International Movement of Japanese Pharmaceutical Industry: Reform of Japanese Health Policy, Part II

Since 1970 the Japanese pharmaceutical industry has grown 30-fold, mainly due to the favorable market created by Japan's national health insurance, but also because of the independent research and development of innovative new drugs begun after the introduction of Western technologies from abroad. The industry's annual output totaled 5,059,500 million yen in 1988. Although the rate of growth slowed in the early 1990s, the annual output has surpassed 6 trillion yen (36.3 billion U.S. dollars) in the current period (see Table 1), making Japan second only to the U.S. (with a 29.5% share of the market) in the output of pharmaceutical products. Japan has an 18% share worldwide, surpassing Germany, France, Italy, Switzerland, and Great Britain.

In Part I of this article, which was published in the November/December 1997 issue of JMCP, (Volume 3, Number 6), we discussed the development of Japanese health policy as it has influenced pharmaceutical consumption. Drug usage in Japan relies on physicians' heavy prescribing habits and their dispensing role, the levels of government reimbursement, and the industry's dynamics within the larger Japanese economy.

Part II of this three-part series examines the overseas movement of the Japanese pharmaceutical industry in its political/economic context, which is relevant to the managed care industry and the U.S. pharmaceutical industry. Part III of the series will appear in the July/August 1998 issue of JMCP. It will describe major Japanese pharmaceutical companies and their overseas activities.

An understanding of the development of the Japanese pharmaceutical industry requires an awareness of national industrial policy, changes in the domestic health care system after the 1960s, and dynamics of the worldwide marketplace. Some sectors of the Japanese economy—most notably electronics and autos—have been aggressively penetrating international markets for decades. But the international marketing of pharmaceuticals lagged behind substantially until several policy changes, amidst social and economic pressures, converged to lead Japan's pharmaceutical firms to pursue overseas markets in the 1990s.

NATIONAL INDUSTRIAL POLICY IN THE JAPANESE DOMESTIC MARKET THROUGH THE 1980s

Before the 1980s, national industrial policies (over such issues as drug approvals, capital liberalization, and patents) protected the Japanese pharmaceutical industry from international competition within its domestic market. Until 1967, Japan did not require domestic clinical trials for safety and efficacy of foreign products. Japan accepted already-approved products from overseas that were listed in an official pharmacopoeia. The Japanese government readily licensed pharmaceuti-
Table 1. Production of Pharmaceuticals in Japan

<table>
<thead>
<tr>
<th>Year</th>
<th>Amount (in 100 million yen)</th>
<th>Annual Growth (%)</th>
<th>For Medical Care</th>
<th>Import Approvals</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Amount (in 100 million yen)</td>
<td>Annual Growth (%)</td>
<td>For Medical Care</td>
<td>Import Approvals</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1970</td>
<td>10,253</td>
<td>21.7</td>
<td>7,705</td>
<td>25.1</td>
</tr>
<tr>
<td>1975</td>
<td>17,924</td>
<td>5.5</td>
<td>14,640</td>
<td>5.9</td>
</tr>
<tr>
<td>1980</td>
<td>34,822</td>
<td>14.5</td>
<td>29,784</td>
<td>16.3</td>
</tr>
<tr>
<td>1985</td>
<td>40,018</td>
<td>-0.6</td>
<td>33,837</td>
<td>-1.3</td>
</tr>
<tr>
<td>1990</td>
<td>55,954</td>
<td>1.7</td>
<td>47,203</td>
<td>0.9</td>
</tr>
<tr>
<td>1991</td>
<td>56,872</td>
<td>1.8</td>
<td>48,122</td>
<td>1.9</td>
</tr>
<tr>
<td>1992</td>
<td>55,742</td>
<td>-2.2</td>
<td>46,774</td>
<td>-2.8</td>
</tr>
</tbody>
</table>

Source: Pharmaceutical Industry Statistics, MHW, Japan

In the early 1960s, thalidomide, imported from a German pharmaceutical firm, was found to be teratogenic, causing a type of birth defect known as phocomelia, in which the hands and feet were directly attached to the babies’ shoulders and hips. Because of the negative experience with this drug, Japan’s Ministry of Health & Welfare (MHW) amended the drug approval process in 1967 to include efficacy, effects, adverse reactions, names, components, quantity, uses, and dosages. Under the Pharmaceutical Affairs Law, regulations are necessary for the manufacture and/or importation of pharmaceuticals to ensure their quality, effectiveness, and safety. The standard for adequate advertisement of pharmaceutical products in Japan is regulated by the same law.

In the U.S., the incidence of teratogenic thalidomide resulted in the Harris-Kefauver Amendments in 1962, which requires sufficient pharmacological and toxicological testing on animals prior to testing drugs on human beings. The data from such studies must be submitted to the Food and Drug Administration (FDA) in the form of an application for an investigational new drug (IND) before clinical studies can begin. Three phases of clinical tests have evolved to provide the data used to support a new drug application. Proof of efficacy also is required as a term of the risk-to-benefit ratio for diseases. The provisions of these amendments have greatly increased the time and cost required to market new drugs. Prior to the Kesslerian reforms at the FDA, the total time of a drug’s development—from the time of filing of an IND application to final approval—averaged eight to nine years. The Kesslerian reform lessened this time period, particularly for drugs for the desperately ill. The clear purpose of these regulations is to protect the public health, however, the pharmaceutical industry and some health care practitioners still believe the approval of new drugs takes too long.

In Japan, the application for a new drug is submitted to the Central Pharmaceutical Affairs Council. The Council conducts an evaluation and review of safety, effectiveness, adverse reactions, and other regulations. Evidence of safety tests conducted on animals has also been required on the applications since April 1983; standardized human clinical tests were first published in December 1985. As in the U.S., compliance with these requirements increased the time and cost of new drug development in Japan. Moreover, a special pharmaceutical examination system, established in 1988, provides administrative guidance on appropriate clinical testing of pharmaceuticals.

Foreign pharmaceutical firms were prohibited by regulatory policy from applying on their own for the first step of drug approval (shōnin)—the demonstration of safety and efficacy review—
and clinical trials, which must be conducted in Japan on native citizens.\(^3\) This change was a trigger for Japanese pharmaceutical companies to establish their own research facilities, not only for drug approval but also for the development of new drugs.

In addition, before the mid-1970s the Japanese government controlled foreign direct investments and made the establishment of wholly owned subsidiaries extremely difficult. Foreign pharmaceutical firms generally had to license their products to Japanese companies in order to enter the Japanese market. Once products were licensed, only 3% of the relatively modest royalty was returned to the foreign companies.\(^3\) As a result, the benefits of the rapidly growing domestic pharmaceutical market were reserved largely for Japanese pharmaceutical companies.

Industrial policy on patents also contributed to the large expansion of Japan’s domestic pharmaceutical market. In the postwar period, Japanese law only protected process patents (seiho tokkyo) for pharmaceutical products. Hence, Japanese pharmaceutical companies could manufacture specific patented foreign products without violating Japanese law if they developed an alternative production process.\(^3\) However, when Japanese firms began creating their own new drugs, they needed protection for their own unique productions. In 1976, the law was revised to protect compound patents (bushitsu tokkyo), which provided for protection of unique compounds regardless of manufacturing process.\(^3\)

**DOMESTIC MARKET
AFTER 1980s**

When Japan joined the Organization for Economic Cooperation and Development Meaning Advanced Capitalist Economics nations in 1964 and made the yen convertible, its domestic market was gradually opened to foreign firms. A Business Week writer commented, “Critics in the U.S. and Europe said the Japanese government barred the way to any foreign companies that wanted stakes in Japanese corporations or Japanese facilities of their own. There have always been exceptions, of course...In 1995, for example, foreign direct investment in Japan was a mere $3.1 billion (compared with that of) the $68 billion in investments that foreigners made in the U.S. last year, and you see what a fortress Japan has been.”\(^3\)

The article goes on to note that “the door is opening” to foreign investment in Japan today, jumping more than 50% in 1996. Glaxo Wellcome acquired its Nippon Glaxo affiliate for $537 million and the British Amersham International is getting 30% of Nihon MediPhysics for $67 million, among firms in other industrial sectors.

Nevertheless, rising U.S.-Japan trade tensions continue, largely due to a U.S. trade deficit that exceeds $4 billion.\(^7\) The Clinton Administration is demanding that Japan boost its economy through demand rather than through exports. Airline travel is now the single biggest trade dispute with Japan, but the present imbalance also pertains to pharmaceutical products.

A look back is instructive for the pharmaceutical industry. In 1967, 50% foreign ownership of Japanese pharmaceutical companies became legal and 100% foreign ownership was permitted in 1975—changes that still did not make foreign business operations easy in Japan. By 1983, the Japanese domestic market had grown and the number of direct investments in companies doubled to more than 300.\(^3\) These investments diversified into the establishment of wholly owned subsidiaries, the expansion of sales forces, the construction of research laboratories and manufacturing facilities, and outright purchase of Japanese companies. Such investments reflected intensified competition in the Japanese domestic market; the foreign-owned pharmaceutical companies created fully integrated operations in Japan. Pressure from the U.S. in bilateral trade negotiations compelled changes that allowed foreign firms to apply directly for drug approval and permitted the submission of the results of foreign clinical trials.

In the 1980s, Japan still lacked internationally competitive ethical drugs because Japanese companies were concentrating on producing drugs similar to foreign products but with different manufacturing processes due to patent restrictions. In the 1970s, drugs licensed from foreign firms accounted for an average of six of the top 10 ethical drugs sold each year in Japan. Japanese government support for basic research and development (R&d) was lower than in other industrialized countries. In 1979, the Japanese government spent one-third the levels spent in France and Germany and one-fourteenth the level spent in the U.S.

By 1987, the MHW formed the Fund for Research Promotion in Pharmaceuticals to support pharmaceutical research.\(^3\)

By the late 1980s, Japanese companies began to successfully develop new drugs and argued for stronger patent protections for their own products. In December 1993, the TRIP agreement at the General Agreement on Tariffs and Trade’s Uruguay Round paved the way for the introduction of substance patents.\(^8\) Furthermore, at the Tokyo Summit in 1993, the trade ministers pledged to eliminate tariffs and non-tariff barriers on pharmaceuticals, medical equipment, and other goods. The negotiators agreed to phase out most of the tariffs over five years.\(^9\)

**JAPANESE PHARMACEUTICAL INDUSTRY OVERSEAS**

The economic and social environment in which the pharmaceutical industry is working today is producing some of the most profound worldwide changes the industry has ever known.\(^10\) A major factor has been the nonstop climb of health care expenditures for all countries. Costs have skyrocketed both for government-paid health insurance and as a result of the aging of populations. Slower economic growth has resulted in diminished availability of

Vol. 4, No. 2   March/April 1998
health care financing. Consequently, Western governments are trying to curb their health care outlays.

In Japan, the MHW sets a "reasonable zone" of allowable discounts for pharmaceutical product prices and, following surveys conducted every two years or so, imposes a general pharmaceutical reimbursement price cut. Drug prices were reduced an average of 6.8% in 1996, but faced a 10%–20% reduction in 1997 due to severe budgetary constraints imposed by Prime Minister Ryutaro Hashimoto's government. Due to the relative power of the Japanese Medical Association, drug price cuts are one of the few avenues for government budget savings, according to SCRP.

To make up for their tightening revenue streams, Western pharmaceutical firms with distribution networks in Japan have been pushing to sell a larger volume of their products there. At the same time, the Japanese pharmaceutical industry remains highly dependent on its domestic sales. As Western firms increase their share of Japan's domestic market, Japanese firms can no longer expect to grow domestic markets as they have in the past, even though the costs of medical goods make up 30% of the nation's health care expenditure.

In 1982, the MHW established the Pharmaceutical Industrial Policy Consultation Committee as a private advisory body to the MHW's Director of Pharmaceutical Affairs. In 1984, the committee recommended that the Japanese pharmaceutical industry make up domestic losses due to reimbursement cuts and foreign competition by expanding to overseas markets and strengthening research and development.

More recently, The Economist explained the situation as follows:

Contrast, are in the best of health, fed on a nourishing diet of overgenerous reimbursements. At long last the government is doing something to curb costs, and medical suppliers are having to find new ways of doing business.

The 27 trillion yen ($225 billion) a year the Japanese spend on their health care is relatively parsimonious. But the money is not always well spent. Misguided incentives keep patients in costly hospital beds longer than necessary—an average of 36 days, compared with nine in America and 14 in Britain. Another problem is over-prescribing. The reimbursement system for drugs allows doctors and hospitals to take a cut, so they stuff their patients with twice as many pills and potions as their British and American counterparts, driving up costs to the taxpayer and fostering the growth of drug-resistant bugs.

Another important factor in the marketing environment is the growth of foreign pharmaceutical firms operating in Japan that have established their own distribution channels and sales campaigns. They increased their share of the Japanese market to 25% in 1990, and if licensing arrangements are included, the figure would be 45%. In the past, these firms usually commissioned Japanese companies to conduct their sales business for them. Since the Japanese market ranks second largest in the world, it retains its profit-making value to foreign firms. Many of these firms have stepped up their own sales efforts in Japan and are discontinuing previous sales contracts with Japanese companies. As a result, the Japanese companies have lost licensing revenues from innovative Western products while the domestic market has turned highly competitive. In the future, foreign pharmaceutical firms are expected to control 50% of market share in Japan. In addition, more foreign pharmaceutical firms are establishing bases in Japan in order to expand into other Asian markets, in preparation for the rapid growth of China and the Association of Southeast Asian Nations (ASEAN), which includes Thailand, Indonesia, Malaysia, and Philippines.

The third factor affecting the market in Japan is the increased cost of research and development. Only a few years ago, the development of a single new drug cost 5–8 billion yen. The ratio of successful development of new drugs was estimated at about 1:100,000 of discovered drugs within an eight-year period. The cost of creating a new drug has increased to 12–15 billion yen, and the time frame involved has increased to 10–15 years. Computerized drug design and improved searching techniques have improved the success ratio to 1:3,000–4,000.

Without joint research and a global R&D system, new drug development may be very limited for Japanese pharmaceutical companies because their profit margins are smaller than those of Western pharmaceutical firms. Even if they reinvest all of their profits into R&D, the total investment still would be far less than that of Western pharmaceutical firms. The top 10 firms in Japan sell just $2.6 billion annually, whereas the top 10 U.S. companies sell $8 billion in the U.S. and $11.7 billion in Europe. Research and development expenditures in Japan account for only one-third to one-fifth of total R&D sales compared with Western countries: $248 million in Japan, $827 million in the U.S., and $1.163 million in Europe (see Table 2).

The Innovative Drug Vision Committee of the MHW recently recommended that the government increase direct research funding and more actively coordinate the industry's research activities. Commonly, Japan's government supports private industry for trade purposes. One report noted that while Japanese firms are developing more new products than ever before, only a small proportion of them are competitive on the world market. Of all Japanese products approved
domestically between 1986 and 1995, about 75% have not been approved in any other market. Either the firms did not judge that their drugs would merit approval, or the drug applications were submitted but did not gain approval for marketing from other governments. Only three new chemical entities had been developed in the U.S. by Japanese firms through 1993.

Meanwhile, the total value of Japanese drug production rose 1% in 1993, 2.2% in 1994, and 7% in 1995. This last annual figure was 6.168 billion yen ($36.3 billion), with imports of 589 billion yen.¹⁹

To cope with such a changing environment, Japanese pharmaceutical companies have established a global network of distribution and are no longer depending only on their domestic market. They also have changed license agreements to sell their own products through joint ventures and have established more profitable sales activities for Japanese firms in overseas markets. For the future, their R&D strategy also must shift to a global perspective, with development of new products aimed primarily at foreign markets.

A recent MHW reshaping of its Pharmaceutical Affairs Bureau was aimed at a clearer separation of regulatory and promotional functions. A new successor, the Pharmaceutical Safety Bureau, will oversee functions associated with the Japanese Pharmacopeia, while the supervision of production and distribution, the conduct of drug price surveys and revisions of the tariff, and the promotion of industry interests will be assumed by the Economic Affairs Division of the Ministry's Economic Affairs Bureau.²⁰

**ESTABLISHMENT OF AN R&D SYSTEM**

The key to success overseas depends on the development and marketing of internationally acceptable new drugs. Japanese pharmaceutical companies have teamed up with overseas venture enterprises, universities, and research centers and ultimately will strive for the establishment of a global R&D system to create a wide variety of original pharmaceutical products.

The trade balance in transfer of technologies in 1990 produced revenues of 24,971 million yen ($181 million) against payments of 22,514 million yen ($163 million), with a surplus of 2,457 million yen ($18 million). In 1991, revenue stood at 28,488 million yen ($197 million) and payments at 29,160 million yen ($201 million), leaving a small deficit of 673 million yen ($4 million) (see Table 3).¹⁷ The number of drug patents also increased from 249 in 1978 to 836 in 1989.¹⁶ These figures indicate that Japanese companies have increased the numbers of original new drugs, and are beginning to reach an R&D level comparable to that of Western countries.

Applications for approval of new drugs in Japan totaled 75 in 1991 and 73 in 1992. U.S. companies applied for 18 approvals in 1991 and 23 in 1992. Japan appears to have taken the lead in quantity. Many of the Japanese drugs are not cleared, however, for international acceptability due to insufficient quality in clinical trials and lack of compliance with U.S. FDA regulations. In 1985, 46 of the top 100 products were developed solely by the efforts of Japanese pharmaceutical companies. But half of these products were sold

<table>
<thead>
<tr>
<th>Table 2. International Comparison of Top 10 Pharmaceutical Firms in 1992</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Item</strong></td>
</tr>
<tr>
<td>-------------------------------------------------------------</td>
</tr>
<tr>
<td>Average of 10 major Japanese firms</td>
</tr>
<tr>
<td>Average of 10 major U.S. firms</td>
</tr>
<tr>
<td>Average of 10 major European firms</td>
</tr>
</tbody>
</table>

Source: SCRIP
only in Japan due to doubt surrounding the likelihood of approval from the U.S. and Southeast Asia.\(^3\)

**GLOBALIZATION OF JAPANESE PHARMACEUTICAL INDUSTRY**

Globalization of the Japanese pharmaceutical industry still lags behind that of Western nations. According to an international comparison of top 10 pharmaceutical firms in 1992, overseas sales and overseas sales ratios were $291 million and 11.0% in Japan, $3,125 million and 38.9% in the U.S., and $10,627 million and 90.5% in Europe (see Table 2).\(^4\) Also, in comparison to U.S. and European manufacturers, who rely on foreign markets for 50%-90% of their sales, Japanese companies in the Japanese Drug Manufacturers Association—which represents only the major companies—report that foreign markets account for a miniscule 3.8% of sales.\(^5\)

Exports of pharmaceutical products in 1993 totaled $1,370 million (173,683 million yen) against imports of $3,480 million (41,660 million yen), with a marked import surplus of $2,110 million (267,977 million yen) (see Table 4). Because Japanese companies still depend heavily on the domestic market. Although the import surplus persists, exports have been growing at a far faster rate. For example, exports grew 18.1% in 1990, 13.2% in 1991, and 15.3% in 1992, against import growth of 6.7%, 0.4%, and 4.3%, respectively.\(^6\) These figures indicate a steady progress of development in overseas markets. As foreign trade, the main export destinations are Europe (38.5%), the U.S. (33.1%), and Asia (26.3%), while most imports come from Europe (70.8%) and the U.S. (23.8%).\(^7\)

**REASONS FOR UNDERDEVELOPED OVERSEAS ACTIVITY**

At present, there are about 1,550 pharmaceutical companies in Japan, of which approximately 450 supply drugs for medical care.\(^8\) These Japanese pharmaceutical firms are classified into four groups based on origins. Most of the large companies such as Takeda, Fujisawa, and Tanabe were established as traditional wholesalers.\(^9\) Japanese pharmaceutical companies originated as distributors and have been stronger in sales promotion than in academic research. The large wholesale pharmaceutical companies have a long history of importing foreign products and selling them in the domestic market.

In addition, because the Japanese market grew rapidly due to national health insurance and was protected by the National Industrial Policy, Japanese companies did not need to develop an institutional capacity to sell their products in overseas markets nor to innovate internationally acceptable drugs until the 1980s. That was when pressures intensified, as a result of curbed drug prices, to reduce government health expenditures and to compete more effectively with foreign pharmaceutical firms in the domestic market.

The historical focus on Japan's domestic market is also reflected in the

**Table 3. Technology Export-Import Balance in the Pharmaceutical Industry (Unit: 1 Million Yen)**

<table>
<thead>
<tr>
<th>Year</th>
<th>Export</th>
<th>Import</th>
<th>Balance of Loss &amp; Profit</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Items</td>
<td>Value</td>
<td>Items</td>
</tr>
<tr>
<td>1975</td>
<td>63</td>
<td>1,328</td>
<td>90</td>
</tr>
<tr>
<td>1980</td>
<td>148</td>
<td>2,986</td>
<td>132</td>
</tr>
<tr>
<td>1981</td>
<td>151</td>
<td>8,265</td>
<td>107</td>
</tr>
<tr>
<td>1982</td>
<td>198</td>
<td>6,638</td>
<td>118</td>
</tr>
<tr>
<td>1983</td>
<td>218</td>
<td>9,948</td>
<td>222</td>
</tr>
<tr>
<td>1984</td>
<td>204</td>
<td>13,698</td>
<td>123</td>
</tr>
<tr>
<td>1985</td>
<td>239</td>
<td>13,068</td>
<td>166</td>
</tr>
<tr>
<td>1986</td>
<td>244</td>
<td>17,315</td>
<td>278</td>
</tr>
<tr>
<td>1987</td>
<td>285</td>
<td>16,101</td>
<td>210</td>
</tr>
<tr>
<td>1988</td>
<td>294</td>
<td>16,297</td>
<td>231</td>
</tr>
<tr>
<td>1989</td>
<td>317</td>
<td>18,904</td>
<td>252</td>
</tr>
<tr>
<td>1990</td>
<td>385</td>
<td>24,971</td>
<td>247</td>
</tr>
<tr>
<td>1991</td>
<td>399</td>
<td>28,488</td>
<td>270</td>
</tr>
</tbody>
</table>

lack of top managements' overseas experience and understanding. Foreign languages are essential to the overseas activities of Japanese companies because of the high informational requirements in drug approval and marketing, as well as the high degree of government regulations involved. Japanese drug firms have not sufficiently encouraged or rewarded this capability at upper- or middle-management levels. Thus, they must develop the human resources to deal with foreign regulatory and marketing issues.

Regulatory processes in other countries have provided an important obstacle to exportation. U.S. FDA regulations have been particularly difficult for Japanese companies to meet due to a lack of company experience and trained professionals to win approvals. The poor quality of drugs, weaknesses in clinical trials, and nontariff barriers also are problems. Japanese firms have therefore used licensing or joint ventures to get their products into other markets and have depended on the regulatory expertise of their U.S. partners to obtain approvals. While the Japanese are highly skilled in exporting automobiles, electronics, and computers, they are not yet skilled in dealing with the American pharmaceutical market.

By licensing or joint venturing products, profit potential is dramatically reduced. The Japanese companies also have less control and influence in these situations. In some cases, U.S. pharmaceutical companies that have licensed Japanese drugs have not developed or marketed them aggressively because they compete with an existing product of the U.S. company. For example, the H2-antagonist Famotidine, introduced by a Japanese company in 1986, achieved a market share of 41.5% in Japan in 1990. In the U.S., however, Famotidine was only 12.9% of the market in 1990 because other companies had already promoted the competing products, Cimetidine and Ranitidine, which were introduced in 1982 and 1984, respectively.16 The gyrations of the yen in the 1980s also have afflicted Japanese pharmaceutical trade. The strengthened yen made pharmaceutical products even more expensive overseas and discouraged pharmaceutical exports. On the other hand, the stronger yen also contributed to domestic profitability of Japan's pharmaceutical companies by importing foreign products for less, while imported products were sold at the set price by the Japanese government. The profits for a number of foreign pharmaceutical firms in Japan also increased sharply between 1986 and 1987: Torii & Co.(1,153%), Nippon Glaxo (257%), Japan Upjohn (138%), and Warner Lambert (122%). Also, the decreased costs of imports helped Japanese pharmaceutical firms offset the impact of government cuts on official reimbursement rates. Furthermore, the stronger yen lowered some overseas costs of market entry, especially for labor, the establishment of wholly owned subsidiaries, manufacturing plants, and research facilities in overseas areas more attractive to Japanese companies. The recent financial turmoil in the Pacific Rim, most notably involving the Japanese economy, adds new gyrations that will be addressed in Part III of this analysis.

### CONCLUSION

This article discusses the changes in the Japanese pharmaceutical industry as it strategically decided to foster overseas activities from the 1980s. Change in that period was driven by government price reductions and foreign competition in the domestic market, the need to upgrade R&D capabilities, and the creation of favorable industrial policies. Specific Japanese pharmaceutical company activities and the recent economic development will be examined in Part III.
References


5. Spivey RN, Wertheimer AI, Rucker TD. International pharmaceutical services. Pharmaceutical Products Press. New York:


