Deregulation of the Medical Equipment Industry in Japan

-Expansion of Market Access-

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PREFACE

This project was completed to fulfill the M.A. project requirement of the Monterey Institute of International Studies' Master's in Commercial Diplomacy program. For the purposes of the project, I assume the

fictitious role of independent consultant to a ficticious industry association, the Japan Medical Equipment Association (JMEA). JMEA is a trade association that represents over 15 other medical associations that specialize in everything from medical equipment manufacturing to distribution.

The project first describes current problems in Japan's medical equipment market—problems such as unnecessary bureaucratic procedures that slow approval of new products, complex distribution systems that add to the cost of health care, and the health insurance reimbursement system, which effectively negates cost competition for medical equipment. The project also provides economic, commercial, political and legal analyses of each of these problems. Finally, it offers recommendations for improving access to Japan's medical equipment market, as well as a strategy for how JMEA can implement these recommendations.

I would like to thank all my professors and friends who helped me in completing this project. I am especially grateful to Mr. Kimura, Mr. Nagao and Mr. Ishii who took time to meet with me in Japan.

ACRONYMS

ACCJ	American Chamber of Commerce of Japan
CPAC	Central Pharmaceutical Affairs Councils
CS Japan	Commerce Service in Japan
EBC	European Business Community of Japan
EPA	Economic Planning Agency of Japan
FDA	U.S Food and Drug Administration
GATS	General Agreement on Trade in Services
GATT	General Agreement on Tariffs and Trade
GHTF	Global Harmonization Task Force
HIMA	Health Industry Manufacturers Association
ISO	International Standards Organization
ITA	International Trade Administration of the U.S. Department of Commerce
JAAME	Japan Association for the Advancement of Medical Equipment
JETRO	Japan External Trade Organization
JMEA	Japan Medical Equipment Association
JIS	Japanese Industrial Standards
JMA	Japan Medical Association
MHW	Ministry of Heath and Welfare of Japan
MITI	Ministry of International Trade and Industry of Japan
MOSS	Market-Oriented Sector-Selective
PMDEC	Pharmaceutical and Medical Devices Evaluation Center
PMDSB	Pharmaceutical and Medical Devices Safety Bureau
USTR	Office of the United States Trade Representative
WTO	World Trade Organization

EXECUTIVE SUMMARY

It is extremely difficult to introduce new, cost-effective medical equipment products into the Japanese market. There are four main reasons for this difficulty:

1) Japan's Pharmaceutical Affairs Law is redundant and cumbersome and makes timely approval of new medical equipment impossible. Currently, Japan's approval process is longer than that of any other major developed country. This is particularly troublesome in an era when technology changes rapidly and, therefore, product life-cycles are increasingly short.

2) Complex distribution channels impede newcomers' entry to the market and raise the price of medical equipment by 15-25 percent. By simplifying the distribution system, the industry could lower prices and potentially increase its annual sales by over US$ 849 million—more than five percent.

3) The Ministry of Health and Welfare's (MHW's) reimbursement system negates price competition so there is no incentive for hospitals to purchase more cost-effective products.

4) MHW has been too cautious in approving new products, especially high-risk products. Its reluctance to approve products that are already in use in other countries causes a significant opportunity loss for the medical industry, as well as patients who could benefit from the new equipment.

Solving these problems is important not only for the medical equipment industry, but also for the Japanese government. Reducing the cost of health care will be crucial to the government's efforts to reduce its budget deficit and pull Japan out of its prolonged recession. Reducing costs is all the more important because Japan's population is aging and, accordingly, demanding more and better health care.

International forces are also putting pressure on the government to deregulate the medical sector. Foreign medical equipment suppliers are lured to Japan because its medical equipment market is the second largest in the world, but they face the same non-trade barriers to market access that Japanese companies do. Since 1986, Japan and the United States have conducted bilateral negotiations regarding deregulation of Japan's medical system. Although some progress was made in the so called "MOSS talks," the United States is still asking for further deregulation; it surely will raise this issue at the G-8 summit this July (a meeting at which Japan is eager to succeed as host country).

It is time for Japan to start taking action to reduce obstacles to increased business in the medical equipment market. The Japan Medical Equipment Association (JMEA) can and should help jump-start this process by putting pressure on the government to act quickly. On behalf of its member companies, JMEA should take the following actions.

Long-run actions:

- Launch a reform of the distribution channel system.
- Support reform of the reimbursement system.
- Persuade MHW to change its policies regarding approval of new medical equipment.

Short-run actions:

- Ask MHW to change the Pharmaceutical Affairs Law in order to:
  - shorten the time required to gain MHW safety approval for new products from one year to six months;
  - stop redundant examination of "me-too" products conducted by both JAAME and PMDEC; and
  - increase the number of items that do not require MHW approval before being put on the market.
- Ask MHW to increase the number of JAAME and PMDEC personnel who review new and "me-too" product applications.

JMEA's short run domestic strategy should include research on the impact of current regulations on JMEA member companies. It should also include coalition building, legislative and media strategies. In order to gain support of foreign companies, JMEA can work with the Japanese subsidiaries of foreign companies in order to avoid undertaking a comprehensive and costly strategy abroad.

The long-run strategy is very similar to the short-run strategy. However the long-run strategy includes a public awareness campaign designed to support reform of the entire health care system. The long-run strategy also calls for efforts to persuade medical equipment distributors, most of which are JMEA members, to embrace reform of the distribution system.

Cooperation with MITI will be important to achieving the latter objective. JMEA should also use its relationship with MITI to explore measures for boosting the international competitiveness of the Japanese medical industry, which will likely lose business when, after deregulation, it is exposed to increased international competition.

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I. INTRODUCTION

Although it is often somewhat overlooked, the 1,520 billion yen ($11.6 billion)1[1] Japanese medical equipment industry is an important part of the overall Japanese economy. It is one of the few industries in Japan that grew steadily during the country's rapid GDP decline from 1996 to 1998, and domestic production of medical equipment has steadily increased. In 1998, GDP contracted 2.5 percent yet domestic production of medical equipment grew, albeit by less than one percent.

Japan's market for medical equipment is second in size only to that of the United States.2[2] In 1998, medical equipment sales, including foreign company sales, were over 2,000 billion yen ($15 billion).3[3] By 2025, the market is expected to be around $73 billion.

MITI has recognized the significance of the senior services market, including the medical industry, by making it a target for enhanced competitiveness in preparation for the next century. Toward this end, the ministry has promised senior services industries that it will finance programs to enhance relevant collaboration between the government, business and academia.

Nonetheless, companies will still have difficulty introducing new medical equipment into the market unless Japan's regulatory and distribution systems are reformed. Because the estimate for market growth over the next 25 years ($73 billion) assumes current regulatory and distribution systems, the market is likely to grow even larger if reform occurs.

There are four major problems that need to be addressed:

- The Pharmaceutical Affairs Law. This law is redundant and cumbersome. It reasonably requires medical manufacturers to obtain safety approval for all products before they are marketed. However, Japan's approval process is longer than that of any other major developed country. Another problem related to the approval process is that procedures for "me-too" products are redundant. Such products, which incorporate technologies that are already on the market, should

only be examined to determine whether they are equivalent to existing products. Currently, "me-too" products are often reviewed as thoroughly as products that incorporate new technologies.

- Japan's Distribution System. This system is unnecessarily complicated and hinders the introduction of new medical equipment into the market. If the current distribution system were reformed, sales of medical equipment could increase by 5.6 percent.4[4]

- Ministry of Health and Welfare (MHW) Policy. MHW's approval policies for new products are too cautious and thereby impede market entry. While a certain degree of vigilance from MHW is vital to ensuring public health and safety, this vigilance needs to be weighed against opportunity losses incurred by both the medical products industries and patients when MHW's policies are too stringent. Indeed, MHW did not approve the Implantable Cardioverter Defibrillator (ICD) until this device has been in use in other countries for ten years. Yet ICD could save $46,500 per patient, and it offers a better treatment option for many patients.

- The National Medical Insurance Reimbursement System. This system creates a mechanism under which price competition for medical equipment does not work. Because reimbursement prices reflect the cost of a piece of equipment (regardless of its cost-efficiency), hospitals have no incentive to purchase new more cost-effective equipment and manufacturers have no incentive to produce it.

Eliminating these obstacles is an urgent task not only for the industry, but also for the Japanese government. Indeed, the Japanese government will need to adjust its policies to better accommodate the country's aging population. In 1999, the government spent $264 billion on health care.5[5] Estimates indicate that this expenditure will reach about $600 billion in 2010, and about $1,240 billion in 2025.6[6] To provide adequate services to its aging population without yet further increasing its growing national debt, Japan will need to find a way to reduce the cost of health care.

Japan will also continue to face pressure from other countries (especially the United States) until it deregulates its medical sector. Since 1986, Japan and the United States have discussed deregulation in the medical market under "The Market-Oriented Sector-Selective (MOSS) talks" led by the U.S. Department of Commerce. The two countries have also held regular bilateral meetings under "The U.S.-Japan Enhanced Initiative on Deregulation and Competition Policy" led by the Office of the United States Trade

Representative (USTR). USTR has specifically addressed the medical devices sector as part of this second initiative.7[7] USTR's main request is that the Japanese government speed up the approval process for new products. According to USTR, Japan's regulatory system, such as its procedures for approving new medical devices, is unnecessarily cumbersome and restrictive compared to other developed countries' systems.8[8]

It is time for Japan to start taking action to reduce obstacles to increased business in the medical equipment market. JMEA can and should help jump-start this process by putting pressure on the government to act quickly. Indeed, prompt action will be crucial to containing health care expenditures and providing better medical treatment for all Japanese.

II. BACKGROUND

1. Overview of the Japanese Market for Medical Equipment

The Japanese market for medical equipment has grown significantly over the last twenty years. It is one of the few sectors of Japan's economy that has grown steadily despite the country's protracted economic recession. Its growth reflects the public's growing interest in health and its high expectations for medical care.9[9] It also reflects the fact that Japan's population is aging and that medical professionals are increasingly reliant on new, often expensive technologies and treatments—particularly for previously incurable diseases (such as certain cancers and AIDs).

The Ministry of Health and Welfare (MHW) is the governmental agency responsible for regulating the medical equipment sector by implementing the Pharmaceutical Affairs Law. The main objective of the law regarding medical equipment is to protect and improve public health by enforcing regulations concerning quality, effectiveness, and safety. The law was first established in 1943 and was amended in June 1994.10[10]

In 1996, Japan spent $290 billion on medical care, or 7.3 percent of GDP, a figure that is relatively low compared to the United States' 14.2 percent expenditure, Germany's 10.5 percent, France's 9.6, or

Canada's 9.2 percent.11[11] Nonetheless, Japan's market for medical equipment is second in size only to the United States' $30 billion market.12[12]

Japan's demand for medical equipment in 1998 was 2,029 billion yen ($15.5 billion). The market grew 4.7 percent in 1998, 3.8 percent in 1997, and 12.7 percent in 1996. The growth is due to increases in both domestic production and imports. Domestic production of medical equipment in 1998 was 1,521 billion yen. It grew 0.4 percent in 1998, 4.0 percent in 1997, and 9.0 percent in 1996. Imports grew faster than domestic production, growing 11.2 percent in 1998, 5.8 percent in 1997, and 20.5 percent in 1996. In 1998, imports accounted for a full 41 percent of domestic demand. 13[13]

Production, Imports, Exports, and Domestic Demand* for Medical Equipment

(unit: million yen)

	1995	1996	1997	1998
Production	1,336,551	1,456,136	1,514,015	1,521,376
Imports	588,700	709,396	750,760	834,509
Exports	268,870	299,308	327,517	327,328
Domestic demand	1,656,381	1,866,224	1,937,258	2,028,557

* Domestic demand = Production + Imports - Exports

Source: "Annual Statistics of Pharmaceutical Industry's Production Trends," MHW.

The largest exporter of medical equipment to Japan is the United States, which accounted for more than 63.5 percent of total medical equipment imports into Japan in 1998. The United States also accounted for by far the largest portion of imports within nine of the top 10 equipment categories of imports.14[14] The medical equipment sector is one of the few sectors in which the United States enjoys a trade surplus with Japan, and the surplus has grown since 1991. In 1997, the surplus reached 409 billion yen ($3.38 billion), an almost 13 percent increase over 1996.

Germany is the second largest exporter of medical equipment to Japan, although its import share declined from 12 percent in 1991 to six percent 1997. Ireland, Switzerland and the United Kingdom followed with import shares of 3.4 percent, 2.8 percent, and 2.5 percent respectively.15[15]

2. Regulatory Controls

2a. Product Approval and Manufacturer/ Importer Licensing

Japan's Pharmaceutical Affairs Law was enacted in 1943, and from 1961 until 1994 no fundamental changes were made to it. In 1994, however, the law was amended to reflect the demand for better health care along with recent changes in medical technology.

The law is designed to minimize the risks inherent in the manufacture and use of medical products, to improve general health and hygiene, and to promote research and development of medical products.16[16] It applies to medical equipment, as well as drugs, quasi-drugs, and cosmetics.

The law has four main sections:

- definition and names of medical products;
- manufacture and import approval and licensing procedures;
- distribution control; and
- post-marketing surveillance.

Product approval and manufacturer/importer licensing procedures

The Pharmaceutical Affairs Law requires manufacturers and importers to obtain a license from MHW in order to sell medical equipment. A manufacturer must obtain a license for each of its plants that will produce an approved product, and importers must obtain a license for each of its offices that will sell an approved product. Licensing decisions are based on an examination of manufacturers' and importers' facilities, personnel and the qualifications of their technical directors.

A foreign manufacturer may directly apply for a product approval. If it does not have a legal presence in Japan, it can obtain approval by using a Japanese in-country caretaker (ICC) that will file an application on behalf of the foreign manufacturer (see Appendix 2). If necessary, the in-country caretaker has to make itself available for inquiries from relevant parties including MHW.

The standard processing period for obtaining an approval for "new" medical equipment is 12 months.17[17] "New" medical products are defined as products that are significantly different from previously approved products or those new in indications, effects or uses.18[18] It takes up to four months to approve "me-too" medical equipment—equipment that is essentially the same equipment that is already on the market. These

approval periods do not include time spent by the applicant answering questions or supplying additional information during the approval process.

All applications, both new and "me-too," are first submitted to the provincial government, which forwards the application to the Pharmaceutical and Medical Devices Evaluation Center (PMDEC) of the Ministry of Health and Welfare.19[19] PMDEC submits "me-too" applications to the Japan Association for the Advancement of Medical Equipment (JAAME), an independent entity that is responsible for conducting equivalency investigations. PMDEC performs all other necessary evaluations of "me-too" products. PMDEC first reviews new product applications and then consults with the Central Pharmaceutical Affairs Council (CPAC) concerning the application.

PMDEC makes final approval decisions for both new and me-too applications. It then notifies the provincial governor of its decision, and the governor issues the approval to the applicant.20[20] (See Appendices 4 and 5.)

Medical equipment that does not require approval

The law also lists medical products for which no approval is necessary. These products are considered to pose only minimal risk to human health. MHW regularly reviews the list and has steadily increased the number of items on it.21[21]

2b. Application for Insurance Coverage

Japan's national health insurance program covers all citizens. The two major types of health insurance are business and community health insurance. For business insurance, companies collect insurance fees from their employees. For community insurance, the fee is collected at a person's residence. In both cases the fees are forwarded to the government and put in a payment fund.22[22]

When patients receive medical treatment, they pay a part of the cost out of their own pockets. Medical institutions are reimbursed from the payment fund for the rest of the cost (see Appendix 3). Only insurance-approved treatments (including equipment) are eligible for reimbursement. Accordingly, both

medical institutions and doctors are only willing to buy and use insurance-approved equipment. Medical institutions also cannot be reimbursed for the use of approved medical equipment until MHW determines what reimbursement price will apply to the use of that equipment. Not surprisingly, it is almost impossible to sell medical equipment for which MHW has not yet determined a reimbursement price.23[23]

For a product to be covered under the national medical reimbursement system, an importer or a manufacturer of that product must indicate its intention to apply for insurance coverage on its application for product approval. The product's class must also be indicated:

Class A: Medical equipment that has already been evaluated and assigned a reimbursement price (excluding Class B equipment).

Class B: Medical equipment that falls under the existing "Special Insurance-Listed Medical materials.

Class C: Medical equipment other than A and B. This class is for devices that contain new technology.

After MHW approves a new product, there is a 20-day period during which MHW may notify applicants of flaws in their applications for insurance. If manufacturers who request Class A or B insurance for their product receive no notice during the 20-day period, procedures to set the reimbursement price and establish insurance coverage are automatically undertaken. Applicants who chose Class C insurance must wait until the end of the 20-day period and then, if no notice is made, they may apply for insurance. New insurance coverage is introduced four times per year.

3. Bilateral Negotiations between Japan and the United States

The Japanese and U.S. governments began discussing deregulation of Japan's medical equipment market in 1985 as part of the Market-Oriented Sector-Selective (MOSS) talks. The talks where aimed at removing trade barriers that limit market access within specific industrial sectors: medical equipment and pharmaceuticals, telecommunications, electronics, and forest industries.

The MOSS discussions on medical equipment focused on further opening the Japanese health care market. In the United States' view, the Japanese regulatory system was inefficient, inflexible, and prevented new producers and products from entering the Japanese market. The Japanese Government responded that its

regulatory system for the medical sector provided equal opportunities to both foreign and domestic companies. Nonetheless, the Japanese also recognized the importance of simplifying administrative procedures, and as a result, took steps to streamline its approval and licensing procedures and reimbursement system.24[24]

In 1997, both governments launched the U.S.-Japan Enhanced Initiative on Deregulation and Competition Policy (Enhanced Initiative) under the U.S.-Japan Framework for a New Economic Partnership (Framework). The goal of the Enhanced Initiative is to increase efficiency and promote economic activity in order to better serve consumers' interests. Toward this goal, both governments agreed to conduct a serious exchange of views concerning competition policy, distribution practices, and issues related to transparency and government practices.

With the launch of this bilateral dialogue, the MOSS discussion was made into a working level discussion under the Enhanced Initiative. The Initiative includes five expert-level working groups similar to those established in the MOSS process: medical devices and pharmaceuticals, telecommunications, housing, financial services, and competition policy and distribution.

As of May 1999, the Enhanced Initiative had reached agreement on a number of deregulation measures for the medical equipment sector.25[25] These included Japan's agreement to:

- improve the consistency and speed of its approval process for medical equipment;
- improve the consistency and speed of its reimbursement process; and
- accept foreign clinical test data for the approval of new medical equipment.

4. The United States' and Other Developed Countries' Regulatory Systems

Prior to 1997, the United States' approval process for medical equipment was considerably longer than that of Japan and certain European countries. It took two to three years to acquire approval for new equipment in the United States, two months to a year in Japan, and even less time in the United Kingdom, Germany and France. Consequently, U.S. manufacturers sometimes received approval for their products in Europe and Japan before receiving approval in the United States. They also began selling their equipment in Europe and Japan before the United States.

In 1997 in response to requests from its domestic medical industry, the United States amended its law that controls medical equipment, and approval times decreased markedly.26[26] Currently it takes longer to obtain approval in Japan than in the United States.27[27]

Footnotes:

28[1] The following yen-dollar exchange rates are used throughout this paper:

Yen – Dollar Exchange Rate

Year	Yen/US $
1995	94.00
1996	108.78
1997	121.06
1998	130.90
1999	113.91

29[2] Kay S. Wayne, "The plan for EHCR in the US," JAAME News, no.14 (1999), p. 5.

30[3] MHW, Annual Statistics of Pharmaceutical Industry's Production Trends 1998 (Tokyo: MHW, 1999), p. 45.

31[4] This estimate is based on Suznami and Shujiro's estimate of Japan's demand elasticity. For further explanation, see the commercial analysis section of this paper.

32[5] Katu Umeda, "The reform of the insurance system," JAAME News, no.13 (1999), p. 1.

33[6] Koichi Kawabuchi, Introduction to Health Care Economics in Japan – Understanding Japanese Health Care Reform (Tokyo: Yakuji Nippo, Ltd., 1998), p. 31.

34[7] "National Trade Estimate Report on Foreign Trade Barriers 1999" (USTR, 1999), http://www.ustr.gov/reports/nte/1999/contents.html

35[8] Ibid.

36[9] "Industry Sector Analysis: Medical Device Market," (Tokyo: Commerce Service in Japan, 1999), http://www.csjapan.doc.gov/isa99/medicaldevice.html

37[10] MHW, Guide to Medical Device Registration in Japan, (Tokyo: Yakuji Nippo, Ltd., 1997), p. 1.

38[11] Kawabuchi, Introduction, p. 4.

39[12] Kay, p. 5.

40[13] JETRO, Market Report, p. 3.

41[14] MHW, Annual Statistics, p. 44.

42[15] JETRO, Market Report, p. 4.

43[16] MHW, Guide, p. 1.

44[17] JETRO, Market Report, p. 8.

45[18] MHW, Guide, p. 32.

46[19] CS Japan.

47[20] Ibid.

48[21] MHW, Guide, p.31.

49[22] Kawabuchi, Introduction, p. 2.

50[23] JETRO, Market Report, p. 12.

51[24] "MOSS Agreement on Medical Equipment and Pharmaceuticals" (ITA, 1986), http://www.ita.doc.gov/region/japan/ta860109.html

52[25] "Second Joint Status Report on the US-Japan Enhanced on Deregulation and Competition Policy" (Ministry of Foreign Affairs of Japan, 1999), http://www.mofa.go/region/n-america/us/economy/date/dereg9805.html

53[26] "Overview—FDA Modernization Act of 1997" (FDA, 1998), http://www.fda.gov/cdrh/devadvice/371.html, and "Medical Equipment" (JETRO), http://www.jetro.go.jp/ip/e/access/medical.html

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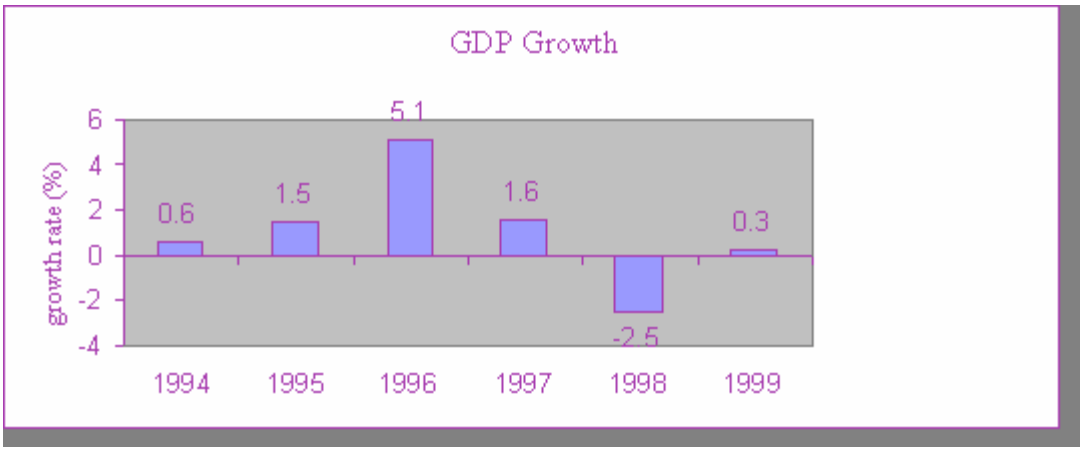
III. ECONOMIC ANALYSIS

The Japanese economy plunged into recession in 1994. It has been slowly recovering ever since but remains weak. Insecurity still prevails in the financial and labor markets. To make matters worse, the government's debt is increasing. Managing health care costs will be important to future economic recovery, particularly because Japan's aging population will demand more health care than ever before in the coming years.

1. Japan's Recession



Japan's GDP was 481,865.2 billion yen ($ 4,230.2 billion) in 1999. Its real GDP growth rate was just 0.3 percent compared to the previous year,54[28] and the capital and financial account ran a deficit of 56,148 million yen ($492.9 million). As of the end of fiscal year 2000, the total long-term governmental debt is projected to reach 645 trillion yen ($5.6 trillion).55[29]

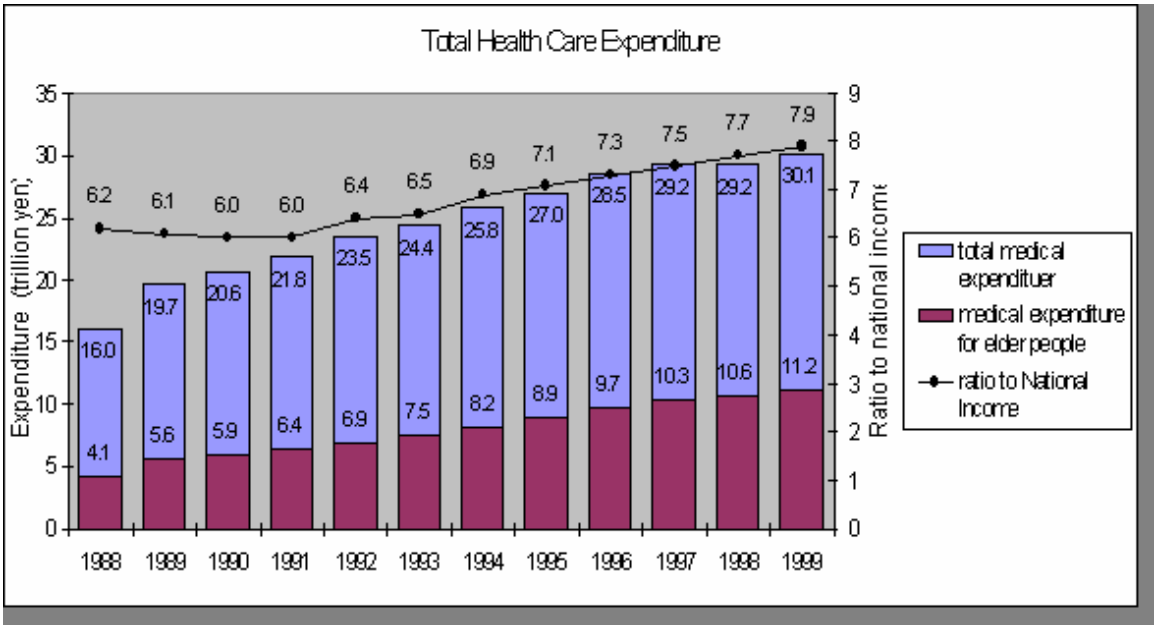
(Source: "Gross Domestic Product: Fourth Quarter 1999 (first preliminary)", EPA, 1999)

Other 1999 indicators are no more encouraging. The unemployment rate hit 4.7 percent—the worst in modern Japan's history—and there were 10,249 bankruptcies, which is almost the same level as the previous year.56[30]

2. Increasing Health Care Expenditures

Japan's health care expenditures are increasing in tandem with the elderly portion of its population. While total medical expenditures in 1998 were the same as the previous year, the ratio of health care expenditures to national income increased slightly (from 7.3 to 7.5 percent). In 1999, national health care expenditures were estimated at 30.1 trillion yen ($264.2 billion), and the expenditure to national income ratio grew to 7.9 percent. MHW estimates that health care expenditures will reach to 38 trillion yen ($333.6 billion) in 2000

and 141 trillion in 2025.57[31]



(Source: JAAME News, JAAME, 1999 September)

The government is researching various means of reducing health care expenditures. MHW, for example, is conducting studies of how to reform the reimbursement and hospital systems. (See the policy analysis section below for a discussion of how new innovative medical equipment can contribute to reducing health care expenditures.)

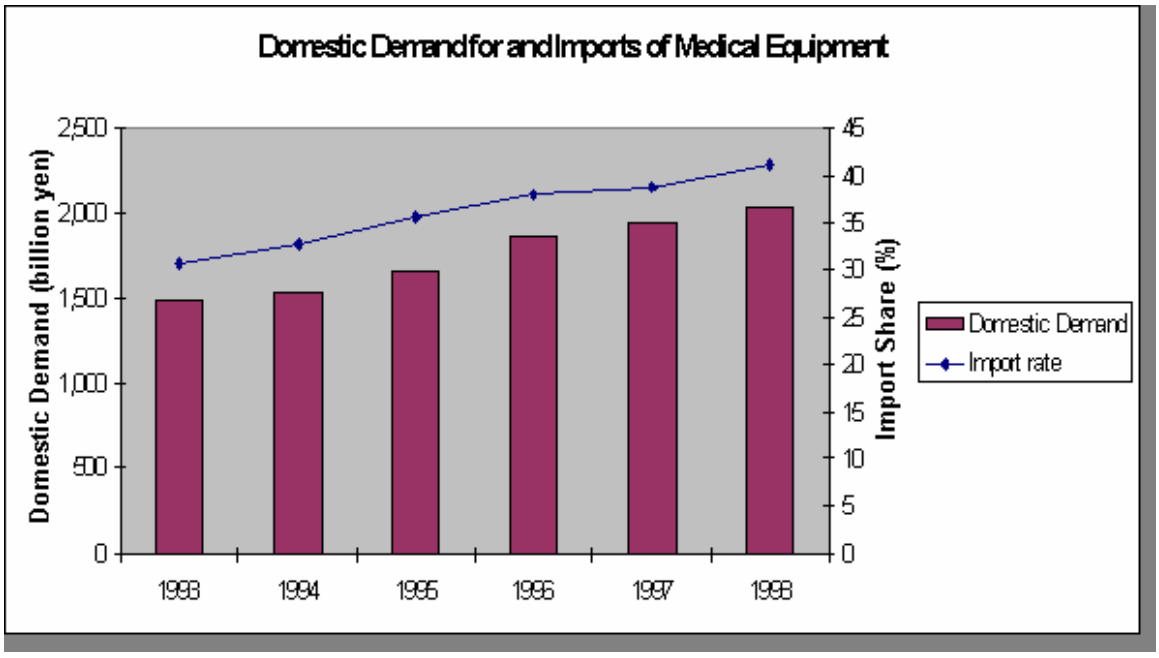
3. Economic Performance of Japan's Medical Equipment Industry

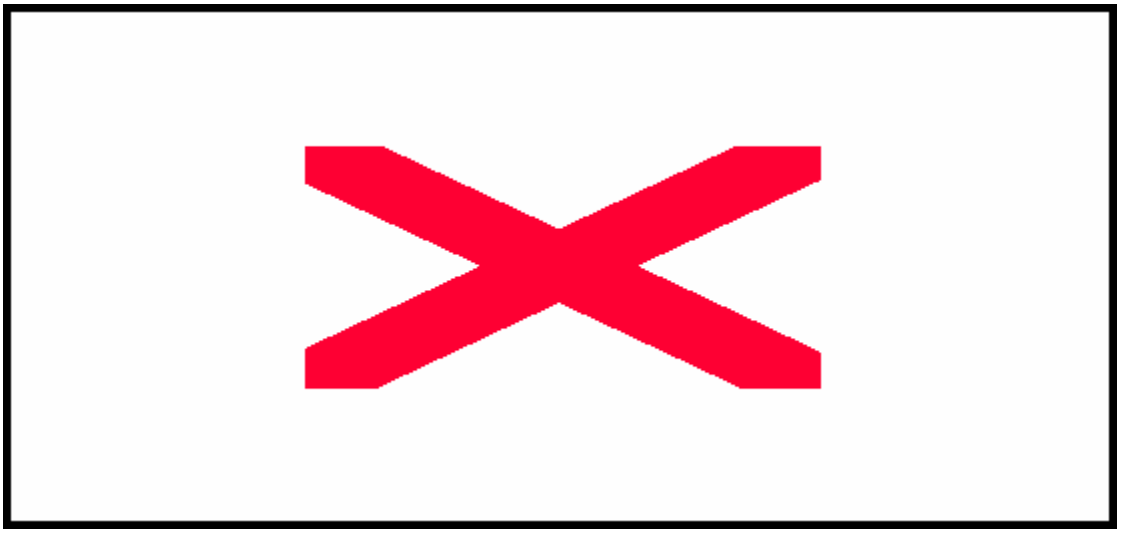
The Japanese medical equipment industry has not received as much attention domestically and internationally as Japan's major leading industries such as the automobile and steel industries. The medical equipment industry, however, is one of the few industries in Japan that has continued to grow despite the country's serious recession. In 1998, domestic production of medical equipment was 1,521.4 billion yen ($11.6 billion or 0.3 percent of GDP). The domestic demand for medical equipment was 2,028.6 billion yen ($15.5 billion or 0.4 percent of aggregate domestic demand). While aggregate national demand and GDP

have declined 1996 to 1998, the country's domestic demand for and production of medical equipment have grown steadily.

IV. COMMERCIAL ANALYSIS

Japan's medical equipment market is extremely attractive to foreign manufacturers because it is large and growing rapidly. In 1995, the cost of medical equipment accounted for 5.9 percent of total medical expenditures. If this ratio were to remain constant (and if MHW's projections for total health care expenditures are accurate), total demand for medical equipment will reach 4,012 billion yen in 2000 and 8,319 trillion yen in 2025. In 1998, the domestic market for medical equipment had already exceeded 2,000 billion yen ($15 billion).





Source: "Japanese Market Report –Regulations & Practices-: Medical Equipment", JETRO (1998)
"Annual Statistics of Pharmaceutical Industry's Production Trends," MHW (1999)

However, despite the fact that imports in 1998 were valued at 834.5 billion yen ($6.4 billion) or 41.1 percent of the total market and despite that imports relative to total market size have risen steadily in recent years, foreign governments have often expressed their concern that the Japanese medical industry is relatively closed. (See Appendix 5 for a comparison of import penetration in the medical equipment market compared to other high-tech markets.) In fact, burdensome government regulations combined with Japan's cumbersome distribution system have hindered both foreign and domestic Japanese companies from entering the market.

Japan has reformed some of its medical equipment regulations as a result of negotiations with major trading partners during GATT and GATS reviews of Japanese trade policy. For instance, tariffs on medical equipment were dramatically reduced through multilateral negotiations, and now medical equipment is imported duty free.58[32] Bilateral negotiations, notably with the United States, have also been successful in achieving reforms. The time it takes to gain approval for new medical equipment has been decreased, approval procedures have been simplified, and the number of items that do not need formal MHW approval have been increased. Nonetheless, unnecessary bureaucratic procedures in the product approval process and certain business practices continue to hinder the entrance of new medical equipment products into the market. Both also increase the cost of supplying medical equipment, which means that Japan's total health care bill is larger than it needs to be.

1. Unnecessary Bureaucratic Procedures

In today's world of fast paced technological innovation, some products are outdated almost as soon as they hit the market. The life-cycle of medical equipment is already down to about two to three years. [59][33]

In this environment, it is crucial to a company's survival for it to get new products to market as quickly as possible and to continually introduce products. Lengthy product approval procedures can significantly diminish a product's profitability, as well as delay the incorporation of new technologies into the research and design of future products.

Japan's approval process is longer than that of any other major developed country; it usually takes a full year to obtain new product approvals in Japan. There are several reasons for this:

- MHW's policies are too risk averse and therefore hurt both medical equipment manufacturers profits and the quality of patient care.
- MHW does not have enough personnel to keep up with new medical product applications.60[34]
- Obligatory third-party investigations unnecessarily slow the approval process for "me-too" products, which incorporate technology that is already widely available on the market.

This last problem concerning third-party investigations is actually a result of the U.S.-Japan MOSS talks. It was the United States that asked Japan to commit a certain part of its new product approval procedures to a third party.61[35] The goal was to improve transparency and to speed up the procedures by using external sources. However, the situation became worse after the reform.

Before the reform, MHW's Pharmaceutical and Medical Devices Evaluation Center (PMDEC) conducted similar approval investigations for both new and "me-too" equipment.62[36] But because "me-too" equipment only incorporates previously approved technology, full-scale new equipment examinations are redundant. "Me-too" products

only need equivalency examinations to ensure that they have the same effect as equipment that has already been approved. The redundancy was compounded by the fact that PMDEC was chronically understaffed and lacked transparency.

In 1995, the Japanese government significantly revised the Pharmaceutical Affairs Law with the goal of providing appropriate regulations for each type of what is a growing diversification of medical devices.63[37] As part of the revision, Japan established a new institution, the Japan Association for the Advancement of Medical Equipment (JAAME), devoted to examining "me-too" products.64[38] JAAME was supposed to review "me-too" applications, make equivalency determinations, and report the results to PMDEC (see Appendix 6). However the new procedures did not shorten (and in some cases even lengthened) the approval period for "me-too" products because PMDEC still reviewed JAAME's findings, and it sometimes rejected these findings and initiated its own equivalency investigation.

2. Business Practices

Most medical equipment is sold in Japan through a complex system of distribution channels. Although manufacturers directly provide expensive and high-tech equipment such as CT scans and MRIs, it is common for hospitals to purchase the rest of their products and equipment from just one or two distributors.65[39] In both the United States and the European Union, the portion of sales that go through distributors is much smaller and the distribution systems are much simpler—which means that medical products are often much cheaper because dealer systems raise the price of medical equipment by 15-25 percent.66[40] A 25 percent drop in prices in Japan could mean a 5.5 percent ($849.1 million) increase in sales.67[41]

Problems surrounding Japan's hospital system are largely responsible for the complex configuration of the country's medical equipment distribution system. These problems are further detailed in the policy analysis section and Appendix 7.

V. POLICY ANALYSIS

In addition to the prolonged process for approving new medical equipment, a number of other factors impede access to Japan's market for medical equipment, including MHW's overly cautious policies, and both the medical equipment and hospital care reimbursement systems. MITI's Millenium Project may help the medical equipment industry grow in the coming years, but the industry has until now maintained only weak relations with this ministry—which means that the industry has not benefited from MITI's industrial policies.

1. MHW's Policy

One of MHW's main missions is to improve public health. Since medical equipment directly impacts human lives, MHW is particularly concerned with ensuring its safety. The public holds not just manufacturers but also MHW responsible for any medical accidents that occur due to faulty equipment. It is not surprising then that, even if a manufacturer has a good track record for introducing safe products into the market, MHW scrutinizes all new product approval applications carefully. However MHW has been somewhat too prudent in accepting new technology, and as a result, medical manufacturers, both domestic and foreign, have lost opportunities to introduce new technologies.

A study conducted by the private management consulting firm, Bain & Company Japan, shows that MHW's policies delay the introduction of new technologies. The study found that the industry has missed business opportunities for many years and that patients and the Japanese government have wasted health care dollars because of these delays. For example, the study found that Japan would save 5.3 million yen ($ 46,500) per patient by approving Implantable Cardioverter Defibrillators (ICDs) for the treatment of tachyarrhythmia (racing of the heart).68[42] In April 1996, after the completion of the study, MHW finally approved the product. Other countries had already been using ICD therapy for up to ten years69[43] (see Appendices 8 and 9).

2. Medical Equipment Reimbursement

Under the Health Insurance Law and the National Health Insurance Law, the Japanese government insures medical services (including equipment use fees) for all Japanese citizens. The government collects medical insurance fees from the public and pools the money into a governmental payment fund, such as the Social Insurance Medical Fee Payment Fund. Doctors and medical institutions are reimbursed for their services by the payment agency based on uniform reimbursement prices set by MHW. As previously noted, it is almost impossible to sell products without reimbursement approval because medical institutions do not want to use products for which they will not reimbursed.

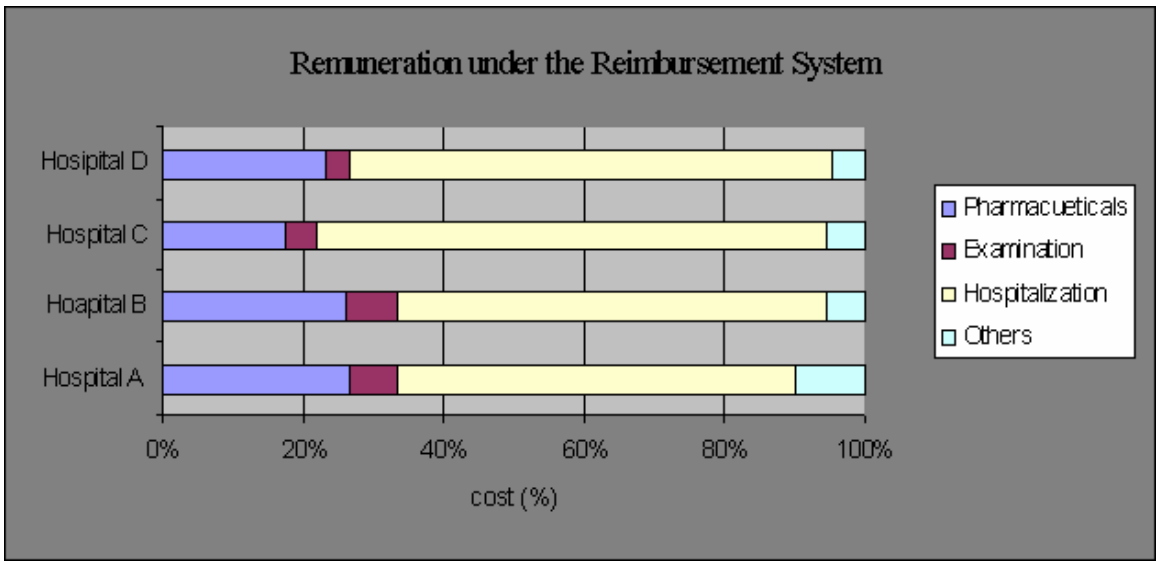
Unfortunately, Japan's reimbursement policy skews competition by creating a situation in which hospitals are price indifferent in their new equipment purchases. [70][44] Hospitals often do not make cost comparisons when buying equipment because reimbursement prices usually reflect the sale price of a piece of equipment; each brand of products is assigned its own reimbursement price (even though a product has the same function as another product) and the government guarantees to pay back the purchase cost of equipment.71[45] Under the current reimbursement system, new, more cost-effective equipment is no more appealing than less cost-effective because the government reimburses more expensive equipment at a higher rate than more cost-effective cheaper equipment.

This system is clearly disadvantageous to newcomers, especially to domestic newcomers because Japanese manufacturing industries have typically grown by producing cheaper versions of foreign products. Japan has the skill and technology to produce cost-effective manufacturing products. However, the current reimbursement system makes it extremely difficult for Japanese companies to get new products into the market.

3. Hospital Care Reimbursement

Japan is famous for its long hospitalizations. In 1996, the average hospital stay in Japan was 33.5 days, whereas in the United States, United Kingdom and Sweden average stays were just 7.5 days, 9.8 days, and 7.5 days respectively.72[46] While this phenomenon is largely due to the fact that the reimbursement system rewards hospitals for keeping patients in the hospital as long as possible,73[47] increased use of innovative medical equipment would likely shorten costly hospital stays. Shortened stays would result in significant

cost savings because the cost of hospitalization accounts for over 50 percent of the remuneration hospitals receive.



(Source: "Health Care Reform", Kawabuchi, 1998)

Length of Hospital Stays in Japan and the United States

I. Procedure	Length of Stay	
	Japan	**US**
PTCA (coronary balloon catheterization)	1 week	2-3 days
Pacemaker Implantation	2-3 week	1-2 days
Implantable Cardioverter Defibrillator Implantation	1 month	2-5 days

(Source: Heath Industry Manufacturers Association)

4. The Medical Equipment Industry's Weak Relationship with MITI

MHW largely controls the medical equipment industry because medical equipment plays a crucial role in maintaining public health. In order to facilitate product approvals, the industry has concentrated its energies on developing good relations with this agency. However, MHW's interest lies in studying

advanced medical technology and protecting public health, not in protecting the industry's commercial interests.

In order to gain more support for the development of a strong industry, the medical equipment sector needs to develop stronger relationships with MITI, the only ministry that promotes commercial interests and industrial competition. MITI has succeeded in enhancing the competitiveness of strategic industries such as the electronics, automobile, and steel industries.

5. MITI's Millennium Project74[48]

In 1999, MITI proposed a comprehensive project, the "Millennium Project," to help build Japan's competitiveness in the 21st century. The project covers 15 technology areas and is geared toward creating "frontier markets" that will create new market and job opportunities.

One of the primary goals of the project is to build greater collaboration between business, universities and the government. Toward this end, the government will provide generous financial support for research and development and the development of smoother technology transfers from the research phase to the product-engineering phase. The project also includes the elimination of regulatory impediments that prevent business form achieving its full potential.

The senior services market was selected as one of the 15 target areas. MITI proposes to promote the development of technologies that help senior citizens lead rich and fulfilling lives. The project will support research and development within the medical industry and help the industry introduce new cost-effective and innovative products into the market.

Footnotes:

75[27] Mr. Kimura, interview by author, 27 January 2000.

76[28] "Gross Domestic Product: The First Preliminary Estimates" (Economic Planning Agency of Japan, 2000), http://www.epa.go.jp/2000/g/qe994/jissuu.gif

77[29] "Fiscal Policy Speech by Minister of Finance, Kiichi Miyazawa, 147th Session of the National Diet" (Ministry of Finance of Japan, 2000), http://www.mof.go.jp/english/busget/e1b057.htm

78[30] "Main Economic Indicators March 2000" (Economic Planning Agency of Japan, 2000), http://www.epa.go.jp/geturei/2000mar-9.gif

79[31] Kawabuchi, Introduction, p. 31.

80[32] JETRO, Market Report, p. 1.

81[33] "Comments by the Health Industry Manufacturers Association on Identification of Priority Practices" (HIMA, 1999), http://www.himanet.com/publicdocs/301watchlistpetition.html

82[34] Mr. Kimura.

83[35] ITA,"MOSS Agreement."

84[36] MHW, Guide, p. 31.

85[37] MHW, Guide, p. 2.

86[38] ITA, "MOSS Agreement."

87[39] ITA, "MOSS Agreement."

88[40] "Medical Technology: Driving Efficiency, Not Costs, in Japan's Health Care System" (HIMA, 1997), http://www.himanet.com/publicdocs/drivingefficiency.htm

89[41] This calculation uses Suzanami and Shujiro's estimate of Japan's demand elasticity (.222). 5.5 percent is arrived at by multiplying the 25 percent price reduction by the .222 estimated demand elasticity. Yoko Suzanami, Shujiro Urata, and Hiroki Kawai, Measuring the Costs of Protection in Japan (Washington, D.C.: Institute for International Economics, 1995), p. 33.

90[42] "Examples of Cost Efficient Technologies As Cited in the Bain Study" (HIMA, 1997) http://www.himanet.com/publicdocs/bainexamples.htm

91[43] "CASE STUDY: The Implantable Cardioverter Defibrillator (ICD)" (HIMA, 1997) http://www.himanet.com/publicdocs/icd.htm

92[44] JETRO, The Survey on Actual Conditions Regarding Access To Japan - Medical Equipment (Tokyo: JETRO, 1996), JETRO, p. 13.

93[45] JETRO, "Market Report", p. 12.

94[46] "The Summary of 1998 White Paper (Japanese version)" (MHW, 1999), http://www.mhw.go.jp/wp/wp99_4/chap-a3.html

95[47] HIMA, "Medical Technology."

96[48] "Fiscal 2000 Priority Trade and Industry Policies" (MITI, 1999), http://www.miti.go.jp/info-e/cIP9982e.html

VI. INTERNATIONAL HARMONIZATION OF STANDARDS

Each government in the world regulates the use of medical technology in order to ensure the public's safety. While such regulations provide a valuable public good, they also can act as technical barriers to trade, and such barriers are becoming more and more of a problem as trade expands. Indeed, concern over such technical barriers to trade has become one of the central issues confronting the international trade system, and medical equipment is one product category in which standards differences are a particular problem. To date, there is no international agreement concerning medical equipment standards.

1. Standards Systems for Medical Equipment

In Japan, the Pharmaceutical Affairs Law requires medical equipment to meet the Japanese Industrial Standards (JIS) of the Industrial Standards Law. Japan is working toward harmonizing JIS with international standards, such as those of the International Standard Organization (ISO) and the International Electronic Commission (IEC), in order to comply with the WTO (TBT) Agreement.97[49]

The Pharmaceutical Affairs Law also requires manufacturers to meet the standards for manufacturing control and quality control of medical devices under the so-called Good Manufacturing Practices (GMP) standards. The United States uses 21CFR820GMP as its standard for manufacturing control, and the European Union uses EN46001~2. ISO 13485 is considered to be the international standard for regulating the manufacture of medical devices. There is a growing movement toward harmonizing each country's GMP with ISO 13485.98[50]

The Uruguay Round trade negotiation yielded considerable success in reducing market access barriers raised by tariffs, rules of origin, custom valuation, import licensing procedure, and pre-shipment inspection. Now some WTO members are considering whether Japan's distribution systems constitute market access barriers. At this stage, there is no agreement as to whether these systems violate any WTO agreements. However, it is true that the business practices that currently prevail in the medical equipment industry make market entry difficult for both domestic and foreign manufacturers.

2. International Harmonization: The Global Harmonization Task Force (GHTF)

In recognition of the increasing need for international harmonization of regulatory controls for medical equipment, representatives of the governments and private sectors of the United States, the European Union, Canada, and Japan formed the Global Harmonization Task Force (GHTF) in 1993. GHTF's primary goal is to harmonize regulatory systems, promote technological innovation, and facilitate international trade.

Members are divided into categories. Principal members are representatives of a national government or relevant industries from the European Union, the United States, Canada, Australia and Japan. General members are any persons, representatives of a governmental body or relevant industries from non-principal countries or NGOs.

GHTF has established four study groups with the following responsibilities:

Study Group 1 -To compare present regulatory systems around the world;
To identify the essential elements/principles for harmonization;
To identify obstacles to uniform regulations; and
To develop a standardized format for pre-market submissions and common labeling.99[51]

Study Group 2 -To harmonize data collection and reporting systems such as post-market surveillance.100[52]

Study Group 3 -To examine existing quality system requirements; and
To identify areas for harmonization.101[53]

Study Group 4 -To examine quality system auditing practices; and
To develop harmonized medical device auditing process.102[54]

GHFT has conducted a series of discussions and information exchanges among its members. To date, however, no specific harmonization measures for medical equipment have been established.

Participation in GHTF is beneficial to the Japanese medical industry for three reasons:

- GHTF will help Japan reform and simplify its regulatory system by providing a forum in which government officials can learn about other countries' regulatory systems.
- GHTF will help Japanese manufacturers promote exports because by harmonizing its standards with other countries' standards, Japan can reduce the additional production costs associated with adjusting products to meet each individual importing countries' standards.

GHFT will help individual medical device manufacturers gain international recognition because private companies and associations are allowed to participate in GHFT meetings as general members. To date, however, few medical device companies have attended the meetings.

VII. POLITICAL ANALYSIS

The Japanese government currently faces two enormous challenges: the country's prolonged recession and the government's growing debt. Since the economic bubble burst in 1994, the government has implemented several policies in an attempt to speed Japan's economic recovery. However, instead of stimulating the economy, some of these policies have only depleted government coffers. A reduction of health care expenditures is especially important given this situation and given that Japan's aging population is expected to significantly increase health care expenditures in the coming years.

Since all political parties recognize the importance of containing health costs, there is no opposition to health care reform per se. Nonetheless, health care will undoubtedly be a large issue in this October's House of Representatives election (which happens once every four years).

Japan also can expect the United States and possibly other governments to raise deregulation issues, including deregulation of the medical industry, at the upcoming July G-8 Summit, which Japan will host.

1. Economic Recovery

While the Japanese government has implemented some programs in an attempt to speed economic recovery, the county's recession continues and many Japanese are increasingly disappointed with the government's inability to resolve the crisis. Some citizens are beginning to not trust governmental policies at all, which will make recovery all the more difficult. In order to reverse this pessimism and regain the public's confidence, the government urgently needs to turn the economy around.

MITI's "Millennium Project" (see policy analysis section) may help in regaining public confidence. Former Prime Minister Obuchi supported this project, and the new Prime Minister, Mr. Mori, has pledged to carry out Mr. Obuchi's policies.103[55] But other countries are also increasingly impatient with the Japanese government's failure to stimulate its economy. A stable Japanese economy is important to economic stability around the world, and especially in Asia.

2. Meeting the Needs of Japan's Aging Population

As discussed in the policy analysis section, MHW has researched measures to reduce health care expenditures and to provide the public with an efficient social welfare system. Prime Minister Mori is also committed to support these efforts to build a sustainable, stable and efficient social welfare system that will be able to provide for Japan's aging population.104[56]

3. House of Representatives Elections

The Japanese government's failure to revive its ailing economy has left many Japanese questioning the government's ability to do its job. Accordingly, gaining public confidence and trust will be essential to winning election to the House of Representatives in October. Voters are expected to cast their ballots for candidates who they believe will be able to jump start the economy and reduce the country's debt. Accordingly, candidates will be eager to show how they have tackled these issues in the past how they will continue to make efforts to solve these problems after the election.

4. The G-8 Summit

Besides the upcoming election, another Japanese political priority is the success of the G-8 Summit this July. At this summit, Japan can expect other governments to push for further deregulation of Japan's economy. The Americans will likely want to discuss health care deregulation because the Health Industry Manufacturers Association (HIMA), an American association, has filed two petitions concerning Japanese medical standards with the USTR. HIMA has asked USTR to include Japanese deregulation of the medical equipment industry on the Summit's agenda, as well as to put the Japanese medical industry on the section 301 "Watch List."105[57] Japan will need to at least acknowledge other countries' concerns at the summit.

VIII. INSTITUTIONAL ANALYSIS

In devising a strategy for pushing the Japanese government to deregulate the medical equipment industry, JMEA will need to account for various institutional interests such as those of MHW and MITI, the Advisory Council on Social Security, JMEA, Japanese business associations and international institutions.

1. MHW and MITI

As previously noted, the medical industry does not have a close relationship with MITI. One reasons for this is the lack of cooperation between MHW and MITI, which is not surprising given that cooperation among all of Japan's ministries is relatively weak. Whereas MHW focuses on public health and welfare, MITI focuses on promoting industrial development and competition. No agency provides a liaison between the two.

1a. MHW

MHW is responsible for a wide range of activities all geared toward ensuring public health and welfare. Following a scandal involving tainted blood in 1995, MHW underwent a comprehensive structural reform, and it also re-doubled its efforts to control and regulate medical equipment in order to prevent further medical accidents. MHW's Pharmaceutical and Medical Devices Safety Bureau (PMDSB) is responsible for ensuring the safety of pharmaceuticals and medical equipment. PMDSB oversees the Pharmaceutical and Medical Devices Evaluation Center (PMDEC), which decides whether or not to grant product approvals and industry licenses (see Appendix 10).

Although it does not have any legislative power, MHW wields a great deal of influence over legislation related to public health, including the Pharmaceutical Affairs Law. If MHW does not support a change to the law, it is unlikely the change will be made.

Another body, the Council on Health Insurance acts as an advisory body to MHW on a wider range of health care issues. The Council is chaired by Mr. Yuichi Shioya and has researched various options for reducing health care expenditures. The Council has recommended that MHW eliminate all possible waste from the health care system and has suggested that the medical insurance system, including the

reimbursement system, needs to be reevaluated.106[58] In response, MHW established the Committee on Review of the Reimbursement System last year. The committee chairman is Mr. Yuichirou Goto, and the vice-chairman is Mr. Hisao Endo. The Council's most recent report urges MHW to implement a comprehensive reform of the insurance system.107[59]

1b. MITI

MITI is responsible for Japan's industry and international trade policy. Its activities cover a wide range of industrial fields, such as basic industries, machinery and information industries, as well as consumer goods industries (see Appendix 11). The current Minister of MITI is Mr. Takashi Fukaya. MITI's Machinery and Information Industries Bureau (led by Mr. Shinichiro Oota) oversees the ministry's Medical and Welfare Equipment Industries Office (led by Ms. Yukiko Araki). The latter office is responsible for planning overall policies and programs for the medical and welfare industries.

Like MHW, MITI does not have any legislative powers. However, because MITI is facing pressure from foreign governments (notably the United States and the European Union), regarding deregulation of the medical equipment industry, MITI is interested in simplifying the Pharmaceutical Affairs Law and other laws related to medical equipment. Under the MOSS talks, MITI negotiated with the U.S. government concerning deregulation in the medical equipment sector. In order to fulfill commitments made in those talks and maintain good relations with the United States and other governments, MITI backs further deregulation of the medical industry, including changes in the Pharmaceutical Affairs Law. MITI's International Trade Policy Bureau (led by Mr. Hidehiro Konno) leads Japan in international trade negotiations.

2. The Advisory Council on Social Security

This Council advises the Prime Minister on social security matters. Its members come from various interest groups, including the House of Representatives, the House of Councilors, academic authorities, and ministries. Mr. Kenichi Miyazawa chairs the

Council. Like the Council on Health Insurance, this council recently submitted a report to the Minister of MHW recommending that MHW make more of an effort to implement a comprehensive reform of the health insurance system.

3. JMEA

JMEA is in a difficult position because it represents 18 different medical organizations with highly divergent interests (see Appendices 12 and 13). Whereas manufacturers are eager to simplify the distribution system as a means of lowering the end-user price of their products, distributors are wary of any reforms that would decrease their business opportunities. However, all of JMEA's members hold the common interest of increasing the sales of medical equipment and creating more job opportunities for members.

JAAME is one of JMEA's members. As mentioned earlier, JAAME is the third party designated by the Japanese government to investigate the equivalence of structures, usage, indications, performance, etc. for "me-too" products. JAAME also supports research and development of medical devices and organizes various seminars to improve the competence of medical care personnel and others.108[60]

4. Business Associations in Japan

Other industry associations are also strong proponents of deregulation, and some of these associations, such as the Keidanren, have close ties with MITI and are very influential in the legislative branch. By building a coalition with these business associations, the medical devices industry will be in a better position to gain the support of MITI and other policymakers.

The building blocks for such a coalition are already in place because some JMEA members are also members of other associations. Both Hitachi and Toshiba, for example, are leading medical equipment manufacturers, and they both have high ranking officers who are also important in the Keidanren. The president of Hitachi (Mr. Kanai) is vice-chairman, chairman of the board, and representative director of the Keidanren; the president of Toshiba (Mr. Nishimura) is the president and chief executive officer of the board of councilors of the Keidanren. In fact, the Keidanren has already publicized a

report in which it requested that the Japanese Government promote regulatory reform in the medical care and welfare system.109[61] The Japan Chamber of Commerce and Industry is another influential business association in Japan. Its chairman is Mr. Kousaku Inaba.

5. International Institutions

Because of its large size and huge potential, many international institutions are interested in deregulation of the Japanese medical market. The United States is especially active in pressuring the Japanese government to open the market. The Health Industry Manufacturers Association (HIMA), an American trade association for medical equipment, is actively pushing for greater opening. In 1998 HIMA opened an office in Tokyo. The Director is Mr. Frank Vaughan.

The American Chamber of Commerce of Japan (ACCJ) is another American institution that is actively tackling deregulation in the Japanese market. ACCJ has a subcommittee on medical devices and an office in Tokyo. The current chairman is Edward Northup. Subsidiaries of major U.S. medical companies in Japan are also members of the subcommittee. ACCJ participates in the meetings of Prime Minister's Committee on Deregulation.110[62]

The European Business Community of Japan (EBC) also has an office in Tokyo and participates in Committee on Deregulation meetings. EBC's chairman is Mr. Alain Coine.111[63]

IX. RECOMMENDATIONS

1. Long-Run Goal

In order to both improve access to the Japanese medical equipment market and reduce Japan's health care expenditures in the long run, three problems need to be addressed:

- Japan's complex product distribution system—which raises the price of medical equipment by 15-25 percent—needs to be simplified;
- The Ministry of Health and Welfare's (MHW's) reimbursement system—which negates price competition—needs to be revised; and
- MHW needs to become less risk-adverse in approving new products.

Addressing these problems is complicated by the fact that they are all interrelated and actions designed to address one problem will likely change the nature of the other problems. Nonetheless, JMEA should take the following actions to push Japan toward needed structural reforms. JMEA should:

- Launch an initiative aimed at reforming of the distribution system;
- Push for reform of the reimbursement system;
- Push MHW to change its policies regarding approval of new medical equipment; and
- Improve the international competitiveness of Japan's medical industry.

2. Short-Run Goal

JMEA should also take short-term actions that can result in more rapid improvements in market access. In the short-run, JMEA can target further liberalization of the Pharmaceutical Affairs Law. Specifically, JMEA should push for an increase in the number of personnel who review applications in JAAME and PMDEC. It should also push for the following changes to the law:

- The time clock for approving new products should be shortened from one year to six months;

- The redundant examination of "me-too" products conducted by both JAAME and PMDEC should be stopped; and
- The number of items that do not require MHW approval should be increased.

Footnotes:

112[49] "Outlook of Industrial Standardization in Japan" (Chiba University), http://www.hike.te.chiba-u-ac.jp/ikeda/JIS/what1.htm

113[50] Ibid.

114[51] "Purpose of Study Group 1" (GHTF), http://www.ghtf.org/sg1/sg1.htm

115[52] "Purpose of Study Group 2" (GHTF), http://www.ghtf.org/sg2/sg2.htm

116[53] "Purpose of Study Group 3" (GHTF), http://www.ghtf.org/sg3/sg3.htm

117[54] "Purpose of Study Group 4" (GHTF), http://www.ghtf.org/sg4/sg4.htm

118[55] "Policy Speech By Prime Minister Yoshiro Mori to the 147th Session of the Diet," Prime Minister's Official Residence, 2000, http://www.kantei.go.jp/foreign/souri/mori/2000/0407policy.htm

119[56] Ibid.

120[57] HIMA, "Comments."

121[58] "White Paper: Section 2. The Medical Insurance System in Transition" (MHW, 1996), http://www.mhw.go.jp/english/white_p/book1/p2_c3/c3_sect2.html

122[59] "A Report" (Council on Health Insurance, 2000), http://www.mhw.go.jp/shingi/s0002/s0203-1_19.html

123[60] "Introduction to JAAME" (JAAME), http://www.jaame.or.jp/English/annai/annai.html

124[61] "Policy Recommendations and Priority Requests to the Japanese Government on the Promotion of Regulatory Reform" (Keidanren, 2000), http://www.keidanre.or.jp/english/policy/2000/003.htm#part2

125[62] "The 43rd Meeting of the Committee on Deregulation (in Japanese)" (Prime Minister's Office, 1996), http://www.sorifu.go.jp/council/gyokaku/kanwa/43.html

126[63] Ibid.

127[64] JETRO, Market Report, p. 4.

X. SHORT-RUN STRATEGY

The preferred outcome of this strategy is to enable medical equipment manufacturers to introduce new medical equipment more quickly and without unnecessary bureaucratic procedures. The two objectives of the short-run strategy are:

1. To change the Pharmaceutical Affairs Law in order to:

   - shorten application approval times from one year to six month for new products and from four months to two months for "me-too" products;
   - prohibit the redundant examination of "me-too" products conducted by both JAAME and PMDEC; and
   - increase the number of medical products that do not require MHW approval before being introduced on the market.

2. To increase the number of personnel who review applications for approval of new medical equipment.

JMEA can employ both domestic and international strategies to help achieve these goals. JMEA does not have enough financial or political resources to build significant alliances internationally. However JMEA can and should take advantage of international

institutions that have offices in Japan in order to build support outside of Japan.

1. Domestic Strategy

1a. Research

JMEA will need to be able to put forth research that demonstrates how the Pharmaceutical Affairs Law is overly burdensome. Specifically, JMEA should be able to show:

- how current regulations negatively impact medical equipment companies (this information can be gleaned from JMEA member companies);
- that products are still safe after the law changes (this information will need to be collected by clinical experts); and
- that the law is much more burdensome than comparable regulatory laws in the United States and European countries.

In order to collect information, JMEA needs to build a coalition with JMEA member companies, academics and clinical experts, and international institutions.

1b. Coalition Building Strategy

In order to increase its influence with policymakers, JMEA should build a coalition including all stakeholders that would benefit from a revised Pharmaceutical Law. JMEA should solicit support from allies within MHW and MITI, as well as ask for direct support from JMEA member companies. Other potential supporters are business associations in Japan, subsidiaries of foreign medical equipment companies, foreign trade associations, and hospitals and doctors.

JMEA members: In order to gain support from its members, JMEA should:

- distribute a white paper (see Exhibit 1);
- send letters (see Exhibit 2) and make phone calls to all member companies to ask for their support;

- hold meetings to explain how deregulating the law will benefit the members;
- conduct research on how current regulation negatively impacts business; and
- make a fact sheet based on information gathered by the research.

MHW: Although MHW does not have the authority to change the Pharmaceuticals Law, it can submit a proposal for changing the law to the Diet. In order to persuade MHW to submit such a proposal, JMEA should:

- send letters with attachments (fact sheet and white paper) asking MHW to propose a change;
- meet with members of MHW to inform them of the facts regarding the disadvantages of the current law;
- submit a research report on product safety conducted by academics and clinical expertise; and
- ask MHW to cooperate with MITI regarding deregulation.

The main target persons and organizations within MHW are:

- Mr. Niwa, Minister of MHW;
- PMDSB of MHW;
- PMDEC of MHW;
- Mr. Shioya, Chairman of the Council on Health Insurance.

MITI: In order to gain MITI's support, JMEA should:

- send letters (with attachments) soliciting MITI's support for changing the law and its assistance in persuading MHW to do so;
- meet with members of MITI to explain how deregulation will benefit MITI in trade negotiations with other governments; and
- ask MITI to pressure MHW to improve its approval procedures for medical equipment.

The main target persons within MITI are:

- Ms. Araki, the Medical and Welfare Equipment Industries Office; and
- Mr. Konno, Director of the International Trade Policy Bureau.

Business associations in Japan: Business associations, such as the Keidanren and the Japan Chamber of Commerce and Industry do not have very much influence with MHW. However, these organizations should be enlisted to push MITI toward a dialogue with MHW. JMEA should:

- send letters with attachments (fact sheet and white paper) asking that these associations bring up the issue with their MITI contacts; and
- hold a meeting to inform business associations of the importance of deregulating the medical industry.

Since Mr. Kanai (Hitachi, Ltd.) and Mr. Nishimuro (Toshiba Corp.) are executive officers in the Keidanren, JMEA can ask them to persuade the other Keidanren executives to support JMEA's position. Another target is Mr. Inaba, the Chairman of the Japan Chamber of Commerce and Industry.

Subsidiaries of foreign medical equipment companies: Foreign medical equipment companies have as much to gain from reform of the Pharmaceutical Law as domestic companies do. Accordingly, they should be willing to support reforms and should be included in JMEA's coalition. Foreign business associations that also should be invited to join the coalition include HIMA, ACCJ, and EBC. JMEA should:

- send letters and make phone calls to subsidiaries to ask for support of JMEA's position. Target companies are:

    ⇒ Johnson and Johnson Medical

    ⇒ Baxter Ltd.

    ⇒ Guidant Japan

    ⇒ Medtronic Japan Co., Ltd.

⇒ Bard Japan Ltd.

⇒ Boston Scientific Japan

- hold meetings with business associations to explain how the deregulation of the law is beneficial to their members. Targets are:

  ⇒ Mr. Vaughan, Director of HIMA in Tokyo office

  ⇒ Mr. Grondine, President of ACCJ

  ⇒ Mr. Coine, Chairman of EBC of Japan

- issue a questionnaire to learn how the current regulation negatively impacts business;

- ask foreign company subsidiaries to provide information about the regulatory system of their own governments;

- ask foreign company subsidiaries to request that their headquarters and governments pressure the Japanese government to change the regulatory system.

Hospitals and doctors: Besides building support from suppliers of medical equipment, it will also be beneficial to build support from the demand side, such as hospitals and doctors. In order to obtain support from doctors for deregulation, it is necessary to show them how deregulation will be beneficial for hospitals and patients. With over 150,000 members, the Japan Medical Association (JMA) is the most influential organization among doctors. JMEA should:

- send letters with attachments (fact sheet and white paper) to ask for JMA's support for changes in the Pharmaceutical Law. Target hospitals and doctors are:

  ⇒ Directors of national hospitals;

  ⇒ Directors of the top 100 private hospitals;

  ⇒ Executives of JMA;

- hold a meeting to inform JMA of the facts regarding how hospitals and doctors would benefit from changes in the law;

- submit a research report completed by academics and clinical experts to show the effects of changes in the law on product safety; and

- request speaking opportunities at JMA's national conferences.

Academic authorities: Without any clinical or scientific data showing that product safety will not suffer under shortened approval procedures, MHW will not support any changes in the law. In order to gather such a data, JMEA should ask clinical experts to conduct research on product safety. Target experts are:

⇒ JAAME researchers;

⇒ doctors who work at the more prestigious hospital; and

⇒ medical professors who teach at the more prestigious universities.

1c. Legislative Strategy

Compared to other manufacturing industries such as the automobile industry, Japan's medical equipment industry is a relatively young. Moreover, its impact on the Japanese economy is not large, partly it is not internationally competitive. Accordingly, the medical industry has not had any real influence with the legislative branch or political parties. Building such influence now will take a great deal of effort.

The first step in the legislative strategy should be to identify supporters among the legislators. JMEA should ask these supporters, including the ten Diet members of the Advisory Council on Social Security (see Appendix 14), to introduce a new bill for changing the law, or at least to support a bill if MHW is persuaded to introduced one. In order to gain legislators' support, JMEA should:

- send letters (see Exhibit 3);
- hold meetings to explain how changes to the Pharmaceutical Law will benefit the government and the public by reducing health care expenditures (white paper and fact sheet).

The coming months will be a particularly good time to solicit legislators' support because a House of Representatives election will be held in October. In order to take advantage of this opportunity, JMEA should send letters and/or visit all political parties as their political campaigns heat up. The letters should explain how changing the law will benefit legislators' constituencies by reducing the cost of medical treatment and improving its

quality. JMEA should also lobby candidates from the districts that are home to major medical equipment manufacturing plants.

Mr. Niwa, the present Minister of MHW, and previous ministers, such as Mr. Koizumi, are other potential supporters. JMEA should send letters to and visit with them to gain their support for changing the law.

Although the House of Councilors (the other house of the Diet) will not have an election anytime soon, it should be another lobbying target because support from its Committee on Health and Welfare will be crucial to the success of any reform effort (see Appendices 15 and 16). It is this Committee that reviews bills concerning medical matters.

1d. Media Strategy

The objectives of the media strategy are to:

- educate all stakeholders, including the public, how deregulation will benefit them;
- inform various stakeholders of JMEA's activities and positions; and
- expand support for JMEA.

To achieve these objectives, JMEA should:

- print articles that support deregulation in "JMEA News," JMEA's Journal;
- write op-ed pieces (see Exhibit 4) for major Japanese newspapers such as Nikkei, Asahi, Mainichi, and Yomiuri, and major international newspapers such as the Japan Times;
- pitch an article that articulates the importance of reforming the Pharmaceuticals law to editors of major business magazines/journals such as Nikkei business, the Economist (Japanese version), Asahi Weekly, Diamond Weekly, and The Weekly Toyo Keizai, as well as major medical journals such as the Japan Medical Association Journal, Nikkei Medical and Asahi Medical;
- attach opinions from medical and clinical authorities to all articles that JMEA sends to the newspapers and magazines mentioned above. The opinions should support JMEA's position from the point of view of medical safety.

2. International Strategy

Due to its market size and high dependency on imports, Japan is one of the most attractive markets for foreign medical equipment manufacturers. Accordingly, many foreign companies and governments can be expected to support JMEA's proposal regarding reform of the medical equipment regulatory system.

The United States accounts for over 60 percent and the European Union accounts for 15 percent of total imports of medical equipment into Japan.128[64] Therefore, as an international strategy, JMEA should focus on the United States and the European Union. However, it does not need to conduct an intensive international strategy for two reasons.

First, major exporting countries have already engaged in negotiations with the Japanese government over deregulation of the Pharmaceutical Affairs Law. The United States, for example, has negotiated with Japan on this issue under the U.S.-Japan MOSS talks. Other governments have already realized the problems with Japan's regulatory system for the medical sector and are eager to change it. JMEA should capitalize on these past efforts by informing foreign government officials of JMEA's efforts to change the law and asking them to pressure the Japanese government.

Second, trade associations such as ACCJ, HIMA and EBC already have offices in Japan and actively participate in discussions on deregulation. ACCJ, for example, has a subcommittee on medical equipment and works closely with HIMA. These associations, as well as foreign company subsidiaries in Japan, are already pushing their own governments to take action on their behalf, and they are surely in a better position to push their own governments than JMEA is. JMEA, however, should hold a meeting for these associations and subsidiaries in order to explain JMEA's own efforts and to explore how foreign associations and subsidiaries can help.

Some media activities can help back up JMEA's actions internationally. Such activities might include sending press releases concerning JMEA's efforts to the Washington Post, Wall Street Journal, New York Times, Financial Times and Inside U.S. Trade.

XI. LONG-RUN STRATEGY

The goal of the long-run strategy is to eliminate any obstacles such as distribution practices and medical insurance reimbursement policies that make it difficult for medical equipment manufacturers to introduce new medical products into the market. The long-run preferred outcomes for JMEA are to:

- reform the distribution system;
- reform the insurance reimbursement system;
- change MHW's policies which are too cautious in approving new medical equipment; and
- improve the international competitiveness of Japan's medical industry.

It will not be easy to make such large changes. However, faced with increasing health care expenditures, the Japanese government has begun to realize the problems of the current system and has already launched debates and studies over these problems.

JMEA should not attempt to pursue a strategy for directly solving these problems. Rather, JMEA's role should be to foster increased public debate concerning solutions and to ensure that resolution of these problems remains on legislators' and government officials' agendas. This will also expedite achievement of JMEA's short-run goals.

At the same time, JMEA has to consider the impact of deregulation and distribution reforms on its own members. Simplification of Japan's distribution system in particular is likely to expose Japanese medical equipment manufacturers to increased international competition. JMEA should take action to bolster the industry's currently weak competitive position.

1. Domestic Strategy

1a. Research

In order to build consensus concerning the problems caused by the current distribution system, the reimbursement system, and MHW's approval policies, JMEA should collect accurate and detailed data on these problems and compose reports and fact sheets articulating the results.

In conducting the research, JMEA should cooperate with the Council on Health Insurance, an advisory body to MHW (see Institutional Analysis), and the Council on Social Security, an advisory body to the Prime Minister (see Institutional Analysis).

Additionally, information concerning waste caused by MHW's policies should be compiled. The study conducted by Bain & Company Japan has already made some calculations of how much could be saved and how much medical care could be improved if MHW were to more readily recognizes the significance of advanced medical technology and quickly accept its use (see Appendix 8). JMEA should cooperate with Hiroshi Uchida, the president of the Bain & Company Japan, to develop further calculations of this sort.

1b. Coalition Building Strategy

There is already general agreement among the Council on Health Insurance, the Committee on Review of the Reimbursement System, and the Advisory Council on Social Security that structural reform of Japan's health care system is needed. However there is plenty of room for building greater consensus among a broader group, including all stakeholders, concerning the details of what, precisely, needs to be reformed.

JMEA members: Except for distributors, JMEA members are potential supporters for reform of the distribution and reimbursement systems and of MHW's polices. In order to make an alliance with members, JMEA can:

- send letters with fact sheets and make phone calls to all member companies to ask for support of JMEA's position;
- have meetings to explain how these reforms are indispensable to creating a sound business climate.

MHW / The Council on Health Insurance / The Council on Social Security: These three groups are already aware of the importance of reforming the distribution and reimbursement systems. Nonetheless, JMEA can encourage these organizations to take stronger stands on reform by:

- providing research results about how more cost-effective medical equipment will contribute to the long-run reduction of the health care expenditures;
- providing research results concerning how MHW's policies cause medical expenditure waste; and

- proposing an ideal reimbursement system for the medical equipment industry.

Foreign medical companies and trade associations: Foreign companies and associations have already asked their governments to pursue reform with the Japanese government. JMEA can use foreigners' assistance by

- asking for support of JMEA's position;
- asking them to provide information about how their own countries' regulatory systems work; and
- asking foreign subsidiaries in Japan to request that their headquarters and governments pressure the Japanese government to change its regulatory system.

MITI: There are two primary reasons for including MITI in the coalition. One is to gain its support for promoting deregulation and reform of the medical equipment industry. The other, which is especially important, is to gain MITI's support for reform of the distribution system. JMEA should:

- send letters and meet with MITI officials to ask for their support for deregulation;
- convince them that deregulation will benefit MITI in future trade negotiations with other governments;
- express JMEA's support for MITI's "Millennium Project" for the senior services market (see Policy Analysis "MITI's Millennium Projects");
- persuade them that reform of the distribution system is essential to the success of the Millennium Project;
- request their support and funding for reform of the distribution system.

A third reason for including MITI in JMEA's coalition is to gain MITI's assistance in improving the international competitiveness of the medical equipment industry. JMEA could request that MITI make this a priority of the Millennium Project.

1c. Neutralizing the Opposition

A major obstacle to reform will be distributors' opposition to any change in the distribution system. Reform of the distribution system directly impacts distributors, some of which are JMEA members. Showing distributors how reform can increase overall medical equipment business and therefore benefit them will be important to overall success of any reform effort. JMEA should hold a meeting for JMEA member distributors to:

- explain to JMEA member distributors how reform of the distribution system will increase business opportunities;
- discuss the vast potential of the market for medical equipment that serves elderly and disabled people and persuade distributors to shift some of their business toward these new markets.

Because MITI has already announced its intention to help create jobs in the senior services market, it's support for the reform effort will be important to distributors. MITI should be asked to work with JMEA on its efforts to convince distributors of the benefits of reform.

1d. Media Strategy

The purpose of the media strategy is to inform the public of the importance of reforming the medical reimbursement system and to gain public support for the reform. JMEA should write op-ed articles, pitch articles to magazines, ask TV broadcasters to pick up this topic for special programs, and distribute posters and pamphlets.

Op-ed articles and pitches to magazines

Both of these can be used to explain how reforms will reduce health care costs and increase access to cost-effective medical treatment. The target is the general public for national newspapers, policymakers for political magazines, and the medical community for medical magazines.

National Newspapers

- Nikkei
- Asahi

- Mainichi
- Yomiuri

Political Magazines

- Weekly Gendai
- Asahi Weekly
- Diamond Weekly
- Voice

Medical Magazines

- Nikkei Medical
- Asahi Medical
- JMA Journal
- Medical Equipment Journal of Japan

Special topic TV programs

TV coverage of an issue is the best way to influence the general public. The following TV programs focus on social and political issues:

- News Station (Radical News Program, daily)
- Special Report (Intensive research and report regarding hot issues, weekly)
- Close-up Gendai (Commentary for hot issues, daily)

Posters and pamphlets

JMEA should print posters and pamphlets explaining the importance of the reform and urging citizens to make reform a priority topic in the upcoming elections. These PR pieces should be distributed, among other places, at national hospitals and major private hospitals.

2. International Strategy

For the long-run strategy (like the short-run strategy), JMEA should enlist the help of foreign companies subsidiaries and trade associations in Japan, rather than conducting a comprehensive strategy abroad.

While international harmonization is not crucial to achieving JMEA's long-run goals, the Global Harmonization Task force (GHTF) provides a forum in which Japan can notify other countries of its efforts to further deregulate its medical market. Through participation in GHTF, JMEA can:

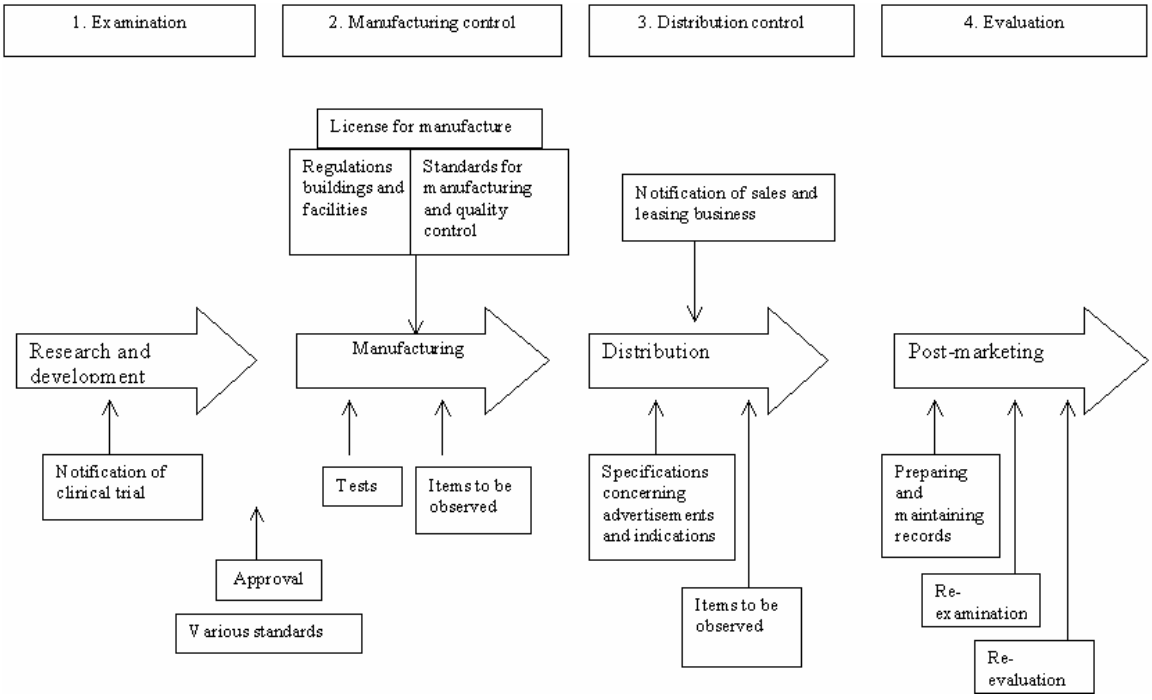
- encourage the creation of an international framework for regulating medical equipment safety; and
- promote joint research for internationally acceptable scientific evidence regarding

Footnotes:
129[64] JETRO, Market Report, p. 4.

APPENDICES

- Japan's Regulations for Medical Equipment
- Product Approval Process for Direct Applications by Foreign Manufacturers
- Nationwide Medical Insurance Reimbursement System
- License and Product Approval Requirements
- International Competitiveness of Japanese Medical Equipment
- Product Approval and Manufacturer/Importer Licensing Process
- Distribution Practices in the Japanese Medical Industry
- Case Study: The Implantable Cardioverter Defibrillator (ICD)
- Examples of Cost Efficient Technologies as Cited in the Bain Study
- Ministry of Health and Welfare—Organization Chart

- Ministry of International Trade and Industry—Organization Chart
- Diet Members of the Advisory Council on Social Security
- Members of the Committee on Health and Welfare of the House of the Councilors
- Japanese Legislative Procedure



(Source: "Guide to Medical Device Registration in Japan," MHW, 1997)

Appendix 2. Approval Process for Direct Applications by Foreign Manufacturers

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Appendix 3. National Medical Insurance Reimbursement System

Appendix 4. License and Product Approval Requirements

Appendix 5. International Competitiveness of Japanese Medical Equipment

Japan's medical equipment industry is not internationally competitiveness, despite the country's high technological manufacturing achievements. Indeed, as shown in Table 2, Japan is much more dependent on imports of medical equipment than it is on imports of other hi-tech equipment.

Table 2. Imports, domestic production, and import penetration, 1989

Sector and product category	**Imports (billion yen)**	**Domestic production (billion yen)**	**Import penetration* (%)**
Medial instruments	158	724	17.9
Radio and television sets	44	1,022	4.1
Electronic computing equipment	574	6,384	8.2
Communication equipment	80	2,723	2.9
Semiconductor devices	358	3,515	9.3
Chemical machinery	59	1,142	4.9

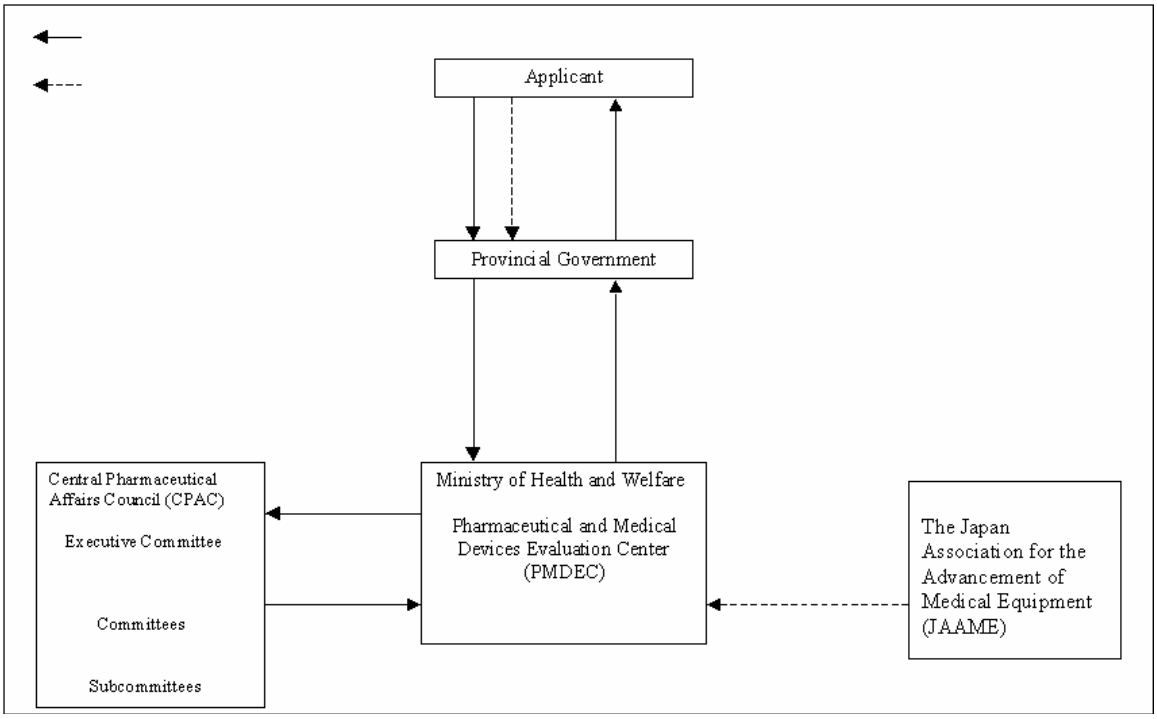
*Import penetration = import volume/(domestic production + import volume). No account is taken

of exports, which are small for most of these products.

(Source: "Measuring the Cost of Protection in Japan," Institute for International Economics, 1995)

Imports accounted for 25.7 percent of domestic demand for medical equipment in 1991. In 1993 that share rose to 30.6 percent, and in 1998, imports accounted for over 40 percent of domestic demand.

Appendix 6. Product Approval and Manufacturer/Importer Licensing Processes



Appendix 7. Distribution Practices in the Japanese Medical Industry

The Japanese medical industry's distribution system often works on a consignment basis.[1] Under this system, distributors supply products to hospitals and then collect payment only for the products that the hospitals actually use. Distributors collect products that are not used. This system benefits hospitals by making it easier to purchase new products without risking the cost of unused inventories. Distributors, however, assume all the risk and have to dispose of obsolete products they collected from hospitals.[2]

Additionally, technical services are often tied to equipment sales in Japan. At a doctor's request, manufacturers and distributors will make emergency deliveries of equipment and technical assistance. Manufacturers, for example, send technical staff to hospitals during implant surgeries to answer doctors' questions and to fix malfunctioning products.[3]

Level of Technical Support Services Received form Dealers

	Pacemaker	PTCA catheter	Oxygenetor	Intraocular lens	Indwelling cannulas with needle for hemodialysis

Support for operation	83.1%	53.7%	57.3%	11.8%	-
Round-the-clock backup	58.9%	48.4%	53.1%	11.9%	15.9%
Support for postoperative periodic examination	52.4%	-	-	-	-
Borrowing measuring instrument free of charge	36.3%	9.6%	4.5%	6.7%	5.5%

(Source: "Research Report on the Price Differences of Medical Equipment," Institute for Health Economics and Policy, 1997)

These services help develop strong relationships between hospitals and distributors. On the other hand, these distribution practices make new market entry difficult because newcomers have to start by building good relationships with hospitals, doctors, and distributors.

Appendix 8. Case Study: The Implantable Cardioverter Defibrillator (ICD)

Product Description: ICDs are used to treat patients with ventricular arrhythmias who are at risk of sudden cardiac death. The latest ICD is the size of a small pager and can be implanted pectorally, similarly to a pacemaker. It monitors the heart and, when a very rapid heart rhythm is detected, sends either a series of electrical impulses or an electrical shock to return the heart to normal rhythm.

Proven Clinical Value: On April 14, 1997, the National Institutes of Health prematurely terminated a clinical study of more than 1,000 patients because the risk of death among those receiving implantable defibrillators was nearly 38 percent less than those receiving drugs in the first year of their therapies. The study was terminated because it was considered unethical to continue to randomize patients to the drug regimen.

Proven Cost-Effectiveness: ICDs have been shown to be superior to drug therapy in terms of both clinical and cost effectiveness. A recent European study shows that costs associated with treatment of patients on ICDs are about 70 percent less per patient per day than costs associated with drug therapy only. When quality-of-life aspects were taken into account, cost-effectiveness of early ICD implantation was even more favorable. Recurrent cardiac arrest and cardiac transplantation occurred in the group treated with drugs, whereas better exercise tolerance, shorter total hospital stays, and fewer invasive procedures were all significantly in favor of early ICD implantation.

Japan's Delays in Patient Access to the Latest, Most Effective Technology: While patients in other countries have had access to ICD therapy for up to ten years, the

therapy was only recently made available to patients in Japan. Delays due to additional, costly clinical data requirements and the insurance system's hesitancy to reimburse for the technology—even after the product had received import approval by the Ministry of Health and Welfare—prevented Japanese patients from gaining access to the technology until April 1996. Moreover, because of the hurdles and resulting delays that new technologies face in Japan, the device approved in 1996 is generations behind the device currently being implanted in other countries. The impact of these delays on the quality and cost of care is dramatic. Patients in Japan still receive devices so large that they have to be implanted in the abdomen, although smaller, pectoral devices are available but have not yet been approved in Japan. Not only are the newer devices smaller, they last almost twice as long, which means fewer replacement procedures are necessary. Improvements in diagnostic capabilities of the device enable physicians to get a more complete picture of the underlying heart disease for better patient management.

(Source: Health Industry Manufacturers Association, Washington D.C., 1997)
http://wwwhimanet.com/publicdocs/icd.htm

Appendix 9. Examples of Cost Efficient Technologies as Cited in the Bain Study

PTCA balloon catheters and coronary stent procedures. PTCA techniques are 70 percent less expensive to perform than the coronary bypass surgery procedures they replace. Used in conjunction with coronary stents, PTCA procedures dramatically reduce the need for future expensive interventions.
Potential Savings to Japan's Health Care System: 200 billion yen/year

Laparoscopic (minimally invasive) equipment, if used for gall bladder removal, is 40 percent less expensive than celiotomy, the traditional method, and reduces hospital stay from one month to one week.
Potential Savings to Japan's Health Care System: 33 billion yen/year

Microbiology testing equipment could reduce the unnecessary administration of pharmaceuticals by 20 to 30 percent by enabling speedier—and more accurate—identification of patient illness. Such testing helps to prevent tentative and often improper judgments concerning initial treatment.
Potential Savings to Japan's Health Care System: 50 billion yen/year

Esophageal stents. Patients suffering from cancer of the esophagus who have difficulty swallowing must be hospitalized for approximately three to five weeks when bypass operations are performed and the esophagus is removed. In contrast, patients can be discharged from the hospital in approximately one week when esophageal stents are inserted and the esophagus is conserved.
Potential Savings to Japan's Health Care System: 900 million yen/year

Blood sugar self-testing equipment. As diabetics learn to properly manage their own blood sugar levels using self-testing equipment, the occurrence of complications declines. Proper blood sugar management has been shown to

reduce the risk of complications, such as renal failure, that might require dialysis treatment.
Potential Savings to Japan's Health Care System: 10 million yen/patient life cycle

ICD (Implantable Cardioverter Defibrillator). ICDs are being used to replace traditional drug therapy for tachyarrhythmia, or racing of the heart, which can cause sudden cardiac death. Moreover, ICD therapy liberates patients on drug therapy from endless hospital stays during which drug therapy is monitored and external defibrillators are used. A European study reveals that ICD therapy is 70 percent less expensive per patient per day than therapy using antiarrhythmic drugs. A recent U.S. study showed there were 38 percent fewer deaths after the first year of treatment of ICD therapy as compared to drug therapy.
Potential Savings to Japan's Health Care System: 5.3 million yen/patient life cycle

Pacemakers. New pacemaker batteries last significantly longer than previous batteries, reducing the need for costly repeat surgeries. Battery life has expanded from two to seven years.
Potential Savings to Japan's Health Care System: 30 billion yen/year

(Source: Health Industry Manufacturers Association, Washington D.C., 1999)
http://www.himanet.com/publicdocs/bainexamples.html

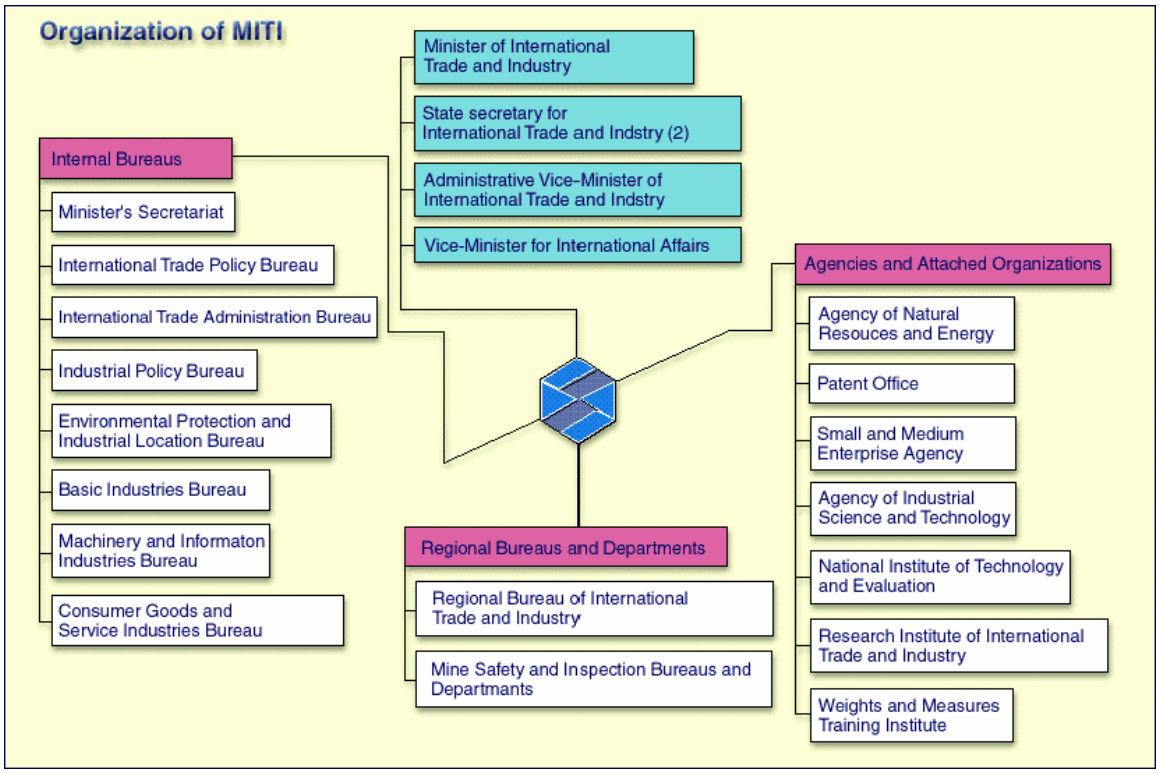
Appendix 10. Ministry of Health and Welfare—Organizational Chart

Ministry of Health and Welfare

- Minister's Secretariat
- Health Policy Bureau
- Health Service Bureau
- Environmental Health Bureau
- Pharmaceutical and Medical Safety Bureau
  - Pharmaceutical and Medical Evaluation Center
- Social Welfare and War Victims' Relief Bureau
- Health and Welfare Bureau for the Elderly
- Children and Families Bureau
- Health Insurance Bureau
- Pension Bureau

Social Insurance Agency

Appendix 11. Ministry of International Trade and Industry—Organization Chart



Footnotes:

[1] JETRO, The Survey on Actual Conditions Regarding Access To Japan - Medical Equipment (Tokyo: JETRO, 1996), p. 7.

[2] "U.S. Industry recommendations for reducing Japan's Health Care Costs" (HIMA, 1997). http://www.himanet.com/publicdocs/recommendations.htm

[3] "Brain Study Executive Summary" (HIMA,1997). http://www.himanet.com/publicdocs/brainexecsum.htm

Appendix 12. Diet Members of the Advisory Council on Social Security

The House of the Representatives

Nagase Zinen
Makiko Tanaka
Syunichi Suzuki
Yutaka Fukushima
Seiichi Kaneda

The House of the Councilors

Yasuhisa Oshima
Kayoko Shimizu
Akira Koike
Takao Watanabe
Masayuki Naoshima

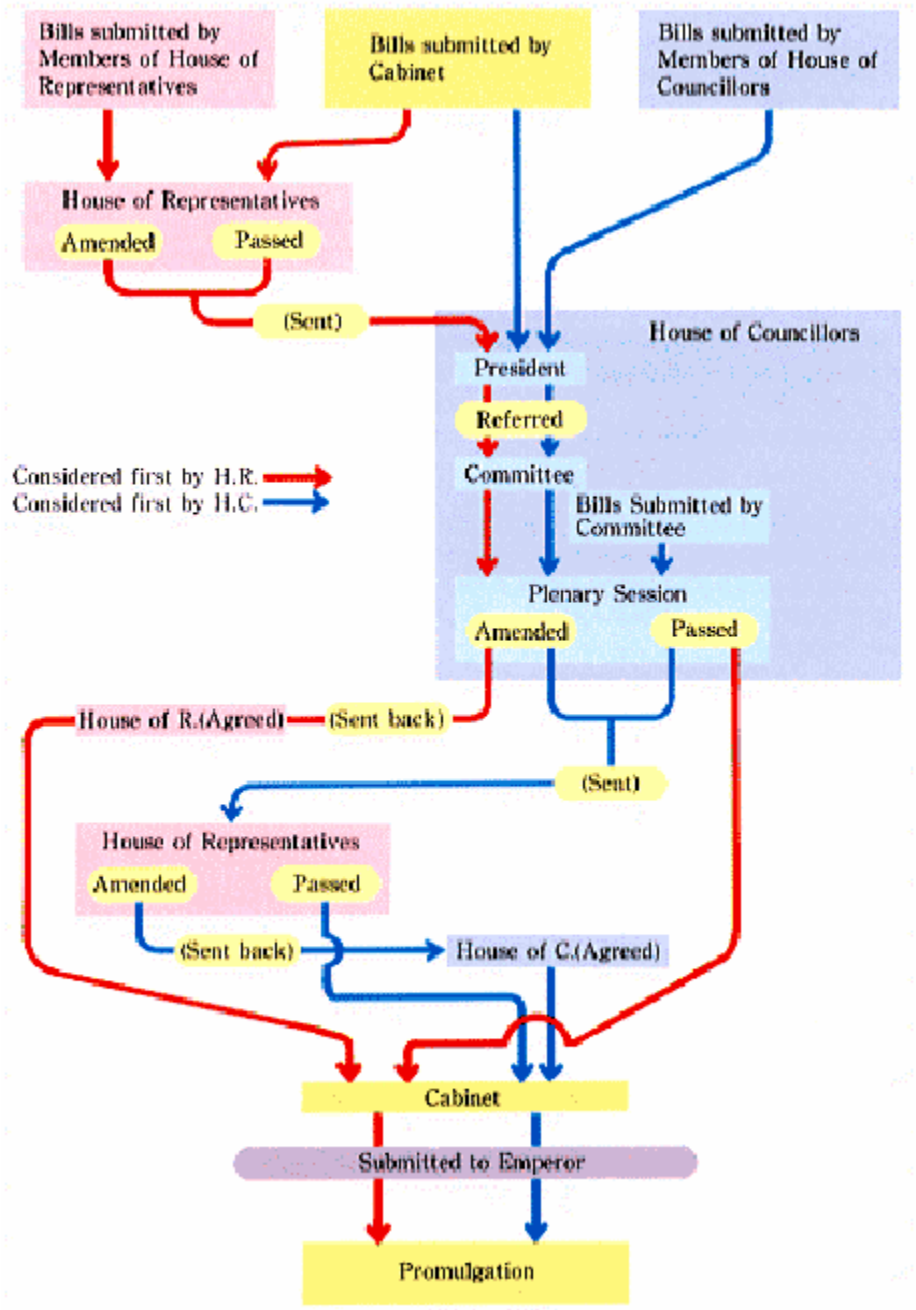
Appendix 13. Members of the Committee on Health and Welfare of the House of the Councilors

Chairman Yasu Kanou
Director Nao Taura
Director Kenji Katsuki
Director Tamotu Yamamoto
Director Akira Koike
Director Masaaki Yamazaki

Hidehisa Otsuji
Kouiti Kuno
Sou Nakahara
Chieko Noono
Yutaka Mizushima
Kiyoshi Imai
Taisuke Satou
Toshihisa Matsuzaki
Minoru Yanagida
Tamaki Sawa
Miyo Inoue
Sumiko Shimizu
Hajimu Irisawa
Akiko Doumoto

Kiyoshi Nishikawa

Appendix 14. Japanese Legislative Procedure



(Source: The House of the Councilors)

EXHIBITS

1. White Paper
2. Sample Letter to JMEA Members
3. Sample Letter to Legislators
4. Sample Op-Ed Article
5. Schedule
6. Budget

Exhibit 1. White Paper

Deregulation of the Pharmaceutical Affairs Law

White Paper

1. Issue

JMEA urges the Ministry of Health and Welfare (MHW) to deregulate the Pharmaceutical Affairs Law. This law was established in 1943 in order to protect and improve public health by regulating medical equipment quality, effectiveness, and safety. In response to recent wide-ranging innovations in medical technology and the shortening of medical equipment life-cycles, the law was amended in June 1994 with the goal of speeding the procedures for obtaining approval for new medical products. However, it is still difficult for the medical equipment industry to introduce new products because Japan's approval process for new medical equipment is the longest of any major developed country. Shortening product approval times will help Japanese medical manufacturers compete by speeding the introduction of new cost-effective medical equipment. Speeding the acceptance of new medical technology will also reduce health care costs and improve patient treatment options.

2. Background

Regulatory System

Because medical equipment directly impacts human lives, the Pharmaceuticals Law regulates all aspects of the medical equipment industry, from manufacturing and importing to post-marketing activities.

The standard processing period for obtaining approval for a product is 12 months for new medical equipment—products that are significantly different from previously approved products or those new in indications, effects or uses. It takes up to four months to gain approval for "me-too" medical equipment—equipment that is essentially the same as equipment already on the market. The Pharmaceutical and Medical Devices Evaluation Center (PMDEC) of the Ministry of Health and Welfare is the authority that makes equipment approvals.

Approval Procedures for New Products. PMDEC reviews applications for new product approvals in consultation with the Central Pharmaceutical Affairs Council. PMDEC then makes a final approval decision.

Approval Procedures for "Me-Too" Products. For "me-too" equipment, PMDEC forwards applications to the Japan Association for the Advanced Medical Equipment (JAAME), the independent organization designated by the Japanese government for investigating the equivalence of structures, usage, indications, performance, etc. of "me-too" medical products. After JAAME's equivalency examination, PMDEC performs all other necessary evaluations and then makes a final approval decision based on its findings.

Non-approval Products. MHW allows some new products to be sold without MHW approval. Under the Pharmaceuticals Law, MHW is required to maintain a list of products that do not need to obtain approval.

3. Analysis

Unnecessary bureaucratic procedures for approving new medical equipment

The Japanese regulatory system blocks medical equipment manufacturers from obtaining product approvals in a timely manner. Currently it takes one year to obtain approval for new products in Japan. Approval procedures in the United States and most European countries are significantly faster than in Japan.

One reason why Japan's approval process is long is that MHW lacks adequate personnel to handle all approval applications quickly. Additionally, in the case of "me-too" products, the review process is redundant. JAAME reviews "me-too" applications to

determine whether a product is equivalent to other, already approved products. It then reports its results to PMDEC. However, PMDEC sometimes rejects JAAME's results and conducts its own review.

MHW's Policy

Another problem with Japan's regulatory system is MHW's reluctance to approve new medical products, especially high-risk products used inside the human body. MHW didn't approve the Implantable Cardioverter Defibrillator (ICD) until it had been in use in other countries for ten years, although the device was known to save $46,500 per patient and to provide a better treatment option for many patients.

4. Proposed Actions

On behalf of its member companies, JMEA strongly encourages MHW to take action to reduce the obstacles to introducing innovative, cost-effective new medical equipment into the Japanese market. Specifically, JMEA urges MHW to take the following actions without delay:

- change the Pharmaceutical Affairs Law to:
  - shorten the approval process for new products from one year to six months;
  - prohibit the redundant examination of "me-too" products conducted by both JAAME and PMDEC;
  - increase the number of items that do not require MHW approval before being marketed;
- increase the number of personnel that review applications in JAAME and PMDEC; and
- recognize the benefits of advanced medical equipment.

Japan's population is aging rapidly. The introduction of cost-effective and innovative medical equipment will be crucial to containing health care expenditures and to provide for an increasingly aged population.

Exhibit 2. Sample Letter to JMEA Members

Dear JMEA Members:

I am writing to ask for your support for changing the Pharmaceutical Affairs Law. Under the current law, it is difficult to introduce new medical equipment into the market. Indeed, Japan's approval process for medical equipment is longer than that of any other major developed country. In today's world of increasingly short product life-cycles, quick approval for new products directly affects a product's profitability.

Japan's market for medical equipment is the second largest in the world. The domestic demand for medical equipment was 2,028 billion yen in 1998. The value of the market is expected to be 8,319 billion yen in 2025. If the regulatory system were deregulated, the market would become even larger.

JMEA is requesting that the Ministry of Health and Welfare:

1. change the Pharmaceutical Law in order to:
    - shorten the approval period from one year to six months for new products and four months to two month for "me-too" products;
    - prohibit the redundant examination of "me-too" products conducted by both the Japan Association for the Advanced Medical Equipment (JAAME) and the Pharmaceutical and Medical Devices Evaluation Center (PMDEC);
    - increase the number of medical products that do not require MHW approval; and
2. increase the number of JAAME and PMDEC personnel that review product applications.

I hope all JMEA members will support this proposal. Additionally, I ask that you respond to the questionnaire that will be sent to you in ten days. The objective of this questionnaire is to collect accurate information on how current regulations negatively impact the medical equipment industry. Your honest answers will help to identify problems prevailing in the regulatory system.

If you have questions, please contact me.

Sincerely,

President of the Japan Medical Equipment Association

Exhibit 3. Sample Letter to Legislators

Dear Members of the Advisory Council on Social Security:

On behalf of Japan Medical Equipment Association (JMEA) members, I am writing to request your support for changing the Pharmaceutical Affairs Law. Under the current law, it is difficult to introduce new medical equipment into the market. Yet new, cost-effective medical technology can help reduce health care costs and improve patient care—goals which are becoming increasingly important as Japan's population ages. The timely introduction of new medical equipment will significantly reduce health care expenditures in the long run. Currently, it takes longer to obtain approval for new medical equipment in Japan than in any other major developed country.

As you know, the Ministry of Health and Welfare (MHW) estimates that over 25 percent of Japan's population will be over the age of 65 by the year 2025. Japan's health care expenditure and the ratio of this expenditure to national income is already steadily increasing. In 1999 the total medical expenditure was 30 trillion yen. Estimates are that the total will reach 141 trillion yen in 2025.

The containment of the health care costs is a crucial issue for building a sustainable and stable social welfare system for the future. I understand that it is for this reason that the Prime Minister established the Advisory Council on Social Security to explore avenues for increasing efficiency within the country's health care system.

The containment of health care costs is JMEA's goal, as well as the Council's. We hope that you will support our efforts to persuade MHW to:

1. change the Pharmaceutical Law in order to:

    li>shorten the product approval process from one year to six months for new products and from four months to two month for "me-too" products;

    - prohibit the redundant examination of "me-too" products conducted by both the Japan Association for the Advanced Medical Equipment (JAAME) and the Pharmaceutical and Medical Devices Evaluation Center (PMDEC);

    - increase the number of items on the list of medical products that do not require MHW approval before being put on the market; and

2. increase the number of JAAME and PMDEC personnel who review product applications.

I am enclosing a report (see Appendix 9) that shows how the rapid introduction of new medical equipment can reduce health care expenditures and improve patient care. If you have questions, please contact me.

Sincerely,
President of the Japan Medical Equipment Association

Exhibit 4. Sample Op-Ed Article

Access to Better, Cheaper Medical Treatment

by the President of JMEA

Japan's health care expenditures are steadily increasing. In 1999, the Japanese people spent over 30 trillion yen on health care through taxes or other means. The Ministry of Health and Welfare estimates that the expenditure will reach 141 trillion yen in 2025. By that time, over 25 percent of the population will be over the age of 65.

In order to satisfy the needs of Japan's aging population—to both improve treatment options and contain health care costs—Japan needs to recognize the significance of advanced medical technology. Containing medical costs will also be important to reducing Japan's budget deficit.

Unfortunately, the Japanese people cannot currently access cost-effective and innovative medical equipment quickly. Under the Pharmaceutical Affairs Law, it regularly takes a full year to gain approval of new medical technologies—approval that is required before these technologies can be sold in Japan. While all countries regulate medical products for public safety purposes, Japan's application and approval process for medical equipment is longer than that of any other major country, and part of Japan's system is redundant.

A recent study showed how the Japanese government's regulations waste health care resources and impede treatment improvements for Japanese citizens. The Ministry of Health and Welfare did not approve the Implantable Cardioverter Defibrillator (ICD) until it had been in use in other countries for ten 10 years—even though the device was projected to save 5.3 million yen annually in health care expenditures and provides a better treatment option for many patients.

In order to speed the introduction of innovative and cost-effective medical equipment into the Japanese market, the Japan Medical Equipment Association (JMEA) is encouraging the Ministry of Health and Welfare to deregulate unnecessary bureaucratic procedures under the Pharmaceutical Affairs Law. JMEA is asking the Ministry of Health and Welfare to shorten the period for granting new product approvals. Quick approval for new products will greatly improve access to cost-effective medical treatment that will benefit all of us.

Exhibit 5. Schedule for Short-Run Strategy

May 8

Prepare for coalition building

- letters
- white paper

May 20

Implement coalition building

- send letters
- phone calls
- meeetings

June 1

Distribute questionnaire (Deadline: June 30)
Implement legislative strategy 1

(July 2000, G-8 Summit)

August 2000

Implement media strategy

September 2000

Implement legislative strategy 2

(October 2000, Election)

December 2000

Propose bill for amending the Pharmaceutical Law

Exhibit 6. Budget for Short-Run Strategy (yen)

Research Contract 4,800,000

- develop questionnaire
- analysis
- report

Lobbying Staff	12,000,000
• one professional • one assistant	750,000 450,000

Coalition Building Expenses 3,000,000

- letters
- meetings
- phone calls

Seminar 3,500,000

Computer System and Web Page 1,000,000

Media

0130[1]

TOTAL	24,300,000
JMEA members	
• Class A (100)	6,000,000 (60,000 per company)
• Class B (300)	6,600,000 (22,000 per company)
• Class C (600)	6,600,000 (11,000 per company)
• Class D (1,000)	5,100,000 (5,100 per company)

REFERENCES

"A Report." Council on Health Insurance, 2000. Available from http://www.mhw.go.jp/shingi/s0002/s0203-1_19.html.

"Bain Study Executive Summary." Health Industry Manufacturers Association, 1997. Available from http://www.himanet.com/publicdocs/recommendations.htm.

"CASE STUDY: The Implantable Cardioverter Defibrillator (ICD)." Health Industry Manufacturers Association, 1997. Available from http://www.himanet.com/publicdocs/icd.htm.

"Comments by the Health Industry Manufacturers Association on Identification of Priority Practices." Health Industry Manufacturers Association, 1999. Available from http://www.himanet.com/publicdocs/301watchlistpetition.html.

"Examples of Cost Efficient Technologies As Cited in the Bain Study." Health Industry Manufacturers Association, 1997. Available from http://www.himanet.com/publicdocs/bainexamples.htm.

"First Joint Status Report on the US-Japan Enhanced on Deregulation and Competition Policy." Ministry of Foreign Affairs of Japan, 1998. Available from http://www.mofa.go/region/n-america/us/economy/date/dereg9805.html.

"Fiscal Policy Speech by Minister of Finance, Kiichi Miyazawa, in the 147th Session of the National Diet." Ministry of Finance of Japan, 2000. Available from http://www.mof.go.jp/english/busget/e1b057.htm.

"Fiscal 2000 Priority Trade and Industry Policies." Ministry of International Trade and Industry of Japan, 1999. Available from http://www.miti.go.jp/info-e/cIP9982e.html.

"GHTF Guiding Principles & Operating Procedures." Global Harmonization Task Force, 1999. Available from http://www.ghtf.org/conferences/7thmeeting/outcomes/proced2.pdf.

"Gross Domestic Product, The First Preliminary Estimates." Economic Planning Agency of Japan, 2000. Available from http://www.epa.go.jp/2000/g/qe994/jissuu.gif.

"Harmonization of the Product Quality System." JMEA News 19 (1998): 11.

"Industry Sector Analysis: Medical Device Market." Commercial Service in Japan, 1999. Available from http://www.csjapan.doc.gov/isa99/medicaldevice.html.

"Introduction to JAAME" Japan Association for the Advanced Medical Equipment. Available from http://www.jaame.or.jp/English/annai/annai.html.

Japan External Trade Organization. JETRO Japanese Market Report – Regulations and Practices-: Medical Equipment. Tokyo: JETRO, 1998

Japan External Trade Organization. The Survey on Actual Conditions Regarding Access to Japan – Medical Equipment. Tokyo: JETRO, 1996

Japanese Ministry of Health and Welfare. Guide to Medical Device Registration in Japan. Tokyo: Yakuji Nippo, Ltd., 1997.

Kawabuchi, Koichi. Introduction to Health Care Economics in Japan – Understanding Japanese Health Care Reform –. Tokyo: Yakuji Nippo, Ltd., 1998

Kawabuchi, Kouichi. Health Care Reform. Tokyo: Yakuji Nippo, Ltd., 1998.

Kay, S. Wayne. "The plan for EHCR in the US." JAAME News 14 (1999): 5.

"Main Economic Indicators March 2000." Economic Planning Agency of Japan, 2000. Available from http://www.epa.go.jp/geturei/2000mar-9.gif.

"Medical and Welfare Industries (in Japanese)." Ministry of International Trade and Industry of Japan, 2000. Available from http://www.miti.go.jp/topic-j/e3275j.html.

"Medical Equipment." Japan External Trade Organization. Available from http://www.jetro.go.jp/ip/e/access/medical.html.

"Medical Technology: Driving Efficiency, Not Costs, in Japan's Health Care System." Health Industry Manufacturers Association, 1997. Available from http://www.himanet.com/publicdocs/drivinggefficiency.htm.

"Membership List of the Advisory Council on Social Security (in Japanese)." Prime Minister's Office, 2000. Available from http://www.sorifu.go.jp/hosho/meibo.html.

Ministry of Health and Welfare of Japan. Annual Statistics of Pharmaceutical Industry's Production Trends 1998. Tokyo: MHW, 1999.

"MOSS Agreement on Medical Equipment and Pharmaceuticals." ITA of the U.S. Department of Commerce, 1986. Available from http://www.ita.doc.gov/region/japan/ta860109.html.

"National Trade Estimate Report on Foreign Trade Barriers 1999." Office of the U.S. Trade Representative, 1999. Available from http://www.ustr.gov/reports/nte/1999/contents.html.

"Outlook of Industrial Standardization in Japan." Chiba University. Available from http://www.hike.te.chiba-u-ac.jp/ikeda/JIS/what1.htm.

"Overview---FDA Modernization Act of 1997." U.S. Food and Drug Administration, 1998. Available from http://www.fda.gov/cdrh/devadvice/371.html

"Policy Recommendations and Priority Requests to the Japanese Government on the Promotion of Regulatory Reform." Keidanren, 2000. Available from http://www.keidanren.or.jp/english/policy/2000/003.htm#part2.

"Policy Speech by Prime Minister Yoshiro Mori to the 147th Session of the Diet." Prime Minister's Official Residence of Japan, 2000. Available from http://www.kantei.go.jp/foreign/souri/mori/2000/0407policy.htm.

"Purpose of Study Group 1." Global Harmonization Task Force. Available from http://www.ghtf.org/sg1/sg1.htm.

"Purpose of Study Group 2." Global Harmonization Task Force. Available from http://www.ghtf.org/sg2/sg2.htm.

"Purpose of Study Group 3." Global Harmonization Task Force. Available from http://www.ghtf.org/sg3/sg3.htm.

"Purpose of Study Group 4." Global Harmonization Task Force. Available from http://www.ghtf.org/sg4/sg4.htm.

"Submission by the Government of the US to the Government of Japan Regarding Deregulation, Competition Policy, and Transparency and Other Governmental Practices in Japan." Office of the U.S. Trade Representative, 1999. Available from http://www.ustr.gov/reports/tpa/1999/index.html.

Suzanami, Yoko, Shujiro Urata, and Hiroki Kawai. Measuring the Costa of Protection in Japan. Washington, D.C.: Institute for International Economics, 1995.

"The Summary of 1998 White Paper (in Japanese)." Ministry of Health and Welfare of Japan, 1999. Available from http://www.mhw.go.jp/wp/wp99_4/chap-a3.html.

"The 43rd Meeting of the Committee on Deregulation (in Japanese)." Prime Minister's Office, 1996. Available from http://www.sorifu.go.jp/council/gyokaku/kanwa/43.html.

Umeda, Katu. "The reform of the insurance system." JAAME News 13 (1999): 1.

"U.S. Industry recommendations for reducing Japan's Health Care Costs." Health Industry Manufacturers Association, 1997. Available from http://www.himanet.com/publicdocs/recommendations.htm.

"White Paper: Section 2. The Medical Insurance System in Transition." Ministry of Health and Welfare of Japan, 1996. Available from http://www.mhw.go.jp/english/white_p/book1/p2_c3/c3_sect2.html.

Footnotes:
131[1] No advertisement. JMEA will send op-ed pieces, press releases, and opinion papers.