COVID-19 Crisis and Japan Medical Association: Failed Prospects and Lost Presence

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The evolution of Japan's political economy has remained static, despite dynamic changes in the global landscape. In the health sector, this inertia can be traced to policy formulation driven by internal incentives and sustained by entrenched political relationships between the ruling parties and the Japan Medical Association (JMA). This study explores how evolution of institutions contributed to Japan's vulnerability and shaped its responses to the COVID-19 pandemic crisis. The JMA has historically functioned as a structural impediment to health policy innovation, exerting considerable influence over medical fee negotiations, obstructing the deregulation of medical practices, and resisting reforms in response to the fundamental challenges of demographic changes as well as global trend of economic, technological, and social shifts. This study examines the historical evolution of health policies and institutions, exploring how each stakeholder or organization responded to the incentives they face within an externally imposed set of constraints.

The JMA's stance have been clear in seeking a raise in medial service fees, and its internal governance aligns with Olson's coercive collective action theory as well as Pempel's corporatism without labor theory. Regarding external constraints, the JMA has been closely connected with welfare zoku politicians in the LDP, however, its influence has been declining particularly with the emergence of Koizumi Junichiro who is antagonistic toward special interest groups like the JMA, and the regime change to the DPJ, which disrupted these ties. Calder's circle of compensation theory primarily applies to the actions of stakeholders, but often proves more complicated than they look. The JMA further declined in power when it was reluctant to collaborate during COVD-19 crisis, contributing to Japan's inadequate response to the pandemic. Interestingly, the gridlock was broken when external players, including Somu sho and the Suga cabinet, directly intervened the healthcare management during the crisis.

I. Introduction

Japan's healthcare system has been faced significant stress due to its aging, shrinking population, and rising social welfare expenses, especially healthcare costs. The government had been revising health insurance law several times in order to fill the gaps, however, because of many stakeholders, including JMA, corporate health unions (*kenporen*), labor unions, patients, corporations, and economic organizations, any changes and/or the reform faced incredible challenges. Underlying understanding was how to better allocate fair burden sharing, as it was clear that elders' healthcare risks are higher as Japanese live longer and longer. The government expects wealthier corporate health unions to shoulder a larger portion of the burden for elderly care, even as these unions face increasing management difficulties. Although rising wages have boosted premium income, medical expenses have also surged due to the inclusion of expensive, newly approved medicines in the health insurance system. *Kenporen* are also heavily burdened of contribution to elderly care where elder's medical expenses increased 10% from previous year. As a result, overall balance turned to the red in 2023, and 23% of corporate health unions are on verge of collapse.[1]

[1] Fifteen percent of corporate health union bara greater burden for elderly insurance contributions than for their own insured members. Nikkei Shimbun, Kogaku iryo de fukuramu iryohi tsuki 1000 man yen ijo seikyu, 4 nen de 2.5 bai. October 4, 2024.

Japanese national healthcare insurance consists of employer-provided insurance (*kumiai kenko hoken*), regional insurance (*kokumin kenko hoken*), and elderly insurance (*koreisha hoken*). Health insurance scheme covers 70% and 30% out of pocket as of 2024.

With so many stakeholders involved, Chuo shakaihoken iryō kyōgikai ("chuikyō" or Central social insurance medical council) becomes a battleground of interests where the JMA, the pharmaceutical industry, payers organization, academia, and the government (welfare ministry) convene every two years to discuss and determine medical service fees. Other than fee discussions, healthcare system and policy deliberations are held at social insurance committee (*shakaihoken shingikai*), informal negotiations also took place outside these committees This study examines the actions of the JMA and its interactions with other stakeholders, exploring how these factors have contributed to the evolution of healthcare policy and the overall ability to respond to COVID-19.

II. Governing mechanisms: Who are the players and what are their incentives?

For the healthcare sector, the Ministry of welfare, Japan Medical Association (JMA), LDP politicians, health insurers, labor unions, economic federations, and healthcare-pharmaceutical industry play important roles. This paper focuses on dominant players of JMA, LDP, the Ministry of welfare. Because their motivation differs, their relationships between these players are not always constant, instead, tensions have frequently emerged. Their power balance is delicately dependent on the issues of public attention and the personnel connections at any given time. Among the payers, JMA has always been getting attention as an influential interest group.

1. JMA ~ historical path and strive to regain past glory?

The JMA's glorious memory probably rests on its early era when dignity and pride, professional freedom with appropriate profit, and influential power over policymaking were established. Since then, JMA has experienced harsh years during prewar and wartime when their professional freedom was restricted and subordinated to military and government, as well as the postwar era when various privileges are stripped away by GHQ and then the authorities leading to the establishment of the universal healthcare system. The legendary JMA chairman, Takemi Taro, emerged and led the JMA through its golden years, restoring its pride and preserving its influence and privileges. He established a robust political institution that engaged with the top LDP leaders, to realize his agendas through campaign finance, votes, and personnel connections. Nevertheless, after Takemi's era, the JMA inevitably marginalized and losing vision, with its political power further weakening as internal and external political landscapes rapidly shifted.

JMA's glorious past

In the early era, physicians in private practices had greater power over the Meiji government, as there existed majority of those physicians in private clinics and almost no public hospitals except military hospital and few university hospitals during interwar and WWII period. The government had to rely on those private physicians for social policy making, especially when introducing a health insurance system. Hōtei nihon ishikai (JMA) was therefore created by the government in 1919 as the sole contractor group to function under the new health insurance system.[2] The former medication association, Dainihon ishi-kai, was founded by Shibasaburo Kitazato et al. in 1916, and physicians already practiced under general practitioner law (ishi kaigyo shaken ho, 1876). In order to get their cooperation and not upsetting private physicians, the general practitioner law

[2] Taku Nomura, Nihon ishi-kai, Tokyo: Keiso shobo, 1976, p27

was kept intact. Although JMA members were frustrated with health insurance law (kenkō hoken ho, 1919), the JMA chairman Kitazato assured Interior Minister Ryuichiro Nagaoka that he will manage internal matter and put this through as he promised.[3] JMA leadership desired to exercise influential power over social policies, while acted as tyrannist manner within the association.

The bureaucrats carefully avoided direct full conflict with JMA, recognizing their motivation of desire to control. JMA's ultimate goal was to maximize physicians' freedom and to increase control by securing JMA's monopolistic position through being the sole institution for medical fee transactions under the health insurance system.[4] The government and JMA agreed in 1926 that medical diagnosis and treatment contract where 1) JMA to designate clinic and handle patients' treatment, 2) diagnosis areas defined from medical consultation, treatment/drugs, measures, to operations, 3) hospitalization if necessary, 4) medical fees to be paid to JMA per head-basis at the end of every month. Having JMA assigned as a gatekeeper, the government tried to keep the budget constant. In fact, the deal was not favorable to JMA members – unit price would go down when patient number increases, making the total income constant.[5]

JMA as an institution desired to exercise predominant influence over government's health-related policies, while JMA leadership was not necessarily maximizing members' benefit. JMA leadership secretly discussed with government for diagnosis and treatment contract without revealing the contents to members. In other words, JMA leadership would do anything to secure institutional political gain and power of control, but no hesitation for sacrificing members' benefit.

However, war drastically changed these privileges. As many other industry organizations impacted from war mobilizations, JMA is reorganized and its freedom and privilege were taken away and forced to follow military's order defined by People's medical service law (kokumin iryo ho, 1942). Under the law, JMA is subordinate to Ministry of Welfare, and JMA's chairman is now assigned by Cabinet with recommendation by the Minister of welfare, not by JMA leadership. Wartime government further strengthened medical mobilization in 1943 under Nihon iryōdan concept, denouncing profit-seeking medical practice and promoting totalitarian management to devote services to the nation. With this concept, physicians should be spread out to poor rural regions, not focused on cities where physicians can get wealthy patients. Physicians were expected to meet the requirement of taking 38 patients and 6 hospitalized patients per one physician, which was overwhelming target compared to prewar numbers. In this totalitarian concept, the wartime government stated that it will seek reorganized and united health system where every citizen can preserve own health by easy access (to the medical institutions), prevention (of disease) and fair treatment with no concerns, and establishing such pervasive health system is serving the best interest of nation.[6] It is interesting to know that the basic idea for Japanese health system has laid out during this period.

Of course, JMA leadership had fought against the idea of government-led medical association. When medical-drug system investigations act (Iyaku seido chosa rei) was discussed in 1940-1941, JMA leadership asked nationwide JMA local chapters to protest, stating that it fundamentally destroys JMA's preciously developed healthcare system and prevent physicians to pursue medical practices, therefore deteriorate citizens' health, while there are critical voices against JMA leadership and called for board of members' resignation, stating that we physicians should collaborate at this national crisis to strengthen citizens' health instead of going against the

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[3] Koji Asakura. Nihon iryo hoken no Keisei katei ni kansuru rekishigaku teki oyobi shakai igakuteki kosatsu. Kokumin Eisei, Vol. 28, No.2, 1959
[4] T. Nomura, p30
[5] Iki jiho No. 1681, October 22, 1926 (T. Nomura, p31)
[6] T. Nomura. Nihon iryodan kankei siryo Vol. 1, Iryo tosho shuppan: 1972

government.[7] JMA continued to fight against war government's actions but it was difficult. For example, at the 1941 renewal discussion of medical diagnosis and treatment contract, the government agreed to raise medical fees but further challenged to confiscate JMA's privileges of 1) investigating functions where determining validity of invoices from physicians is done by municipal department, not by JMA, 2) payment authorization where local municipal health department now directly pay to invoiced physicians, not via JMA, and 3) designating rights of public health certified physicians for various regional areas now done by the government. Almost 3 months of negotiations after the expiration of the contract, JMA finally accepted government proposal at the end of May 1941, and newly appointed Minister of welfare Koizumi reportedly said that it is so wrong to maintain outdated system where we now progressing to new era, and if JMA is not reorganizing itself, the government will reorganize JMA.[8]

People's medical service law (*kokumin iryō hō*) already defined public purpose for citizens by *Nihon iryodan rei* (Japan physician's group act, 1942) and making JMA to follow the same path through newly introduced *ishikai rei* (medical association's act, 1942). JMA's proposed self-reorganization was rejected by the government, and public opinion stated that Nihon iryodan and JMA should merge if there is no difference between two organizations. JMA lost its position when Nihon iryōdan chairman Ryukichi Inada concurrently sit on both organization chairs. Both organizations dissolved after WWII in 1947, and postwar JMA was re-established in 1948 but one of the core functions JMA strived to maintain was taken over by newly created *shakaihoken shinryō hōshu shiharai kikin* (social insurance diagnosis and payment fund)[9]. JMA had to let most of the privileges go during wartime and was finding its role to focus on negotiating medical service fee for the postwar period.

JMA's ideals and principles

Having had a bitter experience during prewar and wartime, the JMA's fundamental principle is ensure medical professional freedom from any systematic constraints. JMA strongly rejects the notion of a totalitarian healthcare system, managed health, and drug price controls. To them, promoting a free-market economy naturally involves raising medical service fees, dissolve the notorious Chuikyo committee, positioning physicians at the center of the healthcare system. As Takemi implied that physicians tends to think themselves as superior in knowledge and practice, and others should follow our guidance. He stated that the welfare ministry is filled with a bunch of amateur bureaucrats with no knowledge of medical treatment, as well as licensed "paper-physicians" who have never practiced.[10] Those amateurs lack the fundamental understanding of treating patient effectively with good medicines, instead prioritizing the use of cheaper alternatives without truly considering the patient's quick recovery.

(1) Resist with control and seeking for "professional freedom"

Since a legendary Taro Takemi inaugurated as the chairman in 1957, JMA gradually regained its presence and once again tried to exercise influential power over health systems and policies. JMA leaders often expressed the desire to regain their old practices through "*Jiyu shinryo,*" which allows physician to charge full medical service fees to patients for a broader range of treatment options. "Professional freedom" refers to the ability of physicians to set price more freely, which fundamentally contradicts government preference. The JMA argues that the government's policy

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[7] Kizaburo Nishi. Letter to everyone and JMA chairman Kitajima, February 4, 1941 (T. Nomura p40-41)
[8] T. Nomura. P46 (Shiryo-shu?)
[9] At the current system, independent organizations of shakaihoken shinryo hoshu shiharai kikin and kokumin kenkohoken dantai rengokai will be investigating appropriateness of each medical service invoice with diagnosis and points. These independent organizations will then send payers' organizations. See MHLW 01b.pdf (mhlw.go.jp)
[10] Takemi Taro. Jitsuroku Nihon ishikai, p127

of maintaining low medical expense is jeopardizing the healthcare system, and defending an almost collapsing system is nonsensical. The JMA has consistently fought for this professional freedom.

For example, introduction of "*danryoku joko*" in 1973 was a success of JMA. Prior to this, all premium raise for health insurance had to go through Diet discussion process through revising health insurance law (*kenko hoken ho*). However, this newly introduced clause now allows premium raise under the judgement of minister of welfare alone without going to Diet process. Furthermore, this 1973 revisions include automatic raise of the social insurance premium when payment for medical services have increased. For maintaining freedom of raising medical service fees and secure its associated government budget, Takemi always advocated maintaining flexibility clause "*danryoku joko*" in various occasions when revisions of health insurance law were discussed.

(2) Privileged tax system for physicians

Physicians has been given favorable tax conditions for the purpose of maintaining stable healthcare and management. However, all parties acknowledged that the rate was considered too high and need to be adjusted by the mid-1970s. The government Tax research committee, the MOF, and the LDP executives brought several occasions to revise the terms. Takemi agreed that this has to be revised but conditioned to revise it with healthcare system adjustments, and agreed with LDP executives to do it by 1984. Takemi proposed LDP to strengthen emergency healthcare system in return. Under the new tax rate, physicians can deduct 72% from annual insurance premium income less than 25 million yen, 70% from income between 25 million to 30 million, 62% from annual income between 30 to 40 million, 57% from annual income between 40 to 50 million, and 52% from annual income above 50 million yen. Takemi was criticized from some JMA members, but he believed that highly paid physicians should pay appropriate tax while those smaller clinics in rural areas need to be compensated[11].

(3) Resist with separating diagnosis and medication fee scheme

One of the most heavily resisted issues in the early era was the separation of medical and drugs fee scheme, a process that took 50 years to achieve only 50% of separations. The ministry submitted the separation bill (*iyaku bungyo hoan*) in 1951, facing robust opposition from the JMA, which was strongly backed by the GHQ. In response, the JMA called on its nationwide members to withdraw from the "hoken-i" scheme as a threat to the government, hoping to disrupt proper healthcare services. However, during the political turmoil surrounding General McArthur's departure from Japan, the JMA successfully inserted exception clauses that allowed physicians to prescribe medications if they deemed the patient had specific issues. The bill also mandated the welfare minister to establish a separate committee to discuss any changes to this law, and delayed implementation of the law for 2 years.[12] The watered-down bill was passed, and law was finally implemented in 1956. While ethe JMA acknowledged the necessity of future separation, it was challenging to relinquish such privileges, as physicians could profit from the difference between authorities' fixed selling price and the negotiable drug purchasing price with wholesalers. Consequently, there were widespread reports of increasing overmedication among patients, with physician's profit from drug price differences accounted for 1.3 trillion yen in 1989 -- a 25% of entire drug expenses.[13] The separation process began in 1974 when the medical service fee scheme was drastically changed to incentivize physicians to prescribe medications to external pharmacies rather than providing in-house prescriptions.[14] Since then, rising inventory costs and

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[11] Takemi Taro. Jitsuroku Nihon ishikai, p216

[12] Jiro Arioka. Nihon ishikai tsushi: Nihon ishikai sengo 50nen no ayumi. Nihon ishikai soritsu kinenshi. 1997, P28-29

[13] Yuri Okina. Iryo bungyo seisaku no hyouka to kadai. JRI review, Vol. 11, No.30, 2015, p44

[14] In 1974, the point (fee) for physician's prescribing drugs at external pharmacy jumped from 6 points (60 yen) to 50 points (500 yen), and hospitals also earn additional points regardless of in-house or pharmacy prescriptions. See Okina. P49-50.

increased medical service fees prompted physicians to begin separating diagnosis and drug prescriptions. It took nearly 40 years to achieve a separation rate of 70% by 2012, up from zero in 1974. There are several ways in which the JMA influence healthcare policies:

1) **Through strikes and boycotts**
JMA has utilized various forms of protest, including boycotts from various committees and strikes, to influence healthcare policy, resulting in significant nationwide movements. Massive strikes by physicians occurred during the 1960s and 1970s, Notably, at July 1971 protest, the JMA threatened to withdraw physicians from "hoken-i" health insurance system, exerting pressure on payers, patients, and municipals. According to the JMA, approximately 71,000 physicians -- 83.9% of JMA members[15] -- participated in this month-long protest. At a 1973 meeting, the JMA called on LDP members to either dissolve the Central Social Insurance Medical Council (Chuikyo) or modernize it, They also advocated for a sliding scale system for medical service fees, where fee increases would automatically adjust for inflation.[16] Although the LDP did not dissolve Chuikyo, partially implemented a sliding scale payment scheme.

2) **JMA's impact worked by scattering JMA members in various committees and send representatives to Diet**
In the very heated negotiation year of 1984, JMA, JDA, and pharmacist organization signed an MOU about what LDP acknowledged and do best as it can to achieve. LDP is incorporating JMA's principal into the MOU that the LDP will 1) achieve unified health insurance system in 5 years, to consider fair burden and payment balance; 2) match with health insurance system and advancing medical and healthcare treatment; 3) respect "professional freedom" and acknowledge public nature of healthcare; 4) provide appropriate evaluation of medical skills conducted within the health insurance scheme; 5) separate labor management and social insurance; 6) stabilize private healthcare institution's management; and 7) provide sufficient public support for medical research in universities. The MOU was signed by all LDP executives of vice president, kanjicho, soumukaicho, seimu chosa kaicho, and 3 medical association chairmen[17]. This is obviously LDP's return for campaign finance.

3) **Find the key persons in the LDP and direct plea ~ Nakagawa Hidenao & Yosano Kaoru**
The JMA had been closely discussing matters with LDP executives, welfare zoku politicians However, PM Koizumi changed the long-lived protocol of JMA's building consensus from bottom-up via committees, internal discussions, through campaign finance. Under Koizumi, the healthcare policy can be changed by top-down decisions regardless of prior consensus. For the first time, Koizumi cut "sacred" healthcare expenses as well as reduced medical service fees for FY 2002. The locus of health policy determination has moved from committees to the Cabinet.

4) **Send institutionally-backed candidate to the Diet**
While it is uncertain if the LDP leaders would accommodate JMA's demand, the JMA had been fully engaged in elections by dispatching chiefs of staff from various branches of JMA's political organization Japan Medical League (*Nihon ishi renmei*) to support particular candidates. The league's mission explicitly stated since 2002 that "support the ruling political

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[15] When a physician is no longer "hoken-I," then a patient cannot get insurance coverage and has to pay 100% of medical fees. According to JMA, it ended up with total of 72,000 physicians, almost 100% of A members (in private clinics), filed the "hoken-i" resignation to local municipals and that is accounted to 61% of entire physicians of 118,000. See JMA. Sengo 50nen no Ayumi. P120

[16] Agenda for "Jiminto gekirei kouteki riko yokyu zenkokuishi taikai" at Tokyo Kudan Kaikan, Octobr 16, 1973 (T. Nomura, p79-80)

[17] Koseisho hoken kyoku. Iryohoken seido 59nen daikaisei no kiseki totenbo. Nenkin kenkyujo. December 1985, p154-155

party, which is the LDP."[18] For example, Ibaragi prefectural medical league (*Ibaragiken ishi renmei*) had heavily involved in supporting LDP politician Niwa Yuya, who once culminated to the welfare minister, for 10 election terms until 2008. Interestingly, the league had never considered the possibility of LDP not being the ruling party until 2009 when Ibaragi medical league supported a DPJ candidate against headquarters' disapproval. LDP health giant Niwa lost his seat for the first time and the regime changed from LDP to DPJ. Ibaragi league stopped supporting Niwa because of his arrogance and frustration with LDP's decision to pass unpopular elder medical healthcare insurance bill against their plea. Even if the number is minimum, having institutionally backed LDP Diet members present on the floors serves as visible collateral JMA can count on.

2. **Payers' organizations:** kenko hoken kumiai rengokai ("kenporen" or health insurance cooperative association) and others

Payers like kenko hoken kumiai rengokai ("kenporen" or health insurance cooperative association) often criticize JMA's aggressive actions, presented itself as a system savior against "evil" players. Kenporen is collecting premium from big corporate members and handle healthcare payment of member employees. Kenporen is supported by big corporations and Nikkeiren (economic federation), as well as welfare ministry bureaucrats as they go work for kenporen after their retirement. Labor unions and capitalists usually against each other, but when it comes to kenporen, they are collaborative. They provide more testing options and different coverage compared to national health insurance subscribers. Kenporen is also a member of the Chuikyo committee, which determine medical service fee every two years. This committee has always been a battle ground for healthcare stakeholders.

The conditions and service fees should be determined at a fair representation of stake holders, Chuo shakaihoken iryō kyōgikai ("chuikyō" or Central social insurance medical council)[19] was created in 1950 and is a legally defined advisory committee to discuss various healthcare related issues. At its founding of Chuikyo, there were four categories of stakeholders represented for 6 persons each, total 24 persons representing payers, patients, providers and public interest. Chuikyo went through several reorganizations, categories and the number of JMA representatives has been gradually reduced due to frictions and scandal[20] (see table 1).

Table 1. Chuikyo's "fair" representation of stakeholders

	Payers	Public interest	Providers	Others
1950 (total 24)	Seaman's insurance, health insurance, national insurance (total 6)	Public interest (total 6)	Physicians, dentists, pharmacists (total 6)	"Insured & business owners" insured, corporate owners, ship owners (total 6)
1961 (total 20)	Social insurance agency, kenporen, Sohyo, Zenro, seaman's union, corporate owners, ship owners (total 8)	Public interest (4)	**JMA (5)**, Japan dentist assoc (2), pharmacist assoc (1) (Total 8)	

[18] The Japan medical league's webpage today no longer have that mission stated. Tatsuno. P28

[19] During initial years of 1925-1942, JMA contracted out from the government to pay fees to physicians when invoiced per head of patient. After the revised health insurance law in 1942 and the government consolidated various insurance schemes, kenkō hoken shinryō hōshu santei kyōgikai was established as an advisory committee and applied workers fixed contribution payment method. One of the reasons of changing per head to fixed method was that they were tired of JMA's prolonged annual negotiations regarding this issue. Point-basis (itten tanka) fees are determined by the Ministry of Welfare, after hearing opinions from JMA and Japan Dentist Association. The Chuikyo was established in 1944 as an advisory committee for this determination. At the 1947 revised health insurance law, Chuikyo has become the legal advisory committee for determining point basis fees.

[20] Chuikyo member was arrested regarding bribery of dentist service fee (Nisshirn oshoku jiken) in April 2004, resulted in Chikyo reform in July 2005. The number of members at Chuikyo stakeholders' groups have changed.

2006 (total 20: 8-4-8-(10))- *From 2007 on, revised # of members (total 20: 7-6-7- (10))	Social insurance agency, kenporen, Rengo (life & patient sections, 2), Kidanren, seamen's union, Shosen mitsui corp., Sakaide mayor (Kagawa) (total 8)	Professors from Waseda Univ., Gakushuin Univ., Kanagawa hoken-fukushi univ., Waseda Univ graduate school (total 4)	**JMA (3),** Japan hospital assoc, National hospital rnmi, dentist assoc (2), pharmacist (total 8)	"Specialists" Itakura mayor (Gunma), National longevity health center, Asteras pharma, Takeda, Mediseo holdings, Asahi kasei medical J&J, Muto inc., Nurse assoc, Teizukayama univ. (total 10)
2023 (total 20+10) Maximum of 10 specialists are appointed only when necessary	Health insurance, kenporen, Rengo (life & patient sections, 2), Keidanren, seamen's union, Suzuka city mayor (total 7)	Professors from Keio, Tokyo univ, Hitotsubashi univ., Yokohama univ, Ochanomizu univ. (total 6)	**JMA (3),** Japan chronical disease associ, hospital associ, dentist associ, pharmacist associ (total 7)	"Specialists" (total 10) Nagano mayor, nurse association, team medical, dentist rehab, Eizai, Shionogi, Baitaru S.K. holding, Toray, Edwards life scince, Maruki ikakiki

Source: T. Nomura. P68-69, Chuo shakaihoken iryo kyogikai iin meibo. November 8, 2023; June 20, 2006. Ministry of Health Labor, and Welfare

JMA had always been attacking payers' organizations and dislike the setting where other stakeholder has a say, The chuikyo battleground always sparked. Chuikyo meetings were understood as the place for "democratic" discussions with various stakeholders, while JMA acted to advance its own interest and directly dealt with LDP politicians to bypass the bureaucracy and Chuikyo.

Players like kenporen not always necessarily represent patients' interest. Even though there included some unpreferable items, Kenporen supported the revision of 1973 health insurance law, because it included 10% government subsidies to payers' organizations and increase of family member coverage rate, so that it is "fair burden sharing"[21] for patients and payers despite the raise as it is to match with inflation. Kenporen also kept quiet about "danryoku joko" JMA insisted, which was critically disadvantageous clause for patients. Payers' organizations embraced fully of this government's proposal of revisions, as they ultimately prioritize their gain of subsidies rather than patient's gain. The question is if Chuikyo has been really providing "fair" representation of stakeholders since 1961, as there is no clear representation of general citizens' perspective. if payers' organizations are seeking their own organizational merit.

Kenporen also protested in January 1965 when the welfare minister Kanda issued ex-officio notice for increase of medical service fee without final agreement at Chuikyo. Seven members of payers' organizations all resigned, and some kenporen members filed a case claiming that notice is invalid at Tokyo district court, which in turn announced to hold the raise until the case is resolved. The government, LDP, seven kenpo organizations met and in return of mediation plan, the kenporen withdrew the case. Two welfare ministry bureaucrats and the welfare minister resigned, and since then the welfare ministry implicitly blamed of losing able bureaucrats to JMA who were behind the ex-officio notice.

The Chuikyo had been criticized for non-transparent decision making for medical service fees, and the 2004 scandal made Chuikyo to change its rules and to taken away some core privileges. Major changes are 1) medical service fee rate change is determined by the Cabinet, 2) basic principle for determining service fee points are decided by health insurance and healthcare chapters under the social security committee (shakai hosho shingikai), 3) add patient representatives to payer group and hospital representatives to provider group, 4) increase public interest members and reduce one from payer's and provider's groups respectively, 5) create public hearing opportunity to get citizen's opinions, and 6) add evaluation section within Chuikyo to assess appropriateness of the service fee revisions.

[21] Kenko hoken Shimbun. February 1st and March 1st, 1973 (T. Nomura, p76-77)

It is interesting case where labor unions had collaboration with JMA in 1951. It was the time during Korean war, and the government had to allocate budget for newly created self-defense force, and therefore cut the social security and health expenses. Labor unions, JMA, and other organizations mobilized resources to resist such budget cut, protested against raising health insurance premium, patient's burden on health costs. While kenporen said no need to raise medical service fees, JMA insisted to raise it that physicians are suffering from inflationary economy. JMA also demanded reducing tax and eliminating restricted practices for "hokn-i" registered physicians.[22] Together with Sohyo and agricultural associations, JMA established "social insurance and healthcare for people" movement. Even though mass resignation of registered physicians spread from Kyoto, Osaka, Tokyo and to nationwide, JMA members were dissatisfied with the compromised medical service fee and JMA chairman resigned.[23]

3. The Ministry of Welfare (reorganized into Ministry of Health, Labor, and Welfare in 2001) and the Ministry of Finance

The Ministry of welfare had jurisdiction over administrative guidance and/or orders related to healthcare, including JMA, dentist association, hospitals, clinics, and physicians. The Ministry's ideal is managed healthcare, and had mostly been taking position against JMA's proposals, as the ministry aimed to reduce and control healthcare expenses. When establishing universal healthcare system, the ministry looked to the British model for determining healthcare expenses, where a general practitioner covers a specific area, and healthcare fees are calculated on the basis of the number of residents.

Based on the principle of manage and control with less costs, the ministry introduced several restrictions. First, the ministry required all physicians and clinics/hospitals to register, and the government won't be paying medical service fee without matched pre-registered clinic-physician pair. Secondly, the ministry introduced a new fee schedule to separate physicians' medical service skill from the use of equipment, testing and medications, despite strongly resistance from the JMA. The pre-existed fee schedule prior to universal healthcare was comprehensive, bundling all testing, prescriptions, and diagnosis into one. The ministry desired to address inefficiencies and overmedication under the new fee schedule to reduce expenses, but JMA resisted and continued to have their version of fee schedule. Furthermore, the ministry tried to restrict physicians income level through setting maximum number of patients by specialties, allocating appropriate numbers of registered "hoken-i" physicians based on the number of anticipated patients, and having cap for number of shots and volume of medications. However, those restricting ordinances were overturned by JMA.

The ministry administers healthcare-related realm with at least 16 committees, including social insurance committee (*shakai hosho shingikai,* est. 2001)[24] to discuss basic principles/policies of social security, social insurance system, and related issues of demographic changes. At least one JMA member is present at all health-related committees among capacity of 30 committee members each. Other than JMA, committee members include academia, hospital association, nurse association, insurers, payer's organization, labor unions, and economic federations, In other words, JMA members are present at every policy discussion and involved in medical service fee

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[22] In order to qualify payment from health insurance system, physicians have to be registered and approved by the Ministry of welfare.

[23] Nihon ishikai sengo 50nen no Ayumi. P30-32

[24] Social insurance committee has two sections of healthcare (iryo bukai) and health insurance (iryohoken bukai), where one JMA and one JDA are present among other representatives from nonprofit, hospital, labor union, economic entity, academia among 21 members (as of September 2024). See MHLW. Shakai hosho shingikai iryohoken bukai iin meibo. 183th meeting memo shiryo. September 30, 2024.

decision-making processes. The ministry recognized that healthcare policies would be unrealistic without the cooperation of physicians, but at the same time, it maintained its stance of not aligning with the JMA's interests in securing benefits for private practitioners.

The ministry of finance (MOF) budget bureau (*shukei kyoku*) is also involved with the process of determining medical service fee. The informal consultation between MOF budget bureau chief and MHLW insurance bureau (*hoken kyoku*) chief starts in the spring of odd years and continues throughout the year. MHLW gather statistics of personnel cost, medical product and material fees, drug costs from healthcare economic surveys and wholesaler's income statements, combined with macro-economic index and estimates of healthcare provider's' income to rebut JMA's argument. They consult healthcare policies, and it's close allies are payers organization like kenporen and MOF budget bureau (*shukei kyoku*). Those entities aim for reducing healthcare and medical costs, as their premium income is limited.

This alliance has always been belligerent to JMA-LDP zoku politician alliance. The ministry serves as a part of secretariat of Chuikyo committee, and aimed to have various opinions and therefore preferred representatives from various groups with different perspectives. However, obviously JMA did not like that stance. For example, in 1958 when the ministry recommended to have one physician represented directly from hospital association for Chuikyo, JMA insisted that Chuikyo's physician members must be recommended by JMA. Takemi got really angry, and he made JMA members boycott from the Chuikyo for a couple of years. For Takemi, medical service fee discussion was important, but securing JMA's institution was also very important.

4. LDP and Ruling party

The liberal democratic party (LDP) has been strong partner of JMA, whose political organizations have been major contributors to LDP campaign financing, votes, and election staff support. It was reported that the JMA mobilized 1.28 million votes at the 1977 upper house election, but by 2010 this figure was down to 200,000 votes[25]. For the LDP, reduction in number of institutional votes means a decreased incentive to offer favor to JMA. Clinging to the LDP in an effort to maintain influence, the JMA continues to ensure full backing for two LDP Diet members. One prominent example today is Jimi Hanako, a rising LDP star and healthcare expert, who received total 234 million yen in 2022 from all national-local levels of Japan Medical League (*Nihon ishi renmei)* and the Association for thinking about national health (*kokumin iryo o kangaeru kai)*.[26]

Historically JMA has been substantially contributing to the LDP. In case of 1984, among JMA's total 1250 million yen political contribution, 840 million or a 70% went to LDP. For LDP, among 13.24 trillion yen received in 1984, JMA was the largest donor 6.3%, if include Japan dentist association (JDA)'s 340 million, total 8.9% of total amount received was from medical affiliated organizations.[27] With the sheer amount of JMA's political contributions to LDP, JMA asks LDP members to be present at Japan medical league's periodical meetings how to advance their agenda. LDP party members acknowledge such agenda, however, not always incorporated into healthcare bills even though JMA chairmen have close personnel connections with core LDP party executives.

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[25] A staff of Ibaragi league of physicians stated no longer mobilize institutional votes, but can impact to public if local JMA is supporting a particular candidate. See Tetsuro Tatsuno. Yuganda ken-i. p67-68

[26] Tokyo Shimbun. Rensai5 "iryo no nedan". December 12, 2023

[27] Innan Kazumichi. Health Policy Making through the struggle of political networks – the reform of Health Insurance Acts in 1984. Nihon seiyaku kogyokai. September, 1990. P47

Table 2. JMA's political contributions toward LDP (million yen)

	1984	1998	2002	2005	2008	2012	2023
Party tickets etc.	na	na	114.6	71.3	68.4	na	56.3
Donation	840	624	672	565.5	475.4	50*	463.4
Total			766.6	636.8	543.7		519.7

*LDP was not a part of the ruling government during 2009-2012, and this figure is only donations to the LDP's kokumin seiji kyokai and it does not include donations to individual LDP politicians. Sources: Innan Kazumichi. Health Policy Making through the struggle of political networks – the reform of Health Insurance Acts in 1984. Nihon seiyaku kogyokai. September, 1990. P47; Tatsumi Tetsuro. Yuganda ken-i – Nihon ishikai. Tokyo: Iyaku Keizai-sha. 2010, p150; Tokyo Shimbun. Rensai5 "iryo no nedan". December 12, 2023. Benoit Leduc. The Anatomy of the Welfare-zoku. Pacific affairs. Winter 2003/2004. P579-182

During Takemi years, JMA and the LDP had very close relationship. Takemi knew physicians would need more medical facilities and advanced testing equipment to prevent medical malpractices, but could not afford to finance them on their own. When Takemi ground worked to establish healthcare financial public corporation in 1960, the MOF was against the idea, because many other industries demanded their own financial corporations to lend money at a lower rate. LDP vice president Ohno Banboku tried to persuade Takemi to give up that idea, but Takemi fought back by telling Ohno that he cannot tell JMA members to vote for LDP without financial corporation.[28] Ohno immediately went back to the minister of finance and established the corporation in 1960. Takemi was very skilled negotiator towards LDP executives and occasionally threatened to achieve his objective through power of JMA votes.

Change in the JMA-LDP relationship was evident in Junichiro Koizumi years. Prime minister Koizumi was a unusual LDP leader for advocating drastic reform for the areas of public works, postal service, and healthcare. Koizumi specifically chosen them because he saw collusion of zoku politicians and interest groups are affecting inefficiencies of such areas. Koizumi tried to link healthcare cost increase with GDP growth, though such idea did not materialize. Struggling with deflation and fiscal budget crisis, Koizumi proceeded with equal burden sharing: patients' out of pocket rate has increased from 20% to 30%, physicians and medical service fees went negative, drug price was lowered, and payers and corporate premium was increased. JMA protested that clinics will not sustainable, but LDP members were more concerned with how constituents perceive such burden increase rather than JMA's claims.[29] For 2004 medical service fee negotiation, JMA pushed the LDP executive by threatening to pull of from 2004 upper house election support, and brought the number from negative to zero increase. Nevertheless, 2006 figure again went negative as Koizumi and the cabinet intervened the medical service fee determination process. During Koizumi years, JMA was vulnerable as usual JMA-LDP zoku politician push did not work and accepted humiliating negative growth on medical service fees. These fee reductions dealt a heavy body blow to healthcare institutions, putting them in difficult situations. Consequently, widespread reports in the media highlighted physician demotivation, hospital bankruptcies, and chronical staff shortage.

2009 regime change also drastically changed the scenes. Because JMA had embraced with the LDP for such a long time, they did not understand what it is mean for JMA to continue supporting LDP candidate under DPJ administration. The JMA leadership apologized members for not being able to shift away from LDP regarding the 2009 general election. While deleting the "support LDP" clause from the league's mission, members first agreed to keep supporting LDP candidate Nishijima Hidetoshi for 2010 upper house election, which obviously invited DPJ's antagonistic action towards JMA. Fearing of further distancing from the DPJ government, the JMA leadership announced to

[28] Takemi Taro. Jitsuroku Nihon ishikai, p82-83

[29] John C. Campbell and Yasuo Takagi. The political economy of the fee schedule in Japan. Chapter six. Naoki Ikegami ed. Universal health coverage for inclusive and sustainable development. Tokyo: JCIE. 2014, P151

support three candidates including both LDP and DPJ candidates to satisfy various group members, but no one was being elected as divided votes were insufficient. DPJ administration rejected to meet any representatives from JMA and harassed JMA in various occasions.[30]

During the DPJ's time in power, the JMA struggled to build a strong political relationship with DPJ executives, however, the DPJ recognized healthcare deterioration caused by consecutive fee reductions. The DPJ administration placed healthcare as a key issue on their manifest, ultimately led to increase in medical service fees first time since 2002. The major difference from the LDP administration was that the DPJ prioritized hospitals over private clinics, setting unified re-diagnosis fee for both hospitals and private clinics. Previously clinic re-diagnosis fees were set approximately 20% higher than hospitals. DPJ government also put greater emphasis on acute care at hospitals, which led to a 400 billion yen increase in income for hospitals.[31] In the following 2012 discussion, JMA did not have strong objection when the DPJ government further prioritized hospitals for supporting pediatrics and obstetrics, advanced medicine, and working physicians' environment.

While it is beneficial for the LDP to receive significant financial support and votes from the JMA, showing explicit favoritism towards the JMA is controversial, as it draws public scrutiny. When Aso Taro's faction received total 50 million donation in 2021 from JMA affiliated political organizations, Aso Taro was reluctant to accept JMA's demand for medical service fee increase.[32]

II. Internal governance of JMA ~ why physicians join JMA?

JMA has been a unique organization among interest groups that had been serving physician's interest, while membership is declining rapidly. It is critical for JMA to maintain the sheer size of membership to exercise influential political power. Over the time, raise in medical service fees physician's interest, why physicians are departing from JMA? Would benefit not enough to keep them in the JMA?

Table 3. Composition and Membership number declines

	1955	1980	2001	2014	2022
Private Practitioner (clinic owners, A-1)	(52299)*	(70393)*	52.3% (81436)	50.4%	47.6% (82,726)
Employed physicians (hospitals: A-2)	(24882)*	(53543)*	20.9% (32668)	23.6%	25.3%
Trainees (B)	-	-	25.8% (40201)	25.9%	26.7%
Total members			155662	166121	173761
Nationwide number of physicians	94563	156235	248611 (62%)	311205 (53%)	343275 (50%)

*these figures are not membership number, they are total number of medical doctors. Sources: JMA annual reports, JMA statistics, MHLW Physician, Dentist, Pharmacist statistics

Who are the JMA members?

In the 1950s, the majority of physicians were members of the JMA, but by 2024, only 50% of the nation's 343,275 physicians were members. Historically, private practitioners who ran clinics dominated the JMA, but today employed physicians are becoming the majority.

[30] Tatsuno. P298-300
[31] Asahi Shimbun. December 26, 2009. P6
[32] Nihon ishikai no seijidantai ga Aso-ha ni irei no Kogaku kenkin. Tokyo Shimbun. March 17, 2023

Concerned about declining membership, the JMA has introduced discounted membership fees for young physicians, but regaining its former size will be challenging.

JMA membership fees are expensive. Memberships are divided into three main categories. A-1 membership is for clinic owners or heads of hospitals, with annual fee of 126,000 yen; A-2 membership is for those employed at hospitals or clinics, with annual fee of 64,000 yen; and B membership is for trainees. A-1 members have historically dominated the JMA, but their numbers are steadily declining. Currently 83.8% of A-1 members are clinic owners.[33] Meanwhile, trainees primarily work at hospitals, leading to a situation where the combined number of A-2 and B members now exceeds that of A-1 members. Increasing membership is crucial for generating income, for example, 82,726 A-1 members alone could contribute 10.4 billion yen to JMA's annual fee income. However, because the JMA leadership is predominantly composed of clinic owners, there is a tendency to prioritize interest of clinic owners over those of employed physicians.

If a member aspires to obtain an executive position within the JMA, he must dedicate a significant amount of time to committee discussions, conferences, lobbying activities, and coordination activities. As a result, they need to arrange for someone to manage their clinic in their absence. Often, their sons or daughters take over the daily operations, but without the family's commitment, this transition can be challenging. To be elected as the JMA chairman, he must be elected as the head of a regional medical association and gather political support from other regional leaders. JMA members have high expectation for an increase in medical service fees, and the JMA chairman is expected to negotiate better terms with other stakeholders to secure favorable increase, otherwise he may not be re-elected for another term.

What do members expect from JMA?

Legendary JMA chairman Takemi Taro portrayed himself as a strong leader, gaining popularity for his bold stance in confronting the government and advancing physicians' interests, particularly in securing material benefits. Takemi's 25-year tenure as JMA chairman was marked by his ability to demonstrate results, which ensured his long-term leadership. While not all JMA member seek aggressive increase in medical service fees, they do care about income growth, and many base their vote for chairman on the outcomes. For example, JMA chairman Nakagawa Toshio, who serviced from 2021 to 2022, chose not to run for a second term after failing to secure a significant fee increase, leading to member dissatisfaction. Nakagawa had initially won the presidency by criticizing his predecessor, Yokokura, for being too conciliatory with the LDP, promising a tougher stance. However, Nakagawa lacked the necessary connections to negotiate effectively with the LDP. His successor, Matsumoto, managed to secure a modest fee increase, which he highlighted as an achievement.

Member's incentive to join the JMA

Even though JMA membership fees are quite expensive, some physicians still see value in joining. A pediatrician who opened his own clinic in Chiba city[34] explains that the information provided by the JMA on daily and weekly basis, as well as access to vaccine allocations, is very beneficial. He is required to join three levels of JMA branches – national, prefectural, and city -- paying total of 420,000 yen per year. In return, he benefit from 1) weekly updates via fax on

[33] JMA. Annual report 2022-2023. Chapter VIII JMA data.
[34] Tadashi Matsunaga. Kanyu shitara jiminto ohen? Ishikai no shirarezaru uragawa. Toyo Keizai online. January 23, 2023 https://toyokeizai.net/articles/-/645469

healthcare news, including guidance for new physicians and where to get supplies, 2) real-time updates through a mailing list about local medical conditions, such as influenza, pneumonia, or any emerging diseases, which he uses in his own diagnoses, and 3) opportunities for consultation and knowledge exchange with other physicians regarding treatment and diagnosis.

However, there are also obligations tied to being a JMA member, such as volunteering at local JMA meetings, which can be time-consuming and burdensome. Some of his physician colleagues are reluctant to join due to these commitments. Younger physicians, in particular, dislike the old-fashioned leadership style, where senior JMA executives sometimes overturn decisions already made by local members. He also felt pressured to take turns for "toban" doctor, filling part-time at other clinics or hospitals. When he declined due to his medical reasons, he faced criticism from other JMA members for not fulfilling his duties.

While some of his colleagues choose not to join, he feels he has no choice. The local municipal government consigns children's vaccination program to the local JMA, so if he is not a member, he may not have the opportunity to secure vaccines – a significant portion of his income as a pediatrician depends on this. Since vaccine distribution is controlled by the local JMA, some pediatric clinics have complained that vaccines should be distributed regardless of JMA membership. However, this does not appear to be the case. Therefore, all pediatricians must join the JMA.

Other incentives for physicians include the medical pension system and optional liability insurance. In the past, there was a stronger pressure and obligations for physicians to join, but this trend has diminished as fewer physicians choose to participate when faced with increasing obligations.

Oppressive Internal Governance in the past

The relationship between JMA leadership and its members has always been hierarchical, with the leadership often treating members in an oppressive manner. During prewar and wartime, the JMA was pressured to reorganize, further strengthening the top-down structure of its headquarters and prefectural chapters in line with government-led mobilizations. This approach continued into the postwar era. In the 1970s, physicians who did not join the JMA were harassed and pressured to become members.[35] The JMA was such a powerful organization that forced nearly every physician to join, or they would face unfavorable treatment in various administrative processes.

There seems to be a big divide between the JMA leadership and its general members. Pemple's concept of "corporatism without labor" aptly describes the relationship between JMA management and majority of its general members. While the JMA executives dominated healthcare policymaking discussions with the LDP, general members were marginalized and left uninformed about how their membership fee were being used. To fund large political donations to the LDP, the JMA rather forcefully collected an extra 5,000 yen from its members. In an open letter to the JMA leadership, a physician from Kobe expressed his refusal to contribute, citing the lack of transparency about how money was being used. He stated that if the funds were being allocated to political campaigns aimed at maintaining high level of medical service fees, he would strongly protest it.[36] General member physicians were largely kept in dark, with leaders keeping negotiations with the LDP secret.

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[35] T. Nomura, p14-15
[36] Hyogo hoken-i Shimbun. August 20, 1973. (Nomura p81)

Why do members continue to stay despite being treated so poorly? For many, it's a matter of avoiding potential harm to their businesses, as they've witnessed harassment directed at those who did not join. The coercive nature of the organization made leaving the JMA a less desirable option, as the consequences of doing so often outweigh the benefits. This aligns with Olson's collective action theory, which suggests that the cost of not participating becomes higher than the cost of membership, compelling members to cooperate. To ensure the system functions as intended, JMA elections select regional leaders from various regional blocs, with the central leadership prioritizing candidates who are obedient or convenient to the current leadership, regardless of abilities.[37]

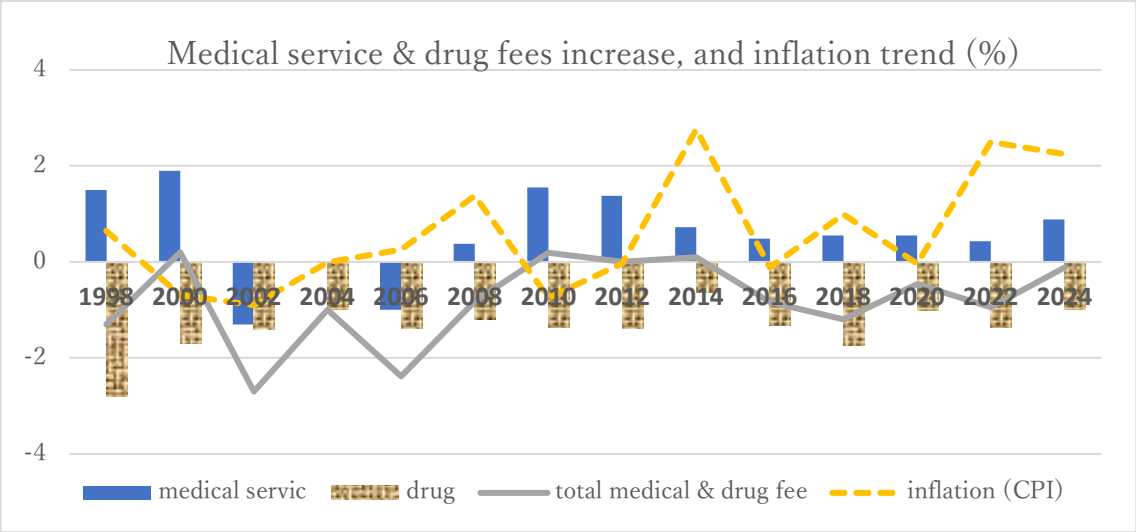
JMA's internal fights for presidential elections

Raising medical service fees raise has been a visible outcome for maintaining power. JMA leadership focuses on controlling the bi-annual negotiations of service fees for physicians, dentists, and pharmacists, ensuring benefits are allocated among its members. There has generally been a positive increase in service fees for physicians, while drug fees, which directly affect pharmaceutical companies, have mostly been set lower. JMA faced challenges between 2002 and 2006 when Prime Minister Koizumi Junichiro was in power, but managed to secure positive growth even during a deflationary economic period (see figure 1). Despite being the leader of the LDP, Koizumi advocated for cutting collusive ties with interest groups, including the JMA.

Except the powerful Takemi Taro years, the JMA has a long history of internal power struggles over the presidency, often driven by competition between Tokyo and Osaka reginal groups. Presidential elections, held every two years, focus on a candidate's ability to secure favorable increases in medical service fees. If a president fails to deliver, they are heavily criticized and often forced out. Rival candidates frequently challenge each other over their personal connections with LDP executives, as the JMAs close ties with the party are seen as essential for advancing members' interests. All the JMA presidential elections are determined not by policy discussions, but by personnel connections and power plays among faction groups. The focus is on building ties with ruling political parties, rather than addressing challenges facing Japan's healthcare system.

[37] Hyogo hoken-i Shimbun. March 5, 1973 (Nomura p84)

Figure 1. Higher medical service fees to secure chairmanship



Source: Ministry of health, labor and welfare white papers, shiryo, IMF World economic outlook database 2024

JMA leadership overlaps with the Japan Medical League (JML), a political organization of JMA. Because JML had been embraced to the LDP, JMA leadership faced challenges during the regime change in 2009. Even though the prospect of LDP's win was unlikely at the eve of 2009 general election, the JML persistently supported LDP candidates while criticizing DPJ's social healthcare policies. This action would put the JMA a severe position if JMA continues to advance its political agenda at a new political environment. The chairman Karasawa admitted on October 20 meeting that he lacked effort towards other political parties to understand JMA's stances and healthcare policies and failed to judge its course change due to long-standing relationship with the LDP. JMA members agreed to delete the first item of the mission "support the ruling party, the LDP" as no longer matched to the current situation.[38] However, members agreed to continue supporting LDP candidate at next upper house election. DPJ's revenge started right after this meeting. DPJ minister of welfare replaced 3 JMA members of Chuikyo with one academia, one hospital president, and Ibaragi medical league executive who supported a DPJ candidate at the election.[39] JMA protested but could not do much except asking the Ibaragi medical league to ask talking to DPJ leadership for generous consideration for medical service fee discussion at the end of 2009. Chuikyo came up with a slight increase in medical service fee, but changed the all re-examination fee to set as the same points where previously clinics were set higher than hospital. Obviously JMA leaders were furious as such revision means downgrading clinic owners' profit.

III. Fundamental of Japan's Healthcare Challenges

While Japan achieved Universal Healthcare (1961), longevity of life expectancy and equal access to medical institutions, ongoing inefficiencies persist. The fundamental issue is exponentially increasing medical/healthcare costs while government debt is also rising. The

[38] Tatsuno Tetsuro. P297
[39] Tatsuno. P300-301

government also has been tried suppress healthcare costs, and introduced elder insurance schemes, however, structural inefficiency is causing increased hospital bankruptcies.

1. **Healthcare system reform**

Universal healthcare system

In 1957 the ministry introduced the double registration system (nijuu shitei) for physicians and clinics, in anticipation of the forthcoming universal health system. The purpose was twofold: first, to prevent fraud or inflated billing from non-existed physicians from registered clinics and physicians from non-registered clinics, and second, the government sought to create a managed system, similar to a nationalized health system, but at a lower cost.[40] Takemi of JMA protested that it is absurd that physicians who have already acquired national qualifications cannot send invoice to health insurance system without such registrations. The government also intended to revoke the registration from clinics that have mal practices. Since the bill was already passed, Takemi pushed for modifications to the cabinet and ministry ordinances before their implementation, successfully eliminating restrictions such as daily limits on patient visits, prescription caps, and the required number of physicians based on average patient numbers.

The welfare ministry proposed two-fee-schedule method or "kou" and "otsu," as JMA fiercely protested to have new pricing system and insisted to keep previous one. The "kou" fee schedule was mainly targeting hospitals for clear separation of physician's skills from medical equipment/testing/drugs, and 2) "otsu" fee schedule was comprehensive fee schedule which JMA insisted to maintain. Chuikyo committee member Kanzaki San'eki, who was also vice chairman of Japan hospital association, supported the "kou" schedule, while JMA, primarily representing the interests of private clinics, opposed the "kou" schedule. JMA was outraged by Kanzaki's stance, especially since he was also a JMA board member and demanded his resignation from Chuikyo but he did not.[41] With the "kou" fee schedule, the welfare ministry aimed to reduce the income of physicians who overprescribed treatments or medications. JMA members were not even satisfied with the new "otsu" proposal JMA submitted as the increase of medical service fee was minimum. JMA chairman Takemi saw this as a tactic of the ministry for intentionally dividing JMA into two camps. Takemi directly negotiated with the welfare minister Hashimoto Ryugo to include economic indicator to "otsu" fee schedule, which welfare ministry bureaucrat were furious as such inclusion increases income of clinics. JMA recommended "otsu" schedule for its members, while the ministry recommended "kou" schedule for public hospitals though utilization rate declined from 10% in 1958 to 6% by 1980.[42]

JMA obviously did not like the Chuikyo setting where all stakeholders discuss matters as JMA's narrowly defined perspectives were often marginalized. JMA stopped sending JMA representative to Chuikyo in 1959, boycotting meetings at several occasions, and started to demand dissolution of Chuikyo.

While demanding privileges to be kept, Takemi sought to change the underlying concept of health insurance system, which still carried prewar authoritarian ideas. He called for the elimination of restrictions on medical care and organized a nationwide physicians' strike on Sunday, February 19, 1961, with 20,000 private physicians -- 40% of the total -- participated. Takemi stated that he wanted all workers who are affiliated in healthcare to think about how to improve comprehensive

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[40] A welfare ministry bureaucrat Koyama Shinjiro commented that having nationalized health system is expensive as the government has to hire physicians, but this double registration system can have a similar impact. See Takemi Taro. Jitsuroku Nihon ishikai. Tokyo: Asahi shuppansha, 1983, p58

[41] The ministry of welfare asked Kanzaki to not to resign. JMA. Sengo 50 nen no Ayumi. P58

[42] Takemi Taro. Jitsuroku Nihon ishikai. P72

health, so that the system can be sustainable, while majority of JMA members desired increase of medical service fee instead of such principles.[43] Takemi's basic stance was to secure "professional freedom" ensuring that physicians could use their discretion to provide the best care for patients, regardless of ministry's protocols. He opposed the idea of authorities placing caps on medications simply because they were not covered by health insurance.

JMA was frustrated with their core demand neither incorporated into the universal health insurance scheme or medical service fee raise. In early 1961, the welfare minister proposed reorganizing Chuikyo to limit its role to the allocation of health expenses, while creating a new entity under the Cabinet to handle discussions on rules and medical service fees. JMA immediately rejected the idea stating that it strengthens the control on healthcare and demanded to limit committee member recommenders to JMA, JDA, Japan pharmacist association (JPA) only. The bill did not go into the floor, but another Chuikyo reorganization bill was submitted by the welfare minister to change the stakeholder from 4 (insurer, insured and business owners, medical service provider, and public interest) to 3 groups of payers, providers, and public interest for 8 persons each. Takemi proposed to reduce public interest from 8 to 4 persons[44] and the bill was passed in October 1961.

LDP executives agreed to incorporate Takemi's request but the welfare minister rejected. There are back and forth with the LDP, the ministry, and Takemi who again threatened to withdraw all JMA members from "hoken-i" insurance scheme, and finally agreed the following.[45]

1) Fundamental reform of health insurance system: Current health insurance system is still insufficient, and need to continuously adjust and coordinate to integrate with social insurance.
2) In order to improve people's healthcare level, medical/pharmaceutical advancement should be swiftly incorporated into health insurance system (it is nonsense to reject advanced medical research just because they are expensive.)
3) Get rid of limitations and secure "freedom" of medication and treatment if patients wish. The current system confines options what we can do to treat patient better.
4) Medical service fee determination system linked with economic growth, and get away from controlled health idea.

Takemi was very proud that he has eliminated all restrictions to cap the use of medications under health insurance system once it is approved by the government. By 2024, healthcare costs are rising exponentially, with newly approved drugs over 10 million yen being automatically incorporated into the health insurance system, and their numbers are increasing. The Tokyo JMA chairman expressed serious concerns about the sustainability of universal healthcare, noting that 80% of private hospitals are chronically operating in the red under the current "distorted" system, where people's premium remains low while healthcare costs are skyrocketing.[46] There is no limit in using such expensive new drugs and the cost is pushed to kenpos who are at blink of bankruptcies. By 2024, Takemi's effort ultimately led to the weakening of kenpo, hospitals, and even the JMA itself. The unlimited use of approved drugs has now spiraled out of control, further deteriorating the health insurance system.

When Takemi became JMA chairman in 1957, he advocated for a fundamental reform of the health insurance system, arguing that existing employer-based health insurances (*Kinrosha hoken*) and kenporen should be consolidated under the regional health insurance (*kokumin hoken*).[47] Takemi's basic idea was to reorganize them into schemes of community health,

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[43] Takemi Taro. Jitsuroku Nihon ishikai, p107-108
[44] JMA sngo 50 nen no Ayumi. P78
[45] Takemi Taro. Jitsuroku Nihon Ishikai, P119-125
[46] Quoted from regular press conference of Ozaki Haruo, JMA Tokyo chairman, October 8, 2024
[47] Takemi Taro. Jitsuroku Nihon ishikai. P181

industrial health, and gerontic health, under a unified community medicine system. He argued that the current social insurance system, which places financial burdens on younger generations to support elderly, is not sustainable. Takemi proposed that regional health insurance and elderly insurance should be financed separately. For example, elderly (social) insurance would paid-in by individuals themselves starting at age 25, with benefits beginning after age 60, supplemented by the government for any inflated costs.

Takemi was furious in 1971 when the welfare ministry submitted a memo ro Chuikyo regarding revision of medical service fees, chiefly aiming to reduce drug use and re-assess the evaluation of physicians' technical skills and points calculated per disease. Those items did not align with Takemi's demands, and the ministry had ignored the four pillars including fundamental health system reform that he had discussed since 1961. In response, Takemi threatened a large-scale strike, the withdrawal of JMA members from Chuikyo, and a nationwide resignation of "hoken-i" from the health insurance system. The strike began in July 1971 and lasted for one month. During a series of open televised debates, Welfare minister Saito Noboru and Takemi discussed a fundamental reform bill for health insurance and reached an outline of agreement on 12 key items. Following this, Takemi decided to end the strike. Nevertheless, he said majority of these 12 items did not realize by 1981. Among 12 agreed items,[48] one of his key focuses was a healthcare basic law, Takemi advocated for introducing competitions among physicians to encourage lifelong learning and improvement. He aimed to create an equal relationship between physicians and patients to realize the concept of regional medicine, moving away from the traditional view of physicians being a superior position. He also called for increased public funding for medical research, highlighting the insufficient resource available at universities. Subsequently achieved elderly insurance in 1973, and done several reforms.

In 2006, **t**he MHLW introduced Health cost burden sharing for elderly insurance system. The basic idea for the elderly healthcare system is to separate high risk from the main part of the national health insurance scheme. Individuals over 75 or with disability over 65 will be placed into elderly health insurance where 10% of insurance premiums are deducted from pensions. JMA was against the idea of the ministry.

Hospital Inefficiency: The "ikyoku" system allows inefficient operations by dispatching MDs from university to various hospitals. With too many hospitals and too few reforms, it is creating chronical shortages of MDs in already overstretched health system.

Structural Labor Exploitation: Under "ikyoku" system, young doctors are placed under seniority pyramid of specialties and put to overwork with inadequate institutional support, leading to a decline in new recruits.

Ikyoku system: "Ikyoku" system[49] is a hierarchical pyramid governing system topped by department professor at medical universities for chiefly providing on-the-job training

[48] His 12 items included: 1) correct the welfare ministry's attitude towards healthcare administration, 2) submit a fundamentally revised bill for health insurance system at next Diet session, 3) create healthcare basic law, 4) establish a sliding scale for supplies and personnel costs at medical service fee determinations, 5) foster solidarity among physicians and patients, 6) ensure healthcare security for all, including those with disabilities, 7) separate labor management and social security, 8) achieve fair burdens and benefits across various insurance schemes, 9) address higher health risks for low income families, 10) improve quality of medical professionals, 11) increase public funding for medical research, and 12) simplify the insurance invoicing system. See Takemi Taro. Jitsuroku Nihon ishikai, p193-197

[49] Ikyoku is also called "kouza" for different medical institutions, and this system has see N. Kuwabara et al. "The Evolution of the Japanese Medical Education System: A Historical Perspective" HAWAI'I JOURNAL OF MEDICINE & PUBLIC HEALTH, MARCH 2015, VOL 74, NO 3.

programs. Ikyoku members are consisted of associated faculties, post-docs, and graduate students who desire to conduct both clinical practices and basic research for advanced specialties including Ph.D. In return, these ikyoku members have duties of caring assigned patients at university's affiliated hospital(s), conducting research, and educating/training younger doctors or graduate students. Ikyoku professors have appointive power of promotions and dispatching members to affiliated hospitals. Ikyoku trainees are paid minimum fees for reported "overwhelming workload."

Patient data sharing – disclosing patient record

JMA resisted to legalize disclosure of patient medical records for at least 6 years since the discussion started in 1997.[50] Prior to this, the general public increasingly questioned medical errors of physicians that was widely reported where patients had no means to know what caused the issues. JMA and physicians refused requests of disclosing medical records, reasoned that data needs organization and patients would not understand professional medical writings even if it is disclosed. The 1999 report of *Iryo Shingikai* (medical committee) discussions postponed the conclusion and stated while there were call of legalizations, disclosure should be determined by JMA guidelines and left to the discretion or self-regulation of physicians. Notably, the JMA guideline said that records should not be disclosed if physicians believed patients were preparing for litigation. Finally, in June 2023, despite ongoing resistance from the JMA, the ministry of welfare issued a principle regarding disclosure of medical records, emphasizing that it is inappropriate for physicians to withhold records based on the potential for patients to take legal action.

Emergency Paramedic and other health professions

Emergency paramedic was able to use AED from 2003 and intravascular intubation only after 2004 as JMA always against curving off physician's privileges and said it is too early to consider it (*jiki sosho*). Emergency paramedics already have trained how to use AED, but it was illegal to use without physician's judgement. The welfare ministry also pushed the government to change the protocol, and public opinion sparked. Since 1995, Fire and disaster management agency (*shobo cho*) have been asking the government to let paramedic use at emergency, and finally public plea triggered by media reporting has led Sakaguchi welfare minister to start discussing about this in 2001. It took almost 10 years for ordinary citizens to use AED if someone needed. The question is why JMA is so afraid of sharing tasks with other professionals?

> **Natural Disaster Response**: The Kobe Earthquake prompted reforms (e.g., DMAT), but JMA resisted integrating more teamwork-based approaches with nurses and social workers.
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> Again in 2010 when MHLW issued a report "discussion for advancing team healthcare" and proposed specially trained nurse (*tokutei kangoshi)* to handle certain medical treatment, the JMA board member publicly rejected the idea as "physicians must conduct such medical treatment, otherwise it will harm people's life" and "it is

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[50] The weekly discussions started at "karute nado no shinryo joho no katsuyo ni kansuru kentokai" at the ministry of welfare on July 9, 1997, led by Morishima Akio of Sophia university and members included JMA board members, academia, hospital presidents. Report published in June 1998, stating legalization necessary, however at iryo shingikai (medical committee) it was concluded in June 1999 that disclosure should follow JMA guidelines that tells physicians no need to disclose if patients are preparing for court cases. Tatsuo. P81-86

confusing when inferior nurses command superior physicians to suggest certain tasks"[51] However, Japan Society of Surgeons plead to expand nurse's task to include certain treatment, as local hospitals suffer physicians shortage and could not handle without nurses' help. JMA had been against introducing nurse practitioners for more than decades. A Japanese medical doctor who teaches at a US college once said, "I left Japan thirty years ago as they are so negative about introducing nurse practitioners, which I thought ridiculous." Finally a supplementary resolution added to health nurse and midwife and nurses law (*Hokenshi josanshi kangoshi ho*) in June 2014, special nurses are allowed to train under the physicians' guidance in 2015, and the MHLW announced to target to train 100,000 special nurses by 2025, but as of March 2023, there are only 6,875 special nurses. Many willing nurses challenge training, but they are required to take courses during their already very busy professions.

Kongo shinryo "mixed medical service" or delaying **Prescription Drug Policy**: Delaying over-the-counter medicine introductions to maintain patient visits and profits?

JMA was pushing for allowing mixed medical services where patients can pay partially under existing health insurance system and partially pay for non-covered items.
Under the Pharmaceutical affairs law, product needs an approval to develop and sell at the market. PMDA investigate if the submitted clinical data can show scientific effectiveness. After passing such examination, MHLW's council will judge if they can grant approval, and then minister of welfare finally approves. Once drug is approved, the government can provide remedy for health hazards, while non-approved drugs are outside the national remedy system. Whether the product be covered under health insurance, Chuikyo will discuss and judge.

Delayed digitalization

JMA delayed digitization or online diagnosis in various ways. When the government set online submission of medical service invoice in late 2009, a JMA member explained that elders and local clinics are short staffed, and therefore having (cumbersome) online invoice is too much work for them. Therefore, JMA successfully made DPJ government to understand such needs and incorporate both paper-based as well as online methods for the ease.[52]
Physicians are slow to adapt online treatment applications. The government approved online applications in 2020 for medical use, but there is only one product for high blood pressure treatment currently in the market. Passing pharmaceutical affairs law (*yakuji ho*) is critical. Major hurdles are 1) physicians and staffs know less about those applications and are reluctant to change their workflow as such applications require clos monitoring, 2) clinical trials are costly, 3) approval process takes time, and 4) it is unknown if the product will b covered under health insurance system.

IV. COVID-19 and the JMA: What Has Changed and What did not Change?

Ministry of internal affairs (Somu sho) played an important role during COVID-19 crisis. Somu sho was not previously a part of this circle, and no attachment to existing stakeholders, and with Suga's strong leadership, somu sho was able to cut through welfare ministry-related committees and influences. Using municipal connection, somu sho successfully mobilized massive vaccine operations.

JMA failed to institutionally support COVID pandemic measures, and resisted various crisis measures

[51] Tatsuno, p389, 395
[52] Osaka fui news. January 2010.

government introduced. Some critical changes are imposed, but how critical were they to JMA?

1. **Vaccination Challenges**:

Under Prime minister Suga, Kono Taro was appointed as minister of vaccines in mid-January 2021 to expedite vaccination nationwide. Suga was furious when MHLW revealed that contract with Pfizer yet to be concluded, and immediately contacted Japanese Embassy in Washington, D.C. to directly get in touch with Pfizer[53] and finally signed on January 20, 2021 for securing 144 million doses. Suga's rapid vaccination was possible as the Cabinet bypassed MHLW which always stagnates the processes and therefore, Suga directly mobilized the ministry of internal affairs and communications (somu-sho) to lead the vaccine operations.

Although the coordination crossed jurisdictions of agencies and ministries, why vaccination could happen so quickly? Operation is led by state minister Taro Kono, and Mr. Hiroto Izumi, former officer at land and transportation assisted and coordinated 4 bureaucracies. Coordination required with MLHW for vaccine approval, with land and transportation ministry for transporting frozen vaccines from the airport to nationwide municipal health organizations, then refrigerated vaccines from municipal's health organizations to total 10,000 end vaccination facilities; with METI for securing ultra-low-temperature freezers to store vaccines, and with ministry of internal affairs and communication (MIAC) for arranging coordination with local municipals.[54]

The next hurdle for vaccination was whom to administer the shots. Because of medical practitioner's law, any shots should be administered by medical practitioner to approve the patients' health condition. In order to achieve the goal of 1 million shots a day, Mr. Suga mitigated restrictions for shot givers to include paramedics (64,000 certified), clinical technologists (200,000 certified), dentists (100,000 certified), pharmacists (310,000 certified). Seeing MHLW's very reluctant attitude to enable dentists to give vaccinations, Suga mobilized MIAC ministry to work around Preventive vaccination law (yobo sesshu ho) where defines only MHLW to coordinate with local municipals. Suga also requested cooperation from JMA and promised to provide financial incentives for hospitals/clinics conducting vaccination from current 2,070 yen to maximum 5,070 yen a shot, and 100,000 yen bonus for hospitals/clinics that had more than 50 shots a day. In addition, gathering experienced MIAC bureaucrats who had previously dispatched to various municipals, the MIAC created a supporting section of "COVID vaccination for municipals" to give phone calls to pick up concerns and local problems. Suga administration decided to issue a joint administrative notification (tsu-chi) under the names of ministers of health and internal affairs, to request municipals and local JMA for cooperating vaccinating operations. This is to give authorities to the municipals to avoid being violated of the Preventive vaccination law. By MIAC taking a lead in contacting municipals for hearing their concerns, the government-municipal vaccination coordination went smoothly, where MHLW had been criticized for never listening municipals' concerns[55].

Suga administration achieved 72.8% of population coverage and 90.8% of seniors above 65 years of age for 1st vaccination by October 2021,[56] eight months since its start. The key was allowing other health professionals (e.g., pharmacists, dentists) to administer vaccinations. The core hurdle was that medical practitioner's law defines the only medical practitioners can judge

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[53] "Wakuchin deashi no okure hibiku." Nikkei Shimbun morning edition, January 23, 2021. p3
[54] "Jinsoku sesshu e nandai zukume." Yomiuri Shimbun. January 20, 2021, p4
[55] "Sesshu ichinichi 60 mankai zo e soryoku." Nikkei Shimbun May 26, 2021. P3
[56] Also achieved 63.1% population coverage that had 2 doses of vaccinations. Since its start, 172 million doses are consumed. National institute for infectious research, October 15, 2021.

if the person is healthy to receive vaccines. In other words, nurses, dentists, paramedics, midwife or public health nurses could not administer shots. This is outdated rule as a result of JMA's protecting physician's jurisdiction policy and rejecting introduction of nurse practitioners for decades. Other nations in general do not require medical practitioner's permission to shot vaccines, and for example in the United States, vaccines can be shot by nurses at pharmacies or supermarkets. COVID crisis revealed legal bottleneck preventing the government's emergency massive vaccinations. Since giving a shot is considered as medical "practice," nurses (1.5 million certified) are just there to check the patient's medical history surveys, but cannot give a shot. Only when medical doctor order nurses to do so, nurses are able to shot vaccines. So municipals used this method to have medical practitioners somehow, either online or in-person, to let a broader medical professionals to administer vaccinations. If Suga can do it, then why others cannot breakthrough bureaucratic silos and have various innovative ideas and tactics to go beyond impeding institutions?

COVID hit the overwork of physicians through maintained dominance Over Other Health Professions: JMA's success in preserving medical doctors' dominance, marginalizing roles for other professionals via medical practitioner's law had acted impediments to crisis measures. For example, in order to become a certified midwife, it is required to pass national certified exam for nurse first, then has to study more than a hear at designated midwife training school to receive a permission to take national exam for midwife.

2. **JMA resistance and the failure of PCR self-testing kits distribution**

When CDC had quickly distributed PCR testing kits in the U.S. in early 2020, there was only National institute for infectious disease that was handling PCR testing in Japan. On May 4, 2020, the government admitted that number of PCR tests were minuscule, where conducted per 100,000 population from mid-February to April 2020 was only 187 cases, compared to 4,500 cases in the state of New York alone. The shortcoming was due to rigidity and limited jurisdiction in sharing tasks between public institutions and private corporations. The institute and regional public health research centers (*chiho eisei kenkyujo*) were solely responsible for addressing public health issues, and therefore, PCR testing remained within their domain despite the increasing demand for tests. Their operations were not designated to mass produce or mass conduct PCR testing for new viruses, yet they continued to hold testing privileges.

Local health centers (*hokenjo*) handled tracking of people who had close contact with COVID-19 patients, but again they are overwhelmed. The bottleneck was caused by staff shortages, a lack of masks, and an overwhelming number of tasks beyond their regular operations. As expected, because only physicians and clinical technicians were allowed to collect specimen, the MHLW decided to also permit "trained" dentists to conduct such tasks. At that time, it was beyond their imagination to collaborate with corporations to mass-produce reliable PCR testing kits, even though Omi Shigeru the chairman of the special advisory committee to the Cabinet, expressed a desire to make PCR testing kits widely available, similar to influenza testing kits. However, he never pushed that idea further.

The government proceeded with establishing walk-in PCR centers, but PCR testing kits were never made available to ordinary citizens at accessible drug stores. It wasn't until the end of September 2021, when the MHLW approved limited sales of official kits at pharmacies where pharmacists are present to provide consultations. Prior to this, unapproved versions of PCR testing kits for the research purposes were available online, though they took a few of days to deliver results and some required individuals to visit hospitals if they tested positive.

What fuels this issue is the insufficient allocation of funds for COVID-19 related purposes. The Japan Agency for Medical Research and Development (AMED, *Nihon iryo kenkyu kaihatsu kiko*) which is supposed to guide and support the development of testing kits, vaccines, and medicines, lacks the capability to support emergency COVID-19 research. In comparison to the U.S. National Institute for Allergy and Infectious Disease, which as a budget of 5.9 billion USD, AMED operates with less than one-fourth of that amount. When it was necessary to support COVID-19 product development in early 2020, AMED only had scraped leftover funds from the FY2019 budget, amounting to 500 million yen. While the chairman of AMED could have tapped into science and technology innovation budget, most of the FY2019 budget had already been allocated to genome medical research, leaving only 80 million yen at his discretion.[57] The lack of emergency budget was glaringly evident when it was needed the most.

The major reason PCR self-testing kits were not made available to the public was due to resistance from MHLW committees and the JMA. There is the process of "Switch OTC," which involves approving medicines for over-the-counter sales after its safety is confirmed by specialized committees, allowing people to obtain them without needing a prescription. The PMDA committee and MHLW committee discuss whether to switch to OTC for items like PCR kits. Physicians argued that "thorough review is necessary to confirm kit's safety" and refused to include PCR testing kits in discussion for over-the-counter availability, despite repeated requests from the regulatory reform committee. An expert stated, "there is concern if it shows a false negative, which could lead to misdiagnosis and further virus spread."[58] Additionally, the JMA opposed the move because widespread availability of self-testing kits would reduce patient visits, potentially affecting physicians' income. As a result, PCR self-testing kits never became available on drugstore shelves in Japan. Private corporations that are capable and available to mass-produce PCR self-testing kits, but it was the physicians resisted to make it widely available.

The process of "Switch OTC," is often prolonged, with some items stalled for over ten years. According to a survey for 16 pharmaceutical companies, there are fifteen items still prolonging and nine items still have been "reviewing" for 5-10 years and two items for 10-15 years since they filed a request.[59] Emergency contraception (after pills) was obviously the one which the PMDA committee and MHLW committee don't want to bring it to the OTC. The JMA is reluctant to support this switch, as it would reduce patient visits and consequently lead to a decline in income. Furthermore, the MHLW committee is populated with JMA members who express concerns about error in use and medication abuse.

The emergency contraception pill, which has faced significant delays in switching to OTC since negative comments were made at the MHLW committee in 2017. Despite numerous pleas, the committee only resumed the review process in 2021, but again discussion halted when a JMA member claimed there were "too many documents to read before the committee"[60] and refused to conclude the discussion, further delaying the process. The emergency contraception pill finally started "trial sales" as an OTC option in November 2023 under a "research" project evaluating whether it can be appropriately managed without a physician's prescription. The MHLW extended the research period for one more year, ending in March 2025, as the evaluation data collected within FY 2024 was deemed insufficient. Meanwhile, consumer groups protested furiously, asking "how many more years do you (the MHLW) need to

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[57] Shingata haien kenku nitibei de kakusa. Nikkei Shimbun. February 13, 2020. P2
[58] Shingata korona kogen kensa kit yakkyoku de hanbai e. NHK news September 28, 2021
[59] Shoho yaku no shihan naze susumanu. Nikkei Shimbun. April 28, 2022. P5
[60] Shohoyaku no Shihan naze susumanu. Nikkei Shimbun. April 28, 2022. P5

officially approve the after pill?"[61] Additionally, there are further hurdles for individuals under 18 years old: they must be accompanied by a parent and make a phone call before visiting the cooperative clinic to purchase the after pill. There are only 145 cooperative clinic available nationwide, but the pharmacist association announced plans to increase this number to 340 by March 2025.

3. **Failed Medicine and Vaccine Development**

The lack of emergency protocols resulted in slow approvals and hindered the timely development of medicines, vaccines, and treatments. In addition, there was insufficient preparedness for vaccine development capabilities, which require continuous efforts to foster innovation. The approval entities also failed to support innovative technologies and did not cultivate a mindset conducive to nurturing those companies.

As of April 2021, five domestic companies were developing vaccines, with four of them in clinical trials.[62] However, first domestically approved vaccine only became available in July 2023, after the COVID-19 pandemic had already subsided. Despite the government allocated 20 billion yen in May 2020 for vaccine research and development, the challenges were not only financial but structural impediments also hindered vaccine development. While the Ministry of education oversees basic research for new drugs, the MHLW affiliated PMDA handles the review of clinical trials, the MHLW approves new drugs, and the National institute of infectious disease handle production and quality investigations. Even during the COVID-19 crisis, these ministries' responsibilities remain divided, and the process from the research to implementation is poorly coordinated. The government had been reluctant to strengthen vaccine development capabilities. When the H1N1 virus affected 20 million people in 2009-2010, the government provided subsidies to three vaccine companies to organize H1N1 vaccine productions, however, as the virus subsided, production was not activated. Vaccine companies faced difficulties maintaining expensive production lines, bearing costs themselves. In 2014 when a domestic firm requested an approval for a new influenza vaccine utilizing gene technology -- more efficient and effective -- the Pharmaceuticals and Medical Devices Agency (PMDA, *Iyakuhin iryokiki sogo kiko*) committee was hesitant to approve it, as they did not see a necessity to move away from the traditional egg-based production method, even though such technology was already in use in the U.S. Consequently, the company withdrew its approval request. In fact, one of national research centers had begun developing mRNA vaccines in the past, but the clinical trial budget was cut in 2018, halting the project.[63] It was too late when the government realized in January 2020 that the traditional vaccine production method was inadequate for developing COVID-19 vaccines.

In addition to the lack of emergency protocol, there was also a reduced incentive for innovation. For newly developed vaccines to reach the market, they must first pass the national examination (*kokka kentei*), where the government randomly tests product lots to ensure vaccine quality is stable. This process can take up to two months. Furthermore, meeting clinical trial requirements in Japan is challenging due to the low number of participants, making it difficult for pharmaceutical companies find mass collaborators. The Japan pharmaceutical industry association (*Nihon Seiyaku kogyo kyokai*) urged the government to expedite the approval process, simplify packaging requirements, and conduct examination based on paperwork to

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[61] Quoted NPO pirukon chairperson Someya Asuka. Shohosen nashi kinkyu hinin-yaku shiken hanbai kakudai e. Asahi Shimbun. June 11, 2024.

[62] Vaccines developed by Shionogi Seiyaku, KM biologics, Daiichi Sankyo, ID pharma, and Anges, where first 4 had already started clinical trials. Wakuchin Kaihatsu chikuseki busoku ada. Yomiuri Shimbun. April 1, 2021, p11

[63] National institutes of bio medical innovation, Health, and Nutrition (*Iyakukiban kenko eiyo kenkyujo*)

remain competitive in the global race for vaccine development. However, the pharmaceutical companies are hesitant to invest a lot where emergency approval protocol is nonexistent. Additionally, drug prices are kept low under universal healthcare system, which means development costs often do not meet the profitability thresholds, reducing the incentive for corporations to invest. It also reduces incentives for physicians and researchers to specialize in infectious diseases, as there are fewer opportunities for publishing academic papers or participating in major projects. This low drug price policy was implemented to reduce the incentive for physician to overprescribe medications, which complicates the overall situation. Unfortunately, it has a negative impact on the development of new vaccines or medicines and discourages researchers from pursuing infectious diseases.

Coincidently, in 2016, a taskforce of advisors submitted a policy proposal to Welfare Minister Shiozaki Yasuhisa, advocating a depart from the old-fashioned, government-guided development model that specified particular firms, instead, they proposed a new development approach aimed global market and encouraging innovation with fundings from public-private institutions[64]. Nevertheless, that proposal was left untouched. The government could shift their mindset from subsidies to purchase in order to secure production capabilities. The president of Shionogi Seiyaku, a Japanese pharmaceutical company, suggested that the government could support the industry's production capabilities by subscribing priority distribution rights for vaccines or antibiotics when needed, referring the UK government's contract for antimicrobial resistance (AMR) antibiotics as a model for such an approach.[65]

Another aspect of this issue is that the welfare ministry does not view vaccines as a proactive treatment option, despite significant advancements in using vaccine to prevent cancer. The ministry's mindset remains outdated, as its relevant department is still called the TB and infectious disease section (*kekkaku kansensho ka*), viewing vaccines merely as a part of public health administration, rather than addressing them as national security concerns like in the US. For welfare bureaucrats, dealing with the unprecedented COVID-19 situation was beyond their imagination, where solutions were not always guaranteed to be safe and often accompanies risks.

The backwardness of Japanese health authorities is hindering domestic pharmaceutical development. Statements like "foreign approved vaccines are safer" or "it is difficult for us to approve domestic vaccines prior to other nations' approval"[66] suggest that Japanese authorities avoid making independent judgement, preferring to adopt vaccines or medicines already approved overseas. This reluctance to take responsibility disadvantages Japanese pharmaceutical companies, reflecting the slow approval process and hesitation to take risks.

Regarding COVID-19 treatment, the Japanese authorities once again avoided making their own judgments, delaying the approval process for domestic drug favipiravir, while expediting the approval of remdesivir, which had received "emergency" approval from US authorities. The Japanese government even revised implementing rules for the Pharmaceuticals and medical devices law (*iyakuhin iryo kiki ho*) to allow a special approval process (*tokurei shonin*), reducing the review period from one year to one week.[67] The US emergency approval process was temporal but legally backed by the Project BioShield Act (2004), recognizing risks that may have serious side effect. Emergency approval does not guarantee the same level of safety

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[64] Shigru Omi, Kenji Shibuya, et al. wakuchin ketsueki seizai Sangyo taskforce komon kara no Teigen. October 2016.
[65] Kokka senryaku de ato oshi o. Yomiuri Shimbun. April 1, 2021. P11
[66] Kokusan no Kaihatsu shukai okure. Yomiuri Shimbun. Jun 1, 2021. P4
[67] Statement by the Welfare minister Kato Masanobu quoted in "kansn bakuhatsu soshi speed ninka" Nikkei Shimbun. May 3rd, 2020. P7

and effectiveness as a full regulatory review would provide. However, Japanese authorities were overly reliant on US approval, making their decisions with less scrutiny. On of the issue is the absence of an independent evaluating body, that is both professionally responsible and insulated from political interference. The MHLW remains too susceptible to interventions from the ruling party, leading to an increasingly inward-oriented and risk averse approach. What Japan truly needs is the establishment of an independent review body, grounded in scientific evidence and staffed by diverse group of professionals, to thoroughly and flexibly address these challenges.

Another fundamental issue with the Japanese approval process is that it is notoriously rigid, requiring the completion of all clinical trial phases before a review can take place. Unfortunately, in October 2022, Fujifilm, the producer of Avigan (favipiravir), announced the termination of its development and withdrew from the approval process after the MHLW committee determined that its effectiveness was difficult to confirm. It was the MHLW that decided to conduct not an official clinical trial, but with "observational studies" (*kansatsu kenkyu*) where requires both patient and physician judged it necessary. However, the MHLW neither organized incentive for nationwide hospitals to join clinical trials nor set priority for which medicines would receive early clinical trials during the pandemic emergency. It was left to Fujifilm and e few willing local hospitals and a university to volunteer. As a result, Fujifilm was only able to gather comparative clinical trial data from 89 and 156 participants, as small Japanese hospitals faced challenges in recruiting a sufficient number of participants while COVID-19 cases were declining. This not only prolonged the process but also incurred high costs for Fujifilm, resulting in too few participants to reliably assess the drug's efficacy. It was not Fujifilm but the authorities that failed to properly set goals and priorities, and to sufficiently coordinate institutions and hospitals to achieve critical objective during the pandemic. Shionogi's research director stated that a sense of urgency has finally been shared, noting "foreign companies will not develop solutions for us if the virus is specific to Japan, and therefore it is critical to have domestic capabilities."[68] The Suga administration placed more than 300 billion yen in FY2020 to expedite vaccine development. On June 1, 2021, his cabinet finalized a strategic plan to strengthen vaccine development and production capabilities, which included establishing a permanent organization under AMED to foster an environment that encourages corporations to develop vaccines. However, the question remains whether the authorities have truly learned the lesson and will establish emergency code of conduct once the crisis has passed.

V. Conclusion

Despite the government's request for collaboration, the JMA was hesitant to fully engage, which further diminished its influence. The JMA could have strengthened its position by partnering with the government to provide essential expertise. While an advisory group of specialists was quickly formed, it was not initiated by the JMA. The government faced significant challenges, lacking effective command and control, particularly due to bureaucratic silos and a shortage of infectious disease specialists within the system. The institutions developed in the postwar era among the JMA, the LDP, academia, and other organizations were not designed to address national challenges but rather to coordinate interests among stakeholders. During unprecedented crises, many of policies that protected JMA's interests ended up working against it. Over time, efforts to shield physicians' roles from other professions, resist digitization, and delay over-the-counter medicines and PCR testing kits all contributed to inefficiencies in the healthcare system and fostered an anti-innovation mindset. While Takemi Taro had a vision for the future sustainability of the healthcare system, his

[68] Interview of Kiyama Ryuichi, Shionogi Seiyaku pharmaceutical research director. Nihon no wakuchin Kaihatsu. Mainichi Shimbun. March 30, 2021, p11

successors failed to plan for the future and instead focused solely on medical fee negotiations. Internal incentives and structural barriers linked to the JMA’s influence severely hindered Japan's ability to respond effectively to the COVID-19 crisis, exposing deep-rooted vulnerabilities.