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Presents

***Japan's Next Big Bang: Healthcare Reform
Implications for U.S. Policy***

A Japan Information Access Project Working Paper

by

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Japan's Next Big Bang: Healthcare Reform

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I: Executive Summary

Japan, like many industrialized countries, is faced with the twin pressures of escalating healthcare costs and an aging population. In 1999, Japan's healthcare system will undergo its most extensive reform since the establishment of universal health insurance in 1961. These reforms, as currently proposed by Japan's Ministry of Health and Welfare (MHW), are designed to cut government spending on healthcare and to compel the consumer to reduce expenditures. The effect, unfortunately, will be only short-term solutions that will undermine Japanese access to quality healthcare. These reforms also act as new informal trade barriers that will further threaten Japanese access to the best and most innovative international pharmaceuticals and medical devices.

If these reforms are carried forth, the elderly and chronically ill will bear the costs. These proposals include a number of regressive pricing and fee structures, such as:

- *A new reference- pricing system* for prescription drugs
- *Reduction in reimbursements* for medical devices
- *Increasing co-payments for patients*, especially the elderly

These restrictive proposals have been pushed forward with minimal or perfunctory consultation with the range of domestic and foreign interests involved in Japan's healthcare system. Worst of all, the proposed reforms act to replace the clinical judgement of physicians with the budget-balancing priorities of bureaucrats. In the end, the government's decisions are based on neither good medical science nor sound economic analysis.

Although U.S. and other foreign firms have had some success in the Japanese market, the regulatory obstacles they face have been the subjects of international and bilateral negotiations since 1986. In pharmaceuticals alone, the annual revenue losses to foreign firms from barriers are estimated between \$2.5 to \$3.5 billion, according to current industry estimates. Proposed reforms would reverse progress made in negotiations in the pharmaceutical and medical device section.

This Working Paper provides an overview of current reform proposals and politics. The author shows how bureaucratic-led reform of the Japanese healthcare system is bad public health policy and risky trade policy. In addition, he discusses how increased foreign participation and transparent communication between political and healthcare interests will improve the prospects of meaningful reform in Japan. The author advocates a policy of "structured engagement"—in-depth understanding of Japan's political process with appropriate efforts to seek industry and government accountability—to open Japan's markets.

II. Japan's Healthcare System: A Political Showdown

Japan's Ministry of Health and Welfare (MHW) has warned that the country's healthcare system, as presently organized, will soon be bankrupt. The ministry's latest reforms fail, however, to address significant inefficiencies in healthcare delivery, which contribute to the high costs. Instead, MHW focuses on prices. As evidence of the imminent "collapse of the universal healthcare system" MHW points to several market and demographic trends.

- *Total healthcare spending rose 1.5 percent in 1997, while national income fell by 0.4 percent.*
- *Healthcare spending as a share of national income rose to 7.3 percent in 1996 from 6.0 percent in 1990.*
- *Healthcare spending on people over 65 increased from 42.9 percent of total costs in 1993 to 46.3 percent by 1996.*
- *The population is aging rapidly: 14.5 percent of the population was over 65 years old in 1995, and is projected to reach 17.0 percent by 2000.*
- *Low costs and cultural factors result in overuse of the healthcare system, particularly in long hospital stays.*

In response to these conditions, the Japanese government's sweeping healthcare reform initiative is advancing at a pace unprecedented in that country's legislative circles. First discussed in 1996, the Cabinet is expected to introduce MHW-designed reform bills into the Japanese legislature (Diet) by April 1999. These major reforms, however, have been formulated with little meaningful consultation with either consumers or industry leaders, and fall short of solving serious problems in the organization of Japanese healthcare.

To be sure, these reforms are not the first by Japan's bureaucrats to contain the burgeoning healthcare costs of an aging population. One promising development is the new long-term care insurance system for the elderly that will be implemented in April 2000. Past efforts include cutting reimbursements for pharmaceuticals (biannually since 1965); establishing a separate insurance system for the elderly (1984); raising user fees for the elderly (1997), and raising user fees for ordinary salaried employees (1997). The difference is that the new changes in pricing systems and informal regulations are broader, more dramatic, and potentially more damaging to the long-term health of the nation.

The "Big Bang" Theory

Overall, the unprecedented changes posed by this reform to patient and provider will be the source of a "Big Bang" in Japan's healthcare industry. This is a reference to Japan's much-heralded "Big Bang" in financial services regulation, a series of reforms designed to liberalize a tightly administered sector by 2002. The goal of the financial "Big Bang" is to improve the health of Japan's domestic banks and securities firms by introducing market mechanisms in place of traditional administrative guidance. Japan's financial community viewed these changes, which moved Japanese practices closer to international norms, as both dramatic and unsettling.

The healthcare regulation “Big Bang,” slated for implementation in 2000, does not appear to be designed to improve the health of Japan’s citizens nor its healthcare institutions. The “Big Bang” in healthcare is designed primarily for reducing overall healthcare spending.¹ Individual choice is being restricted rather than expanded because new pricing structures discourage innovation and new options for treatment. The proposed reforms also veer from international norms and erect indirect market entry barriers to foreign pharmaceutical and medical device manufacturers. By setting prices much lower than world market prices, Japan in effect enjoys a free ride. American consumers would subsidize lower healthcare expenditures in Japan, since companies would have to recoup significant R&D investments in the U.S. where markets not bureaucrats set prices.

The Process and the Parties

The political process that developed this single-minded approach to cost-cutting has been surprisingly one-sided. Politicians and industry leaders were barely consulted. When the U.S.-based Pharmaceutical Research and Manufacturing Association (PhRMA), the Japan Medical Association (JMA) and the Japan Pharmaceutical Manufacturers Association (JPMA) suggested concrete alternatives, they were ignored. It should be noted that it was a precedent-setting event for these associations to submit publicly detailed, written recommendations backed by extensive research and analysis.

The ordinary procedure for considering reforms in any policy sector starts with a request from a cabinet minister to a *shingikai*, an affiliated consultative council. *Shingikai* consist of representatives from the private sector, but the staff members who draft the council’s reports are usually bureaucrats. Healthcare consultative councils and task forces are typically composed of representatives from the JMA, the Federation of Employer Insurance Associations (*Kenporen*), the Japan Federation of Labor (*Rengo*), and academics appointed by MHW. Although consultative councils can issue criticisms on occasion, they can easily be used as rubberstamps for policies worked out far in advance inside a ministry.

Notwithstanding Japan’s image as a consensus-based political system, the reform process has come under sharp criticism. Specifically, members of *shingikai* participating in the healthcare reform review have questioned the impact of the proposed new reference pricing system. This proposal would replace the present system of individual product pricing with a system much like Germany’s, that sets the same price for each product in several functional categories. Researchers and physicians participating on the *shingikai*, who object to these changes, have complained that the recommendations of their committees do not reflect their concerns. For the first time, public records posted on the Internet reveal the depth of their objections.²

From September 1998 to early January 1999, consultative councils including *Ifukushin* (MHW’s Medical Insurance and Welfare Advisory Council) reviewed MHW’s initial plan for introduction of reference-pricing system and other reforms. *Ifukushin*’s January 1999 report to MHW Minister Miyashita was quickly met with criticism from healthcare providers and the domestic pharmaceutical industry. They protested that it threatened the ability of doctors to choose the best care for their patients and of domestic pharmaceutical companies to realize an adequate return on high research and development costs.

Informal consultations continue over the final shape of reforms.³ Unlike in the U.S., politicians in Japan almost never draft legislation for introduction into the legislature (Diet). Customarily, politicians are not even directly involved in responding to reform legislation until the Ministry issues its recommendations. By that point, however, the options for change have already been narrowed. In February 1999, Japan's politicians are only beginning to become involved in the process. Lower-ranking members of the ruling Liberal Democratic Party (LDP) Research Commission on Fundamental Policies for Medical Care (*Iryo Kihon Mondai Chosakai*) have stated their opposition to the reference price system.

Final decisions are made at the leadership level of the LDP, which has myriad other issues to debate. Implementing the new U.S.-Japan Defense Guidelines, constitutional revision, and special measures to restart Japan's stalled economy have priority. There is no guarantee that they will focus on healthcare issues. The upcoming May Clinton-Obuchi summit may, however, provide a graceful resolution. By claiming that this primarily domestic concern is an international trade issue, senior politicians can absolve themselves of responsibility. They can defer to "*gaiatsu*" (foreign pressure) as the basis for their decisions.

International Trade Implications

Since 1986, international trade negotiations have worked toward liberalizing the pharmaceutical and medical devices market in Japan. The General Agreement on Trade and Tariffs (GATT) and its successor, the World Trade Organization (WTO), have negotiated the reduction of formal barriers to trade in medical products. Trilateral negotiations among regulatory agencies in Japan, the U.S., and the European Union are beginning to standardize regulatory approval processes in the International Conference on Harmonization (ICH). Bilateral talks between the U.S. and Japan, beginning with the Market-Oriented Sector Specific (MOSS) Talks in 1986 and continuing today through the Enhanced Initiative on Deregulation and Competition Policy, promise to further improve access and transparency in Japan's healthcare market. The Joint Status Report signed in Birmingham in May 1998 by the U.S. Government and the Government of Japan committed Japan to recognize the value of innovative products and market pricing in healthcare.

Elements of proposed Japanese healthcare reforms threaten to undermine the progress made through the above international negotiations. In particular, reference pricing for pharmaceuticals, price reductions for certain classes of medical devices, and informal guidance on contracts for medical devices are opposite to the goals of liberalization and market opening. There is little incentive for foreign or domestic firms to introduce innovative products or to invest in R&D in Japan. The regressive pricing reforms will create new non-tariff barriers in a trade segment in which the U.S. and the U.K. have technological leadership. Together, U.S., U.K., and Japanese companies originated 63 percent of the most innovative new pharmaceuticals—new chemical entities—in 1992. But U.K. and U.S. firms each had sales of NCE products twice as large as their Japanese companies.⁴

III. Japan's Current Healthcare System

Bureaucratic Oversight

Japan's current healthcare system consists of public insurance and mostly private healthcare facilities.⁵ Bureaucrats have the power to make significant decisions affecting medical treatment, as in U.S. HMO's. Bureaucratic direction means decisions need not reflect concerns of the major stakeholders. The tradition of price-based controls on healthcare spending restricts freedom for doctors to decide the most appropriate treatment for their patients. The "savings" is passed on to the patient, in the form of fewer choices and higher user fees.

Created in 1961, Japan's healthcare system is based on the principle of equal access for all to any healthcare facility, and some form of health insurance for each citizen. The primary form of health insurance is employer-based insurance (*hiyosha kenko hoken*). Employer-based insurance is operated by employer health insurance associations (*kenko hoken kumiai*) or by the government (*seifu kansho kenko hoken*). The elderly have a separate health insurance system, which relies heavily on subsidies from employer and community-based insurance plans. Like Medicare, elderly health insurance guarantees insurance for all on the basis of age. Unlike Medicare, the age for eligibility is 70 years old. For those under 70 years old without employer insurance, there is a national system of community-based health insurance (*kokumin kenko hoken*) where coverage for farmers, single-proprietor businesses, and the unemployed is provided by local governments. Community-based insurance has a uniform minimum set of benefits decided by MHW.

All medical insurance is valid at virtually any healthcare facility. Until recently, the official cost of seeing a specialist, even in the most famous university hospital, was the same as seeing a primary care physician in a small town. Unofficial costs, including gratuities for famous surgeons, specialists, and nursing staff at many hospitals, can add significantly to the cost. Officially, medical care spending takes about two percent of the average monthly Japanese household budget. However, Japan's health insurance *premiums* are indexed to income rather than to actuarial risks. By the time an employee reaches middle age, the burden can feel quite high.⁶

The MHW currently controls the premium structure. Insurance premiums differ among, and within, policies offered by employers, employer associations, or local governments. The MHW sets co-payments and acceptable premium rate ranges for each system. This leaves limited discretion for individual employers and local governments to negotiate premiums or extend additional benefits. Likewise, individual insurance plans or employers may not negotiate discounted fees from healthcare facilities. The employer health insurance plans have a direct voice in negotiating system-wide prices through the fee schedule (discussed below) determined by the Federation of Employer Health Insurance Associations (*Kenko Hoken Kumiai Rengokai*, or *Kenporen*).

Most important, the MHW Minister has the power to set fees paid to doctors through a central

fee schedule (*shinryo hoshu*) which mandates what insurance systems must pay for all treatments. In the fee schedule, the MHW also sets the reimbursement price for pharmaceuticals sold to patients and medical devices purchased by healthcare facilities. Central pricing authority and a system of cross-subsidies among each insurance plan, coupled with limits on autonomy of individual insurance societies, means that policy decisions flow through MHW and its consultative bodies.⁷ The primary consultative council is the Central Social Medical Insurance Council (*Chuikyo*), which sets fees for healthcare services, pharmaceuticals, and medical devices. See *Appendix I* for a list of major MHW consultative councils.

Private Sector Participation

Largely private, physician-owned hospitals and clinics provide healthcare services. By law, only physicians can own hospitals. In October 1998, there were 100,024 medical facilities, of which 9,328 were hospitals, and 90,696 were clinics. 6,913 hospitals with 961,439 beds are under some form of private ownership and 2,320 hospitals with 694,388 beds are operated by public authorities. All but 4,755 clinics were under private ownership.⁸ According to MHW's 1993 *Patient Survey*, the majority of healthcare treatments, especially outpatient treatments, take place in private hospitals or clinics. The Japan Medical Association (JMA, *Nihon Ishikai*) represents physician in most MHW consultative councils represents their owners.

Every insurance plan and every healthcare facility uses the MHW fee schedule for reimbursements, giving virtually the same amount for the same healthcare services and goods (including pharmaceuticals) at virtually any facility.⁹ The fee schedule is set in biennial deliberations of the Central Social Insurance Medical Council (*Chuikyo*). Hospitals in particular have long complained about chronic operating losses due to the relatively low fees given for outpatient and inpatient care.¹⁰ The Japan Hospital Association (JHA, *Nihon Byoinkai*), however, gained direct representation only in 1997.

Facilities compensate for low per-visit fees by earning revenue based on the difference between wholesale prices and insurance reimbursements for pharmaceuticals. Unlike in the U.S. and most European countries, pharmaceuticals are sold to the patient directly by hospitals and clinics. Only 14.7 percent of prescriptions in 1996 were filled by independent pharmacies.¹¹ Thus facilities supplement their revenue through the *yakkasa* (difference between official insurance reimbursement prices and wholesale prices). This practice has always attracted criticism as profit-seeking by a not-for-profit organization.¹² Reference prices are designed to curtail healthcare spending by ending the *yakkasa*. But there are other ways to reduce costs, including a market-based system for pharmaceutical prices, and reforming glaring inefficiencies in the delivery of healthcare.

Many Voices, But Few Choices

MHW uses several consultation councils and less-formal discussion groups to operate the healthcare and health insurance system, as well as to discuss reform proposals. The most important for system operation is the Central Social Insurance Medical Council (*Chuikyo*), which governs the fee schedule (*shinryo hoshu*) for healthcare goods and services. It reports directly to the MHW Minister, who then stipulates changes to the fee schedule without further legislative review. The Central Pharmaceutical Affairs Council (*Chuo Yakuji Shingikai*) governs approvals for new drug and medical device licensing, as well as changes in the Pharmaceutical

Affairs Law. In all, ten consultative councils (*shingikai*) and 21 discussion committees (*kentokai*, *konwakai*, *kondankai*) serve as venues for discussion of new regulations and regulatory approval in the healthcare sector.

The areas of responsibility of the groups most connected with current reforms are summarized in *Appendix 1*. Note, however, that the functional assignments are subject to change, often at the discretion of MHW. Reform discussions, in particular, are often transferred from formal, standing bodies to informal, ad-hoc committees.

In the current round of healthcare reform, the most important council is *Ifukushin*, (Advisory Council on Health and Welfare). The other major MHW councils concerning healthcare policy are the General Council on National Healthcare Policy (*Kokumin Iryo Sogo Seisaku Kaigi*), the Health Insurance Council (*Iryo Hoken Shingikai*, the Council on Health Services and Welfare for the Elderly (*Rojin Hoken Fukushi Shingikai*), and the Healthcare Council (*Iryo Shingikai*). The two most important councils in the current reforms are both under the control of the Health Insurance Division (*Hoken Kyoku*), which is responsible for negotiating the common fee schedule. The Health Policy Division (*Kenko Seisaku Kyoku*) has three major councils, which govern healthcare facility management, healthcare personnel, and medical ethics. The other major councils address issues of public health and sanitation, and health sciences.

Other discussion groups are concentrated in the Ministry's Secretariat, and they are mostly concerned with assigning topics to the major consultative councils, and reviewing the products of working teams made up entirely of ministry personnel. As noted above, council members do not usually introduce their own proposals. Rather, the council staff prepares proposals and adjusts the wording of drafts to reflect council member concerns. Seldom are the proposals drafted in detail; implementation is often left to subsequent ministry regulatory discretion. *Ifukushin* meeting minutes, in particular, reveal this dynamic as well as the frustration of council members.¹³

Serious gaps in representation exist in these deliberation councils. The industry is systematically excluded from formal discussions, except as infrequent guests at occasional subcommittee hearings. Pharmaceutical manufacturers are not represented on the major consultation councils, nor are hospital associations. They are sometimes consulted in the more informal discussion committees, which meet at the convenience of MHW. But the recommendations of these informal councils are not binding.

In the case of the 1996 Discussion Group on the Future of the Pharmaceutical Industry (*Seiyaku Gyokai Shoraizo Kondankai*), members often disagreed with the final report. In all cases, the staff of the councils or discussion groups, whose members are almost always drawn from MHW, draft the final reports. This information gap presents an opportunity for the Ministry to ensure that only its recommendations are heard, or sufficiently documented, to become the draft for new regulations or legislation.¹⁴

In the same way that large reform issues fall into the jurisdiction of several different committees or subcommittees in the U.S. Congress, Japanese healthcare reform crosses the boundaries of several different public/private consultation councils within MHW and the Prime Minister's

office. Ordinarily, legislative committees within the Japanese Diet do not participate in nor even monitor developments in reform discussions until a final bill is issued from the Cabinet. Most proposals take shape within consultative councils, which for healthcare, fall largely under the jurisdiction of either MHW or the Prime Minister.¹⁵ And while Liberal Democratic Party (LDP) Policy Affairs Research Council subcommittee members hold meetings and occasional public hearings, subcommittee chairmen are not usually senior party leaders. Again, MHW consultation councils are the main forums for detailed discussion of proposals for healthcare reform.

IV. The Reform Movement

Reform's Starting Point

The crisis of an aging society has been a prominent theme in Japanese healthcare planning and politics since the 1955 *White Paper on Health and Welfare*. At the time, only five percent of the population was over 65. Healthcare reform has also been a regular discussion topic since the beginning of the system of guaranteed health insurance in 1961. It took a push from a more broad-based reform movement, however, to start the process of large-scale reform. The first episode of “major reform” (*bappo kaikaku*) came in 1983, as part of the Second Administrative Council on Reform launched in several sectors in 1979.

Major reforms implemented in 1984 included a completely new health insurance system for the elderly over 70 years old (*rojin iryo hoken seido*), new user fees for employees and higher user fees for their families. It also financed higher fees for doctors by cutting prices for pharmaceutical reimbursements by as much as 18 percent per year. Between 1984 and 1990, a period of rapid economic growth in Japan, increases in health insurance costs were kept to a rate lower than the rate of increase in national income. Raising fees and cutting pharmaceutical prices became established as the preferred pattern of healthcare reform.

A 1995 report from the Social Security System Council (*Shakai Hoshō Seido Shingikai*) to the Prime Minister on pensions, welfare, and healthcare reforms initiated the most recent wave of major healthcare reform in Japan. In the 1950s, this body issued reports advocating the structuring of Japan's postwar social security system into a social insurance system instead of a tax-funded system. This council, however, had been silent since 1962. Its 1995 report urged a careful reconsideration of the relations among each part of the social security system, to support social changes, including fewer children being born, a higher share of the population over 65, and rising medical costs.

For the first time, specific recommendations for healthcare reform were discussed in relation to broader social security considerations. In medical care, the Council identified securing adequate financing, differentiating better the functional workings of clinics and hospitals, improving the management of chronic diseases, reducing the length of hospital stays, and coordinating geriatric care and ordinary medical care¹⁶ as areas of focus. Another important part of the report stressed the need to build public understanding of the nature of the crisis and the need for raising more revenue, in any reform.¹⁷ By 1999, however, reforms addressed the revenue-raising portion of the report's recommendations, but not the broader reforms of facility functional differentiation, or building public understanding.

Corporate Interest in Reform

Recent reform measures are also rooted in a concern over the effects of burgeoning healthcare costs on Japanese business. The overarching interest in all reforms is an urgency to move Japan out of its current recession. The objective is to reduce company costs in pensions, insurance, and taxes. Japan's leading economic groups, the powerful Federation of Economic Associations (*Keidanren*) and Federation of Employer Associations (*Nikkeiren*), have pushed the ruling Liberal Democratic Party (LDP) to lighten corporate obligations to their employees and the state.

Corporate Japan has recommended reducing the “national contribution” (*kokumin futan*)—anything that reduces disposable income, such as taxes and social security contributions, i.e., healthcare costs—to a minimum. Although in 1996 this figure was only approximately 37 percent of national income (the same as in the U.S.),¹⁸ by 2020, the total national contribution is expected to rise to between 48 percent and 60 percent of national income (the same as in Europe). Analysts see this as seriously affecting the competitiveness of businesses, and the morale of individual workers, which might prompt an exodus of skilled workers from Japan.¹⁹

Traditionally, most efforts at reducing the national contribution have targeted pensions, rather than healthcare. That may change as healthcare costs continue to rise at a rate faster than national income. In the 1990s, the Japanese government has slowed the overall budget increases in pensions, welfare support, and healthcare. From 1995 to 1996, actual social security payments grew only 4.4 percent, the smallest increase in eight years.²⁰ And from 1997 to 1998, healthcare expenditures grew by only 0.7 percent.²¹

The Government of Japan's desire to restrain national healthcare spending is understandable, especially given its current economic woes. For more than 30 years, the share of healthcare spending borne by individuals, employers, and the government has not fluctuated significantly.²² Demographics and politics are about to change this pattern and bring more costs to patients. In their present form, however, reforms are limited to stopgap pricing measures. A more thorough reform could reduce expenditures far more than the Band-Aid reforms proposed in 1999. And even in an era of cost cutting, Japan's business and government leaders need to be reminded that domestic decisions may have international trade repercussions. Elements of proposed 1999 reforms give cause for concern.

MHW Response

The MHW responded to the 1995 recommendations, that their officials had helped draft, to begin a series of general discussions examining a complete overhaul of the healthcare system. The starting point in all the deliberations was the total expenditure on healthcare, per person, and as a share of national income. In 1995, projected healthcare spending was projected to rise to ¥27.2 trillion (\$226 billion²³), which was ¥217,000 (\$1,808) per person, or 7.2 percent of national income. MHW was most concerned with the rate of increase in healthcare spending, which averaged 5.9 percent, while national income grew by only an average of 1.8 percent.²⁴

The focus of MHW reforms has been to contain costs. In 1997, MHW drafted legislation to raise user fees (co-payments) to 20 percent for most employees. A new surcharge for prescription drugs was aimed at reducing over-consumption of unnecessary medication. Senior citizens saw their monthly user fees increased for inpatient and outpatient visits. The final bill passed on June

16, 1997, after review by the ruling coalition added a delay for implementation of prescription surcharges for the elderly.²⁵

As a result of the June 1997 healthcare reform, co-payments for employees on the employee health insurance system rose from 10 percent to 20 percent, and a new surcharge for prescription drugs was added. Outpatient costs rose for the elderly by an average of 250 percent, and for employee insurance by an average of 240 percent. Inpatient and outpatient co-payments were raised to 20 percent for private company employees. Higher user fees lowered usage, but healthcare spending for the elderly continued to rise.

Politicians intervened in 1997 at the request of the JMA to lower the reform burden on the elderly. Reforms under discussion in 1999, including reference pricing for pharmaceuticals and higher co-payments, as part of a policy of cost restraint, again promise to make care more expensive and less certain for this vulnerable group. Again in December 1998, the LDP acted to limit the impact of reforms, by lifting surcharges on prescriptions for the elderly.²⁶

V. Reform's Round Two

Health Insurance Reforms

After launching the call for reform, Japan's Social Security System Council gave its reluctant approval to co-payment increases that were implemented in September 1997. The Council's January 1997 report asked the government to move beyond short-term thinking and consider the value of comprehensive reforms. The Council also questioned the wisdom of adding an increase in co-payments at the same time that consumption tax would be raised, particularly in the absence of any long-term plans for systemic reforms.²⁷ These calls would go unheeded.

In August 1997, in response to continued calls for reform, the MHW issued a draft reform plan entitled *The 21st Century Health Insurance System: Direction of Complete Reform in Health Insurance and Healthcare Provision* to the Governing Coalition Council on Health Insurance System Reform. This document was explicitly based on the April 1997 "Governing Coalition Agreement on Principles of Healthcare System Reform" and the June 1997 Cabinet agreement on "Promoting Fiscal Restructuring."²⁸

This starting point, however, was itself the product of late-stage political negotiations between existing ministry proposals and subsequent reviews by political parties. The revision of the Health Insurance Act on June 20, 1997 marked a new commitment to raising the costs to patients, one policy agreed upon by the LDP, the Clean Government Party, and the Pioneer Party. One hope was to deter frivolous visits to hospitals, where waiting rooms were said to serve as a sort of low-cost entertainment for the elderly. But another effect was to raise costs of those on fixed income—elderly pensioners. More important, the governing coalition agreement in 1997 took place almost two years ago. Politicians and parties have not been formally consulted early in the stages of drafting the 1999 reforms.

With the increase in user fees as a starting point, the next round of reform deliberations began in

October 1997. Although the present system was seen as inefficient, no better alternative could be agreed upon. The formation of the Medical Insurance and Welfare Advisory Council (*Iryo Hoken Fukushi Shingikai*) under the Health Insurance Bureau in October 1997 created a new unity among government interests and offered the promise of improvements on piecemeal approaches to developing systematic healthcare reform. The outcome, though, would ultimately leave many participants unsatisfied with the direction of reform.

Faced with rising burdens on the elderly, politicians scrambled to devise temporary measures, such as the lifting of surcharges on outpatient pharmaceuticals for the elderly in December 1998, effective April 1999.²⁹ But such temporary measures were not designed as part of a coherent strategy. The speed of the reforms prevents adequate deliberation and risks pushing through only one solution to a complex set of problems.

Ultimately, the consultation councils reflect none of the protests by any of the parties affected by the policy changes. This exclusion increases the likelihood of direct domestic or foreign appeals for last-minute political politician intervention. Stopgap measures, such as imposing ceilings on maximum monthly out-of-pocket spending can provide temporary solutions but will not improve the efficiency of the healthcare system. There is also no discussion of the escalation of costs not covered under the insurance system and passed on to patients and their families such as meals, inpatient personal care, and private rooms.³⁰ In the end, costs should be reduced through improved efficiency of distribution of healthcare resources, and the use of innovative products, which enable patients to return home more quickly and return to an active life.

Politicians and Their Constituents

Even though individual Diet members have a strong interest in protecting the elderly, the structure of the policy process system raises the possibility that reforms under discussion in 1999 may pass the Diet. These reforms will raise costs to the elderly and have serious implications for international trade. Nevertheless, the cabinet has made a basic commitment to lower government expenditures. For example, the new (January 1999) ruling coalition forged between the LDP and the Liberal Party set reducing total social security expenditures as a key policy goal along with rethinking the distribution of resources in an era of few children and a growing elderly population. These goals make it likely that some kind of healthcare reform will pass. In February 1999, the only proposals formally on the table have emerged from bureaucratic consultative councils.

Lack of an LDP majority in the upper house, even in coalition with the Liberal Party, also weakens the ability of politicians to develop an independent alternative to ready-made MHW reforms. They may be able to modify somewhat or delay introduction of ministry-sponsored bills. But they cannot easily be the source of independent legislation. Given the lack of adequate consultation and detailed presentation of alternatives for public examination, the current package of healthcare reforms can only be changed at the last moment, after the legislation is introduced. A late amendment did protect the elderly in 1997, in the face of proposals to change the co-payment system for the elderly from a flat fee to a fixed percentage of charges. But such last-minute intervention is much less reliable than a process designed to consider needs from the beginning.

Finally, there is little precedent for Diet members introducing substantive legislation relating to licensing approval or any other healthcare regulatory matter, unless it originated with MHW. Diet member initiative is even less likely when the LDP does not have a majority of seats. Therefore, the process rides on the compromises established at the stages of LDP party review before legislation is introduced, in the MHW consultation councils and discussion groups.

Pharmaceutical Regulatory Reforms: Reference Price System

One of the most hotly debated reform proposals is reference pricing for pharmaceuticals. This method, also used in Germany, sets a single price ceiling for a group of drugs of similar composition and effectiveness. If a drug costs more than the reference price, then the patient pays the excess amount; drugs costing less will be reimbursed at the lower amount.

Doctors, hospitals, and pharmaceutical companies have been most vocal in this debate. All have proposed concrete alternative pricing systems. The U.S. Pharmaceutical Research and Manufacturing Association (PhRMA) calls for a new market pricing system. The Japan Medical Association (JMA) calls for a new system of distribution and per-prescription fees for physicians, ending the practice of product-by-product price gap.³¹ The Japan Hospital Association support changes to the existing system to increase transparency—a goal which the reference price system does little to achieve.³²

Members of various government consultation councils, including the Social Security System Council that reports directly to the Prime Minister, have also voiced opposition to reference pricing. In a February 1998 hearing of the MHW Health Insurance Bureau, Council members questioned why patients with little medical knowledge must choose among different drugs. They further argued that such patients might choose the most expensive drugs, in the hope that it would be the best available product. Finally, they asked why the system of universal entitlement to medical benefits had to be changed. A MHW official replied that the reference price system is designed to introduce *some* form of incentive for patients to choose cheaper products, and, with higher co-payments for all pharmaceuticals, this system could reduce frivolous requests.³³

Policy Adrift: Pricing As a Market Driver

MHW healthcare policy seems to have drifted off course. The original intent of containing total system costs has turned into micro-managing individual components of the system.³⁴ Thus, the bureaucrats have become reliant on reducing official reimbursement prices for individual pharmaceutical products. To calculate the reduction in official prices, the MHW first determines the actual wholesale price of drugs, then calculates new official prices as a percentage of the old price, on an item-by-item basis.

Price reductions in the form of a reference price system do not encourage innovation. It has been argued that Japan's continuous reduction of pricing could actually stimulate the Japanese pharmaceutical industry's new product development, as a form of industrial policy.³⁵ Countering that argument is a study of Germany's reference price system. This 1996 study found that as pricing procedures became less transparent, prices did not necessarily reflect clinical differences in effectiveness, thus discouraging the use of the most effective drugs. Further, the study found this condition actually introduced serious disincentives for improvements on existing products, as well as research and development.³⁶ Yet this study's findings do not discourage Japanese

bureaucrats and some health economists from urging adoption of a “Japanese style” reference pricing system.

Other recent analyses of the German reference price system, released by MHW in December 1998, show a real impact on prices (an 11 percent average drop in drug prices since 1990) and the limiting of drug prices increases to the ceiling imposed on a particular group.³⁷ Still, neither MHW study referred to effects on care, new drug R&D, or actual costs to patients, which are the focus of deep opposition to reference pricing

Reform and Healthcare Players

Another goal of the new reference-price system is to eliminate margins on drugs earned by hospitals and clinics buying from wholesalers at lower prices than the official insurance reimbursement price, then selling drugs to patients directly. Although the proposed reference-price system may reduce this margin, it may not achieve one of its primary goals, to lower overall spending. Further, a reference-price system hampers economic incentives that might lower costs for pharmaceuticals, since volume discounting in other markets is a normal activity.³⁸

Systematic Problems Not Addressed By Reference Pricing

Even a reference pricing system will not solve the sources of high costs in Japan’s healthcare system. Roughly 10,000 hospitals and 100,000 clinics require manufacturers and wholesalers to maintain huge sales forces. Lack of specialization among facilities also increases demands on sales representatives. Reference pricing does not address facility differentiation and restructuring as a source of high personnel costs in the distribution sector.

Reference pricing threatens to reduce the revenues of wholesalers without reducing their costs

Previous rounds of price-cutting have reduced wholesaler margins almost to zero. And unlike Germany’s large, full-line distributors, Japan’s distribution sector consists of small-scale or limited-line firms. They also do not have arm’s length relationships with manufacturers or suppliers. Profit margins depend on negotiations with manufacturers and customers alike. Recent reforms, which make wholesalers nominally responsible for setting prices, have overturned customary anti-competitive practices that long attracted the scrutiny of the Japan Fair Trade Commission (JFTC). By placing pressure on hospital and clinic owners who rely on drug margins for revenue, reference pricing may also erode the progress toward more transparent distribution channels throughout the market. A move to establish a reference pricing system may accentuate these nontransparent aspects of the pharmaceutical sector.

Political Support of Reference Pricing

Political support for the reference-pricing system among the top leadership of the Liberal Democratic Party (LDP) seemed solid in November 1998, but had weakened considerably by late January 1999 as a result of JMA pressure. Nevertheless, opposition to the bill faces the considerable weight of the Financial System Council (under the Ministry of Finance), which publicly endorsed the bill in late 1998.³⁹ This council is a powerful leader in the fiscal restructuring of all government spending currently underway.

Indeed, the LDP’s coalition partner, the Liberal Party, composed of former LDP members), also expressed support for the reference-price system as late as November 1998. Only the

Democratic Party, the largest opposition party, opposes publicly the introduction of the reference-price system. It does, however, support some form of new fee schedule system for drugs by the year 2000.⁴⁰ The delicate coalition between the LDP (with a lower-house majority) and the Liberal party leave room for revision. This would be needed to pass the Upper House as well, where the Democratic Party has more of a presence.⁴¹ On the whole, the possibility for direct political intervention in other than flat-out opposition is limited.

The future of reference pricing is uncertain. As of February 1999, there is no other major reform proposal on the table. The attitude of MHW seems to be to adopt reference pricing or nothing at all. This is a far from the full-scale reform effort promised by 2000. Despite high prospects for savings in overall spending by introducing innovative pharmaceutical products, MHW insists on adopting a policy that will inhibit innovation. This underscores the need for ongoing, structure dialogues with MHW, to consider the global implications of proposed healthcare reforms at the earliest stage possible, rather than waiting until a formal position is taken.

The danger of swift reform in a policy sector dominated by MHW is that politicians have neither the expertise nor the time to generate independent alternative solutions. Each legislator (Diet member) is given public funds for only three assistants. The Prime Minister's Office depends on bureaucrats on temporary assignment for staff. And legislative committees do not, as a rule, introduce legislation directly. Despite recent public protests by some LDP Diet members, it is not certain that the leadership will stop the introduction. It is, therefore, important for foreign governments to speak up and represent the global health interests in these seemingly domestic healthcare reforms in Japan.

Pharmaceutical Regulatory Reforms: Drug Approval System

One area that is experiencing true deregulation is the drug approval process. The changes can, in part, be credited as resulting from continuing pressure of U.S.-Japan negotiations. Current estimates by the U.S. Foreign Commercial Service put the actual time for new drug approval in Japan at 27 months, while the benchmark of 18 months was established by the 1986 Market Oriented, Sector-Selective (MOSS) talks between Japan and the U.S. The 1998 Enhanced Initiative on Deregulation and Competition Policy produced a joint declaration of commitment of the Japanese Government to reduce the time to approve new drugs to 12 months by April 2000.

The MHW has begun shifting the review process from external to internal accountability to meet some of the demands of expedited review. On January 1, 1998, non-clinical data became subject to internal review in MHW's Pharmaceutical Safety Bureau. Clinical data may be also coming under internal review. One reason for this change is the difficulty of accelerating the process of review by the Central Pharmaceutical Affairs Council.⁴²

There are limits to the MHW's ability to expand internal review. The hiring of more central government employees is difficult in an era of national recession and massive restructuring of central government agencies. An expedited process already has been instituted for foreign-origin "orphan drugs" to treat diseases with relatively few Japanese patients.⁴³ This new "permissive" directive, however, has yet to be transformed into any specific directive making foreign clinical

data acceptable for most or all applications.

As a participant in the ongoing International Conference on Harmonization sponsored by American, Japanese, and European regulatory agencies, MHW is committed to bringing Japanese clinical trials up to international standards, known as “Good Clinical Practice (GCP).”⁴⁴ One goal is allow the use of data from one country anywhere in the world in the approval process. Some progress has been made, but full implementation is still far off.

Delays in approvals also affect foreign manufacturers. PhRMA estimates that regulatory barriers will cost American pharmaceutical manufacturers up to \$2.5 billion in 1999. These barriers have been the subjects of long negotiation, dating back to 1986. Commitments must be followed through, or not only American firms, but also ordinary Japanese patients will suffer.

Orphans in Reform

For example, clinical research done entirely abroad will now be sufficient in the final stage of approval for HIV treatment drugs. The drugs must be approved for sale abroad and undergo a certification process from the Center for Testing of Pharmaceuticals and Medical Devices and the AIDS products subcommittee of the Central Pharmaceutical Deliberation Council. If additional tests are not necessary, foreign research may be used for approval. But the determination of additional data provision is left to the discretion of MHW, and guidelines are established only on a case-by-case basis.

Once approved, the drugs are part of the new orphan drug system and eligible for research grants and special review committees. This is expected to significantly expedite the process.⁴⁵ Japanese patients could benefit greatly from wider application of the process to permit foreign clinical data for non-orphan drug applications as well. Of the 38 drugs approved by the FDA in 1998, only Viagra has so far been approved in Japan. Major anti-cancer and HIV treatments are as yet unavailable in Japan. And while the six-month approval process for Viagra offers some prospects for more rapid approvals in the future, low-dose birth control pills remain unavailable in Japan. Japan’s need to accept more foreign data is particularly acute because its clinical trials are generally not recognized by foreign approval agencies. Traditional clinical trials occur at multiple locations with few subjects. But some of these drugs are sold only in Japan, and have been found ineffective by foreign standards. Insufficient controls on clinical trials lead directly to useless or harmful drugs receiving approval, including anti-cancer⁴⁶ and cerebral enhancer drugs.⁴⁷ Many drugs in both categories have been recently removed from the list of products approved for reimbursement under the health insurance system.

It is possible to import drugs unavailable in Japan directly through a “gray market,” but only in limited quantities and with no medical supervision. This form of trade openness should not be encouraged. If reference pricing is implemented, however, foreign firms may find the Japanese market too unprofitable to make their products available. Thus gray market imports may increase.

Medical Device Regulatory Reforms: Discriminating Against Foreigners?

Cost-cutting reform in the medical device sector promises to have the same negative effects on the welfare of Japanese citizens as the reference pricing system reform. Moreover, two recent

policy shifts appear to favor domestic manufacturers over foreign manufacturers. Domestic manufacturers and MHW officials need to acknowledge the impact of domestic reforms on foreign trade.

The first area of concern is the regular price reductions imposed on medical devices as part of the annual fee schedule revision. Each year the prices for equipment and drugs are recalculated based on the spread between the official reimbursement price and the actual price determined by a survey of wholesalers. If the goods trade at an average price of 85 percent of the official price, and the “R-zone” is set at 15 percent, then no price reduction is imposed. Reductions implemented in April 1998 narrowed this “R-zone” from 15 to 7.5 percent for both PCTA catheters and pacemakers, both of which are largely produced by American firms. At the same time, the film market, dominated by domestic manufacturers, was reduced only slightly to 10 percent. It appears that price reductions are targeted against product areas in which foreign manufacturers have a considerable technical advantage. Like their Japanese domestic counterparts, foreign manufacturers have no representation on the Central Social Insurance Medical Council—the group that calculates price reductions.

The other method, that appears directed primarily at foreign products, involves targeting service-intensive medical products for “rationalization” (*tekiseika*) under the auspices of the Japan Fair Trade Commission (JFTC). The Fair Trade Council for Medical Devices, chaired by the president of the Japan Federation of Medical Device Associations (JFMDA), has recommended requiring manufacturers and wholesalers to use a “voluntary” contract. This contract would require listing separate fees for products and services. Since pacemakers are service-intensive devices, the only purpose to require separation of service fees would be to create a target for reductions, again at the cost of foreign manufacturers. A “voluntary” agreement also pre-empts formal hearings or a full legislative review.

Finally, recent meetings between the Japanese medical device industry executives and their government cohorts gives the impression of a return to old-style industrial policy. The three medical equipment manufacturer associations are developing the *Iryo Sangyo Senta* (Japan Medical Industry Center). This Center is to promote the development of domestic medical equipment manufacturers with a classic partnership of business, government and academics. It is significant that at a meeting convened in January 1999 by the Japan Federation of Medical Device Associations (JFMDA), the Tokyo Medical Device Industry Association, and the Japan Medical Device Manufacturers Association that the plans for this research center were announced to an audience crowded with representatives from MHW and MITI, including the MHW Minister.

The direction of medical device regulation needs to be rethought in consideration of its effect on consumers and foreign manufacturers alike. A combination of long approval times, and the new industrial policies described above, will reduce foreign access to Japanese market. Consumers will continue not to have access to the best medical devices. For example, in December 1997, implantable cardioverter defibrillators, widely available in the U.S., were highly restricted in Japan, and advanced cardiac stents had yet to receive approval.⁴⁸ It is clear that if foreign devices are restricted in order to promote domestic industry, then both ordinary Japanese citizens and the climate of international trade will suffer.

Foreign Pressures and Results

Several international initiatives hold promise for opening the medical device market in Japan. The May 1998 *Joint Statement on Deregulation and Competition Policy* committed Japan to recognize the increased value provided by advanced medical devices. This commitment also called for new medical equipment approval times to be shortened to 12 months by April 2000.⁴⁹ MITI's implementation of the Local Autonomy Provisions, part of the WTO agreement in 1997, has resulted in regulatory reform favorable to foreign manufacturers of medical devices.⁵⁰ Following this agreement, MITI in October 1998 opened a program to coordinate procurement information for municipal government public health and hospital facilities in Tokyo, Osaka, and Yokohama.⁵¹

Nevertheless, final decisions on pricing remain with the Central Social Medical Insurance Council (*Chuikyo*). The process is not transparent and the approval period does not include time to prepare any required re-submissions, or answers to questions.⁵² Even Japanese medical device manufacturers protest the delays in the present device approval system.⁵³

Finally, domestic efforts under the broad heading of “deregulation” have implications for permit and approval procedures across a number of fields. On October 28, 1998, the Management and Coordination Agency announced a cross-ministry agreement to implement the cabinet directive for a “Three-Year Plan to Advance Deregulation” by speeding the processing of applications for licenses. In this agreement, MHW committed to reducing the current 18-month procedure to 12 months for the import and manufacture of pharmaceutical products.⁵⁴ Implementation of these recommendations is essential for lifting bureaucratic controls that reduce incentives for foreign manufacturers to enter a costly process. Moreover, improved transparency and faster approval will lead to better access to state-of-the-art medical devices for ordinary Japanese citizens.

VI. Structured Engagement

Weak political institutions and strong bureaucratic organizations have given little recognition to the direct interests of Japan's citizens. Curiously, foreign efforts to pry open markets have worked as indirect advocates for the Japanese people. The benefits of deregulation, reduced prices, and wider choices have accrued after often rancorous trade negotiations. Never has this model of foreign pressure potentially bringing significant advantages to Japan been truer, and more urgent than on the issue of healthcare reform.

Contentious legislative issues in Japan are discussed informally long before emerging in a consultative council. When a bill has been introduced into the Diet, it is already late in the negotiation stage. Most of the interested parties have already agreed to a compromise. The important arena for action toward desired legislation, therefore, is at the domestic level prior to the emergence of specific legislation. By working side-by-side with Japanese industry groups, recognized experts/academics, and others involved in the early policy deliberations, foreign governments and businesses can affect the content of discussions as well as the shape of the final product of policy proposals.

Foreign companies will find that building alliances with Japanese groups is important to opening

Japan's markets as well as to rationalizing Japanese healthcare. A policy of "structured engagement" encourages activist participation in every step of the Japanese public policy process. It can result in formal reform commitments with observable results. Specifically, it is necessary for foreign interests to seek common ground with their Japanese counterparts and to forge potential allies through a series of informal consultations and mutually recognized objectives. The objective is for foreign business interests to become part of the decisionmaking process through informal support of Japanese domestic interests. Formal government-to-government negotiations back up this process by unifying foreign interests and by defining standards for procedures and results.

Bureaucrats

The Japanese bureaucracy has considerable power, but is by no means an infallible monolith. Policies are generally formed at an early stage in informal discussions inside the ministries. Once a consensus emerges, it is difficult to suggest a different course, though it remains possible to block a reform entirely. At each stage, reform-minded allies can be found within the bureaucracy. Particularly within MHW, an independent track of physician-officials (*gikan*) often has significantly different opinions from the ordinary career-ladder officials (*jimukan*).

Another area where the U.S. industry and government may find allies within the Japanese bureaucracy is in assuring adequate staffing levels to follow through on international commitments. Regulatory reform involved in reorganizing all central government ministries by 2010 includes specific provisions to reduce the number of central government personnel. Such a reduction threatens to reduce the ability to speed approvals for new pharmaceuticals and medical devices. MHW should welcome U.S. help in maintaining and expanding the number of its employees and budget resources.

Another tact is to join forces with Japanese domestic groups seeking greater accountability from their bureaucracy. Japan's new (April 1999) Freedom of Information laws combined with new citizen advocacy are important tools in ensuring bureaucratic responsiveness. A few prefectural governments have disclosure laws that reveal the minutes of important regulatory meetings. With decentralization, many approval powers, including on drugs, will devolve to the prefectures. Thus it is important to monitor prefectural laws and political developments. Several Japanese citizens' groups, notably the Association of Citizen Ombudsmen (*Shimin Onbuzuman No Kai*), actively monitor freedom-of-information laws and other public access regulations in each prefecture and major city. These citizens' groups could be valuable partners, at least as information providers, to ensure that reforms reach all levels of government relevant for healthcare regulations.

Information disclosure, transparent consultation procedures, and prior notification of non-legislative directives that implement healthcare reform, should be sought at the prefectural level. The "Submission by the Government of the United States to the Government of Japan Regarding Deregulation, Competition Policy, and Transparency and Other Government Practices in Japan" (October 7, 1998) already calls for these measures at the national level. This is one illustration of the important role for the U.S. Government in "structuring" the discussion and defining observable reforms that will benefit ordinary Japanese citizens as well as foreign interests.

Politicians

Links can also be established with Diet members who have long-standing interests in health policy. These politicians are not necessarily the ones in charge of party or legislative (Diet) committees responsible for health policy. Rather, the politicians most able to help are senior party leaders, former Ministers of Health and Welfare, and senior Diet members with multiple cabinet postings. Lower House members are in a somewhat better position to block undesired legislation, but in the current Diet, where the LDP is lacking a majority in the Upper House, opposition Upper House members also have a role to play. By contrast, MHW Ministers, with rare exceptions such as Naoto Kan⁵⁵, rarely overturn decisions that emerge from the internal MHW deliberation process. Their position was much stronger when the LDP had a majority in both houses.

The location for influence within the LDP is in the three key party organs through which policy decisions must pass: the Party Policy Affairs Research Council (PARC, *Seimu Chosakai*), the Party Management Committee (*Somu Kai*), and the Diet Policy Committee (*Kokkai Taisaku Inkai*). The first group conducts long-running discussions of all policy matters. Legislation may be reviewed informally by leaders of the relevant PARC sections even at the stage of an internal ministry draft. Before receiving the approval of the PARC general committee, however, there can be no major opposition from the senior officials of the PARC. Again, these bodies are limited to blocking or modifying MHW-proposed legislation.

The latter two committees are where top leaders can exert considerable influence in establishing priorities for introducing legislation, largely prepared by the ministries. These committees are also where opposition party members and top officials of related ministries are informed of LDP party policy priorities. Significant modifications and delays can be obtained by LDP leaders prior to the introduction of bills for cabinet recommendation to the full legislature. It is possible to modify legislation once introduced into the Diet, but this is the riskiest strategy. These bills are seldom reworked, since the backroom agreements necessary to bring the legislation to the floor have already been made.

Private Sector

It is possible to business find groups in Japan with policy interests similar to those of their foreign counterparts.⁵⁶ For example, most physician and hospital organizations oppose the proposed reference price system that they viewed as an inefficient method for achieving transparency and lower national healthcare spending. In addition, reference prices are seen as a threat to patients and the public nature of the healthcare system. Healthcare providers criticize efforts to establish “mixed medical care” (called *kongo shinryo*), that allows patients to opt for higher-cost treatment but pay any price differences from the official insurance reimbursement. The Japan Hospital Association has argued that this practice robs the health insurance system of universal coverage, since the rich can afford better care.⁵⁷

Japanese pharmaceutical manufacturers, for the most part, also oppose the reference pricing system. These companies are in contact with their U.S. counterparts, and joint meetings can mobilize a strategy to work through formal and informal channels to present the case for changing the direction of reforms. Moreover, they have a keen interest in the implementation of pharmaceutical sector reforms agreed to by the governments of the United States and Japan in

the May 15, 1998 *First Joint Status Report on the U.S.-Japan Enhanced Initiative on Deregulation and Competition Policy*. The direct effectiveness of industry groups is limited, however, by their exclusion from almost all of the formal deliberation over healthcare reforms.

Medical devices are another example in which foreign manufacturers can find common ground with domestic Japanese interests. The Japan Medical Association supports the inclusion of service costs as an integral part of medical device purchase contracts, a goal of the U.S. Health Instrument Manufacturers' Association (HIMA). In a hearing held by Japan Fair Trade Commission, a JMA executive director stated that "increased technical assistance from manufacturers' representatives is essential with medical devices, since there are many cases where the doctor cannot make judgements alone." He also urged that the practice of after-sales service should be explicitly recognized in the proposed new law as a different form of activity from improper provision of incentives and gifts.⁵⁸

In the area of sluggish approvals for medical devices, the Japan Council of Medical Devices Related Associations submitted a complaint to the National Pharmaceutical and Medical Devices Testing Center. The Center blamed the delays on lack of personnel, lack of training and experience, and several cases of defective products that diverted resources into in-depth reviews, stalling routine reviews.⁵⁹ American manufacturers and policy-makers, by coordinating with such groups, would have the opportunity to make concurrent claims, lending international pressure to make timely regulatory decisions.

Both examples above suggest the possibility of a policy of "structured engagement" which would integrate formal intergovernmental negotiations and regular informal meetings with domestic Japanese interests in a coherent strategy to maintain and expand market openness. To accomplish this strategy it is important to watch closely developments within Japanese industrial associations. These associations can suggest how domestic manufacturers use industrial policy to compensate for the impact of healthcare reforms. Furthermore, a study of industry practices in all reform areas and past reforms can expose patterns of industry and government collaboration in healthcare reform with implications for foreign trade.

In general, reforms in Japan tend to follow patterns set by other areas. One example is the 1991 reforms to the Wholesaler Practices Regulations in all sectors set by the Japan Fair Trade Commission. These reforms addressed issues similar to those facing the medical device manufacturers and distributors in the current discussion of sector-specific fair-trade regulations under discussion in early 1999. A recent example in the healthcare sector is the pattern of industry-government discussions and industry association guidelines that address distribution sector issues, based on the 1990 report "The Modernization of the Ethical Drug Distribution System."⁶⁰ One issue was the use of free samples and free technical support after sales, which were severely restricted in the case of pharmaceuticals.⁶¹ Already, these practices in medical supplies are the target of a JFTC guideline issued November 16, 1998.

Citizen Advocacy

The logic for ongoing discussions with physician and hospital groups is clear: private doctors and hospitals make most of the purchasing decisions for Japan's \$300 billion healthcare expenditure. Less obvious, citizens' groups and investigative reporters are also useful contacts.

They serve as important conduits of information about deficiencies in the system. Many show a deep commitment to a healthcare system that serves the needs of individual patients. As such, many of their interests coincide with foreign interests. These groups call for reforms to make the system more transparent, less expensive for vulnerable patients, and better for society through adoption of the best techniques and technologies. These are the same reforms advocated by the United States government to promote fair competition.

U.S. manufacturers of pharmaceutical and medical devices have successfully developed many products more advanced than those available in Japan. Even these highly critical groups are receptive to foreign products as solutions. In the HIV-infected blood tragedy revealed in 1996, the failure to import safer heat-treated blood product manufacturing techniques at an early stage was seen by activists to be a massive failure of the entire system of pharmaceutical regulation in Japan. Moreover, MHW was criticized for its negligence in promoting the use of unsafe domestic products at the expense of foreign products.⁶² More recently, the Pharmaceutical Ombudsman League called for importation of safer measles-mumps-rubella vaccine from abroad.⁶³ In both cases, citizen advocacy pointed out problems with the system that could be addressed by use of better products available abroad.

Coordination with groups critical of the domestic policy process and domestic industry may seem odd. Some domestic critics are motivated by partisanship, feelings against large corporations, or, occasionally, distrust of foreign products. Anecdotes about tight MHW control over the healthcare press through officially-sanctioned “reporter clubs” (*kisha kurabu*) make reliance on journalists problematic. Nevertheless, substantive opposition groups and investigative reporters do exist and share a common interest in regulatory transparency. These groups provide a valuable source of inside information and data that documents deficiencies in the Japanese system, and illustrates its effect on individuals.

VII. Conclusion & Recommendations

The history of Japanese healthcare legislation and regulation is one of long-term vision and short-term solutions. Efforts to contain costs and nurture domestic industries have clashed with the realities of contemporary medicine and dramatic, rapid innovation throughout the medical field. It is unfortunate that the immediate need to contain costs will have troubling consequences for the average Japanese citizen/healthcare consumer. For now, there is no single constituency within Japan that can effectively advocate new, more consumer-friendly solutions. Foreign pressures replace, in part, this lack of solid activist reform coalitions.

It is important to proceed with a policy of “structured engagement” that defines specific goals and uses subtle pressures within Japan’s policy process to promote desired changes in Japan. For example, the Enhanced Initiative for Deregulation and Competition Policy allows for a broad framework of goals to be coordinated across individual sectors. To augment the formal agreements, a series of regular on-going consultations with relevant interests should be established. The purpose of these ties with political leaders, industry leaders, and government officials is to explain American priorities clearly at a very early stage in the policy process. By

the time draft legislation emerges from the consultative councils, it is already late in the game. A policy of “structured engagement” would link the two efforts to build informal efforts into observable results. It also allows for early identification of issues difficult to agree upon, so that resources can be allocated toward areas likely to succeed.

Recommendations for U.S. Policymakers

To ensure that American interests in transparency and trade liberalization are promoted in the context of Japanese healthcare reforms, it is important that the U.S.:

- Find common ground with Japanese counterparts
- Establish long-term connections with relevant industry and consumer groups in Japan
- Monitor the political landscape to recognize policy shifts and important Political Actors
- Press for Information Disclosure Laws, regulatory transparency, and other relevant reforms outside healthcare reform
- Learn from similar reforms in related sectors
- Know when to be the team player or foreign advocate.

Recommendations for Japanese Policymakers

To ensure that the Japanese people can at least benefit from the innovations, safety, and cost savings of foreign pharmaceutical and medical devices it is important to:

- Consider carefully the implications of reform on international trade as well as the quality of care, such as the reference pricing system and the model contract for medical devices
- Speed reforms that enable faster licensing review, allow more extensive use of foreign clinical data, improve the standards of clinical trials, and improve transparency of the system for domestic and international healthcare interests
- Embark on comprehensive reforms, including revisions to the health care facilities system, such as establishing centers of excellence, reducing length-of-stay, implementing the long-term care insurance system (*kaigo hoken*), and other measures designed to improve the efficiency of the healthcare system, rather than focusing on reducing costs by retooling fee schedules or singling out particular products for reductions
- Exempt the MHW from guidelines to reduce the number of central government employees.

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IX. Appendix 1

Main Advisory Councils (*Shingikai*) on Healthcare Issues

Each Council is listed by its English name, its Japanese name, the agency and division to which it reports, brief description of tasks, and the web address with meeting records, if available.

Social Security System Council

Shakai Hosho Seido Shingikai

<http://www.sorifu.go.jp/hoshou/>

Office of the Prime Minister

Issues recommendations on draft legislation related to social security systems. At times, discusses the “big picture” of coordinating reforms across various systems.

Advisory Council on Medical Insurance and Welfare

Iryo Hoken Fukushi Shingikai (Ifukushin)

<http://www.mhw.go.jp/shingi/hoken.html#iryohoken>

Health Insurance Bureau and Health Service and Welfare for the Elderly Bureau, MHW
Merged tasks of two other standing councils, the Healthcare Council and the Council on Health Service and Welfare for the Elderly. Current forum for discussion of proposals on reference pricing for pharmaceuticals.

Central Social Insurance Medical Council

Chuo Shakai Hoken Iryo Kyogikai (Chuikyo)

<http://www.mhw.go.jp/shingi/hoken.html#chuo-shakai>

Health Insurance Bureau, MHW

Sets fee schedule for health insurance reimbursement for all goods and services.
Currently discussing fee schedule system reform.

Central Pharmaceutical Affairs Council

Chuo Yakuji Shingikai

<http://www.mhw.go.jp/shingi/yakumu.html#yakuji>

Pharmaceutical Safety Bureau, MHW

Composed of medical and pharmaceutical specialists.
Approves licenses for new drugs, conducts re-licensing hearings for existing drugs.

Healthcare Consultative Council

Iryo Shingikai

<http://www.mhw.go.jp/shingi/kenkou.html#iryosou>

Health Policy Bureau, MHW

Currently deliberating proposals on functional differentiation and other healthcare facility system issues.

Council on Health Service and Welfare for the Elderly

Rojin Hoken Fukushi Shingikai

<http://www.mhw.go.jp/shingi/roujin.html#roujin-hoken>

Health Service and Welfare for the Elderly Bureau, MHW

Currently debating implementation of long-term care insurance system (*kaigo hoken*).

Health Sciences Council

Kosei Kagaku Shingikai

<http://www.mhw.go.jp/shingi/kouseika.html#kousei-kagaku>

Minister's Secretariat, MHW

Sets guidelines for clinical research and basic policy direction for health sciences research funding.⁶⁴

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XI. Endnotes

¹ See Ikegami and Campbell (1996) on cost containment as the paramount goal of health care policy in recent years. Ryu (1995) presents the argument that real costs to individuals are rising faster as more areas are excluded from health insurance coverage. (In Japanese)

² See, for example, comments by Hitotsubashi University professor of economics, Dr. Masatoshi Tokita, included in the January 7, 1999 statement of opinion on the reference price system by the Operating Subcommittee (*Un'ei Inukai*) of the Medical Insurance and Welfare Advisory Council, (*Ifukushin*). In Japanese at http://www.mhw.go.jp/shingi/s9901/s0107-2_19.html. Downloaded January 18, 1999.

³ MHW Minister Miyashita has expressed some willingness to deal directly with concerned groups, and consider delaying implementation. *Yakuji Nippo*, online edition, January 12, 1999. Downloaded January 12, 1999.

⁴ See Richard Graham Halliday, "Success In Pharmaceutical R&D: The Different Strategies Of Western And Japanese Companies," *Drug Information Journal*, Vol. 30, (1996): 821–837.

⁵ The best recent overview of the health care system and analysis of the players in health care policy is Campbell and Ikegami (1998). For a somewhat older, but still useful examination of the operation and history of each aspect the system, see Okimoto and Yoshikawa (1993).

⁶ Yoshino Akio, *Nihon no iryo ga wakaru hon* [Understanding Health Care in Japan], Nihon Iryo Kikaku, 1992, 4th edition. (In Japanese)

⁷ See Mikitaka Masuyama and John Campbell, "The Evolution of Fee-Schedule Politics in Japan", in Naoki Ikegami and John Campbell, eds., *Controlling Health Care Costs in Japan* (Ann Arbor: University of Michigan Press, 1996) on the importance of the fee schedule in the policy process.

⁸ MHW, *Iryo shisetsu chosa* (Health Care Facilities Survey), October 1998. http://www.mhw.go.jp/toukei/iryosd/is1010_8.html (In Japanese). Downloaded December 15th, 1998.

⁹ Some payments are adjusted by facility type, such as lower reimbursements for outpatient services at large hospitals, higher fees for hospitals with a higher ratio of nurses to inpatients, and lower daily hospital fees for long-term care wards (*ryoyo gata byosho*).

¹⁰ Reliable data on operating expenses of private facilities is difficult to obtain. MHW officials dispute the extent of actual operating losses. See Kikuchi Takatoshi, "NPO to byoin keiei." *Iryo Keizai Kenkyu Kiko Reta* (IHEP Letter) #27, (February 1996), p. 6 (In Japanese)

¹¹ *Zenkoku kosei kankei bukyokuchō kaigi shiryō* (Materials from National Meeting of Health-Related Division and Bureau Chiefs), "Iyaku Anzen Kyoku" (Pharmaceutical Safety Bureau), Item 6. January 18, 1998, http://www.mhw.go.jp/topics/h11-kyoku_2/iyaku-an/tp0120-1f.html.

¹² The Japan Communist Party criticism of the practice for giving excess profits to pharmaceutical companies, and its solution—basing pharmaceutical prices on actual production costs, while compensating health care facilities directly through higher fees—is fairly representative of objections to the old system. Japan Communist Party, *Nihon Kyosanto no iryo kaikaku e no teigen* [The Japan Communist Party Declaration On Fundamental Health Care Reform] (Tokyo: JCP Central Committee, 1987): 49-53.

¹³ Many recent council meetings have minutes posted on the World Wide Web at <http://www.mhw.go.jp/shingi/index>. (In Japanese)

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- ¹⁴ Junko Kato, *The Problem of Bureaucratic Rationality* (University of Tokyo, 1996).
- ¹⁵ The most complete account of the role of consultative councils (*shingikai*) in Japanese politics is Frank Schwartz, *Advice and Consent: The Politics of Consultation in Japan* (Cambridge and New York: Cambridge University Press, 1998).
- ¹⁶ Shakai Hosho Seido Shingikai, “Shakai hosho taisei no sai kochiku (kankoku): anshin shite kuraseru 21 seiki no shakai wo mezashite” (Report of the Social Security Consultation Council to the Prime Minister, “Rebuilding Social Security: Aiming for a Stable, Secure Society in the 21st Century”) Tokyo: July 4, 1995.
- ¹⁷ Report of the Social Security Consultation Council t, section 9: “Kokumin no rikai wo eru tame” (What to Do to Obtain Public Understanding”).
- ¹⁸ Liberal Democratic Party, Discussion Group on the National Contribution, “Kokumin futan no shoraizo ni tsuite” [Future Image of the National Contribution], December 23, 1998 (in Japanese).
- ¹⁹ *Nikkei Shimbun*, February 26, 1997, p. 1.
- ²⁰ *Nikkei News*, online edition, December 14, 1998. Downloaded January 16, 1999.
- ²¹ *Nikkei News*, online edition, December 7, 1998. Downloaded January 16, 1999.
- ²² MHW, Minister’s Secretariat, Statistics Bureau. 1998. “Heisei hachinendo kokumin iryohi no gaikyo. Dai 3 Hyo: Zaigenbetsu kokumin iryohi – kosei wariai no nenji suii” <http://www.mhw.go.jp/toukei/k-iryohi/hyo3.html>. Downloaded January 5, 1999.
- ²³ A conversion rate of 1\$=120 yen is used throughout this paper.
- ²⁴ Iryo Hoken Seido Kenkyukai (Health Insurance System Study Group), ed. 1996. *Me de miru iryo hoken hakusho*. [Visual Report on Health Insurance]. Tokyo: Gyosei (in Japanese). Original figures from MHW Statistical Section.
- ²⁵ An overview of the process and major components of the 1997 reform can be found at <http://www.mhw.go.jp/topics/kenpo/tp0624-1.html>. Downloaded February 6, 1999.
- ²⁶ JMA officials have a direct channel to the LDP leadership. One association of Diet members, the “Twenty-First Century Social Security System Study League” (*21 Seki no Shakai Hosho Seido o Kangaeru Giin Renmei*) has 200 members, and is headed by Noboru Takeshita, former prime minister. See <http://www.med.or.jp/japanese/ippan/nichinews/n110105h.html>. Downloaded February 9, 1999.
- ²⁷ Shakai Hosho Seido Shingikai, “Iryo hoken seido no kaisei ni tsuite,” (Report on the Revision of the Health Care Insurance System,” January 31, 1997.
- ²⁸ The 21st Century Health Insurance System (MHW Draft): Direction of Complete Reform in Health Insurance and Health Care Provision. Introduction. August 7, 1997.
- ²⁹ *Asahi Shimbun*, December 18, 1998 (in Japanese). Downloaded from Asahi Shimbun database at asahi-net.or.jp on January 6, 1999.
- ³⁰ Ryu Niki (1995).
- ³¹ Japan Medical Association, September 1996.
- ³² *Nihon Byoin Kyokai News* (Japan Hospital Association News) 576: 6 (November 25, 1998, p. 6). <http://www.hospital.or.jp/576.htm> (in Japanese). Downloaded February 15, 1999.
- ³³ Summary of February 23, 1998 general assembly of the Social Security System Council. At <http://www.sorifu.go.jp/hoshou/council/council/h9/11.html>. Downloaded January 10, 1999.
- ³⁴ Yukiko Fujita, *Showa 50 nendai iko no iryoseisaku no henyo* [Health Care Policy Shift Since 1975], Master’s Thesis, University of Tokyo, Faculty of Law, 1995.
- ³⁵ P.J. Maurer, “Crisis at Koseisho: Japan’s Mega-Agency Finally Faces Change.”

Pharmaceutical Executive (January 1997): 62.

³⁶ Bernhard M. Maassen, *Reimbursement of Medicinal Products: The German Reference Price System Law, Administrative Practice and Economics* (Brussels: Center for the New Europe, February 1996).

³⁷ *Kagaku Kogyo*, December 15, 1998, *Nikkan Yakugyo*, December 18, 1998.

³⁸ *Yakuji Nippo*, online edition, November 6, 1998. Downloaded January 15, 1999.

³⁹ *Nikkan Yakugyo*, December 22, 1998.

⁴⁰ *Nikkan Yakugyo*, November 24, 1998.

⁴¹ *Yomiuri Shimbun*, online edition, December 8, 1998. Downloaded December 8, 1998.

⁴² *Yakuji Nippo*, online edition, June 29, 1998. Downloaded January 15, 1999.

⁴³ *Yakuji Nippo*, online edition, November 13, 1998. Downloaded January 15, 1999.

⁴⁴ *Yakuji Nippo*, online edition, June 29, 1998. Downloaded January 15, 1999.

⁴⁵ *Yakuji Nippo*, online edition, November 13, 1998. Downloaded January 15, 1999.

⁴⁶ Yoshikawa and Woodall (1996).

⁴⁷ *Yakuji Nippo*, online edition, June 29, 1998. Downloaded January 15, 1999.

⁴⁸ Neil Weinberg, "Bad Medicine," *Forbes* December 29, 1997: 46.

⁴⁹ First Joint Status Report on the U.S.-Japan Enhanced Initiative on Deregulation and Competition Policy, May 15, 1998, p. 6.

⁵⁰ Miyoko Ami, "Health Care '99 Import Fair," *International Market Insight*, US Commercial Service—Japan, August 14, 1998 (<http://www.csjapan.doc.gov/imi9808/healthcare99.txt>). Downloaded January 18, 1999.

⁵¹ The program has a webpage at <http://www.miti.go.jp/report-e/giryu01e.html>. Downloaded January 15, 1999.

⁵² *Yakuji Nippo*, online edition, May 22, 1998. Downloaded January 15, 1999.

⁵³ *Yakuji Nippo*, online edition, August 28, 1998. Downloaded January 15, 1999.

⁵⁴ *Kyodo Tsushin*, September 29, 1998 (in Japanese). Downloaded January 15, 1999.

⁵⁵ Mainichi Shimbun shakaibu yakugai AIDS kenkyuha [Mainichi News Society Bureau AIDS ADR team], *Koseisho no "hanzai" yakugai* [Adverse Drug Reactions: MHW's "crimes"] Tokyo: Nippon Hyoronsha, 1997.

⁵⁶ Previous analyses of US-Japan negotiations by Steven Vogel and Leonard Schoppa argue the importance of coordinating with domestic interests. See Steven Vogel, "Japanese Politics and Economic Liberalization: Constraints and Opportunities," Council on Foreign Relations Study Group on US-Japan Relations (December 1998), and Leonard Schoppa, *Bargaining with Japan: What American Pressure Can and Cannot Do* (Columbia University Press, 1997).

⁵⁷ Japan Hospital Association, "Nichibyō ni yakka mondai tokubetsu inkai wo secchi: sansho kagaku seido no hanron ni chakute" [Establishment of JHA special committee on pharmaceutical price issues: reaching the decision to opposition to the reference price system] *Nihon Byōin Kai Nyusu 567 go* (*Japan Hospital Association News #567*) (November 25, 1998). (in Japanese)

⁵⁸ *Yakuji Nippo*, online edition, October 10, 1998. Downloaded January 16, 1999.

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⁶⁰ MHW, *Annual Report on Health and Welfare 1992-1993* (Tokyo: MHW, 1994), p. 270.

⁶¹ One useful analysis of the impact of the 1991 Japan FTC policy guidelines on the distribution system was written by a former FTC commissioner. Shuji Kakabe, "Iyakuhin ryūtsu to kosei torihiki hō" [Pharmaceutical Distribution and the Fair Trade Law]. Tokyo: Yakugyo Jipposha, 1992. (In Japanese)

⁶² A thorough account of criticisms of the MHW review of blood products in 1982 is presented by Wataru Hosaka of Kyodo News Service in *Koseisho AIDS fairu* [The MHW AIDS File], Tokyo: Iwanami Shoten, 1997.

⁶³ *Asahi Shimbun*, Tokyo Morning Edition, November 17, 1998 (In Japanese). Downloaded from Asahi Shimbun Database at asahi-net.or.jp, December 20, 1998.

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