2016), *adapted from* Scott J. Burnham & Kristen Juras, *Chapter 9*, *in* SALES AND LEASES: A PROBLEM-BASED APPROACH (CALI eLangdell, 2016).
[76] Murray, *supra* note 6.
[77] Arthur H. Gale, *Bigger but Not Better: Hospital Mergers Increase Costs and Do Not Improve Quality*, 112 MO MED. 4-5 (2015).
[78] *Id.*
[79] *See Health Care Competition*, FED. TRADE COMM'N, https://www.ftc.gov/news-events/media-resources/mergers-competition/health-care-competition (last visited May 5, 2020).

they begin.[80] One fundamental reason mergers fail is because of a faulty transaction design.[81] In other words, what may sound appealing in an informal meeting may not have the same allure in a final written agreement.[82] The finality of the document before the parties is daunting.[83] What if they overlooked a crucial detail, or there was a misunderstanding between parties about their expectations? What if the fluid nature of the healthcare system brings about an unanticipated change that affects the relationship and needs of the parties?

### *A. Letter of Intent*

Healthcare mergers and acquisitions go through a number of steps before the agreement is finalized.[84] The first of these steps is due diligence on behalf of each party and identifying a company they want to merge with.[85] Once due diligence is complete, and Company A has selected Company B to acquire, the parties will begin negotiating the letter of intent (LoI). The LoI is composed of both binding and nonbinding provisions.[86] The binding provisions contain sensitive information that warrants confidentiality, while the nonbinding provisions establish the structure of the transaction, the purchase price, and basic deal information.[87] The nonbinding provisions in the LoI are a critical foundation of the transaction.[88] Rushing through this part of the transaction can be detrimental because, once agreed upon, the terms become increasingly difficult to alter.[89] The more terms that are settled upon in the LoI, the less room there is for negotiation later.[90]

Jordan Shields, a vice president at Juniper Advisory in Chicago, argues that hospitals should develop detailed LoIs that lay out specific transaction terms.[91] This article argues the opposite. Once included, these detailed transaction terms are

---

[80] Molly Gamble, *Calling It Off: Why Some Hospital Mergers Fail and Others Don't*, BECKER'S HOSP. REV. (2011), https://www.beckershospitalreview.com/hospital-transactions-and-valuation/calling-it-off-why-some-hospital-mergers-fail-and-others-dont.html (last visited Nov. 3, 2021).
[81] *Id.*
[82] *Id.*
[83] *Id.*
[84] Aaron Murski, *Healthcare Merger & Acquisition Due Diligence and Financial Reporting*, VMG HEALTH (Jan. 2018), https://vmghealth.com/wp-content/uploads/2018/01/Healthcare-Merger-Acquisition-Due-Diligence-and-Financial-Reporting_Murski_HFMA-McMahon-Illini.pdf (last visited Nov. 3, 2021).
[85] *Id.*
[86] Wenzel, *supra* note 11.
[87] *Id.*
[88] *Id.*
[89] *Id.*
[90] *Id.*
[91] Gamble, *supra* note 80.

irrefutable due to the merger clause in the agreement. Instead, parties should endeavor to create a fluid agreement that includes a "soft" LoI that outlines agreement expectations and terms, and thus, does away with the daunting finality requirement that a merger clause imposes.[92] Doing away with the merger clause will allow parties to have an ongoing conversation about the successes of their agreement and where it needs improvement. Facilitating communication will prompt growth as a company, acknowledgment of power imbalances, and prevention of bad faith terms in a "take it or leave it" situation.

### *B. Consequences of Failed Mergers*

Fluid relationships are conducive to healthcare public policy and work to avoid the repercussions of a failed merger. Failed mergers, especially those publicly announced, subject the entity to a tarnished reputation, questioned reliability, and financial woes.[93] Intra-hospital relationships may also be tainted if physicians and administrators are forced to revert adaptations that they made to their practices in anticipation of the agreement, or if executive officers are asked to step down in cases of perceived negligence or oversight.[94]

In 2015, Anthem anticipated purchasing Cigna for approximately $54 billion.[95] The relationship between the two companies became bitter when Anthem accused Cigna of sabotaging the deal and failing to comply with contractual obligations, which led Anthem to suffer massive damages.[96] Because Anthem believed that Cigna willfully sabotaged the merger, it refused to pay the hefty $1.8 billion "breakup fee," and further sought $21 billion from Cigna for tanking the deal.[97] In a very public, very sloppy breakup, the Delaware Supreme Court ruled that neither entity would receive any funds from the separation.[98] The judge stated that "each must deal independently with the consequences of their costly and ill-fated attempt

[92] *Id.*
[93] *Id.*
[94] *Id.*
[95] Susan Morse, *UPDATED: Anthem Terminates Merger Agreement with Cigna, Won't Pay Break-Up Fee*, HEALTHCARE FIN. (May 12, 2017), https://www.healthcarefinancenews.com/news/judge-rules-against-anthems-attempt-keep-cigna-merger-agreement (last visited Nov. 21, 2021).
[96] *Id.*
[97] Jeff Lagasse, *Cigna Won't Receive $1.85 Billion from the Breakup with Anthem, Court Rules*, HEALTHCARE FIN. (May 4, 2020), https://www.healthcarefinancenews.com/news/cigna-wont-receive-185-billion-breakup-anthem-court-rules (last visited Nov. 21, 2021).
[98] *Id.*

to merge."[99] This decision came down in 2020, leaving the two entities with about five years of legal, publicity, and recovery costs to cope with.[100]

Another major anticipated merger announced in late 2015 was between Aetna and Humana.[101] The $34 billion merger was terminated when a federal court ruled that the combination was not in the best interest of the consumers.[102] As a result, Aetna had to pay Humana a $1 billion breakup fee.[103] The CEO of Aetna stated that, after 19 months of planning, they were disappointed by the termination.[104] Moving forward, Aetna and Humana had to rework strategies and fiscal resources to continue to meet the needs of their members independently.[105]

## III. TRADITIONAL MERGER CLAUSE LANGUAGE AND INHERENT TENSIONS

The traditional language of merger clauses is vague and often hidden among the remaining paragraphs of a one hundred-plus page, 12-point font document.[106] The language used in the clause is even more underwhelming than its placement. For example, "this contract is intended by the parties to be the full and final expression of their agreement and shall not be contradicted by any prior written or oral agreement."[107] Or, even less clear, "this Agreement...constitutes the entire agreement of the parties hereto with respect to the subject matter hereof and thereof and supersede all prior agreements and undertakings..."[108] This clause, or more accurately, sentence, can alter the entire agreement. This clause serves to nullify any previous agreements between the parties, whether oral or written.[109] The entire manifestation of each parties' interest must be explicitly stated in a single, dense document.[110] The implications of a merger clause are too drastic for an industry that strives for and relies on change and improvements.

---

[99] *Id.*
[100] *Id.*
[101] Bruce Japsen, *Aetna Gives Up on Merger, Will Pay Humana $1B Breakup Fee*, FORBES (Feb. 14, 2017), https://www.forbes.com/sites/brucejapsen/2017/02/14/aetna-gives-up-on-merger-will-pay-humana-1b-breakup-fee/?sh=157acfe5c7cf (last visited Nov. 3, 2021).
[102] *Id.*
[103] *Id.*
[104] *Id.*
[105] *Id.*
[106] *See generally Agreement and Plan of Merger*, SEC ARCHIVES (May 20, 2012), https://www.sec.gov/Archives/edgar/data/927066/000119312512240734/d354633dex101.htm (last visited Nov. 3, 2021).
[107] Murray, *supra* note 6.
[108] *Agreement and Plan of Merger*, *supra* note 106.
[109] Murray, *supra* note 6.
[110] *Id.*

The healthcare sector is especially susceptible to change because it rests at the intersection of advancing medicine, technology, and human interaction. The year 2020 showed breakthroughs in telemedicine accessibility, Alzheimer's research and treatment, disposable medical tube technology, and novel genetic discoveries.[111] This list is far from exhaustive, and incredible innovations continue to be revealed in 2021.[112] The Cleveland Clinic has discussed developments in universal Hepatitis C treatment, smartphone-connected pacemaker devices, bubble CPAP for increased lung function in premature babies, and new Cystic Fibrosis medications.[113] New developments and breakthroughs occur at a pace that is incompatible with stagnant agreements between the healthcare entities driving these innovations.

In addition to continuous medical advancements, merger clauses are irreconcilable with healthcare because it is one of the most heavily regulated industries in the United States.[114] The U.S. Department of Health and Human Services' Office of the Inspector General is the governmental wing responsible for protecting patient privacy, ensuring quality care, and combatting fraud by ensuring compliance with federal healthcare laws.[115] The False Claims Act "establishes civil liability for offenses related to certain acts, including knowingly presenting a false or fraudulent claim to the government for payment."[116] To ensure healthcare worker safety, the Occupational Safety and Health Administration created a multistep compliance procedure. This list is far from exhaustive, and it changes often.[117] With each new regulation, the landscape grows increasingly more complex.[118] Abiding by each of these regulations requires agreements between parties to be fluid to accommodate these changes.

Finally, healthcare is incompatible with merger agreements because of the need for adaptable partnerships. Mergers happen for a variety of reasons.[119] An independent

---

[111] Alicia Reale-Cooney, *Cleveland Clinic Unveils Top 10 Medical Innovations For 2021*, CLEVELAND CLINIC (Oct. 6, 2020), https://newsroom.clevelandclinic.org/2020/10/06/cleveland-clinic-unveils-top-10-medical-innovations-for-2021/ (last visited Nov. 3, 2021).
[112] *Id.*
[113] *Id.*
[114] *A Guide to Healthcare Compliance Regulations*, *supra* note 29.
[115] *Id.*
[116] *Id.*
[117] *Id.*
[118] *Id.*
[119] Paul Vitale, *Healthcare Mergers and Acquisitions- Making Waves in 2020*, HEALTH MGMT (Oct. 8, 2020), https://healthmanagement.org/c/hospital/post/healthcare-mergers-and-acquisitions-making-waves-in-2020 (last visited Dec. 3, 2021).

physician's office may merge with a larger hospital for access to better resources and more funds. A small research corporation may merge with a pharmaceutical company with similar goals to collaborate on research and drug development. As these individual corporations grow together as a single entity, their interests will progress with them. These partnerships allow for increased access to resources, financial stability, expedited research-to-action effects, and are necessary for comprehensive patient care. To reach the full potential of these partnerships, the parties need flexibility and the opportunity to grow without the confines of a single written document.

## IV. WHO'S MERGING, ANYWAYS?

Each sector of the healthcare industry plays a unique and indispensable role in the ecosystem. Acquisitions occur in each of these sectors and have massive implications on providers, investors, patients, and technology developers.[120] In November of 2020, Centene Corporation signed a definitive agreement to acquire Apixio, Inc., an analytics company that offers an artificial intelligence platform to healthcare organizations.[121]

Centene Corporation, a multi-national healthcare enterprise, is a Fortune 500 company that leads in providing fully integrated and cost-effective services.[122] Centene's primary focus is on under-insured and uninsured individuals.[123] In 2020, there were 28 million uninsured American citizens.[124] Centene is also the biggest provider of Affordable Care Act plans.[125] There are approximately 75 million individuals enrolled in Medicaid.[126] To put it modestly, Centene has a colossal impact on healthcare.

Apixio, Inc. developed technology that compiles and analyzes large volumes of disparate, unstructured patient data, such as physician notes and electronic health

[120] *Id.*
[121] *See Centene Signs Definitive Agreement to Acquire Apixio*, CENTENE CORP. (Nov. 9, 2020), https://investors.centene.com/news-releases/news-release-details/centene-signs-definitive-agreement-acquire-apixio (last visited Nov. 2, 2021); *see also Oveview,* APIXIO, https://www.apixio.com/about-us/ (last visited Nov. 2, 2021).
[122] *Id.*
[123] *Id.*
[124] Starkey-Keisler, et al., *Health Insurance Coverage in the United States: 2020,* U.S. CENSUS BUREAU (Sept. 14, 2021).
[125] Rebecca Pifer, *Centene Closes Buy of Analytics Firm Apixio*, HEALTHCARE DIVE (Dec. 9, 2020), https://www.healthcaredive.com/news/centene-closes-buy-of-analytics-firm-apixio/591900/ (last visited Dec. 3, 2021).
[126] Matej Mikulic, *Medicaid- Statistics & Facts*, STATISTA (May 4, 2020), https://www.statista.com/topics/1091 (last visited Dec. 3, 2021).

records, and analyzes it using artificial intelligence.[127] Apixio has the ultimate goal of strengthening administrative functions within the healthcare system.[128] Apixio's platform has been proven capable of handling the persisting challenges and complexities of the healthcare industry.[129]

Centene explained that their intention in acquiring Apixio was to "digitize the administration of healthcare and to leverage comprehensive data to help improve the lives of [its] members."[130] By weaving technology into its operative and administration functions, Centene aimed to diminish waste and save money.[131] Because Centene's members are primarily comprised of under/uninsured individuals as well as Medicaid users, this acquisition would affect approximately 100 million patients.

To illustrate the effect of this acquisition on a micro scale, imagine that one of Centene's uninsured consumers is Cosmo Johnson. Mr. Johnson is uninsured, and because of his inconsistent employment status, he moves relatively often. Mr. Johnson has a number of health issues, including diabetes and persistent migraines. He has moved three times in the last year and has subsequently changed providers three times. With each new provider, he is forced to explain the complexity of his comorbidities, his current medications, and treatment plan. While doing so, Mr. Johnson is also forced to reconcile his treatment and doctor visits with his uninsured status. Unfortunately, millions of patients are familiar with this complicated situation. Centene's acquisition would allow Mr. Johnson to continue to switch providers as required by his employment while being able to rely on Apixio's artificial intelligence technology to communicate his ailments, medications, and treatments to his doctors. The digitalization of Mr. Johnson's medical data would help him receive higher quality and more comprehensive care. The Centene-Apixio acquisition would be just one of the hundreds of acquisitions that have already taken place.

The life sciences sector of healthcare also reveals the massive implications of acquisitions and mergers on providers and patients.[132] Eli Lilly (Lilly) is a global

---

[127] Hannah Nelson, *Centene Eyes Value-Based Care with AI Vendor Apixio Acquisition*, HEALTH PAYER INTELL. (Nov. 13, 2020), https://healthpayerintelligence.com/news/centene-eyes-value-based-care-with-ai-vendor-apixio-acquisition (last visited Dec. 3, 2021).
[128] *Id.*
[129] *Id.*
[130] *Id.*
[131] *Id.*
[132] *M&A Trends in Life Sciences and Health Care: Growth at the Global Intersection of Change,* DELOITTE (Sept. 2014), https://www2.deloitte.com/us/en/pages/life-sciences-and-health-care/articles/mergers-and-acquisitions-trends-survey-life-sciences.html (last visited Nov. 21, 2021).

pharmaceutical company that conducts clinical research in more than 55 countries and has products marketed in over 100 countries.[133] Prevail Therapeutics, founded in 2017, develops gene therapies using precision medicine to slow or stop underlying causes of neurodegenerative disorders.[134] In 2021, Lilly acquired Prevail Therapeutics and initiated a gene therapy program. Lilly's Vice President of Pain and Neurodegeneraration research, Mark Mintun, stated that the program "has the potential to deliver transformative treatments for patients with neurodegenerative diseases such as Parkinson's, Gaucher, and Dementia."[135] There are over 600 neurodegenerative disorders affecting nearly 50 million Americans each year.[136] Eli Lilly's acquisition of Prevail Therapeutics has the potential to be groundbreaking in neurodegenerative treatments and to benefit millions of patients. Because these acquisitions undoubtedly impact tens of millions of patients, it is vital that these agreements are written with these lives in mind and are sensitive to the progressive nature of the healthcare industry.

## V. THE EFFECT OF COVID-19

The COVID-19 pandemic is leading researchers to anticipate higher merger and acquisition activity because of exposed infrastructure gaps.[137] For example, hospitals and ICU beds were pushed beyond capacity, and smaller physician groups became increasingly financially unstable.[138] More fundamentally, hospitals found that their core business strengths needed to be reinforced to help maintain financial stability to successfully create new partnerships in order to improve in their underperforming areas.[139]

---

[133] *Key Facts,* LILLY (2021) https://www.lilly.com/who-we-are/about-lilly/key-facts (last visited Nov. 3, 2021).
[134] *About Us - Gene Therapies to Slow or Stop the Neurodegenerative Process*, PREVAIL THERAPEUTICS, https://www.prevailtherapeutics.com/about-prevail/#about-us (last visited Nov. 3, 2021).
[135] *Lilly Completes Acquisition of Prevail Therapeutics*, *supra* note 28.
[136] Rebecca C. Brown, Alan H. Lockwood, & Babasaheb R. Sonawane, *Neurodegenerative Diseases: An Overview of Environmental Risk Factors*, 113 ENVTL. HEALTH PERSPECTIVES 1250 (2005).
[137] Jacqueline LaPointe, *COVID-19 a Catalyst for Healthcare Merger and Acquisition Activity*, REVCYCLE INTELL. (Jan. 13, 2021), https://revcycleintelligence.com/news/covid-19-a-catalyst-for-healthcare-merger-and-acquisition-activity (last visited Nov. 3, 2021).
[138] *Id.*
[139] *Id.*

The severity and duration of COVID-19 was unanticipated and has highlighted the unpredictable nature of the healthcare system.[140] The sudden changes demanded flexibility and swift responses as nurses and doctors were spread painfully thin.[141] A report published by Investment Bank Advisory identified ways in the which pandemic will likely impact the healthcare merger market.[142]

First, hospitals and health systems are experiencing financial strain and are seeking cash infusions and other support systems to help stay open.[143] As we begin to enter a post-pandemic world, hospitals are likely to need more support until they are able to recover.[144] The merger and acquisition agreements between combining parties must be fluid to account for the health system's fluctuating needs.[145] Should another crisis occur, a fluid agreement will optimize the entity's ability to adapt and respond.[146] Fluidity can be achieved by recognizing that the relationship between parties is subject to forces outside of their control.[147] While a public health emergency is certainly one of these factors, another is newly enacted regulations.[148] A stagnant agreement that requires court intervention is not adequate to quickly acclimate.[149]

Second, the pandemic highlighted a need for quick access to capital, supplies, equipment, and operational expertise.[150] COVID-19 led to an extreme shortage in hospital space, medical devices, and personal protective equipment (PPE) for

---

[140] Alan D. Kaye, Chikezie N. Okeagu, Alex D. Pham, et al., *Economic Impact of COVID-19 Pandemic on Healthcare Facilities and Systems: International Perspectives*, 35 BEST PRAC. & RSCH. CLINICAL ANESTHESIOLOGY 293 (2021).
[141] *Id.*
[142] Larry Kaiser, *Healthcare M&A and the Effects from COVID-19*, OPTIMUM HEALTHCARE IT (Dec. 2, 2020), https://optimumhit.com/insights/blog/global/healthcare-ma-and-the-effects-from-covid-19/ (last visited Nov. 3, 2021).
[143] *Id.*
[144] *Id.*
[145] Nata Laiteerapong, et al., *The Pace of Change in Medical Practice and Health Policy, Collision or Coexistence?,* NAT'L INST. OF HEALTH (Jan. 22, 2015), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4441682/ (last visited Nov. 3, 2021).
[146] Joel Sauer, *Adaptability as a Permanent Attribute of Health Care,* CARDIAC INTERVENTIONS TODAY (July/Aug. 2020), https://citoday.com/articles/2020-july-aug/adaptability-as-a-permanent-attribute-of-health-care (last visited Nov. 3, 2021).
[147] Adria E. Warren, *Top 10 Considerations for Healthcare M&A,* ASS'N OF CORP. COUNS. (Oct. 28, 2020), https://www.acc.com/resource-library/top-ten-considerations-healthcare-ma (last visited Nov. 3, 2021).
[148] Laiteerapong, *supra* note 145.
[149] *How Long Does a Breach of Contract Case Take to Resolve In Court?,* BROWN & CHARBONNEAU, LLP, https://www.bc-llp.com/length-breach-contract-case-take-resolve-court/ (last visited Nov. 6, 2021).
[150] Kaiser, *supra* note 142.

frontline workers, including respirators, gloves, face shields, gowns, and hand sanitizer.[151] Because of the newly identified demands, hospital boards may choose to prioritize clinical success over self-sufficiency.[152] Post-pandemic, the desire for stability outweighs that of autonomy and adaptability.[153] Stability is relative to the entity and the current environment in healthcare. Post-pandemic, stability will likely mean financial security and reliable supplier relationships. Once these needs are satisfied, stability could mean a new leadership team to propel the company towards new objectives. It could also mean developing a new service staffed with qualified personnel to offer more comprehensive patient care. Companies will continue to adapt the interests they have in their existing partnerships and seek new partnerships in order to obtain stability.

Third, in-market collaborations have been permitted during the crisis.[154] In an effort to optimize care, health systems are transferring patients, staff, and supplies between hospitals.[155] It is important to note that in-market collaborations begin to overlap with the Federal Trade Commission, and if hospitals seek to maintain these relationships, they will need to evaluate if and to what extent they have anti-competitive effects.[156]

Finally, non-profit development teams and investor-owned health systems are strategizing new partnerships to explore as the pandemic begins to subside.[157] The pandemic unveiled the unparalleled need for flexibility and adaptation in the healthcare industry, which can only be accomplished by fluid agreements that are not subject to merger clauses. Agreements that are limited to what is written within the four corners of the page are unnecessarily limited in their potential. In times of healthcare crisis, changing the terms of agreements without lengthy litigation will expedite our ability to accommodate the needs of the public.

## CONCLUSION

No matter how long a healthcare merger agreement is, contract language cannot accurately and completely manifest the interests of the parties. The healthcare

[151] Megan L. Ranney, Valerie Griffeth, & Ashisk K. Jha, *Critical Supply Shortages- The Need for Ventilators and Personal Protective Equipment During the COVID-19 Pandemic*, NEW ENGLAND JOURNAL OF MED. (2020), https://www.nejm.org/doi/full/10.1056/NEJMp2006141 (last visited Nov. 3, 2021).
[152] Kaiser, *supra* note 142.
[153] *Id.*
[154] *Id.*
[155] *Id.*
[156] *Id.*
[157] *Id.*

industry is subject to strict regulation and forces of nature but continues to stake its claim at the cutting edge of innovation. It makes little sense to demand stagnancy in the collaborative efforts of these entities. Rather, the parties should eliminate merger clauses in their agreements and allow evolution in their terms as their interests advance. When faced with a dispute, courts should consider the interests of the parties, the predicted effects on the community and public health, and the interest of a continued relationship between the parties.

The UCC, as well as the Restatement (Second), adopted the view that writing could be interpreted according to the actual intention of the parties, notwithstanding the objective meaning that a judge might attach to the words.[158] However, in the context of healthcare mergers and acquisitions, judges will benefit from a perspective that allows them to consider and determine the public policy implications of the merger or dispute.[159] Allowing a contract to be the sole expression of a party's agreement dismisses the effect on both the healthcare system as well as the patients subject to this system.[160] Doing away with the merger clause will allow judges to make more informed decisions that benefit public health and help to reconcile the business objectives.[161]

Merger and acquisition activity is increasing in healthcare, and contract law principles must evolve in equal stride. These complex transactions, with staggering implications, can no longer be interpreted solely from the letters on a page. As Linda Lombardi, Chief Strategy Officer at NYC Health and Hospitals, stated, "adopting a continuous learning mindset is and will continue to be needed to adjust to the changing healthcare landscape."[162] Fluid merger and acquisition agreements, free from the constraints of a merger clause, are consistent with a continuous learning mindset.

---

[158] Murray, *supra* note 6.
[159] *See* Farshad Ghodoosi, *The Concept of Public Policy in Law: Revisiting the Role of the Public Policy Doctrine in the Enforcement of Private Legal Arrangements,* 94 NEB. L. REV. 719 (2016).
[160] *See The Impact of Hospital Consolidation on Medical Costs,* NAT'L COUNCIL ON COMP. INS. (July 11, 2018), https://www.ncci.com/Articles/Pages/II_Insights_QEB_Impact-of-Hospital-Consolidation-on-Medical-Costs.aspx; *see also* Noether, Monica, *Suggestions on Framing the Benefits of Hospital Mergers,* AM. HOSP. ASS'N (Jan. 2017), https://www.aha.org/system/files/content/17/framing-benefits-hospital-mergers.pdf (last visited Dec. 3, 2021).
[161] Farshad Ghodoosi, *supra* note 162.
[162] Andrea Park, *The Biggest Challenge Facing Healthcare? 'Embracing the Eembeddedness of IT,' says Bellevue CXO,* BECKER'S HOSP. REV. (2019) https://www.beckershospitalreview.com/healthcare-information-technology/the-biggest-challenge-facing-healthcare-embracing-the-embeddedness-of-it-says-bellevue-cxo.html (last visited Dec. 3, 2021).

# COVID-19 AND THE LAW: HOW CAN GOVERNMENTS ENSURE THAT CITIZENS FULFILL THEIR OBLIGATIONS? A LOOK INTO JAPANESE LAW†

*Dr. Yuichiro Tsuji**

## TABLE OF CONTENTS

INTRODUCTION ..... 21

I. THE MEANS BY WHICH THE JAPANESE GOVERNMENT ACHIEVES ITS OBJECTIVES ..... 22

*A. CSMA 2021 Order to Reduce Hours and Penalties* ..... 23

*B. 2021 Infectious Diseases Act and Penalties* ..... 24

II. GOVERNMENT METHODS TO ENSURE THE OBLIGATIONS IMPOSED BY LAWS REGARDING COVID-19 ..... 26

*A. Substitute Execution by Administration* ..... 27

*B. Execution Penalty* ..... 28

*C. Direct Coercion* ..... 31

*D. Immediate Coercion* ..... 35

*E. Immediate Coercion Under the 2021 Infectious Diseases Act* ..... 35

CONCLUSION ..... 38

† *Select sources cited in this article are only available in their original Japanese and have been validated to the extent possible with assistance by the author. Please contact the Editor-in-Chief with source-related questions or if you desire copies of any original sources.*

* *Dr. Yuichiro Tsuji is an Associate Professor of Law at Meiji University School of Law. He received an LL.M in 2005 and a J.S.D. in 2006 from UC Berkeley School of Law. He also received an LL.M from Kyoto University in 2002. His fields of specialization are constitutional law, administrative law, cyber law, comparative law, and international human rights law. https://ssrn.com/author=979824*

## INTRODUCTION

This article evaluates the Coronavirus Special Measures Act (CSMA)[1] and the Infectious Diseases Act of 2021, as amended in response to COVID-19, as mechanisms that Japan used to achieve its objectives in combatting the COVID-19 pandemic. Society has various tools to control human behavior, such as religion, morality, and the market. Law is one such tool, although not necessarily a universal one. As described in this article, COVID-19 exemplifies the limitations of law as a tool to control human behavior.

Japan amended the CSMA and the Infectious Diseases Act[2] in 2021. The CSMA, as amended in February 2021, allows the government to impose penalties upon businesses who violate the requirement to close or shorten their business hours under a declared state of emergency.[3] In response to this amendment, some argue that uniformly imposing penalties without considering the efforts of individual restaurants to prevent infection is a violation of the purpose of the law and infringes on the freedom of business[4] guaranteed by the Constitution.

The Infectious Diseases Act, amended in 2021, allows for epidemiological questioning and investigation[5] of citizens suspected of being infected with COVID-19, revises hospitalization measures, and strengthens the authority of the Minister of Health, Labor, and Welfare, and prefectural governors. Some academic theories claim that the hospitalization measure under the Infectious Diseases Act is unconstitutional.[6]

---

[1] SHINGATA INFLUENZA TŌ TAISAKU TOKBETSU SOCHI HŌ [CORONAVIRUS SPECIAL MEASURES ACT], Law No. 31 of 2012 (revised as Law No. 5 of 2021) (Japan) [hereinafter CSMA]*; see also* Yuichiro Tsuji, *Japanese Government Actions against COVID-19 under the Directives of Constitutional and Administrative Law*, 4 CARDOZO J. INT'L COMP. L. 1, 1–34 (2021) (discussing the constitutional issues of CSMA in 2020).

[2] LAW TO PARTIALLY REVISE THE LAW ON SPECIAL MEASURES FOR NEW INFLUENZA, ETC., Law No. 5 of 2021 (Japan) (amending KANSENSHŌ NO YOBŌ OYOBI KANSENSHŌ NO KANJA NI TAISURU IRYŌ NI KANSRU HŌ [ACT ON THE PREVENTION OF INFECTIOUS DISEASES AND MEDICAL CARE FOR PATIENTS WITH INFECTIOUS DISEASES], Law No. 114 of 1998. [hereinafter INFECTIOUS DISEASES ACT].

[3] *Id.* art. 31-6(1), art. 80.

[4] NIHON KOKU KENPŌ [CONSTITUTION], art. 22 (Japan).

[5] INFECTIOUS DISEASES ACT, *supra* note 2, art.16-2, 15, 81.

[6] Asahi Shimbun, *Nyūin kobameba bassoku' dōomou? Kokkai de giron no kansenshōhō kaisei-an* [*What do you think of "penalties for refusing hospitalization"? Amendment to the Infectious Diseases Act under debate in the Diet*] (Jan. 19, 2021) (statement of Prof. Satoru Yokodaido) The current proposed amendments to the Infectious Diseases Act give the governor broad and powerful powers, and the mechanisms to ensure the proper exercise of these powers appear inadequate. There is a strong suspicion that it is unconstitutional.

The government achieves the objectives of law through several means. Theoretically, Japanese administrative law contains four methods: Substitute Execution by Administration[7], Execution Penalty, Direct Coercion (enforcement or compulsion), and Immediate Coercion (enforcement or compulsion). Unlike the pre-war period, there is no comprehensive law under which the government can enforce its administrative purposes. Currently, there is only the Act on Substitute Execution by Administration, which allows the administration to enforce obligations that are enforceable by others. In order for the administration to enforce its own objectives, it needs a basis in law. In this context, the government needs a legal basis to use sanctions to force people to be hospitalized or to shorten their business hours against the will of the citizens. This article examines whether the sanctions in the Infectious Diseases Act and the CSMA fall under any of these categories.

## I. THE MEANS BY WHICH THE JAPANESE GOVERNMENT ACHIEVES ITS OBJECTIVES

The government can achieve its legal objectives in several ways. Private parties involve courts to enforce obligations owed by citizens under contract, and courts enforce those obligations based on a final judgment.[8] The court enforces the obligation based on a finalized judgment. Unlike the relationship between private individuals, the relationship between the government and citizens does not require the government to approach the court to implement the obligations it imposes on citizens. The administrative body can fulfill such obligations through its self-executing power.[9]

In accordance with the Constitution of Japan[10], which is the supreme law of the land, the state is obligated to take specific measures to protect the lives and health of its citizens. However, laws enacted by the Diet stipulate the specifics of such

[7] GYOSEI DAI SIKKO HO [ACT ON SUBSTITUTE EXECUTION BY ADMINISTRATION], Law. no. 43 of 1952 (Japan) [hereinafter ACT ON SUBSTITUTE EXECUTION].
[8] Hiroshi Shiono, *Gyōseihō 1* [*Administrative Law 1*] 251 (6th ed., Yuhikaku 2019). The purpose of allowing the government to fulfill legal obligations in addition to the judiciary's fulfillment of legal obligations is that there are cases where it is more appropriate to allow the government to make decisions regarding law enforcement within the framework of the law. Sakurai and Hashimoto, *Gyōseihō [Administrative Law]* 167 (2019).
[9] Shiono, *supra* note 8, at 244. Cases in which the judiciary requires the intervention of the courts to realize administrative obligations and cases in which it does not (granting the executive the power of self-execution) do not stand in an exclusive relationship. For certain obligations, there are criminal penalties with court intervention and administrative enforcement without court intervention. Shiono analyzes that American law emphasizes judicial enforcement, while German law emphasizes administrative enforcement. *See id.*
[10] NIHON KOKU KENPŌ, *supra* note 4, art. 98.

measures.[11] In this section, we will examine the CSMA and the Infectious Diseases Act, as amended in 2021.

### *A. CSMA 2021 Order to Reduce Business Hours and Penalties*

In the CSMA 2020, the reduction of business hours was an administrative guidance and thus not enforceable. The administrative guidance was only intended to encourage citizens to act voluntarily, without sanction.[12] Therefore, the guidance had no provision for compensation for the reduction in business hours. The CSMA includes certain requirements for health care providers and hospitals, in addition to a provision[13] that compensates such providers and facilities for damages incurred in complying with these requests. [14] Each prefecture published the names of pachinko parlors that did not shorten their hours of operation; however, the publication of the names inadvertently informed the public that the parlors were open for business and attracted them to those parlors.[15]

In 2021, the government amended the CSMA to require restaurants to shorten their hours of operation to now include a sanction.[16] The Constitution guarantees the freedom of occupational choice and protects the freedom to do business;[17] however, this right is subject to restrictions imposed by public welfare.[18] While the CSMA 2021 would have been unconstitutional if it banned the operation of restaurants, the constitutionality of reducing the hours of business for restaurants depends on the

[11] *Id.* art. 41.
[12] There is no sanction instructing businesses to shorten operating hours. Instead, this request is an administrative guidance, an attempt by the government to achieve administrative objectives through the voluntary action of citizens. Sakurai & Hashimoto, *supra* note 8, at 152. Shiono analyzes that since the late 1960s, the function of administrative guidance has been attracting attention, court cases have accumulated, and research has progressed. Administrative guidance in Japan is to realize administrative objectives through informal means without using formal legal forms. Shiono, *supra* note 8, at 220-221.
[13] CSMA, *supra* note 1, art. 31 (regarding requests to medical personnel and hospitals that provide medical care to patients), art. 63 (regarding compensation for damages).
[14] ACT ON SUBSTITUTE EXECUTION, *supra* note 7, art. 43. This Act is a law that provides a basis for cases where the administration can execute obligations on behalf of the obligated party. The Act cannot be used for orders to shorten business hours because only the store operator can realize such orders.
[15] Tsuji, *supra* note 1, at 9; s*ee also, Tenmei kohyō jichitai aitsugu kyugyō yōsei ōujinu pachinko ten* [*Publication of store name, pachinko parlors that do not respond to requests for closure one after another*], ASAHI SHIMBUN DIGITAL (Apr. 25, 2020), https://www.asahi.com/articles/DA3S14455289.html (last visited Dec. 3, 2021).
[16] CSMA, *supra* note 1, art. 24(9), 45(2).
[17] NIHON KOKU KENPŌ, *supra* note 4, art. 22.
[18] *Id.*

extent of restrictions on the freedom of business.[19] When revising the CSMA 2020, Parliament decided against providing for criminal sanctions and instead provided administrative penalties.[20] CSMA 2020 effectively operated as a non-legally binding, administrative guidance to encourage those operating businesses to reduce their hours of operation.[21] The Parliament did not amend CSMA 2020 to directly prohibit only the operation of facilities that could become clusters of COVID-19 activity.[22] This was not sufficient from the perspective of democratic legitimacy because CSMA 2021 did not stipulate whether enforcement would depend on the degree of infection and the efforts of the business, but rather delegated the details to the government.[23] To restrict the freedom to operate businesses for the purpose of protecting public health, it is necessary to debate the substance of the bill carefully to avoid amending the law poorly and disrespecting constitutional rights.[24]

### *B. 2021 Infectious Diseases Act and Penalties*

The Infectious Diseases Act, as amended in 2021, allows for both recommended and mandatory hospitalization of those suspected of contracting the COVID-19 virus.[25] These measures target[26] patients who do not comply with at-home or at-accommodation quarantine recommendations. If a patient leaves a mandated

[19] *See* Eric Johnston, *Legal revisions would add weight to Japan's COVID-19 response*, JAPAN TIMES (Jan. 6, 2021), https://www.japantimes.co.jp/news/2021/01/06/national/japan-coronavirus-response (last visited Nov. 15, 2021).
[20] *See id*.
[21] *See id.*
[22] *See id.*
[23] *See* Jun Tabushi, *Serious COVID cases only' policy for hospitals draws fire*, THE ASAHI SHIMBUN (Aug. 3, 2021), https://www.asahi.com/ajw/articles/14409902 (last visited Dec. 3, 2021) ("The government's new policy of providing hospital treatment only for COVID-19 patients in serious condition or at high risk of becoming severely ill has sparked criticism that other infected people are being 'abandoned'"); *see also, Japan govt's COVID-19 hospitalization restriction plan to put patients at risk*, THE MAINICHI (Aug. 4, 2021), https://mainichi.jp/english/articles/20210804/p2a/00m/0op/022000c.
[24] *See, e.g.*, *Japan's opposition parties demand extended Diet session*, JAPAN TIMES (Jun. 6, 2021), https://www.japantimes.co.jp/news/2021/06/06/national/politics-diplomacy/opposition-parties-diet-extension (last visited Nov. 15, 2021).
[25] *See* INFECTIOUS DISEASES ACT, *supra* note 2, art. 19(1) (stating that the prefectural governor can mandate hospitalization of an individual to prevent the spread of first class infectious disease, or that hospitalization can be recommended for those with first class infectious diseases); art. 26(2) (stating that the protocols that apply to first class infectious diseases under Infectious Diseases Act will be applied mutatis mutandis to new influenza infections).
[26] *See id.* art. 44-3(2).

hospitalization period prematurely, the government will impose a non-penal fine.[27] The following is a detailed explanation of the procedure.

In accordance with Articles 6(8), 7(1), 66 of the CSMA, the Cabinet Order of CSMA classified COVID-19 as a "Designated Infectious Disease."[28] In accordance with the amendment of the Infectious Diseases Act, implemented on February 13, 2021, the CSMA changed its COVID-19 "Designated Infectious Disease" classification to "New Influenza and Other Infectious Diseases."[29] The prefectural governor may, when they find it necessary to prevent the spread of infection, recommend[30] that a person with evidence of infection be hospitalized for a period not exceeding ten days at a designated medical institution[31] for specified infectious diseases. When the governor intends to recommend hospitalization, they shall make efforts to provide appropriate explanations to the infected person to ensure their understanding and shall give an opportunity for designated officials to state their opinions on the patient's case.[32] The infected person, or their guardian, may have their representative appear and submit evidence in their favor.[33] Japanese textbooks on administrative law categorize and explain the procedures for hospitalization as either direct enforcement or immediate enforcement,[34] which the next chapter will discuss.

The 2021 Infectious Diseases Act strengthened the authority of the government[35] to question and investigate citizens suspected of being infected. Epidemiological investigations impose an obligation on patients to cooperate, including asymptomatic infected persons. The Act grants the Minister of Health Labor and

---

[27] *See id*. art. 80.
[28] *See generally,* CSMA, *supra* note 1, art. 2(1)
[29] *See* CSMA, *supra* note 1, art. 2(1); INFECTIOUS DISEASES ACT, *supra* note 2, art. 6(7)3. The government ordinance classified COVID-19 as a designated infectious disease with a time limit (one year from January 31, 2021), but by classifying it as an influenza infectious disease, the government will be able to deal with it even after the expiration of the designated infectious disease. If the Minister of Health, Labor and Welfare decides that COVID-19 does not fall under the category of influenza infection, COVID-19 will no longer be covered by the Infectious Disease Act.
[30] *See* CSMA, *supra* note 1, art. 20. Article 9 in the case of continuing to recommend hospitalization for the first category applies mutatis mutandis.
[31] INFECTIOUS DISEASES ACT, *supra* note 2, art. 6(12).
[32] *Id.* art. 20(6).
[33] *See id.* art. 20(7).
[34] *See, e.g.*, Sakurai & Hashimoto, *supra* note 8; Shiono, *supra* note 8. Sakurai classifies measure hospitalization as immediate coercion. Sakurai & Hashimoto, *supra* note 8, at 185. Shiono classifies hospitalization under the Infectious Diseases Act as immediate enforcement (he uses the term enforcement, not coercion). According to him, immediate enforcement is similar to direct one. He argues that we should refrain from the easy use of direct enforcement in the form of immediate one. Shiono, *supra* note 8, at 280.
[35] *See* INFECTIOUS DISEASES ACT, *supra* note 2*,* art.15(8), 16-2.

Welfare and prefectural governors the authority to share information and make cooperative recommendations to medical institutions and laboratories, including public announcements, if the recommendations are not followed.[36] The Infectious Diseases Act of 2021 allows for hospitalization recommended and mandatory hospitalizations of patients suspected of carrying the COVID-19 virus [37] before their diagnosis is confirmed.[38] Similar to the CSMA of 2021, the Infectious Diseases Act of 2021 restricts individuals' freedom of movement and communication.[39]

## II. GOVERNMENT METHODS TO ENSURE THE OBLIGATIONS IMPOSED BY LAWS REGARDING COVID-19 ARE MET

The 2021 amendments to the CSMA and the Infectious Diseases Act regarding COVID-19 challenge administrative law scholars with how the government can achieve the objectives of the law. In Japan, the government frequently uses administrative guidance to ensure that citizens fulfill their obligations voluntarily.[40] Because the relationship between the government and citizens is ongoing, citizens generally tend to fulfill their obligations. In the CSMA 2020, the order to reduce business hours was an administrative guidance, without obligations or sanctions imposed on citizens.

Although it is inherently desirable for citizens to perform their obligations, they may not always do so voluntarily. The law provides various means of ensuring that private citizens fulfill their legal obligations. To ensure compliance, the government may use certain coercive measures, assuming it notified its citizens of the imposed obligations in advance.[41]

---

[36] *See id.* art.16-2(2)-(3). The 2021 CSMA was amended to reflect the fact that private laboratories were not being utilized, and that even if a private laboratory tested positive for COVID-19, it was not necessarily linked to retesting at a public laboratory or hospitalization at a medical institution. *See* CSMA, *supra* note 1.

[37] *See id.* art. 6(10). The term "Suspected Disease Carrier" as used in this Act means a person who is suspected to have contracted an Infectious Disease in light of their pathological condition. *See id.*

[38] *See id.* art. 8.

[39] *See generally,* INFECTIOUS DISEASES ACT, *supra* note 2.

[40] *See* Sakurai & Hashimoto, *supra* note 8, at 132. Since the relationship between government and citizens is ongoing, citizens think that if they refuse one administrative guidance, they may be disadvantaged somewhere else. *See also,* Shiono, *supra* note 8, at 221.

[41] *See* Sakurai & Hashimoto, *supra* note 8, at 166-167; Shiono, *supra* note 8, at 251. The rule of law extends to administrative law enforcement. When the administration enforces the law, it must follow the general principles of law (the principle of proportionality) and procedures. When the government enforces the law, it must have a basis in law because it restricts the rights of citizens.

The National Tax Collection Act[42] and the Act on Substitute Execution by Administration[43] are two acts that allow the government to perform its obligations on behalf of citizens. In addition to the Act on Substitute Execution by Administration, individual laws provide for direct coercion and execution penalties, and allow the government to fulfill the obligations of citizens.[44]

The National Tax Collection Act and Act on Substitute Execution by Administration established four ways the government can enforce its obligations to citizens;[45]substitute execution by administration, execution penalty, direct coercion, and immediate coercion. Administrative agencies cannot choose any of these four methods at will, but must be empowered to enforce through statute, based on the rule of law.[46]

### *A. Substitute Execution by Administration*

Substitute execution by administration allows an administrative agency to realize an alternative obligation to perform an act in place of and collect the costs of realization from the obligated person.[47] Citizens owe several types of obligations: action, inaction (e.g., not operating a business), and acceptance (e.g., undergoing a medical inspection). The Act on Substitute Execution by Administration[48] only targets actions by others in place of the individual who owes the obligation to ensure that only the individual who owes the obligation can perform it.

---

[42] *See generally,* KOKUZEI CHOSHU HŌ [NATIONAL TAX COLLECTION ACT], No. 147 (1959) (Japan) [hereinafter NATIONAL TAX COLLECTION ACT]. Originally, the National Tax Collection Act was a law concerning the collection of national taxes, so it cannot be called a general law itself. However, the Act is applied mutatis mutandis in many other laws and regulations and is effectively positioned as a general law with respect to monetary claims.

[43] *See generally,* ACT ON SUBSTITUTE EXECUTION, *supra* note 8.

[44] *See* Sakurai & Hashimoto, *supra* note 8, at 166; Shiono, *supra* note 8, at 260. Due to the experience of direct coercion violating human rights, direct coercion is not positioned as a last resort for administrative enforcement. There is no law comprehensively recognizing direct coercion; it is provided for in individual laws.

[45] The Administrative Enforcement Act, created under the Constitution of Japan, comprehensively provided for these four types of means. If a duty was imposed on a citizen by an administrative act, the administration could use any of the four to force the citizen to fulfill the duty, and the danger of human rights violation existed. Therefore, the Administrative Execution Law was abolished, and the current Act on Substitute Execution by Administration was enacted. *See* Sowa, Yamad & Watari, GENDAI GYŌSEIHŌ NYUMON [INTRODUCTION TO ADMINISTRATIVE LAW], 87.

[46] *See* ACT ON SUBSTITUTE EXECUTION, *supra* note 8, art.1.

[47] *See id.*

[48] *See id.*

When the government imposes obligations on citizens through administrative acts based on laws, it may carry out substitutional execution per the Act on Substitute Execution by Administration even if the relevant laws do not stipulate the means to realize such obligations. To apply the provisions of the Act[49] on Substitute Execution by Administration, two conditions be met: first, it must be difficult to realize the obligations that citizens owe by means other than substitute execution by administration and, second, the failure of citizens to fulfill their obligations must significantly harm public interest. When this is used, the government agency will issue a warning to the citizens who are obligated to comply, set a deadline for them to fulfill their obligations, and carry out the substitute execution when the deadline arrives.[50] If citizens do not comply with the warning, the government will perform an administrative substitute execution after issuing a notice.[51] In cases of emergency, however, the government can omit the warning and notice.[52]

Under the CSMA 2021, the orders to shorten business hours for restaurants cannot use the Act on Substitute Execution by Administration because the administrative agency cannot shorten business hours in place of the business owner.[53] Similarly, the government cannot use the Act on Substitute Execution by Administration regarding hospitalizations under the Infectious Diseases Act 2021[54] because it is not an obligation that a third party can fulfill; the government cannot obtain a medical examination on behalf of an individual suspected to be infected.

### *B. Execution Penalty*

The execution penalty is an indirect method of coercion in which the government, to compel obligated citizens to perform their obligations, gives advance notice of the imposition of a fine in the event of non-performance and collects the fine each time the obligation is not performed. Execution penalties are notices to citizens that money will be collected in *the future* and, through the effect of intimidation, encourage a change in the behavior of citizens who are obligated to comply with orders.[55]

---

[49] *Id.* art. 2.
[50] *Id.* art. 3(1).
[51] *Id.* art. 2.
[52] ACT ON SUBSTITUTE EXECUTION, *supra* note 8, art. 3(3).
[53] *Id*.
[54] INFECTIOUS DISEASES ACT, *supra* note 2, art. 19.
[55] Sakurai & Hashimoto, *supra* note 8, at 177; Katsuya Uga, GYŌSEIHŌ [ADMINISTRATIVE LAW] 131 (2d ed.); Yoshikazu Shibaike, GYŌSEIHŌ [ADMINISTRATIVE LAW] 137 (4th ed.) (stating that psychological coercion does not include threatening words or actions and persuasion, which is another possible method of executive penalty, is a method of psychological coercion of the other party and may be classified as administrative guidance).

Perhaps because execution penalties are considered more threatening, as the government collects money to force citizens to fulfill their obligations without involving the court, only Article 36 of the Erosion Control Act[56] provides execution penalties for the government to use. Under the Erosion Control Act, if a citizen fails to perform their duty, the Minister of Land, Infrastructure, Transport and Tourism or the prefectural governor may impose a certain time limit for compliance and provide a notice to the obligee that they risk being fined for failure to perform the duty within the time limit.[57] Execution penalties are one of the means to ensure the future fulfillment of obligations and are described in Article 172[58] of the Civil Execution Act between civil parties with involvement of the court.

Under the Erosion Control Act, the Minister of Land, Infrastructure, Transport and Tourism or prefectural governor may impose an unlimited amount of execution penalties on noncompliant citizens. Since the execution penalty amount is different in nature from a fine for criminal punishment, the administration is afforded discretion to set fines at a reasonable amount.[59] Lawyer Itagaki advocated for the introduction of execution penalties in the CSMA 2020 before the 2021 amendment.[60] He argues that the execution penalties are the best way to ensure the effectiveness of orders to reduce business hours.[61] Execution penalties are indirect coercive measures and the government can impose them for failure to perform any of the alternative, non-alternative, or inaction obligations.[62] As execution penalties are imposed for the future non-fulfillment of an obligation, they do not violate the prohibition of double punishment[63] in Article 39 of the Constitution, even if they are repeatedly imposed until the private individual fulfills the obligation. Itagaki

---

[56] SABŌ HŌ [EROSION CONTROL ACT], Law No. 29, art. 36 (1897) (Japan).
[57] *Id.*
[58] MINJI SIKKŌ HŌ [CIVIL EXECUTION ACT], Law No. 4, art. 172 (1979) (Japan) (stating that compulsory execution shall be carried out by the method whereby the court orders the obligor to pay the obligee a certain amount of money that it finds reasonable in order to secure performance of the obligation, in proportion to the period of delay or immediately if the obligor fails to perform within a certain period that it finds reasonable).
[59] Sakurai & Hashimoto, *supra* note 8, at 178; Shiono, *supra* note 8, at 262.
[60] Katsuhiko Itagaki, *Legal Study of Measures against COVID-19 — Request for Leave, Shutdown and Compensation, Lockdown*, 29(1) YOKOHAMA 185, 200-203 (2020), available at: http://doi.org/10.18880/00013396.
[61] *Id.* at 204 (arguing that as a means of ensuring effectiveness, it is worth considering not only the current administrative penalties, but also direct enforcement and enforcement penalties linked to cease and desist orders).
[62] Sakurai & Hashimoto, *supra* note 8, at 177; Shiono, *supra* note 8, at 262 (stating that execution penalties were considered to be less effective in deterring than criminal penalties. However, with pollution control, it can be applied again and again until the obligation is realized in reality).
[63] *See* NIHON KOKU KENPŌ, *supra* note 4, ch. 3, art. 39.

argues that the pachinko parlors that do not shorten their hours of operation will quickly comply if the CSMA 2020 sets a fine amount per day and imposes an execution penalty on noncompliant businesses. He advocates that the best way to control people's behavior is through economic principles.[64] Because there were no sanctions for requests to shorten business hours in the CSMA 2020, publicizing the names of pachinko parlors informed citizens about which pachinko parlors were open for business, and they began gathering there instead. Therefore, in revising the CSMA 2021, the government discussed the type of enforcement power it could add in order to effectively reduce restaurant business hours.

As mentioned previously, there are two types of fines: execution penalties and administrative penalties. The CSMA 2021 uses an administrative penalty. Administrative penalties are imposed as a sanction for violation of administrative obligations *in the past*.[65] In order to impose administrative penalties, the prefectural government must notify the court of the violation, thus requiring court involvement.[66]

Execution penalties are imposed by the government on violators who are fined for *the future*, without the involvement of the courts.[67] Recently, the usefulness of execution penalties became an emerging debate in administrative jurisprudence. Since the government can impose execution penalties multiple times, depending on the fine amount, execution penalties can be an effective means of intimidating citizens into fulfilling their obligations.[68]

Execution penalties are similar to civil monetary penalties in the U.S., as discussed in the Administrative Conference of the United States.[69] The imposition of a civil monetary penalty in the U.S. involves a proceeding with the court and one without the court. Under the 2021 Coronavirus Special Measurement Act, the government must notify the court of a violation of the order to shorten business hours.[70] It uses judicial proceedings.[71] In the process of the civil penalty in the U.S., the subject is

[64] Itagaki, *supra* note 60, at 203.
[65] Sakurai & Hashimoto, *supra* note 8, at 178; Uga, *supra* note 55 (citing that there are two types of administrative punishments: administrative criminal penalties and punishments for disturbing administrative order).
[66] HISHŌ JIKEN TETSUDUKI HŌ [NON-CONTENTIOUS CASE PROCEDURES ACT], Law No. 51, art. 119-120 (2013) (Japan).
[67] Sakurai & Hashimoto, *supra* 8, at 178; Shiono, *supra* 8, at 272.
[68] Sakurai & Hashimoto, *supra* 8, at 178; Uga, *supra* note 55.
[69] Administrative Conference of the United States 72-6, *Civil Money Penalties as a Sanction* (1972), https://www.acus.gov/recommendation/civil-money-penalties-sanction.
[70] CSMA, *supra* note 1, art. 3 – 6(3), 45(3).
[71] NON-CONTENTIOUS CASE PROCEDURES ACT, *supra* note 67, art. 119-120.

notified of the violation and given an opportunity for a formal hearing before a judicial judge or administrative law judge.[72] If the defendant is dissatisfied with the hearing's outcome, they may appeal to the court, and the substantial evidence principle applies.[73]

Japanese administrative law scholars have focused on the enforcement of law by courts in America and have become less interested in the methods of enforcing law through administrative agencies themselves.[74] Executive penalties seek to implement administrative objectives by indirectly influencing the psychology of citizens through monetary payment.[75] If the potential offender is not intimidated, the administrative objective cannot be achieved. For example, if hospitalization of infected individuals with COVD-19 cannot be maintained, infection will spread. Even with an ex post facto penalty for the actions of the infected patient, if the individual does not pay attention to the existence of the penalty, the government will be "powerless" to prevent the spread of the infectious disease.[76] This is because under Article 80 of the Infectious Disease Act, administrative penalties are imposed on those who receive hospitalization orders but fail to be hospitalized by the beginning of their required hospitalization period without a valid reason.[77] This hospitalization measure, as described in Article 19 and 20 of the Infectious Diseases Act, does not distinguish between asymptomatic or mildly and severely ill persons.[78] As a result, once the number of people requiring hospital treatment exceeds the capacity of the hospital, the mildly ill or asymptomatic will be treated at home and may leave their homes at will.

### *C. Direct Coercion*

Direct coercion is the use of direct, concrete force against the body or property of an obligated citizen to effectuate an obligation. With direct coercion, it does not matter whether a citizen's duty is an action or inaction; it covers both the duty of

[72] Jonathan I. Charney, *Need for Constitutional Protections for Defendants in Civil Penalty Cases*, 59 CORNELL L. REV. 478 (1974).
[73] *Id.* at 487 (stating that civil penalties can be imposed in civil or administrative proceedings for violations of the law, but the degree of proof of a "violation of law" can be based on a "preponderance of the evidence" standard, which makes it easier to prove a violation of law than in criminal proceedings, which require proof "beyond a reasonable doubt).
[74] Toshifumi Sowa, *GYŌSEIHO SIKKŌ SISUTEMU NO HŌ RIRON* [*LEGAL THEORY OF ADMINISTRATIVE LAW ENFORCEMENT SYSTEM*] 43-138 (2011).
[75] *See* Sakurai & Hashimoto, *supra* 8, at 178.
[76] Yoko Sudo, *Ein Rückblick auf die klassische Theorie über den Verwaltungszwang (1) [Reconsideration in administrative law, Theoretical basis for compulsory measures]*, RITSUMEIKAN HOGAKU 49, 62 (2020) (Japan).
[77] *See* INFECTIOUS DISEASES ACT, *supra* note 2, art. 80.
[78] *See id.* at art. 19–20.

inaction, which others cannot perform in its place, and the duty of action, which others can perform in its place.[79]

Today, few laws allow for direct coercion.[80] When implemented, direct coercion is limited to cases of exigent circumstances, as it is not possible to compel citizens to do or not to do something by means of substitute execution or administrative punishment.[81] This is because direct coercion has a high risk of violating human rights as it involves coercion of an individual's body and destruction of their property. Although there is a real need to allow direct coercion in certain circumstances, the government refrains from utilizing it and instead opts for immediate coercion, as described in the next section.

An example of a provision in an existing individual law that allows for direct coercion is the Act on Emergency Measures to Ensure the Safety of Narita International Airport.[82] Under this Act, the Minister may issue an order prohibiting the use of a structure around the airport, and if the obligated citizen uses the structure, the Minister may seal the structure.[83] Although it could have, the CSMA 2021 did not utilize a similar methodology; it did not establish a direct coercion to seal off stores that do not comply with the order to reduce business hours, for example.

The Infectious Diseases Act did, however, stipulate a fine[84] on citizens who fail to comply with the recommendation to be hospitalized when they are suspected of infection. Similar to the provision under the Infectious Diseases Act, there is a system called "hospitalization under measures"[85] in the Act on Mental Health and

[79] Sakurai & Hashimoto, *supra* 8, at 176. The pre-war Administrative Enforcement Act, which no longer exists, also allowed direct enforcement only when it could not be achieved by either substitute execution or execution penalty.
[80] *See, e.g.*, GAKKŌ SHISETSU NO KAKUHO NI KANSURU SEIREI [CABINET ORDER ON SECURING SCHOOL FACILITIES], Order No. 34, Art. 21 (1949) (Japan). *See also,* Shiono, *supra* note 8, at 260. There is no law that comprehensively recognizes direct coercion. There are few laws that allow for direct enforcement.
[81] Sakurai & Hashimoto, *supra* 8, at 260.
[82] *See* Sudo, *supra* note 75, at 71 (citing *ACT ON EMERGENCY MEASURES CONCERNING SECURITY CONTROL OF NARITA INTERNATIONAL AIRPORT*, Law No. 42 art. 3(8) (1972) (Japan)).
[83] NARITAKOKUSAIKŪKŌ NO ANZEN KAKUHO NI KANSURU KINKYŪ SOCHI-HŌ [ACT ON EMERGENCY MEASURES CONCERNING SECURITY CONTROL OF NARITA INTERNATIONAL AIRPORT], Law No. 42, art. 3(8) (1978) (Japan).
[84] INFECTIOUS DISEASES ACT, *supra* note 2, art. 20.
[85] SEISHIN HOKEN OYOBI SEISHIN SHŌGAISHAFUKUSHI NI KANSURU HŌ [ACT ON MENTAL HEALTH AND WELFARE OF PERSONS WITH MENTAL DISABILITIES], Law No. 123 art. 29-2 (1950) (Japan) [hereinafter ACT ON MENTAL HEALTH AND WELFARE].

Welfare of Persons with Mental Disabilities.[86] This Act stipulates that a prefectural governor may hospitalize a mentally disabled person who is at risk of self-injury or other harm if not hospitalized. Both of these provisions in the Act on Mental Health and Welfare Law and the Infectious Diseases are examples of direct coercion.

Hospitalization measures under the Infectious Diseases Act are based on the assumption that a person suspected of infection will be hospitalized at their own will.[87] Under the Infectious Diseases Act 2021, a person who is "subject to hospitalization measures" is subject to a fine[88] if they are "not hospitalized by the beginning of the period for which he or she should be hospitalized." [89] The prefecture recommends suspected infected individuals for hospitalization.[90] If the patient voluntarily follows the recommendation, there will be no further action; if the patient does not follow the recommendation, they will be forcibly hospitalized.[91] The sanction for not complying with the hospitalization measure is an administrative penalty. The Ministry of Health, Labor and Welfare (MHLW) explains that even if an administrative fine is paid by a suspected infected person, they can still be forcibly hospitalized.[92]

If COVID-19 is classified as a new type of infectious disease as defined by the 2020 CSMA or a new type of influenza infection as defined by the 2021 CSMA under the Infectious Diseases Act, hospitalization measures will be taken in principle. Although 80% of suspected COVID-19 infections resolve with mild or no symptoms, the rest are likely to be severe.[93] As a rule, hospitalization is required for those suspected of infection even if their symptoms are mild or asymptomatic.[94] To mitigate hospital bed shortages,[95] the Infectious Diseases Act 2021 allows

[86] *Id.* art. 29-2.
[87] *Id*. art. 20; INFECTIOUS DISEASES ACT, *supra* note 2, art. 20.
[88] INFECTIOUS DISEASES ACT, *supra* note 2, art. 80.
[88]*Id*. at art. 80.
[89] *Id*. at art. 44-3.
[90] *Id*. at art. 19.
[91] *Id*. at art. 20.
[92] *Q&A on Revisions to the Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases, etc*., MINISTRY OF HEALTH, LABOR AND WELFARE (Feb. 10, 2021), https://www.mhlw.go.jp/content/000737653.pdf (last visited Dec.3, 2021).
[93] Vicky Wang, *Coronavirus Cases Are Mild. That's Good and Bad News,* NEW YORK TIMES (Feb. 27, 2020), https://www.nytimes.com/2020/02/27/world/asia/coronavirus-treament-recovery.html.
[94] INFECTIOUS DISEASES ACT, *supra* note 2, art. 19 (specifying hospitalization to prevent the spread of infection, but not the degree of symptoms for those suspected of being infected).
[95]*No lack of hospital beds in Japan unless you have the coronavirus,* THE ASAHI SHIMBUN (Jan. 31, 2021), https://www.asahi.com/ajw/articles/14151132 (last visited Dec. 3, 2021).

prefectural governors to request the necessary cooperation from mildly ill or asymptomatic patients to treat them in accommodations or at home.[96]

The prefectural governor is obligated to provide meals, daily necessities, and other services or goods necessary for daily living in response to medical needs at home or in accommodations. Citizens suspected of infection who are under 65 years old or who do not have respiratory diseases will be asked to stay in accommodations or at home.[97] If such a citizen does not comply, the prefectural governor will issue a recommendation for hospitalization.[98] The government will implement hospitalization measures for citizens who do not comply with the hospitalization recommendations. Under the Act, citizens suspected of being infected have the option of hospitalization. If the governor can use force to coerce a citizen who does not comply with the hospitalization measure, the hospitalization is completed using that measure.

While the Infectious Disease Act 2021 imposes penalties on those who fail to comply with mandatory hospitalization measures, the addition of further penalties, as prescribed by the CSMA 2021, on those who refuse to comply with orders to shorten business hours calls into question the effectiveness of both approaches. For instance, those who suspect they are infected may avoid testing or lie about their test results, thereby reducing the effectiveness of measures to control infection. Similarly, some restaurants may deliberately disobey the order to shorten business hours because they believe that disobeying the order will attract more customers and generate more profits than the money they will pay as administrative penalties, or that these orders are not being well enforced.

---

[96] INFECTIOUS DISEASES ACT, *supra* note 2, art. 44-3(1)-(2).

[97] *COVID-19 Guidance for Medical Treatment 5th ed,* MINISTRY of HEALTH, LABOR AND WELFARE. (Patients with COVID-19 have been uniformly hospitalized, but the Ministry of Health, Labor and Welfare limited the scope of "hospitalization" to those aged 65 or older, those with respiratory disease, those with impaired organ function, those with impaired immune function, pregnant women, and patients with severe or moderate disease, starting October 24, 2020.).

[98] INFECTIOUS DISEASES ACT, *supra* note 2, art. 22-3. When there is a risk of a shortage of designated medical institutions for infectious diseases in all or part of the area under the jurisdiction of the prefectural governor due to the spread of a category 1 infectious disease, or when the prefectural governor finds it necessary to prevent the spread of said infectious disease, the prefectural governor shall make recommendations for hospitalization or comprehensive coordination concerning hospitalization measures pursuant to the provisions of Article 19 or Article 20 to the heads of cities, etc. with public health centers, medical institutions, and other persons concerned.

### *D. Immediate Coercion*

Immediate coercion refers to the use of direct, concrete force against the body or property to achieve an administrative purpose, without assuming the existence of a duty on the part of the citizen. Immediate means to compel citizens to suddenly do something. Immediate coercion is not precisely a means of compelling citizens to fulfill their obligations as it does not presuppose the existence of such obligations.[99] Because immediate coercion is to the detriment of a person's body or property, a legal basis must exist to restrict a citizen's rights. While many of the immediate coercions are substantive in nature, as provided for in respective laws, some procedures are prescribed, such as the need for a council opinion or prior court warrant.[100]

### *E. Immediate Coercion Under the 2021 Infectious Diseases Act*

A common use of immediate coercion against a person's body is in situations where an individual enters Japan illegally without a passport or landing permission and is physically detained by an immigration guard then handed over to an immigration inspector. If certified as a person subject to deportation, deportation is enforced based on a written order. This is called forced detention and deportation.[101] Comparably, the Act on Mental Health and Welfare of Persons with Mental Disabled provides for hospitalization by measure.[102] The prefectural governor can compel a person to be checked by a designated doctor and, depending on the results of the checkup, compulsorily hospitalized under certain requirements.

Under the Infectious Diseases Act, a prefectural governor may recommend[103] or compel[104] that a person, whom they have reasonable grounds to suspect of infection, undergo a medical examination. The Infectious Diseases Act 2021 gives

---

[99] Shiono, *supra* note 8, at 277-78. Shiono defined immediate enforcement (not coercion) as the direct use of force by the administrative body without imposing any obligation on the other party, thereby realizing the administrative purpose. Citing an old text on administrative law by Jiro Tanaka, an administrative law scholar, Shiono classified immediate enforcement into two categories. One is administrative investigation, and the other is forced quarantine or blocking of traffic, according to him. He analyzes that it was probably put together as immediate enforcement in that there is no obligation on the targeted citizen. Shiono understands that the meaning of immediate in immediate enforcement is not imminence in time, but rather that it does not intervene with the obligations of the other party.

[100] Sakurai & Hashimoto, *supra* 8, at 185-6.

[101] SHUTSU NYŪKOKU KANRI OYOBI NANMIN NINTEI HŌ [IMMIGRATION CONTROL AND REFUGEE RECOGNITION ACT], Cabinet order no. 319 of 1951 (Japan).

[102] ACT ON MENTAL HEALTH AND WELFARE, *supra* note 85, art. 29-2.

[103] INFECTIOUS DISEASES ACT, *supra* note 2, art. 17(1).

[104] *Id.* art. 17(2).

citizens the opportunity to comply with hospitalization recommendations, but also has the authority to mandate hospitalization.[105] These compulsory medical examinations and hospitalizations require a prior recommendation based on suspected infection.[106]

The government describes the hospitalization measures in the Infectious Diseases Act of 2021 as immediate coercion; however, it is not necessarily clear whether the measures would classify as direct coercion or immediate coercion.[107] This is an issue for future consideration in administrative jurisprudence. The use of immediate coercion does not require an obligation on the part of the citizen but can assume an obligation not to infect others. The former Infectious Diseases Act was enacted in 1897 to designate infectious diseases that are highly contagious and potentially life-threatening, and to protect the public from infectious diseases through preventive measures. The purpose of this law was to prevent the introduction into Japan of infectious diseases that did not exist domestically but had been introduced from abroad, and to prevent the spread of major infectious diseases in Japan. However, several deficiencies existed. Article 7 of the former Infectious Diseases Act allowed for the forced isolation of infected and suspected infected patients; Article 8 allowed for the blocking of traffic in the houses and neighborhoods of infected people; Article 5 allowed for forced disinfection. This law was created before the war. Under the Japanese Imperial Constitution, human rights were granted by the Emperor to his subjects and were not necessarily guaranteed, and there was no notion of due process of law. This law has been revised, but sometimes brought discrimination on the grounds that it was an infectious disease until 1998.

The Infectious Diseases Act of 1998[108] adopted a new understanding of immediate coercion that deviated from the previous understanding – it separated "immediacy" from the previous notion about immediate coercion and placed a non-mandatory

[105] *See id.*
[106] *See id.*
[107] The 2021 amendments to the CSMA created a lot of controversy for immediate enforcement. *See* Sudo, *supra* note 75, at 109.
[108] Jiro Exaki, *COVID-19 – Clinical Approaches and the Law*, IATSS REVIEW, no. 46-1, 2021, at 6. The former Infectious Disease Prevention Act, enacted in 1897, has been of great benefit to the development of modern Japan. In Japan, the number of deaths from cholera no longer exceeds 100,000 per year. However, the former Act on the Prevention of Infectious Diseases did not require compulsory preventive measures and did not cover dangerous infectious diseases such as Ebola. In addition, with regard to preventive measures against infectious diseases, the law was biased toward post-occurrence measures after an outbreak of infectious diseases, and there were no systematic procedural safeguards in place to ensure respect for human rights when restricting patients' actions. INFECTIOUS DISEASES ACT, Law No. 36 of 1897, art.1, 5, 7, 8 (Japan); DAI NIHON TEIKOKU KENPO, Art.1, 18 (Japan); Yuichiro Tsuji, *Forgotten People: A Judicial Apology for Leprosy Patients in Japan*, 19 OR. REV. INT'L. L. 223 (2018).

"recommendation" before immediate coercion in an attempt to justify hospitalization measures.[109]

An argument arose that it would be unconstitutional to impose criminal penalties, instead of a fine, on those who do not comply with hospitalization measures in the CSMA 2021 amendment.[110] If we categorize hospitalization measures as immediate coercion, it is possible to achieve the law's purpose of controlling COVID-19 sufficiently, and thus no need to impose a fine. Although there is a real need for the government to use direct coercion in implementing the law, the government uses immediate coercion in practice. Immediate coercion allows the government to use force without imposing obligations on citizens. Direct coercion, however, which assumes the existence of obligations, should be the more appropriate means – Since immediate coercion does not presuppose a citizen's obligation not to infect others with the disease, a suspected infected person will be forcibly hospitalized regardless of the citizen's claims. If we classify hospitalization measures as direct coercion, citizens will be aware of the existence of their obligation not to infect others.

Article 1 of the Act on Substitute Execution by Administration stipulates that "with respect to securing the performance of administrative obligations, except as otherwise provided by law, the provisions of this Act shall apply," and thus it is not possible to provide for direct coercion based on ordinances of the local parliament. The local parliament can create immediate coercion by ordinance regardless of whether citizens are obligated.[111] Immediate coercion is an exercise of public power and is an administrative disposition. If a citizen is dissatisfied with an administrative disposition (e.g., hospitalization), they may seek redress through administrative appeals and administrative litigation procedures.[112] It might be possible in the future to accept the interpretation that execution penalties are

[109] Sudo, *supra* note 75, at 55. Sudo analyzes that after World War II, legal enforcement was not created under the influence of American law like other legal systems but followed the system of substitute execution, execution penalty, and direct compulsion in accordance with Article 5 of the Administrative Execution Act. *See supra* text accompanying note 46.
[110] *Korona-ka no jiyū to bassoku Hakuōdaigaku no Shimizu jun kyōju ni kiku*, [*Freedom and Penalties for Corona Disasters Interview with Associate Professor Shimizu of Hakuo University*], THE ASAHI SHIMBUN, (Feb. 4, 2021), https://www.asahi.com/articles/ASP23766SP21UUHB001.html (last visited Dec. 3, 2021).
[111] Uga, *supra* note 55, at 123. Article 1 of the Act on Substitute Execution by the Administration provides that the realization of obligations by the administration shall be regulated by this Act, except as otherwise provided by "law." It is believed that the text "law" in this Article 1 does not include ordinances. Uga argues for the possibility of execution penalties by ordinance as a policy, even though it is generally believed that they cannot be created by ordinance.
[112] ADMINISTRATIVE APPEAL ACT, Art. 2(1).

prescribed by ordinance as a matter of policy.[113] The classification of direct and immediate coercion in laws and ordinances must be rearranged based on the administrative purpose, nature of rights, and the nature of prior procedures.[114]

## CONCLUSION

Religion, morality, the market, and many other tools exist in society to control human behavior, and law is just one of those tools. However, the COVID-19 pandemic revealed the limits of the law as an instrument to control human behavior. This article evaluated how the Infectious Diseases Act of 2021 and the CSMA 2021 may have used the four methods of governmental enforcement – substitute execution by administration, execution penalty, direct coercion, and immediate coercion – to control the spread of COVID-19.

As discussed, the CSMA 2021 provides that the fine for violating the request to reduce business hours is an administrative penalty, not a criminal penalty.[115] There was an argument that execution penalty should be used in the amendment because they can be adjusted in amount to encourage the fulfillment of obligations and imposed repeatedly.[116]

Under the Infectious Diseases Act of 2021,[117] medical examinations, recommendations for hospitalization, and hospitalization measures can be compelled for individuals suspected of being infected with COVID-19. Comparable in effect, the Act 2021 gives citizens the opportunity to choose whether to be hospitalized in response to the governor's recommendation.[118] The Act stipulates a fine for not following the recommendation for hospitalization,[119] an apparent legislative tactic to compel citizens to follow the recommendation for hospitalization through the threat of monetary payment. As we have seen, it is not clear whether the hospitalization measures under the Infectious Diseases Act of 2021 use either direct or immediate coercion. The difference between direct and immediate coercion is whether a citizen is under obligation. Direct coercion

[113] *Id.*
[114] Shiono, *supra* note 8, at 280. Direct compulsion (enforcement) cannot be enacted by ordinance. Immediate compulsion (enforcement) can be enacted by ordinance because it is not administrative enforcement. However, the distinction between immediate compulsion and direct execution is not always clear.).
[115] Johnston, *supra* note 19.
[116] Itagaki, *supra* note 60, at 200-203.
[117] INFECTIOUS DISEASES ACT, *supra* note 2, art. 19(1).
[118] *Id.*
[119] *Id.*

requires that a citizen be under some obligation.[120] Immediate coercion does not subject an individual to an obligation.[121] If we assume that citizens suspected of infection have an obligation not to infect others, it is possible to consider that hospitalization, as a measure, constitutes *direct coercion*. The government, however, describes hospitalization under the Infectious Diseases Act as *immediate coercion*.[122]

The classification of direct coercion and immediate coercion in laws and ordinances must be rearranged based on the administrative purpose in addition to the nature of the right and prior procedures. The CSMA and Infectious Diseases Act were amended in 2021 to include sanctions, which raised the contentious issue of impermissible restrictions on constitutional rights. There are inadequacies in the law, and the deliberations of the Parliament have not been sufficient.

[120] Shiono, *supra* note 8, at 277-278.
[121] Uga, *supra* note 55, at 123.
[122] Sudo, *supra* note 75, at 109.

# COVID-19 VACCINATION IN JAPAN: REMEDIES FOR INJURED PATIENTS†

*Dr. Yuichiro Tsuji**

TABLE OF CONTENTS

INTRODUCTION ..... 41
I. VACCINATION IN JAPAN ..... 43
*A. Structure of Vaccination in Japan* ..... 43
*B. COVID-19 Vaccination* ..... 46
II. VACCINATION INJURY AND RELIEF ..... 47
*A. Compulsory Vaccination in Japan* ..... 48
*B. Judicial Remedies for Injured Patients* ..... 49
*C. Academic Theories of Compensation* ..... 50
*D. COVID-19 Vaccination Compensation Mechanisms* ..... 53
CONCLUSION ..... 53

*† Select sources cited in this article are only available in their original Japanese and have been validated to the extent possible with assistance by the author. Please contact the Editor-in-Chief with source-related questions or if you desire copies of any original sources.*

** Dr. Yuichiro Tsuji is an Associate Professor of Law at Meiji University School of Law. He received an LL.M in 2005 and a J.S.D. in 2006 from UC Berkeley School of Law. He also received an LL.M from Kyoto University in 2002. His fields of specialization are constitutional law, administrative law, cyber law, comparative law, and international human rights law. https://ssrn.com/author=979824*

## INTRODUCTION

This article examines COVID-19 vaccination in Japan and possible compensation rights for those who experience adverse reactions. In Japan, the Constitution[1] and the Local Autonomy Act[2] place regular vaccination of citizens as a municipal task. If a disaster occurs that is beyond the jurisdiction of the municipality, the prefectural government, which is positioned above the municipality, responds. The central government is constitutionally responsible for coordinating prefectures in the event of a disaster that exceeds their capacity to handle.

Japanese constitutional jurisprudence holds that social restrictions inherent to property rights do not necessitate compensation, but it is possible that compensation would be necessary if society's evaluation of compensation for property rights changes significantly. [3] A lower court decided that compensation under the property rights provision could be applied if the vaccination caused serious damage to the health or life of citizens.[4] The Supreme Court of Japan has recognized the government's liability, judging that negligence exists in the system of vaccination itself in the obligation of doctors to question patients during vaccination when serious damage to health or life occurs due to vaccination.[5] This decision would also apply to adverse reactions caused by COVID-19.

---

[1] NIHON KOKU KENPŌ [CONSTITUTION], art. 92–95 (Japan) (providing that local public entities shall establish assemblies and manage property, affairs, and administration).
[2] CHIHŌ JICHI HŌ [LOCAL AUTONOMY ACT], Law No. 67 of 1947, art. 2, para. 8 (Japan) [hereinafter LOCAL AUTONOMY ACT].
[3] NIHON KOKU KENPŌ, *supra* note 1, art. 29, para. 2–3, art. 92–95; *see* also Nobuyoshi Ashibe, *Kenpō* [*Constitution*] 247–78 (7th ed. 1997) (explaining that public use means that the expropriation of property rights is of broad social and public interest, and that social restrictions inherent to property rights do not require compensation); *see also,* Yuichiro Tsuji, *Reflection of Public Interest in the Japanese Constitution: Constitutional Amendment*, 46 DENVER J. INT'L L. & POL'Y, 159–190 n.2 (2018). Human rights provisions are provided in the Constitution from Article 10 to 40 of Chapter 3, and the term public welfare is present only in Articles 12, 13, 22 and 29. However, it is believed that public welfare is inherent in Articles 10 to 40 of Chapter 3 as a principle to address human rights conflicts. Before World War II, there was a theory that human rights could be restricted in any way through laws for the sake of the public welfare. The idea that is now accepted in constitutional law can lead to the same idea as before the War if we do not look carefully at the degree of restriction by public welfare, the types of human rights to be restricted, and the manner of restriction.
[4] Tokyo Chihō Saibansho [Tokyo Dist. Ct.], May 18, 1984, 1978 (wa) no. 4793, 1118 Hanrei Jiho [Hanji] 28 (Japan) (holding that when restrictions on property rights impose special sacrifices on certain individuals, compensation can be claimed on the basis of Article 29(3) of the Constitution even if there is no provision for compensation in the law).
[5] Saikō Saibansho [Sup. Ct.] April 19, 1991, 1986 (o) no. 1493, 45 Saikō Saibansho Minji Hanreishu [Minshu] 4 (Japan) (arguing that if a vaccination causes death or serious sequelae in the inoculated

COVID-19's Special Measures Act (CSMA)[6] was an amendment to the Influenza Special Measures Act by the Parliament. This CSMA provides for compensation,[7] for the use of land and other property to establish temporary medical facilities,[8] for the transfer of supplies, [9] and for requests to medical personnel,[10] but the provision for compensation for vaccination accidents was not discussed. The CSMA was further amended in 2021, and even then, administrative sanctions for violations of reduced hours of operation orders were discussed, but compensation for accidents caused by vaccination was not fully discussed.[11]

The debate on whether compensation is necessary or unnecessary gives a scathing assessment of the negligence of the political branches. Even if compensation based on property rights is not necessary, provisions based on social rights can be used to require the government to take steps in parliament and governance to help the socio-economically vulnerable. Constitutional scholars should be careful when they argue that compensation for property rights is unnecessary, as citizens may misunderstand that socioeconomic support based on social rights is also unnecessary.

---

person, the Minister of Health and Welfare is presumed to be negligent in failing to perform his duty to avoid contraindicated persons); Saikō Saibansho [Sup. Ct.] Sept. 30, 1976, 1975 (o) no. 140, 827 Hanrei Jiho [Hanji] 14 (Japan) (holding that with vaccinations, it is not enough for the doctor to ask abstract questions about the subject's health condition; he or she must ask specific questions about symptoms, diseases, and physical predisposition. If a doctor fails to ask the appropriate questions and death or serious adverse reaction occurs, he or she will be found negligent).

[6] SHINGATA INFLUENZA TŌ TAISAKU TOKBETSU SOCHI HŌ [CORONAVIRUS SPECIAL MEASURES ACT], Law No. 31 of 2012 (revised as Law No. 5 of 2021) (Japan) [hereinafter CSMA].

[7] *Id.* art. 62–63.

[8] *Id.* art. 31-3.

[9] *Id.* art. 55.

[10] *Id*. art. 31, para. 1.

[11] YOBŌ SESSHU HŌ [IMMUNIZATION ACT], Law no. 68 of 1948 (revised as Law No. 51 of 1994, art. 4) (Japan), supp. provisions art. 8 [hereinafter IMMUNIZATION ACT]; *see also,* GUIDELINE FOR ENFORCEMENT OF THE LAW FOR PARTIAL REVISION OF THE VACCINATION ACT AND THE QUARANTINE ACT, Ministerial Ordinance No. 1209 of 2020. MHLW explains that the government may conclude a contract with a manufacturer or seller of a vaccine or a person related to the development or manufacture of a vaccine other than the manufacturer or seller of a vaccine, in which the Government undertakes to compensate for any loss arising from compensation for damage to health caused by vaccination using the vaccine pertaining to the contract, or any other loss that is necessary to be compensated by the Government based on the nature of the vaccine pertaining to the contract. *See id.*

## I. VACCINATION IN JAPAN

In Japan, vaccinations used to be compulsory under the Immunization Act.[12] As with all medical treatments, those who are administered vaccines carry some probability that they make experience serious side effects that cause death or injury.

If the vaccination causes serious damage, the patient or parent can seek damage against the national hospital using Article 1 of the State Redress Act, or if it is a private hospital, using the tort of Article 709 of the Civil Code. In both cases, the victim must prove the intent or negligence of the perpetrator, the damage, and the causal relationship between the perpetrated act and the damage. In cases where an individual suffered an injury or death, it was extremely difficult to prove the negligence of the government to the courts. While it is easy for parents to prove that their child has suffered health damage, it is difficult for non-medical experts to establish a causal relationship between the damage and the vaccination.[13] To help victims, the courts turned to the property loss compensation provisions. Before examining the mechanisms that provide relief to patients who suffered an injury from vaccination, a review of the basic framework for vaccination in Japan is essential.

### *A. Structure of Vaccination in Japan*

In Japan, the local government is responsible for vaccinating its citizens. Chapter 8[14] of the Constitution of Japan provides for local autonomy, and the Local Autonomy Act constitutes local governments at two levels: prefectures and municipalities.[15] In formulating systems and implementing measures concerning local governments, the national government shall ensure that local governments are able to fully exercise their autonomy and independence.[16] Local governments are responsible for autonomous and comprehensive implementation of administration in the region, based on the promotion of residents' welfare.[17] The prefectural

[12] IMMUNIZATION ACT, *supra* note 11.
[13] *See* MINPŌ [CIVIL CODE] 1896, art. 709 (Japan); KOKKA BAISHŌ HŌ [STATE REDRESS ACT], Law No. 25 of 1947, art.1 (Japan) (explaining that under Article 709 of the Civil Code or Article 1 of the State Redress Act, the plaintiff must prove that the damage was caused by the intentional or negligent act of the assailant. For ordinary citizens who are neither experts nor doctors, the burden of proving negligence and causality is extremely heavy).
[14] NIHON KOKU KENPŌ, *supra* note 1, art. 92–95.
[15] CHIHŌ JICHI HŌ [LOCAL AUTONOMY ACT], Law No. 67 of 1947, art.1-3 (Japan).
[16] *Id.* art.1-2, para. 2.
[17] *Id.* art. 2, para. 8–9. Among the affairs handled by local governments, those other than legally delegated affairs are called autonomous affairs. Legally delegated affairs are those affairs that the

government, as a wide-area local government encompassing municipalities, is supposed to handle wide-area affairs, liaison and coordination affairs related to municipalities, and affairs that are deemed inappropriate for general municipalities to handle in terms of their scale or nature.[18] Municipalities, as basic local governments, generally handle regional and other affairs prescribed by laws and regulations, except for those that are supposed to be handled by prefectures.[19]

The Immunization Act distinguishes between routine[20] and temporary vaccination.[21] Municipalities oversee routine vaccination[22], making a list of people to be vaccinated[23], and cover its cost.[24] If the prefectural governor finds an urgent need to prevent the spreading of a disease specified to be among Category A[25] and B[26] diseases by the Minister of Health, Labor and Welfare (MHLW), the governor may designate recipients and the date or the period, and implement a temporary vaccination or instruct the mayor of the municipality to do so.[27] The MHLW can then issue the same instructions to prefectures.[28] The central government instructs the prefectural governors on implementation,[29] and it bears a certain ratio of the

national or prefectural government or a municipality or a special ward is supposed to handle according to laws and ordinances, and which are specifically specified by laws and ordinances as those affairs that the national or prefectural government or a municipality or a special ward is supposed to play a role in and for which the national or prefectural government or a municipality or a special ward is required to ensure proper handling.

[18] *Id.* art. 2, para. 5.

[19] *Id.* art. 2, para. 3.

[20] IMMUNIZATION ACT, *supra* note 11, art. 2, para. 4.

[21] *Id.* art. 2, para. 5.

[22] *Id.* art. 5.

[23] YOBŌ SESSHU HŌ SIKŌ REI [ORDINANCE FOR ENFORCEMENT OF THE IMMUNIZATION ACT], Ordinance No. 197 of 1948, art. 6 (Japan) [hereinafter IMMUNIZATION ACT ENFORCEMENT ORDINANCE].

[24] *Id*.

[25] IMMUNIZATION ACT, *supra* note 11, art. 2(2). The term "category A diseases" as used in this act refers to (i) diphtheria; (ii) pertussis; (iii) polio; (iv) measles; (v) rubella; (vi) Japanese encephalitis; (vii) tetanus; (viii) tuberculosis; (ix) Hib infection; (x) pneumococcal infectious disease; (xi) human papilloma virus infection; and (xii) beyond the diseases listed in the preceding items, diseases provided for by Cabinet Order as diseases against which vaccinations are deemed a required necessity to prevent an outbreak and a spread from person to person, or to prevent an outbreak or a spreading as the condition of a person infected can become serious or will likely become serious.

[26] *Id.* art. 2(3). The term "category B diseases" as used in this Act means (i) influenza; and (ii) beyond the diseases listed in the preceding items, diseases provided for by Cabinet Order as diseases against which vaccinations are deemed a required necessity to prevent individuals from developing the disease or the condition from getting worse, and to contribute to preventing the disease from spreading.

[27] *Id.* art. 6, para. 1.

[28] *Id.* art. 6, para. 2.

[29] *Id*, art. 6, para. 2.

vaccination costs borne by the municipality[30], prefectural government[31], and the national treasury.[32]

The central government promotes vaccination in accordance with the Immunization Act and the Infectious Diseases Act as follows: First, in the event of an outbreak of a new infectious disease overseas, the government (through the MHLW) shall designate the target disease, taking into consideration the infectiousness and severity of the disease, the efficacy and safety of the vaccine, and other factors in a comprehensive manner.[33] Second, the government shall instruct prefectures or municipalities to vaccinate in urgent cases, taking into consideration the outbreak situation in Japan.[34] Third, temporary vaccinations would be conducted by prefectures, considering the urgency of the situation. These are designed to be conducted at large-scale facilities.[35]

[30] *Id.* art. 25. In temporary vaccinations conducted by municipalities, the municipality pays the expenses required for vaccinations.
[31] *Id.* art. 26. In temporary vaccinations conducted by municipalities, the prefectural government bears two-thirds of the burden of the city. For temporary vaccinations conducted by municipalities through prefectures at the instruction of the national government, the prefectural government bears three-quarters of the burden of the municipality.
[32] *Id.* art. 27. In temporary vaccinations conducted by municipalities, the national government bears one half of the burden of the prefectural government. For temporary vaccinations conducted by municipalities through prefectures at the instruction of the national government, the national government bears two-thirds of the burden of the prefectural government.
[33] Kansenshō hō [ACT ON THE PREVENTION OF INFECTIOUS DISEASES AND MEDICAL CARE FOR PATIENTS WITH INFECTIOUS DISEASES], Law No. 114 of 1998, art. 44-6, para.1, (Japan); *see also id.* art. 31-6, para. 1, art. 80.
[34] IMMUNIZATION ACT, *supra* note 11, art. 6, para. 2–3; see also, MHL
[35] *Temporary Vaccination under the Current Immunization Act*, MINISTRY OF HEALTH, LAB., & WELFARE (Feb. 2010) https://www.mhlw.go.jp/shingi/2010/02/dl/s0209-4c_0003.pdf. Vaccination is considered to be the business of municipalities according to the Immunization Act. Vaccination at the Self-Defense Forces Large-scale Vaccination Center is also based in the Immunization Act and is conducted under a consignment contract with municipalities. The Ministry of Defense explains on April 27, 2021, that the SDF provided Tokyo with a massive inoculation. This was enabled by Article 27(1) of the Self-Defense Forces Act and Article 46(3) of the Self-Defense Forces Act Enforcement Order. These provisions state that the SDF may provide medical treatment for other persons as determined by the Minister of Defense to the extent that it does not affect the medical treatment of members of the SDF, their dependents, and their dependents.) *See* Jieitai hō [Self Defense Force Act], Law No. 165 of 1954, art.27, para.1, (Japan); Jieitai hō sikō rei [Self-Defense Forces Act Enforcement Order], Ordinance No.179 of 1954, art.56, para.3, (Japan); *Minister of Defense Extraordinary Press Conference,* MINISTRY OF DEFENSE, (Apr. 27, 2021), https://www.mod.go.jp/j/press/kisha/2021/0427a_r.html (last visited Dec. 3, 2021).

### *B. COVID-19 Vaccination*

COVID-19 vaccination is positioned as a temporary vaccination under Article 6(1) of the Immunization Act, and the municipalities are thus responsible for this task.[36] It is further classified as a Type 1 statutory entrusted task,[37] in which the national government entrusts administrative work to prefectures and municipalities. Statutory entrusted affairs are defined as those affairs pertaining to the role that the government is supposed to play, which are specifically stipulated in laws as those that require the government to ensure the proper handling of such affairs. Based on the magnitude of the risk of serious illness and the need to ensure a medical care delivery system, priority will be given to vaccinating healthcare workers, followed by the elderly, then those other than the elderly with chronic diseases, and those working in facilities for the elderly.[38] Subsequently, vaccination of other people will begin based on the amount of vaccine supply and other factors. Therefore, the central government plays a role in coordinating local governments, such as municipalities and prefectures.

The lack of coordination in the distribution of the COVID-19 vaccine has generated dissatisfaction among the public.[39] Because of the delay in vaccination, the central government has often issued statements trying to blame the municipalities and prefectures.[40] As discussed, the central Government has placed COVID-19 vaccination as a municipal task in Article 6(1) of the Immunization Act, leaving it

---

[36] IMMUNIZATION ACT, *supra* note 11, supp. provisions, art. 7, para. 1. The MHLW may, when he/she/they find(s) it urgently necessary for the prevention of the spread of new coronavirus infections, instruct the mayor of a municipality through the prefectural governor to conduct an extraordinary vaccination, designating the target population, the date or period of the vaccination, and the vaccine to be used. In this case, the prefectural governor shall provide the necessary cooperation to the mayor of the municipality so that the vaccination can be conducted smoothly within the area of said prefectural government. *See also id.* art. 7, para. 2. The provisions shall be applied by deeming the vaccinations conducted by the mayors of municipalities as vaccinations under the provisions of Article 6(1).

[37] LOCAL AUTONOMY ACT, *supra* note 2, art.1–3.

[38] Cabinet Secretariat, Shingata koronauirusukansenshō ni kakaru wakuchin no sesshu ni tsuite [Vaccination Against New Coronavirus Infections], MINISTRY OF HEALTH, LAB., & WELFARE (Feb. 9, 2021), https://www.mhlw.go.jp/content/10601000/000739090.pdf (last visited Nov. 15, 2021).

[39] *COVID-19 Delta Variant Outpacing Vaccine Impact as Daily Cases Top 10,000 in Japan*, MAINICHI (July 30, 2021), https://mainichi.jp/english/articles/20210730/p2a/00m/0na/038000c (last visited Nov. 15, 2021); s*ee also, Wakuchin sesshu nihon ha dōsite osoi* [*Vaccination: Why is Japan so slow?*], NHK (May 13, 2021), https://www3.nhk.or.jp/news/html/20210513/k10013026071000.html (last visited Nov. 15, 2021).

[40] *Vaccination: Why is Japan so slow, supra* note 39. In December 2020, the national government decided that vaccinations would be carried out mainly by municipalities within the framework of the Immunization Act. For this reason, each municipality has its own way of proceeding with the vaccination and making appointments, and each municipality is exploring its own way.

to the municipalities to decide how to proceed with the vaccination and how to arrange appointments.[41] However, since municipalities are not provided with sufficient information by the government on when and how many vaccines will be delivered, they are unable to secure medical personnel and locations and are unable to develop procedures for citizens to take appointments for vaccination.[42] In Japan, there is no system in place for the central government to centrally record and manage the vaccination of its citizens.[43] The newspapers criticized that the central government neglected the fact that management of COVID-19 is a cross-ministry task,[44] and the MHLW set up multiple systems but failed to share information among them, causing municipalities to experience significant delays in vaccination prospects due to the burden of inputting citizens' vaccination information into multiple databases.[45]

## II. VACCINATION DAMAGE AND RELIEF

The Constitution of Japan has provisions for state liability when the rights of citizens are infringed by the illegal exercise of public power[46]. Vaccination, which is conducted for the health of citizens, is not evaluated as an illegal act. Article 17 of the Constitution provides that every person may sue for redress from the State or a public entity, when he has suffered damage through an illegal act of any public

---

[41] IMMUNIZATION ACT, *supra* note 11, art. 6-1, supp. provisions, art. 7, para. 1. The MHLW may, when he/she/they find(s) it urgently necessary for the prevention of the spread of new coronavirus infections, instruct the mayor of a municipality through the prefectural governor to conduct an extraordinary vaccination, designating the target population, the date or period of the vaccination, and the vaccine to be used. In this case, the prefectural governor shall provide the necessary cooperation to the mayor of the municipality so that the vaccination can be conducted smoothly within the area of said prefectural government. *See also id.* art. 7, para. 2. The provisions shall be applied by deeming the vaccinations conducted by the mayors of municipalities as vaccinations under the provisions of Article 6(1).

[42] *Vaccination: Why is Japan so slow, supra* note 39. For local governments, there was no clear information on "when" and "how much" the vaccine would be delivered. Even when local governments try to prepare reservation slots, they cannot start concrete preparations without such information.

[43] Yuka Honda & Junya Sakamoto, *Slow Data Entry Causing Snafu in Supplying COVID-19 Doses*, ASAHI SHIMBUN (July 6, 2021), https://www.asahi.com/ajw/articles/14388634 (last visited Nov. 15, 2021).The vaccination recording system (VRS), developed by MHLW, keeps track of the supply of vaccines and determines the amount to be allocated.

[44] William Pesek, *Japan's Coronavirus Response is Too Little, Too Late*, WASH. POST (Apr. 10, 2021), https://www.washingtonpost.com/opinions/2020/04/10/japans-coronavirus-response-is-too-little-too-late/ (last visited Nov. 15, 2021).

[45] *Limited Testing Leaves COVID-19 App Glitches Overlooked*, JAPAN TIMES (Apr. 16, 2021), https://www.japantimes.co.jp/news/2021/04/16/national/virus-app-glitches/ (last visited Nov. 15, 2021).

[46] NIHON KOKU KENPŌ, *supra* note 1, art. 17; STATE REDRESS ACT, *supra* note 13.

official. The State Redress Act, established in 1947 after World War II, provides similar mechanisms for relief. [47]

Prior to the current Japanese Constitution, it was believed that the nation was not responsible (King can do no wrong). However, it was expected that the government would cause damage to the people through activities unrelated to public power. The possibility of recognizing government liability in the tort of civil law existed. However, based on the dualism of public and private law, the courts had denied that civil law applied to public law relationships and that public officials were liable. The current Japanese Constitution rejected the legal doctrine of the state not being responsible in Article 17.[48] It recognized responsibility for the activities of the government, regardless of whether they are power or non-power activities.

In Japan, there is a distinction between compensation for lawful acts and redress for unlawful acts. Under the Constitution,[49] compensation is required when property rights are expropriated for the public good. The government is constitutionally obligated to compensate when property rights are violated through the exercise of lawful public power.[50] However, there is no provision in the Constitution for cases where serious damage to the life or health of a citizen is caused by the lawful exercise of public power. The word "damage" is a remedy for illegal government action under the State Redress Act and Article 17 of the Constitution, and "compensation" means the sharing of burdens caused by lawful government action under Article 29 of the Constitution by society at large.

### *A. Compulsory Vaccination in Japan*

Until the Immunization Act was first enacted in 1948 and revised in 1987, vaccination was compulsory, and all children were vaccinated at school.[51] In 1987, the Immunization Act was amended to require that vaccinations be given only to children who wish to be vaccinated with the consent of their parents.[52] In 1994, the Immunization Act was amended to make vaccinations a recommendation and to shift from mass vaccination to individual vaccination.[53] The Japanese vaccination system has a unique classification of "regular vaccination"[54] and "voluntary

[47] STATE REDRESS ACT, *supra* note 13, art. 1.
[48] NIHON KOKU KENPŌ, *supra* note 1, art. 17.
[49] *Id.* art. 29, para. 3.
[50] *Id.*
[51] *See generally,* IMMUNIZATION ACT, *supra* note 11.
[52] *Id.*
[53] *Id.*
[54] *Id*, art. 5, para. 2. It is conducted by municipalities and is free of charge.

vaccination."[55] The former is regulated by the Immunization Act, and as a rule, there is no cost for vaccination. The latter is not regulated by the Immunization Act and is paid for by the guardian, unless it is subsidized by the local government. The diseases covered by the Immunization Act are diphtheria, pertussis, acute myelitis, measles, rubella, Japanese encephalitis, tetanus, and other diseases specified by government ordinance.[56] The vaccine for COVID-19 is administered as a vaccination (temporary vaccination) under the Immunization Act.[57]

### *B. Judicial Remedies for Injured Patients*

As discussed, COVID-19 vaccination will benefit the entire population to mitigate the transmission of the pandemic, but, as with all vaccines and pharmaceuticals, there will inevitably be patients who suffer from side effects.

The courts have tried to help injured patients through the accumulation of precedents. From the perspective of victim relief, the lower courts in Japan first thought of using the compensation provision for property rights to provide relief to victims.[58] Since the Constitution requires the government to compensate even for property rights, they interpreted the property rights provision to mean that the government should compensate for special sacrifices in social life for life and health, which are more valuable than property.[59] Because the compensation provision for property rights is based on the principle of monetary compensation, it may lead to the conclusion that the government is allowed to violate life and health if money is paid.[60] Additionally, while the infringement of property rights can be objectively evaluated in the market, the infringement of life and health is so diverse that an objective evaluation may be difficult.

In 1987, Osaka District Court[61] held that to realize the public interest purpose of vaccination, which is to prevent the outbreak and spread of communicable diseases and contribute to the improvement and promotion of public health, the government

---

[55] See *id.* Voluntary vaccinations are those that are not specified in the Immunization Act but are approved by the government. The cost is borne by the vaccinator.
[56] IMMUNIZATION ACT, *supra* note 11, art. 2, para. 2, 4; IMMUNIZATION ACT ENFORCEMENT ORDINANCE, *supra* note 23, art. 1-3.
[57] IMMUNIZATION ACT, *supra* note 11, art. 6, para. 1.
[58] *See* 1118 Hanrei Jiho [Hanji] 28 *supra* note 4. When restrictions on property rights impose special sacrifices on certain individuals, compensation can be claimed on the basis of Article 29(3) of the Constitution, even if there is no provision for compensation in the law.
[59] *Id*.
[60] Hiroshi Shiono, *Gyōseihō II* [*Administrative Law II*] 408 (6th ed., Yuhikaku 2019)
[61] Osaka Chihō Saibansho [Osaka Dist. Ct.] September 30, 1987, 1979 (wa) no. 5473, 649 Hanrei Taimuzu [Hanta] 147.

enforces vaccination through penalties or laws, or through de facto binding recommendations. The Osaka District Court explained that compensation for property rights could be applied because the result of compulsory vaccination is a special sacrifice by certain individuals for the public good.

In a 1992 case, the Tokyo High Court ruled that if the Minister of Health and Welfare had taken sufficient measures to screen out those with contraindications, the damage of adverse reactions could have been avoided.[62] The government was found to be negligent for not taking sufficient measures to select those who could not be vaccinated and liable under the State Redress Act.[63] The vaccination staff made a mistake in identifying contraindications and vaccinated those who fell under the contraindications, resulting in serious adverse reactions and damage to health and life. The government cannot avoid its responsibility for damage to life and health because of the cost and expense limitations of vaccination. This 1992 Tokyo High Court decision cited two Supreme Court rulings in 1976[64] and 1991[65] that found the state responsible for negligence.

In a 1991 case, the Supreme Court[66] recognized the liability of the government in these kinds of situations, explaining that the judiciary could presume that the vaccinated person was a contraindicated person if the inoculated person suffers serious damage to life or health, except special circumstances were recognized. The Supreme Court cited precedents[67] that doctors in charge of vaccination are subject to a high degree of duty of care.

### *C. Academic Theories of Compensation*

Yasutaka Abe,[68] a professor emeritus at Kobe University who has studied vaccination accident lawsuits as an administrative law professor, advocates compensation according to Article 29(3). He insists on full compensation according to Article 29(3) of the Constitution for patients who have suffered an injury. Abe argues that today, when the Immunization Act has enhanced medical checkups, a claim under the State Redress Act cannot help victims in cases where doctors are not negligent.[69]

---

[62] Tokyo Kotō Saibansho [Tokyo Dist. Ct.] Dec. 18, 1992, 1984 (ne) no.1517, 1985 (ne) no. 2887, 807 Hanrei Taimuzu [Hanta] 78.
[63] *See id.*
[64] Saikō Saibansho [Sup. Ct.] Sept. 30, 1976, 30(8) Saikō Saibansho Minji Hanreishu [Minshū] 816.
[65] Saikō Saibansho [S. Ct.] Apr. 19, 1991, 45(4) Saikō Saibansho Minji Hanreishu [Minshū] 367.
[66] *Id.*
[67] Saikō Saibansho [Sup. Ct.] Sept. 30, 1976, 30(8) Saikō Saibansho Minji Hanreishu [Minshū] 816.
[68] Yasutaka Abe, *Gyōsheihō Ge* [*Administrative Law 2*] 208–09 (Shinzansha 2015).
[69] *Id.* at 109.

Noriho Urabe, a former professor specializing in constitutional law, was of the same generation as Abe.[70] He argues that Article 17 of the Constitution should be used to provide relief to victims who have suffered an injury. He, like Abe, disagrees with the notion that the remedy under Article 29 of the Constitution is flawed because it can be remedied monetarily.[71] He considers state liability as a kind of risk responsibility in which the activities of the state inevitably have the potential to violate the rights of the people. Urabe argues that if we consider a claim for damages under the State Redress Act to be better than compensation for property rights, we need to consider the intent and negligence of the public officials in question. Urabe believes that both compensation for loss of property rights and claims for damages under the State Redress Act can be established. In the event of a vaccination accident, negligence is presumed in the system itself, even if there is no subjective negligence on the part of the doctor who administered the vaccination.[72] Urabe believes that if a statute based on Article 25 of the Constitution has not been enacted, citizens can ask the court for damages under the State Redress Act for legislative inaction. Further, he believes that compensation for property rights under Article 29(3) of the Constitution should not only protect property rights, but also encompass existence and livelihood. Urabe[73] points out that if the purpose of the expropriation is to protect the health and life of the people, it would be contrary to justice to use the expropriation of the building as an excuse not to grant any compensation. He interprets Article 29(3) of the Constitution to mean that if the building is the basis of the owner's life, then the owner's right to life is deprived, and therefore, they should be compensated as per the right to life.

Koji Tonami,[74] also of the same generation as Urabe and Abe and a professor emeritus at Waseda University specializing in constitutional law, advocates a framework for redressing victims based on Article 25[75]—a general provision of social rights—and Article 13,[76] which provides for the pursuit of happiness. Tonami emphasizes that the damage caused by vaccination is accidental, not intentional. Focusing on the substance of damage to life and body, he argues that

[70] Noriho Urabe, *Kenpō Jirei Siki Enshu Kyositsu* [Constitution Case Study Class] 109–10 (Keisō shobō 1996).
[71] *Id.* at 109.
[72] *Id*. at 110 (arguing that cases where victims may receive relief because no negligence exists on the part of public officials—doctors—involved in vaccination should be considered. He points out that if there is no subjective negligence of public officials as a requirement of Article 1 of the State Redress Act, the victims cannot be redressed).
[73] *Id.* at 237.
[74] Koji Tonami, *Kenpō* [*Constitution*] 252 (Gyosei 1994).
[75] NIHON KOKU KENPŌ, *supra* note 1, art. 25.
[76] *Id.* art. 13.

the assessment of damages in a claim for State Redress Act is more appropriate than compensation for property rights because it includes mental distress. According to him, Article 25[77] requires the government to ensure a healthy and cultural life. Based on this article, he argues that if a healthy life is harmed, the victim should be rescued for his or her living. In response to Tonami's interpretation, it has been pointed out that it goes beyond the limits of the interpretation of Article 25 to recognize the responsibility of vaccination to the government based on Article 25, which is a general provision of social rights.[78]

Kazuyuki Takahashi,[79] a professor emeritus of constitutional law and disciple of Nobuyoshi Ashibe, argues that lawsuits over privacy have much in common with lawsuits over vaccination accidents in that they seek to redress those who are victims of the interests of the whole.

Koji Sato[80], who developed the American constitutional theory of privacy in Japan, and Kazuyuki Takahashi[81], who inherited a textbook by Ashibe who developed the theory of the American Constitution in Japan, argue that Article 13 of the Constitution, [82] which describes the right to the pursuit of happiness and is used to recognize constitutionally unwritten rights, should be used as the basis for relief for those injured from vaccination. Since compensation is provided for special sacrifices of property rights in the Constitution, it would be contrary to the purpose of Article 13 for the government to provide no relief in the event of serious disabilities related to life and body. They note that the new right, which was not envisioned at the time the Constitution was enacted, is claimed based on the text of Article 13, the pursuit of happiness. According to them, since Article 29(3)[83] of the Constitution provides for compensation by the State for special sacrifices of property rights, and Article 40[84] of the Constitution also provides for compensation in criminal proceedings, claims for redress based on vaccination injuries should be recognized as a new human right based on Article 13.

---

[77] *Id.* art. 25.
[78] Akira Nishino, *Yobōsesshu soshō no seisitsu* [*The Nature of Immunization Litigation*], GYOSEIHŌ O SO TEN [ISSUES OF ADMINISTRATIVE LAW] 184–85 (1980).
[79] Kazuyuki Takahashi, *Rikkenshugi To Nihonkokukenpō* [*Constitutionalism and the Constitution of Japan*] 281 (4th ed., Yuhikaku 2017).
[80] Kōji Sato, *Nihonkoku Kenpō* [*Constitution of Japan*] 174 (SEIBUNDO 2011).
[81] Takahashi, *supra* note 90, at 281.
[82] NIHON KOKU KENPŌ, *supra* note 1, art. 13.
[83] *Id.* art. 29, para. 3.
[84] *Id.* art. 40.

### *D. COVID-19 Vaccination Compensation Mechanisms*

Under the revised Immunization Act, which went into effect in December 2020, vaccination against COVID-19 is not a legal obligation for citizens, and is not mandatory. The revised Immunization Act positioned vaccination against COVID-19 as a special case of temporary vaccination. Under the Vaccination Act, the government is supposed to take necessary measures for the proper implementation of vaccinations, such as documenting symptoms suspected to result from adverse reactions occurring after vaccinations, reporting these to the Health Sciences Council, listening to their opinions, and providing information on the safety of vaccinations.[85]

Article 15[86] of the Immunization Act provides for a health damage relief system. Health problems caused by adverse reactions to vaccinations are inevitable, even if they are extremely rare. Regardless of whether there was negligence related to the administration of vaccination, those who are found to have a causal relationship between the vaccination and the health damage will be promptly compensated. If a person who has received a vaccination included in the Immunization Act suffers from a health problem, benefits will be provided by the municipality when the Minister of MHLW certifies that the health problem is caused by the vaccination. In the certification by the Minister of MHLW, a review pertaining to the causal relationship will be conducted by the Review Board for Certification of Diseases and Disabilities composed of third parties.[87] In addition to the remedies under Article 15 of the Immunization Act, it is possible to file a claim for state compensation against the government.[88]

## CONCLUSION

In Japan, vaccinations were once required to be administered en masse. Since no remedy existed in the law for the lawful acts of public officials without negligence, the courts initially attempted to use compensation under the property rights provisions to remedy those whose lives or health were seriously damaged by vaccination. Among the academic theories, there was an opinion that Article 29(3) of the Constitution, which discusses compensation for special sacrifices of property rights, should of course be applied to violations of life and health.[89] Others argued

[85] IMMUNIZATION ACT, *supra* note 11, art.13.
[86] *Id.* art. 15.
[87] *Id.* art.15, para. 2; *see also* IMMUNIZATION ACT ENFORCEMENT ORDINANCE, *supra* note 23, art. 9.
[88] Katsuya Uga, *Yobō sesshu higai ni taisuru kyusai* [*Relief for damages caused by vaccination*], GYŌSEI HŌ NO SŌTEN [ISSUES OF ADMINISTRATIVE LAW] (Yuhikaku 2004) 162.
[89] Abe, *supra* note 79, at 208–09; Urabe, *supra* note 81, at 109.

for using the provision on the right to life in social rights or the provision on the right to pursue happiness in Article 13.[90] The law enacted by the Parliament was inadequate, and academics argue that relief for the injured existed as a new right under the Constitution.

Eventually, the Supreme Court emphasized the importance of providing relief to those injured and decided to allow claims under the State Redress Act. In line with the decision of the Supreme Court, the Vaccination Act was revised, and the vaccination was changed from a mass mandate to an individual choice. A remedy system under the Vaccination Act was added. Some academic theories consider this as an embodiment of new rights under Article 13 and social rights under Article 25 of the Constitution.

We can look to the future from our past experiences. This paper seeks to show that the experience of Japan's vaccination response and mechanisms for injury compensation may be useful for other countries.

[90] Sato, *supra* note 91, at 174; Takahashi, *supra* note 90, at 281.