Why the Japanese Don’t Export More Pharmaceuticals: Health Policy as Industrial Policy

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Compared to other Japanese industries and to the pharmaceutical industry of other industrialized countries, the Japanese pharmaceutical industry has been remarkably unsuccessful in exports. Japan has the second largest single-country market for pharmaceutical products in the world, but is one of the lowest exporters among the major producer countries. According to the most commonly cited statistics, the Japanese pharmaceutical industry for most of the postwar period has exported only about 3% of total production (Figure 1). Even in 1987, imports exceeded exports by about two and a half times (Figure 2).

Yet in the 1980s, Japan emerged as a global competitor in the pharmaceutical industry. Articles in the U.S. business press predicted a surge of Japanese pharmaceutical exports and stock analysts wrote about an imminent globalization of the Japanese pharmaceutical industry. Japan now ranks among the small group of Western nations (U.S., U.K., Switzerland, Germany, France) that produce the vast majority of the world’s new drugs. Japanese pharmaceutical firms have improved the quality of their products and have adopted global R&D strategies. Japan is perceived as a major challenger in biotechnology. In 1988, one Japanese company, Takeda, advanced to number seven in world sales of drugs, from number 12 in 1986 (in part due to shifting exchange rates). And the industry newsletter SCRP predicted that Japan will become the world’s largest single-nation pharmaceutical market by the year 2000. Although the exports-to-production ratio has not varied appreciably, the composition of pharmaceutical exports has changed significantly. The conclusion seems to be spreading that the Japanese have done it again, this time with the pharmaceutical industry.
To explain the transformation of the Japanese pharmaceutical industry since the 1950s, one could rely on two conventional models. The government intervention model of Japanese industrial policy argues that the country’s elite bureaucrats intentionally created internationally competitive industries through measures designed by the Ministry of International Trade and Industry (MITI), with long-range strategic planning and a strong export orientation. The free market model proposes that Japan’s economic successes resulted from firms that responded to normal market forces and intense domestic competition; that industrial development came from efficient markets and not from bureaucratic intervention.

I argue in this article that neither model is accurate. The success of the Japanese pharmaceutical industry transpired without significant intervention by MITI, without explicit industrial policy for the pharmaceutical sector, and without export-oriented public policy. On the other hand, neither did the changes occur as the result of unbridled competition under a free market. Instead, the pharmaceutical industry has been nurtured and promoted through a highly regulated market with government-set prices, where health policy has served as implicit industrial policy.

This conclusion fits with a third model, which stresses political economy for analyzing industrial policy. In his study of the Japanese machine tool industry, David Friedman argued that competitive successes in Japan have resulted neither from bureaucratic guidance nor from market forces, but rather from political structuring of the economy. Similarly, Chalmers Johnson has written about the importance of political economy for understanding Japanese industrial successes and for illustrating how markets actually work: "It is through institutions and the struggle to institutionalize rules that are favorable to one group or another that politics and political preferences structure the ways economic processes work." This article analyzes the globalization of the Japanese pharmaceutical industry to illustrate these broader themes of political economy.

**Patterns of Pharmaceutical Exports**

Japanese industries have typically followed a pattern of first developing products for the large domestic market, under government policies of protection from direct international competition, and then moving into the "low end" of foreign markets with relatively inexpensive but good quality products, based on the foundation of solid domestic sales. The pharmaceutical industry followed the domestic stage of this pattern, but has not yet developed into the global stage of exports already achieved by other sectors, such as the automobile, electronics, and machine tool industries. The exception of Japan’s pharmaceutical industry—as domestically oriented rather than export oriented—demonstrates that not all Japanese industries have
been successful exporters, and also that an industry can be highly profitable without reliance on exports.

There are nine basic patterns of Japanese pharmaceutical exports:\textsuperscript{12}

- Prewar exports of the Japanese pharmaceutical industry reached substantial levels, but dropped sharply after the war.\textsuperscript{13}
- The postwar ratio of exports to production has remained fairly constant at a relatively low level (Figure 1), reflecting similar growth rates in both exports and production.
- An international comparison shows Japan’s ratio of pharmaceutical exports to total production as significantly below that of other industrialized countries.\textsuperscript{14}
- Japan continues to import significantly more than it exports in pharmaceuticals (Figure 2), in contrast to other major producer countries.\textsuperscript{15}
- The industry’s ratio of exports to production remains low, compared to that ratio for other Japanese industrial sectors.\textsuperscript{16}
- The ratio of exports to production for Japanese pharmaceutical companies remains much lower than that ratio for pharmaceutical firms in other countries.\textsuperscript{17}
- The pattern of pharmaceutical exports has shifted in the past three decades from an emphasis on non-patented bulk products to patented products.\textsuperscript{18}
- The target countries for exports have shifted from Asian countries to Europe and the United States, although Asia remains the most important market for finished products.\textsuperscript{19}
- An increase in the value of exports of pharmaceutical technology, now exceeding the value of technology imports, indicates greater international acceptance of new Japanese drugs (Figure 3).

\textbf{Figure 1. Ratio of Exports to Production Japanese Pharmaceuticals, 1955–85}

![Graph showing the ratio of exports to production for Japanese pharmaceuticals from 1955 to 1985.](image)

\textbf{Source:} Yakugyo Kogyo Seisan Dotai Teikoku Kenpo (Pharmaceutical Industry Production Statistics Annual), Tokyo; Yakugyo Keizai Kenkyujo (Institute for Pharmaceutical Industry Economics), various years; and Wagakuni Yakuin Boeki no Jitsuyo (Situation of Japanese Pharmaceutical Trade), Tokyo; Yakugyo Keizai Kenkyujo (Institute for Pharmaceutical Industry Economics), various years.
Figure 2. Pharmaceutical Trade of Japan, 1975–87


Figure 3. Technology Exports and Imports in the Japanese Pharmaceutical Industry
Total Contracts, by Value, 1975–87

Conclusions about Exports—The overall conclusion is more complicated than the conventional image of low exports would suggest. At first sight, Japanese pharmaceutical exports are remarkably low, from several important perspectives: as a proportion of total production, and as compared to other rich countries, to pharmaceutical imports, and to other Japanese industries. This conclusion holds from an industry as well as a firm perspective.

But the conventional wisdom does not account for an important development: significant changes in the composition of Japanese pharmaceutical exports—in the quality of products, the target markets, and technology sales—as well as the increasing overseas presence through joint ventures and direct foreign investment. The overseas presence of Japan’s pharmaceutical industry thus has evolved from direct export of bulk products, to indirect export through licensing agreements, then joint ventures, with some limited efforts at overseas production and direct sales.20 Explaining this more complicated image of pharmaceutical exports—the persistent low levels and the accompanying transformations—requires an analysis of Japanese public policy.

Reasons for Low Exports

Four major explanations account for the relatively low level of exports from the Japanese pharmaceutical industry. National health policy created powerful incentives for a rapid expansion of the domestic pharmaceutical market in the 1960s and 1970s, thereby reducing the incentives for firms to look overseas for sales. Second, Japan’s general industrial policy until the mid-1970s served to protect the domestic market and local companies from direct competition by foreign firms, thereby assuring that the benefits of growth in the Japanese market would accrue largely to Japanese companies. Third, Japanese firms had a lack of ethical drugs that were internationally competitive, due to a combination of government policy and corporate strategy. And finally, external obstacles, in contractual, regulatory and non-regulatory forms, provided barriers to entry, even as Japanese firms developed potentially competitive products. These conditions held until the early 1980s, when changes in Japanese political and economic circumstances led to public policies that began restructuring the pharmaceutical industry and pushing it into overseas markets.

The Role of National Health Policy—National health policy has shaped the strategy of the Japanese pharmaceutical industry throughout the postwar period. Health policy created a rapidly growing domestic market for pharmaceuticals, which provided firms with substantial profits at home and therefore little incentive for a strategic emphasis on exports. A major difference between the pharmaceutical industry and other protected industries that became export-oriented (cameras, autos, machine tools) was the
existence of an assured domestic market with government-set prices, through national health policy. This made the pharmaceutical industry more complacent about exports. Even when other Japanese industries experienced a slowdown in growth after the first oil shock in 1973, the pharmaceutical industry continued to grow rapidly, due to expansionary changes in health policy. Only in the early 1980s did growth in the pharmaceutical industry weaken, actually showing a decline in production in 1984 and 1985 for the first time in the postwar period, due to sharp cuts in reimbursement prices as part of government efforts to contain medical costs.

Whether health policy was intended to serve as industrial promotion policy remains a point of debate. The combination of policies was not explicitly designed for industrial promotion. And as explained later, pharmaceutical policy remained within the domain of the Ministry of Health and Welfare (MHW), not MITI. Nevertheless, until about 1980, a series of health policies combined to produce a golden age for pharmaceuticals in Japan. In effect, national health policy unofficially served as industrial promotion policy for pharmaceuticals. Five key health policies, described below, promoted the expansion of the domestic medical market and provided positive support for the pharmaceutical industry.

**Drug Approval Policy**—Until the late 1960s, Japanese companies could easily license foreign products, get them approved in Japan for production or import, and then sell the drugs domestically at quite handsome profits. Relatively low barriers to entry existed for Japanese firms to introduce foreign drugs that were already approved overseas. Prior to 1967, Japan did not require domestic clinical trials on safety or efficacy for foreign products listed in an accepted official pharmacopoeia. These products were excluded from the definition of “new drugs” and therefore received rapid approval. Consequently, the main strategic emphasis of Japanese pharmaceutical companies, until the mid-1960s, focused on identifying foreign products to license for manufacture or importation. In the late 1960s, imports accounted for 35-40% of final products of ethical pharmaceuticals in the Japanese market; this trend has declined slightly, but even in 1983 the figure remained at 31%. Drug approval policy in Japan provided strong incentives for importing foreign pharmaceutical technologies, and domestic companies responded enthusiastically.

Drug approval regulations also helped keep foreign firms out of the Japanese market. Foreign firms were prohibited by regulatory policy from applying on their own for the first step of drug approval (shonin), the demonstration of efficacy and safety review, and clinical trials had to be conducted in Japan on native citizens. Both policies remained in effect until the mid-1980s, when pressure from the United States in bilateral trade negotiations compelled changes that allowed foreign firms to apply directly and permitted the submission of the results of foreign clinical trials.
Health Insurance Policy—Changes in Japan’s health insurance policy have progressively reduced patient restrictions on access to medical care, thereby providing the basis for continued expansion of the domestic pharmaceutical market through the 1970s. The policy changes created incentives for the pharmaceutical industry to focus on domestic demand rather than on exports.

In the late 1950s the Japanese government adopted the goal of health insurance for the entire nation. The National Health Insurance Law was revised in 1958 to provide insurance based on residence for the uncovered 30% of the population. And in 1961, universal health insurance coverage was achieved, although many inequities remained. Throughout the 1960s, the government reduced the level of patient copayments for various health insurance plans, thereby raising demand for medical services. These policies of universal coverage and reduced copayments contributed to the rapid expansion of domestic consumption of pharmaceuticals in the 1960s (averaging over 15% a year growth). In 1973, the government introduced free medical care for the elderly, which contributed to increased utilization of medical services by this growing population segment in Japan, and also catastrophic illness insurance.

Physician Dispensing Policy—Throughout the postwar period, Japanese physicians have both prescribed and dispensed pharmaceuticals to patients, with a portion of insurance reimbursement for drugs serving as income. This system contributed to the expansion of the domestic market, by creating economic incentives for physicians to prescribe liberally and to choose products with higher margins.

In 1951, under pressure from the U.S. Occupation, the Japanese Diet revised several laws to separate dispensing from prescribing by physicians, known in Japanese as iyaku bungyo. But in 1955, after the Occupation’s end and before the changes went into effect, the laws were revised again to introduce a series of exceptions that would allow physician dispensing, which effectively reversed the policy of separation. This reform effort failed due to opposition by the Japan Medical Association (JMA), which argued that dispensing constituted medical care, for which physicians alone held responsibility, and that pharmacists lacked adequate training to fill most prescriptions. But the underlying fear of most physicians was that if they lost dispensing, they would lose their main source of income.

Private physicians have strongly supported the combined system of prescribing and dispensing, in part because they derive a substantial portion of their income from the profit or “doctor’s margin” (yakka saeki, literally “pharmaceutical margin”)—the difference between the purchase price from the supplier and the reimbursement price set by the government. The same incentive does not operate for salaried physicians in large hospitals, especially public and university hospitals. But for private physicians, who re-
ceive the profits of pharmaceutical sales as part of the fee for service, the combination of prescribing and dispensing creates an incentive structure that has raised concerns about overprescription by physicians, conflicts between medical and economic interests, and ethical issues of physician-patient relations—concerns also expressed about a policy proposed in the United States to allow physician dispensing.

The Japanese system has developed strong institutional forces against change, given the total value of drug reimbursements (5.16 trillion yen in 1987, or $35 billion at ¥ 146 = $1) and that one-quarter goes to the “doctor’s margin.” The group with the greatest interest in the separation of prescribing and dispensing, the independent pharmacists, has lacked the political power to implement this policy change, defeated by the greater organizational strength of physicians. Consumers, as patients, have tended to respect the authority of physicians and have also faced declining costs of pharmaceuticals through expanded health insurance coverage. Finally, pharmaceutical companies have seen little interest in changing a system that provided a growing market for their products and a political channel to the government. Although some in the pharmaceutical industry have called for cooperating “as much as possible” in the implementation of iyaku bungyo, the dominant industry position has supported the status quo.

Consequently, the combined prescribing-dispensing system has persisted, and nearly all prescription drugs are still dispensed directly by physicians or hospitals. In 1985, an estimated 10% of prescriptions were filled by pharmacies outside of hospitals and physician clinics. This represents a gradual increase from the early 1970s, when hospitals and physicians dispensed about 98% of all prescriptions. The change reflects efforts by the MHW since the mid-1970s to implement iyaku bungyo, through monetary incentives for physicians to write prescriptions and for pharmacists to fill them. In the mid-1970s, the JMA adopted a more supportive policy on separation, perhaps due to increased payments for physicians to write prescriptions as well as the growing professional strength of pharmacists. Nevertheless, by volume, pharmacies in 1981 dispensed only 2.1% of all ethical drugs, and physician clinics still accounted for 41.1%, with the remainder dispensed by hospitals.

While the combined prescribing-dispensing system has not directly affected pharmaceutical exports from Japan, it did provide an important incentive that contributed to rapid growth of the domestic market. Without the direct economic incentive for physicians to prescribe, the domestic market might have expanded more slowly, profits for companies might have been lower, and the attention to overseas markets might have arisen earlier.

Fee-for-Service Reimbursement Policy—Reimbursement policy has similarly contributed to the expansion of pharmaceutical consumption. Physicians are paid through fee-for-service reimbursement, with relatively few con-
strains imposed by insurers in reviewing charges submitted by physicians. The doctor has reigned as king, and the prescriptions dispensed have been reimbursed with little challenge. The lack of effective controls over prescribing patterns by physicians has resulted in part from the lobbying power of the JMA and its emphasis on the principle of professional freedom of physicians and on the principle of non-interference by government or other "third parties" in the physician-patient relationship. 40

Pharmaceutical Price Policy—Price policy for pharmaceuticals has created major incentives for the expansion of the Japanese domestic market. Under the health insurance system, the prices set by the government for pharmaceutical reimbursement (material points) have had relatively higher profit margins than those for physician services (skill points). Material points (the fees for diagnostic tests and drugs) are overvalued in relation to costs, while skill points (the fees for consultation, treatment, and operation) are undervalued. The discrepancy between material prices and skill prices has provided a powerful incentive for physicians to prescribe pharmaceuticals, in solo practices and medical institutions. "The consequence has been that excessive amounts of diagnostic tests and drugs are applied to recover losses from consultation and operations. To many hospitals, complicated operations represent a drain of financial resources that must be recovered from less serious operations and from prescribing more tests and drugs." 41

Reimbursement price policy has effectively required physicians, clinics and hospitals to use profits from pharmaceuticals sales to cross-subsidize other functions. Drugs are reimbursed by the insurer at a government-set price, but are purchased from a manufacturer or wholesaler at a discounted price. In the more competitive therapeutic segments (such as antibiotics), the discounts tend to go deeper. For the solo practitioner, the margins on pharmaceutical prices provide a secure and profitable source of revenue. Price policy thus created incentives for physicians to dispense pharmaceuticals liberally and to select products with relatively higher profit margins. Until the 1980s, price cuts in the official tariffs for pharmaceuticals remained rare and minimal. Price policy provided a powerful mechanism to expand the Japanese pharmaceutical market for the financial benefit of physicians as well as producers.

While international comparisons of pharmaceutical prices are subject to various uncertainties (due to product variation and exchange rates), one study in 1982 reported Japanese prices as significantly above those in Switzerland, West Germany, the U.K., Italy, and France. 42 In commenting on this analysis, Robert Chew and coauthors concluded, "The level of prices in Japan reflects both the strength of the yen and the fact that Japan has consistently supported its home-based industry in order to strengthen its future worldwide development. Recent price reductions in Japan have not altered this general situation." 43 Whether this conclusion holds at the
end of the 1980s is debatable. But the historical point still remains that prior to the 1980s generous reimbursement rates in Japan served as an indirect support mechanism for the domestic industry.

The Role of National Industrial Policy—National industrial policy in Japan has also affected the pharmaceutical industry and its approach to exports. Through the mid-1970s, two policies in particular, for capital liberalization and for patents, served to protect Japanese pharmaceutical companies from international competition within the domestic market, while giving domestic firms the benefits of foreign products through licensing. These policies belonged to the overall industrial strategy of conserving foreign exchange and promoting local production. The combination of a protected domestic market through general industrial policy, along with assured growth through national health policy, reduced the incentives for Japanese pharmaceutical firms to export.

Capital Liberalization Policy—Before the mid-1970s, Japanese government controls on foreign direct investment made the establishment of wholly owned subsidiaries extremely difficult. Japan began a step-by-step liberalization process in 1964, when the country joined the Organization for Economic Cooperation and Development (OECD) and made the yen convertible. In 1967, 50% foreign ownership of pharmaceutical companies became legal (along with 33 other industries), with 100% foreign ownership going into effect in 1975.44

While in effect, the restrictions on ownership, together with regulations for drug approval described above, meant that pharmaceutical firms located abroad generally had to license their products to a Japanese company in order to enter the Japanese market. Once a product was licensed, the royalty fee, often about 3%, represented a relatively low return to the foreign company. As a result, the high benefits of the rapidly growing Japanese pharmaceutical market were largely reserved for Japanese firms.45

The removal of government controls on foreign investment contributed to a surge in the number of foreign pharmaceutical companies in Japan. From 1975 to 1983 the number doubled to over 300 companies with direct investments.46 In the 1980s, these investments diversified, including the creation of wholly owned subsidiaries, the expansion of sales forces,47 the construction of research laboratories48 and production facilities, and outright purchase of Japanese companies. The investments reflected an intensified foreign presence and competition in the Japanese market,49 and a trend for foreign-owned pharmaceutical companies to create fully integrated operations in Japan.

The step-by-step capital liberalization policy in Japan delayed the opening of the domestic pharmaceutical market to direct international competition and gave profits to Japanese companies that might otherwise have gone to
foreign firms. National industrial policy on capital liberalization, along with drug regulatory policy, protected the domestic market and thereby reduced the need for exports by Japanese pharmaceutical companies.

*Patent Policy*—Industrial policy on patents also contributed to allocating the benefits from the expanding pharmaceutical market largely to domestic firms. For most of the postwar period, Japanese law provided protection only for process patents (*seiho tokkyo*) for pharmaceutical products. Japanese companies that developed alternative production processes for a specific patented drug could legally manufacture and sell their product in Japan. In 1976, the law was revised to protect compound patents (*busshitoku tokkyo*), which provided protection for unique compounds, regardless of manufacturing process.

The prolonged policy of process patents allowed and encouraged Japanese companies to manufacture unique foreign products, without violation of Japanese law, if a different process could be developed. Valium, for example, was sold mostly by domestic firms in Japan, with Roche holding only a small percentage of the domestic market. In this way, national industrial policy on patents reduced the incentives for pharmaceutical exports, by reserving large benefits of the growing Japanese pharmaceutical market for domestic companies. Only when the research-oriented Japanese firms had achieved some R&D maturity in the mid-1970s (as described below) and needed protection for their own unique products, did the pharmaceutical industry accept compound patent protection. And only in the late 1980s did the Japanese R&D-oriented firms begin to argue for stronger patent protection in Third World countries.

The transformation of Japanese patent policy for pharmaceuticals thus followed the development of the domestic industry. The changes closely resemble the evolution in policy proposed by the United Nations Industrial Development Organization for developing countries: first, to weaken the patent system to promote cheap imports; then, to provide some patent restrictions that do not interfere with domestic industrial development; and finally, to create a strong patent system for the protection of major domestic R&D efforts.

*The Lack of Competitive Ethical Drugs*—Another explanation for Japan’s low level of exports is the lack of domestically developed ethical drugs that could compete in the major markets of industrialized countries. Japanese origin drugs even had difficulty competing in the domestic market. In the 1970s, drugs licensed from overseas companies accounted for an average of six of the top ten ethical drugs sold each year in Japan. Japan’s lack of internationally competitive ethical drugs resulted from a combination of government policies and corporate strategies.
Government R&D Policy—Japanese government support of basic R&D in various fields, including biomedicine and pharmaceuticals, is known to be lower than such support in other industrialized countries. In 1979, the Japanese government spent one-third the levels in France and Germany and one-fourteenth the level in the United States, for health-related basic research on a per capita basis. A group from the Japanese pharmaceutical industry, while emphasizing the large corporate expenditures on applied research, criticized the government’s low level of investment in basic R&D and called for a change in policy. The lack of government investment in basic R&D contributed to Japan’s delay in developing pharmaceutical products capable of international competition.

In the 1980s, however, the Japanese government increased its expenditures and efforts on basic R&D in biomedicine, especially in relation to biotechnology. Government ministries began competing actively for R&D funds on biotechnology, with separate projects at MITI, the MHW, and the Ministry of Agriculture, Forestry, and Fisheries. As part of its efforts to promote biomedical R&D, the MHW initiated two research projects in 1988 that supported interfirm collaborative R&D to develop new pharmaceutical products using biotechnology.

The pharmaceutical industry has greeted these government-supported projects with a mixture of skepticism and approval, reflecting the relatively small sums involved and the general difficulties of interfirm collaborative research in the private sector. These attitudes also reflected concern by some established firms in the pharmaceutical industry that the new funds for biotechnology are being used to assist newcomers to the market (including companies strong in fermentation as well as those with no prior connection to pharmaceuticals). While these projects tend toward applied research, the government’s proposal for a global Human Frontiers Science Program could become a major international initiative in basic R&D. Overall, the array of projects in recent years reflects a more interventionist approach by the Japanese government toward biomedical research.

Pharmaceutical Price Policy and Innovation—Reimbursement price policy for pharmaceuticals has played a major role in determining the strategic allocation of corporate R&D funds. In providing signals to private companies and in defining the market, pharmaceutical price policy has served as an important implicit form of industrial policy.

One example of the impact of price policy on pharmaceutical innovation is for antibiotics, where the relatively higher reimbursements for antibiotics (through the 1970s) encouraged companies to invest their R&D funds in that therapeutic segment. Price policy thus contributed to Japanese strength in antibiotics. Other factors also influenced Japanese success in developing new antibiotics, including the historical strength of fermentation technology,
the existence of world-class scientists in this field in Japan,\textsuperscript{60} the early start of penicillin production in 1946 under the U.S. Occupation,\textsuperscript{61} and the relative ease of demonstrating the effectiveness of antibiotics without complicated clinical trials.

In the 1980s, the government cut the official pharmaceutical price list by a cumulative average of 61.4\%, as part of a major effort to slow down the rise in medical expenditures.\textsuperscript{62} These cuts resulted primarily from pressure by the Ministry of Finance on the MHW to contain costs, due to the government's overall budget deficit. The reimbursement rate for pharmaceuticals represented a prime area for cutbacks. The political strength of the Finance Ministry could easily defeat the declining power of the Japan Medical Association (symbolized by the retirement of its 25-year president, Dr. Taro Takemi, in 1983) and followed by dissent within the organization. The pharmaceutical industry, which had depended on the JMA as its political channel, was unable to effectively oppose the price revisions by the MHW.

The price cuts significantly reduced the profits in some companies, but the cuts also created incentives for products whose prices were not decreased as much (especially new drugs). The cuts also created incentives for exports, since prices in foreign markets are not subject to the MHW. While pharmaceutical prices fell sharply in Japan during the 1980s, prices for the daily dosage of the top 43 prescription drugs in the United States rose by an average of 40\% between 1982 and 1988, with an increase of 32\% in Italy, 9\% in France, 7\% in Holland, 6\% in Switzerland, and 5\% in England.\textsuperscript{63} The prospects of rising prices and potential profits overseas—especially given the size of the U.S. market and lack of government price controls, and the approaching consolidation of the European market in 1992—have created strong incentives for Japanese companies to become more directly involved in those markets.

The price cuts produced a differential impact on Japanese firms: Those firms unable to develop new products or increase exports have been driven into greater financial troubles, while firms able to develop new products and increase exports have gained market share and profits. An analysis of sales and profit trends in the 1980s showed that Japan's top pharmaceutical companies have not suffered as severely as have others.\textsuperscript{64} Price policy thereby could drive a restructuring of the Japanese pharmaceutical industry.

Price cuts in the 1980s affected therapeutic segments differently. In fiercely competitive segments, such as antibiotics, companies deeply discounted their products to physicians and hospitals, in order to gain or maintain market share. In the 1980s, those discounts resulted in continued price cuts by the government, because of the formula used to calculate the official tariff for reimbursement. The MHW's price policy thus created incentives for a strategic reorientation in corporate research. And firms responded, shifting their research focus away from the sharply cut therapeutic segments (such as antibiotics) to other less-cut categories (such as cardiovascular and anticancer drugs).
These price cuts had an unintended impact in substantially shortening the life cycle of pharmaceutical products in highly competitive therapeutic segments. The reduced market life resulted from changes in physician prescription patterns, as physicians responded to government cuts in the official reimbursement rates by shifting to products with higher profit margins. This required that a company keep developing and introducing new drugs in order to assure large sales volumes for higher priced drugs, and thereby maintain cash flow needed for growing research activities. In 1988, new products introduced since 1978 constituted two-thirds of the total ethical drug market in Japan by value. These “new” drugs, however, tended to be more adaptive than innovative products, thereby contributing to the shortened life cycle. The impact of the shortened life cycle and rapid turnover of drugs on the quality of medical care remains an unresearched topic in the Japanese context.

**Government Policy for Corporate R&D**—In 1967, the MHW amended the drug approval process (through administrative guidance) to require for the first time that companies do clinical trials in Japan on the safety and efficacy of new products prior to approval. This policy had a major impact on corporate strategy, inducing many firms to initiate their first serious research efforts. Ironically, a drug disaster with an imported product—Thalidomide—became the catalyst for initiating serious research by Japanese pharmaceutical firms. Companies decided to establish research facilities not only for drug approval but also for the development of new products.

Government policy, however, did not directly address the issue of developing adequate R&D capacity in the pharmaceutical industry. That objective emerged, instead, as an unintended consequence of drug approval policy. Similarly, until the 1980s, the MHW did not address its policies toward the development of internationally competitive pharmaceutical products.

**Mandate of the MHW**—The MHW, by its legal mandate and organizational nature, has focused on domestic health affairs, with little attention to industrial policy or the international economy—areas where the ministry has limited expertise. Historically, the MHW has been oriented towards the consumption side more than the production side of the pharmaceutical industry.

But the MHW does not necessarily act more oriented to consumers than to producers. As I argued above, health policies have often served to promote the industry. Friendly ties between the industry and the ministry are strengthened by amakudari (“retirements to heaven”) by government officials who move to high positions in pharmaceutical companies and trade associations. Moreover, tension between regulating and promoting the industry exists within the ministry, between the Health Insurance Bureau (responsible for reimbursement price setting) and the Economic Affairs
Division in the Pharmaceutical Affairs Bureau (responsible for official contacts with the industry on production issues).

From the industry's perspective, however, the MHW has not been adequately supportive on overseas issues, for example, on questions of international harmonization of pharmaceutical regulations.\(^\text{60}\) Southeast Asian countries do not generally recognize Japanese drug approval as equal to drug approval in the United States or some European countries, which result in automatic approval in certain Southeast Asian countries. Industry sources consider as inadequate and ineffective MHW's efforts to explain Japanese drug approval policy to Southeast Asian countries—export markets with significant growth potential.

The MHW's first official mention of export activities for the pharmaceutical industry occurred with the creation of the Pharmaceuticals Industrial Policy Consultation Committee, which was formed in 1982 as a private advisory body for the MHW's Director of Pharmaceutical Affairs and delivered its final report in 1984.\(^\text{70}\) Once the MHW began to consider "industrial policy" as an official activity, the question of pharmaceutical exports could no longer be avoided. This foray into industrial policy by the MHW occurred as the result of a bargain with the trade association, as part of the ministry's efforts to persuade the industry to accept the 1981 slash of 18.6\% in pharmaceutical reimbursement prices.\(^\text{71}\) Indeed, the advisory committee's key members came from the trade association, and the recommendations tended to favor the research-oriented major firms over the small and middle-sized companies. In effect, the report proposed that the industry make up domestic losses from reimbursement cuts by strengthening R&D and expanding in overseas markets.\(^\text{72}\)

Importantly, the pharmaceutical industry has been out of bounds for MITI. MITI has confronted a 'no-touch' rule for the pharmaceutical industry, which remained firmly within the MHW's bailiwick, even on issues of industrial policy and exports. In sharp contrast to the MHW, MITI maintained a strong export orientation from the early postwar period until recently, with substantial experience (but debated effectiveness) in coordinating export drives for various industries.\(^\text{73}\) Only in the 1980s did MITI become involved with the pharmaceutical industry through the back door, with the establishment of the ministry's Office of "Bioindustry," the initiation of a ten-year research support program, and the formation of the Research Association for Biotechnology.

From the MHW's perspective, however, MITI developed its biotechnology program because MITI could find no other way to approach the pharmaceutical industry and because MITI wanted access to new research budgets from the Ministry of Finance. Bureaucratic competition between government agencies in Japan thus has affected policy (and non-policy) for the pharmaceutical industry. MITI's historic lack of involvement with the pharmaceutical industry probably contributed to the sector's diminished export orientation.
The entry of MHW into the field of industrial policy also reflected a shift in the balance of groups within the ministry. In the late 1970s, the more economically and internationally oriented bureaucrats assumed more influence within the MHW, exemplified by the appointment of the late Mr. Yoshimura Jin to Vice-Minister. Yoshimura and his allies in the MHW worked for a more modern ministry, including “rational” policy on reimbursement prices (advocating the price cuts of the 1980s) as well as direct measures to support pharmaceutical research (through the Fund for Research Promotion in Pharmaceuticals, formed in 1987). This change in the organizational character of the MHW helped produce the more explicit stick-and-carrot approach to the pharmaceutical industry in the 1980s.

Limited Corporate R&D Efforts—Until the 1970s, most Japanese pharmaceutical companies had limited R&D capability, as reflected in low R&D expenditures as a percentage of sales. In 1975, the ratio of pharmaceutical R&D to sales was about 5%, rising to about 7% ten years later. These weak R&D efforts not only restricted the development of truly innovative products, but also meant the firms did not need export markets to recoup the relatively low costs of R&D.

Japanese pharmaceutical firms began to establish research laboratories in the mid to late 1960s, prodded by government requirements for local R&D on proposed new drugs (as noted above). But even then, most efforts focused on incremental research rather than breakthrough research, with an emphasis on adaptation rather than innovation. The efforts sought to develop “me-too” drugs that would be quickly approved and posted on the national health insurance price list, thereby reducing the risk of research and assuring financial returns. Attention also focused on developing new processes for existing products, due to the process patent system. In these ways, government policy on drug approval, pharmaceutical prices, and patents shaped corporate strategy on R&D. As a result, according to the number of new chemical entities introduced between 1961 and 1985, only one Japanese company ranked among the top 25 research-based firms worldwide (Takeda at 21).

From the mid-1970s, corporate investment in pharmaceutical R&D rose rapidly, increasingly nearly four-fold between 1975 and 1985. The more research-oriented firms reached a ratio of almost 11% R&D to sales in 1985. As Japanese companies increased their R&D activities, they needed to develop overseas markets to help support the higher expenditure.

General Nature of Pharmaceutical R&D—The research and development efforts necessary for a new product in the pharmaceutical industry are both time and money intensive. In Japan, 10–16 years and 8 billion yen ($55 million at ¥ 146 = $1) are estimated as necessary to develop and introduce a new product into the market. This universal process confronts all pharmaceutical firms that seek to develop new products.
Given Japan's status as a latecomer in the postwar international industry and its slow start in developing corporate R&D capacity, only in the 1980s did a significant number of new products become available with the potential for international competition. The nature of R&D for pharmaceuticals contributed to Japan's historically low level of exports as a percentage of total production. The changes in Japanese R&D also help explain the transformation of pharmaceutical exports from bulk non-patented products to the more recent emphasis on in-house patented products.

Character of Japanese Pharmaceutical Companies—The organizational character of Japanese pharmaceutical companies has also constrained their export activities. Many Japanese companies originated as distributors, with a long history of importing foreign products and marketing them within Japan. In part due to this organizational legacy, and also to the high and easy profits of the domestic market assured by government policy, Japanese pharmaceutical firms did not develop an institutional capacity to sell in overseas markets (outside Asia).

The organizational origins also reduced the capacity of some firms to introduce research scientists into top management in effective ways, thereby hampering the quality of research efforts. The historical focus of pharmaceutical companies on the domestic market has been reflected in the lack of top management with overseas understanding or experience. Few company employees receive overseas training. And those who have developed expertise on foreign markets have commonly remained outsiders to key decision-making positions in the firm.78

Quality of Japanese Drugs—Many Japanese drugs seem inappropriate for export to other markets, due to regulatory problems. According to one U.S. industry observer of the Japanese market:

Many drugs developed in Japan are not marketed in America or Europe. In 1985 for example, 46 of the top 100 products were developed solely through the efforts of Japanese companies. Twenty-three, or half of these products, were sold only in Japan since it was considered doubtful whether approval could be obtained overseas.79

The top-selling product in Japan in 1986, for example, was Krestin, an anticancer agent extracted from mushrooms, with sales of over 50 billion yen ($296 million at ¥169 = $1). Krestin is currently exported by its producer, Kureha Chemical Industry, to Korea and Taiwan, but not to any major industrial country market; nor has the company submitted the product for review in Europe or the United States.80

The quality of Japanese pharmaceutical products is now improving, however, as evidenced by increasing foreign approval and sales of Japanese antibiotic, cardiovascular, and other products. These approvals reflect a fundamental change in the R&D strategy of major Japanese pharmaceutical firms. Previously, these companies developed products first for the Japanese
market and then considered overseas sales. Now, their R&D strategies are shifting to a global perspective, to develop products primarily for foreign markets, with secondary attention to Japan.

**Product Line**—Pharmaceutical exports have also been limited by the number of competitive products available to an individual firm. A company needs a series of products to justify economically an independent entry into foreign markets. A company with only a few products available or on line is more likely to begin with licensing or joint ventures, in order to reduce the up-front investment and the risk of entry into an overseas market. But entry by licensing or joint venture reduces the potential return, compared to independent entry. To date, Japanese companies have experienced “disappointing results” with both approaches to indirect entry, due to the limited profits of licensing and the partnership problems of joint ventures. In some cases, U.S. companies have licensed Japanese drugs but not developed or marketed them aggressively because they compete with an in-house product of the U.S. company. These and other problems confront all companies that use indirect means for market entry.

**Advantages of Overseas Production**—Overseas production or formulation of some products can constitute an important element of a company’s strategy for market entry and expansion. Indeed, local production is sometimes required by national law or desirable to avoid protectionist responses. These advantages of local production for the Japanese pharmaceutical industry have served to reduce potential exports, and they are likely to continue.

**The Role of External Obstacles**—Japanese companies have also confronted obstacles to export, arising largely from external policies and problems.

**Restrictions of Licensing Agreements**—The development of the Japanese pharmaceutical industry in the postwar period depended importantly on the licensing of foreign products, and licensing agreements commonly restricted exports. Those agreements, however, are beginning to expire, which could provide opportunities for exports of products that were licensed early on.

**Regulatory Barriers to Entry**—The regulatory processes in other countries have provided an important obstacle to exports by Japanese firms. The U.S. Food and Drug Administration’s regulations have been particularly problematic for Japanese companies to pass and achieve drug approval. Those regulations have been difficult to fulfill for Japanese pharmaceutical companies (as for other newcomers), due to inexperience, lack of trained personnel, problems with quality of drugs or clinical trials, and possible non-tariff barriers. These regulatory barriers to entry have occurred primarily
for firms that have sought direct and independent approval for their products. Japanese firms that have used licensing or joint ventures have been more successful, by depending on the regulatory expertise of their U.S. partners to achieve approval. Similarly, Japanese subsidiaries of U.S. companies (such as Pfizer) have not encountered such regulatory barriers in moving their Japanese origin products through the U.S. Food and Drug Administration.

The quality of Japanese clinical trials has also served as an obstacle to pharmaceutical exports. These trials meet Japanese regulatory standards but are not readily accepted by regulatory authorities in the United States or Europe—a controversial and sensitive point for the Japanese industry and the MH. Technical problems and conflicts of interest have been reported about the conduct of Japanese clinical trials. Japanese clinicians also tend to resist the use of placebo trials and written assurance of informed consent, which the U.S. Food and Drug Administration requires. These difficulties reflect broader issues in the international harmonization of regulatory standards. As long as problems persist, Japanese firms will need to conduct clinical trials overseas, often through licensing or joint ventures, to deal with regulatory obstacles. Improving the quality of clinical trials would assist Japanese companies in achieving overseas approval of their new drugs.

Non-Regulatory Barriers to Entry—Another obstacle to Japanese pharmaceutical exports is the legal environment, especially in the United States. The problems of liability and the litigious nature of U.S. society have made some Japanese firms reluctant to enter the U.S. market directly. One prominent example where concerns about liability have blocked the availability of a Japanese pharmaceutical product in the United States is the case of the Japanese encephalitis vaccine. Although the product has been submitted to the FDA for review by a U.S. company, that process does not deal with questions of liability; and the vaccine-injury compensation program enacted by Congress does not cover the Japanese encephalitis vaccine.

Strengthening of the Yen—The revaluation of the yen in the 1980s has had conflicting effects on Japanese pharmaceutical trade. On the one hand, the strengthened yen made products manufactured in Japan even more expensive overseas and contributed to discouraging pharmaceutical exports. On the other hand, the stronger yen lowered some overseas costs of market entry (especially for land and labor), making it more attractive for Japanese firms to develop overseas facilities.

In the 1980s, a number of Japanese companies established production and distribution facilities overseas. Takeda Chemical Products USA began production of vitamin B1 in 1986 at the company’s factory in North Carolina, and is adding facilities for vitamin C production, reflecting a strategic decision to shift production overseas. Yamanouchi, as noted earlier, began production of therapeutic compounds in 1988 in Ireland, at the first plant
owned and operated in Europe by a Japanese pharmaceutical company.\textsuperscript{88} Also in 1988, Otsuka Pharmaceutical Co. purchased Pharmavite, one of the largest makers of vitamins and mineral supplements in the United States, to provide distribution channels for Otsuka's nutritional products.\textsuperscript{89} And in 1989, Yamanouchi purchased the Shaklee Corporation, a direct-sales company for vitamins, cosmetics and household products in the United States.\textsuperscript{90} These examples demonstrate the growing capability of Japan's major pharmaceutical companies in developing overseas opportunities.\textsuperscript{91} This trend will undoubtedly continue and expand.

Japanese companies have also established research facilities overseas, to develop global products, enter new markets, and gain access to scientific ideas and resources.\textsuperscript{92} Otsuka founded a research laboratory in Rockville, Maryland, in 1985 and another in Seattle, Washington, in 1987, both with an emphasis on biotechnology.\textsuperscript{93} Eisai Company opened a research facility outside Boston in 1989. And Takeda is pursuing an explicit strategy of global R&D for new products.\textsuperscript{94} The U.S. and European pharmaceutical industries are also internationalizing R&D for similar reasons.\textsuperscript{95}

The stronger yen also contributed to the profitability of pharmaceutical companies in Japan by making imports cheaper, while final products are sold at the government-set yen-based prices. Profits for a number of foreign-owned pharmaceutical companies in Japan rose sharply between 1986 and 1987: Torii & Co. (1,153%), Nippon Glaxo (257%), Japan Upjohn (138%), Warner Lambert (122%), as well as others.\textsuperscript{96} The yen's appreciation and increased profits for imports contributed importantly to these increases. The stronger yen and the decreased costs of imports also helped Japanese pharmaceutical firms offset the impact of government cuts in official reimbursement rates. Shifting exchange rates in the 1980s thus increased the incentives for pharmaceutical imports compared to exports.

Marketing Strategy—Another external obstacle to Japanese pharmaceutical exports results from differences in health systems. Japanese companies have developed an intensive physician-directed marketing strategy not applicable in most other countries. For example, the lack of universal health insurance and the lack of physician dispensing in the United States require a different approach from that used in Japan. Marketing strategy needs to be adapted to the particular circumstances of each country. The similarities of the medical systems in several Asian countries to that in Japan have helped the Japanese pharmaceutical industry in its entry and expansion in those markets.

Language barriers have also slowed down the overseas activities of Japanese pharmaceutical companies. Foreign languages are essential for the overseas regulatory approval and marketing activities of Japanese companies. Foreign language capability tends to be more important for pharmaceuticals than for other products, because of the high informational
requirements in drug approval and marketing, and the high degree of government regulation. Japanese companies have not rewarded this capability at upper or middle management levels. If pharmaceutical companies are to succeed overseas, they must develop these human resources within the firm and use external consulting companies for dealing with foreign regulatory and marketing issues.

While these problems do not represent insurmountable barriers, they do require the development of corporate resources and skills that have not previously existed in Japanese pharmaceutical firms. Creating those resources will require strategic decisions, long-term investments, and adequate time—attributes not unknown in other Japanese industries. No reason exists to assume that the pharmaceutical industry cannot do the same, even if firms have not done so to date.

Conclusions

The Japanese pharmaceutical industry does not fit the conventional image of Japanese firms as export-oriented; it has been domestically oriented, with relatively low levels of exports. Yet, the quality and quantity of pharmaceutical exports have changed significantly over the past three decades, with the industry's emerging globalization. And as I have argued, Japanese public policy shaped this transformation in multiple ways, but mostly through indirect means and sometimes unintentionally.

Japanese health policy has served as implicit industrial promotion policy for pharmaceuticals. Policies adopted for the health of the people also worked to promote the health of the industry. The combined effect of several government policies created a rapidly expanding domestic market of tremendous benefit to the Japanese pharmaceutical industry. This indirect subsidy reduced the incentives for developing exports, while it served to strengthen the industry. Subsidized growth of the pharmaceutical industry through the health insurance system created huge public expenditures, which were tolerated in Japan's period of high economic growth, but not in the 1980s.

Industrial policy on patents and capital liberalization restricted foreign competition within Japan and thereby directed the benefits of the growing domestic market primarily to domestic firms. Until the late 1970s, Japanese pharmaceutical firms did not have to compete in their home market with the larger and much stronger multinational companies from Europe and the United States. This protection from outside competition allowed the Japanese industry to build up its research and organizational capacity and also reduced the need to use exports as a source of growth.

But the Japanese government did not develop clearly articulated sector-specific industrial policy for the pharmaceutical industry. Similarly, the government designed no clear policy on pharmaceutical exports or industry...
structure. The move overseas by the Japanese pharmaceutical industry has not resulted from a specific policy directive from the government. To the contrary, government incentives, until the 1980s, focused the industry on the domestic market.

Public policy in Japan prodded the industry to move overseas by reducing profits at home—mainly as an unintended result of efforts to contain rising medical costs. Ironically, the major government policy to promote pharmaceutical exports is the policy that has hurt the industry the most—the drastic cuts in reimbursement prices in the 1980s. This use of price policy resembles what has happened in another domestically focused and strategically protected Japanese industry: agriculture.97 Government-set prices for rice defined the market and shaped the overall structure of agriculture in Japan. In recent years, budget deficits have motivated cuts in official rice prices, with the potential for driving basic structural changes in Japanese agriculture. Finally, the decisions on price policy have been highly politicized and subject to negotiations with the affected interest groups. The parallels with the pharmaceutical industry are striking.

In sum, the Japanese government has provided few direct positive measures to assist the pharmaceutical industry in globalization. The overseas achievements by the Japanese pharmaceutical industry have proceeded mainly by trial-and-error business strategy, as the industry has moved up the international learning curve.

The low level of exports, however, should not be interpreted as a lack of competitive strength in the Japanese pharmaceutical industry. The 1980s witnessed major changes in the four factors that previously held down Japanese pharmaceutical exports: domestic health policy, general industrial policy, lack of competitive ethical drugs, and external obstacles. The Japanese pharmaceutical industry is now turning to overseas markets, due to: repeated price cuts at home and the changed price structure for reimbursement; greater organizational and research strength, and the increased emphasis on R&D and new products; and the entry of new firms (both Japanese and foreign) into the Japanese market.

These three factors are likely to produce major transformations in the Japanese pharmaceutical industry over the next decade. While this article cannot go into detail on these changes, some speculation is in order. Middle-sized companies in the Japanese industry will face increasing pressures, because of inadequate resources for effective R&D and global competition. Purchases of more firms can be expected, either by foreign companies seeking to enter the Japanese market or by Japanese firms outside the pharmaceutical industry. A limited number of Japanese pharmaceutical companies are likely to succeed in global competition, in terms of overall sales and numbers of new products, first through strategic alliances and then on their own. These firms already have developed strategies for global competition and are implementing worldwide systems of research, marketing, and
production. Even though everything seems on course, developing adequate organizational resources within firms and sorting out the low achievers in the Japanese industry will take time and cause tension. Consequently, we are unlikely to pop Japanese drugs as avidly as we now drive Japanese cars; at least not before the 21st century.

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References

10. Ibid.
12. Additional information on these nine patterns appears in an Appendix available from the author.

15. Ibid.


18. *Yakuji Kogyo Seisan*, various years.

19. Ibid.


30. Ibid., pp. 33-36.

31. A MHW survey estimated that in 1987 in physician clinics an average of 37% of total revenue derived from pharmaceutical sales, yielding an average monthly margin of 700,000 yen ($4,800 at ¥ 146 = $1). “Yakka Saeki, Nen ni Itcho Sanzenoku En,” (Doctor’s Margin, 1.3 trillion yen a year), *Asahi Shinbun*, November 9, 1989, p. 1.

32. What constitutes “over” prescription remains controversial in Japan, as elsewhere, and represents an important topic for research, especially the connections between economic incentives and prescription patterns. While the Ministry of Health and Welfare has data on this topic, showing how prescription patterns have changed in relation to price cuts in the 1980s, little information has been made publicly available. See Ministry of Health and Welfare, *Kosei Hakusho* (Health and Welfare White Paper), (Tokyo: MHW, 1983), p. 65.


34. *Asahi Shinbun*, November 9, 1989, op. cit.


38. Ibid., p. 81.
44. Hasegawa, op. cit., pp. 97-98.
45. A list of total sales of ethical drugs in Japan by company for 1986 showed the first foreign-owned firm ranked at number 11, with only three foreign-owned firms in the top 20. See "Iyaku Rankingu" (Pharmaceutical Ranking), *Deiteruman* (Detailman), September 15, 1987, p. 55.
49. Hasegawa, op. cit., p. 150.
52. Shah et al., op. cit., p. 1.
54. Ibid.
55. Dibner, op. cit.


71. Interview, February 1, 1989.


76. Data Book 1987, op. cit., p. 52.


78. Maurer, op. cit., p. 61.

79. Ibid., p. 116.


81. Seo, op. cit., p. 59.

82. Shah et al., op. cit., p. 2.


92. Yoshikawa, op. cit.