



## The Interplay between Entrepreneurial Initiative and Government Policy: The Shaping of the Japanese Pharmaceutical Industry since 1945

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In this paper, I explore the history of Japan's pharmaceutical industry since 1945 and the interplay between government policy and entrepreneurial initiative. I examine whether the industry has been a success or a failure in developing new therapies or achieving global prominence. I also address the scholarly debate concerning industrial policy, and ask whether responsibility for the current state of industry lies with bureaucrats in the Japanese government or with entrepreneurs within firms. Case studies of two classes of medicines, antibiotics and anti-cancer drugs, are used to explore the history of Japan's post-World War II pharmaceutical industry. Amid the growing body of literature on the history of the pharmaceutical industry in other countries, I attempt to offer insight into how a highly regulated, knowledge-intensive, high technology sector evolved in a late-developing economy.

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Japanese travelers abroad often notice that, whereas the products of certain Japanese firms such as Sony and Toyota are available and known almost everywhere, when one goes to a pharmacy for a prescription in London or New York, the familiar names of Japanese pharmaceutical firms are largely absent. My interest in this topic stems from the question of why Japan developed globally competitive firms in some sectors such as automobiles and electronics, but not in other knowledge-intensive industries such as pharmaceuticals. It is true that Japanese pharmaceutical firms such as Takeda and Eisai have expanded worldwide. Nevertheless, their overseas presence is very recent, occurring long after Japanese carmakers and electronics firms became household names around the world.

The pharmaceutical industry illuminates the paradox of Japan's dual economy. The Japanese internationally competitive tier of industries, such as carmakers and electronics, coexists with non-competitive industries such as aluminum and food processing. The Japanese pharmaceutical industry

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straddles these two tiers; it includes a handful of internationally competitive drug companies such as Takeda, Daiichi-Sankyo, and Eisai and myriad domestically oriented, small- to medium-size enterprises that have survived via protective government policy. Compared to many of the country's stronger sectors, the Japanese pharmaceutical industry is noted for its domestic orientation, heavy reliance on imports, and small- to medium-size firms characterized by family management and ownership. These phenomena require historical explanation.

Both government and entrepreneurs played a distinct role in Japan's postwar pharmaceutical industry. I illustrate how both government and entrepreneurs defined the course of development and are responsible for its mixed results. Government policies defined the operational framework, and firms channeled industrial growth.<sup>1</sup>

Japan's post-World War II industrial policy (or lack thereof) helps explain the relative weakness of the pharmaceutical industry. While the state assumed an extremely active role in guiding industrial development during the American Occupation, its role lessened in subsequent years. Although the 1970s saw a growing role for government in the form of stronger patent protection, only in the 1990s did it return to an actively interventionist approach.

### Debates

I address two major scholarly debates concerning Japanese industrial policy and the performance of the Japanese pharmaceutical industry. In terms of industrial policy, scholars (often associated with Chalmers Johnson) have argued that the Japanese bureaucracy played a central or leading role in guiding postwar economic development.<sup>2</sup> Others, such as Gary Saxonhouse, have argued that the drive and momentum of growth occurred outside the realm of the state.<sup>3</sup>

In most of the existing literature, researchers refer to industries regulated or guided by the Ministry of International Trade and Industry (MITI). The Japanese pharmaceutical industry is an anomaly in that it came under the jurisdiction of the Ministry of Health (MHW), a bureaucracy with different government policy priorities. In this study of Japan's pharmaceutical industry, I engage this debate on government policy, and show how national

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<sup>1</sup> Thomas K. McCraw has outlined this view of Japan's postwar development in "Government, Big Business and the Wealth of Nations" in *Big Business and the Wealth of Nations*, ed. Arthur. D. Chandler, Jr., Franco Amatori, and Takashi Hikino (Cambridge, Mass., 2000), 522-45.

<sup>2</sup> Chalmers Johnson, *MITI and the Japanese Miracle: The Growth of Industrial Policy, 1925-1975* (Stanford, Calif., 1982).

<sup>3</sup> Gary R. Saxonhouse, "Industrial Policy and Factor Markets: Biotechnology in Japan and the United States," in *Japan's High Technology Industries: Lessons and Limitations of Industrial Policy*, ed. Hugh Patrick (Seattle, Wash., 1986), 97-133.

interests, perhaps perceived differently by the MHW and the MITI, might have influenced industrial development.

Scholars' assessments of industrial performance vary, along with whether they should attribute performance to firms or government. L. G. Thomas, for example, has argued that the Japanese pharmaceutical industry has performed poorly, and that this has been the result of failures in government policy.<sup>4</sup> On the other hand, scholars such as Hiroyuki Odagiri have presented a much more positive view, arguing that Japan's postwar pharmaceutical industry has performed well, ascribing the dramatic growth of industry during the postwar period to entrepreneurial initiatives.<sup>5</sup> My research to date supports the middle ground outlined by scholars such as Tomohiro Anegawa and Michael Reich.<sup>6</sup> They have argued that while earlier government policies were effective in nurturing the growth of the pharmaceutical sector, the government failed to encourage the transition to a more mature pharmaceutical industry based on innovation rather than imitation.

In the early postwar period, government and industry collaborated successfully to develop a strong industry, bolstering the optimistic views embraced by scholars such as Odagiri. In later years, however, the endurance of developmental policies, fewer formal government interventions, and informal relations between government and industry all delayed industrial development, supporting the more negative views of Thomas and of Jeremy Howells and Ian Neary.<sup>7</sup>

### **Historical Features of the Japanese Pharmaceutical Industry**

Several features have distinguished the Japanese pharmaceutical industry. Despite a dramatic growth in production over the decades, Japan was until recently a net importer of pharmaceutical technology and remains a net

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<sup>4</sup> L. G. Thomas, "Implicit Industrial Policy: The Triumph of Britain and the Failure of France in Global Pharmaceuticals," *Industrial and Corporate Change* 3 (June 1994): 451-89. See also L. G. Thomas, *The Japanese Pharmaceutical Industry: The New Drug Lag and the Failure of Industrial Policy* (Cheltenham, U.K., 2001).

<sup>5</sup> Hiroyuki Odagiri and Akira Goto, *Technology and Industrial Development in Japan: Building Capabilities by Learning, Innovation and Public Policy* (Oxford, U.K., 1996).

<sup>6</sup> Tomohiro Anegawa, "Successes and Failures of the Japanese Medical, Pharmaceutical, and Insurance System on the Japanese Pharmaceutical Industry," *Doraggu Magajin* [Drug Magazine] 43 (July 2000): 78-88; see also Tomohiro Anegawa, "Nihon no Iyakuin Sangyō: Sono Seikō to Shippai [The Japanese Pharmaceutical Industry: Success and Failure], *Iryō to Shakai* [Journal of Healthcare and Society] 12 (Oct. 2002): 49-78. Michael Reich, "Why the Japanese Don't Export More Pharmaceuticals: Health Policy as Industrial Policy," *California Management Review* 32 (Winter 1990): 124-50.

<sup>7</sup> Jeremy Howells and Ian Neary, *Intervention and Technological Innovation: Government and the Pharmaceutical Industry in the UK and Japan* (Basingstoke, U.K., 1995).

importer of pharmaceutical products.<sup>8</sup> Lack of corporate concentration characterizes the industry, which is comprised of many small firms.<sup>9</sup> The level of concentration in the Japanese industry, is only slightly over half that of the United States.<sup>10</sup> Over time, the industry has become increasingly research focused.<sup>11</sup> In 1975, the government introduced product patent protection; until then, many firms benefited from reverse engineering.

In the early postwar period, infectious diseases were the leading cause of death in Japan. In subsequent decades, diseases of affluence such as cancer became the leading cause of death.<sup>12</sup> As a result, we need to examine how government and industry responded to these conditions and channeled industrial development over the decades.

### The Early Postwar Period

Before World War II, pharmaceutical firms in Japan such as Tanabe, Takeda, and Shionogi were primarily engaged in the distribution of imported Western medicines.<sup>13</sup> When German imports were halted during World War I, however, government policies prompted some domestic production in vitamins, hormonal preparations, and sulfa drugs.<sup>14</sup> Although most of the physical capital was lost during the war, much of the human capital and networks from the prewar industry survived.

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<sup>8</sup> See Ministry of Health and Welfare, *Yakuji Kogyō Seisan Dōtai Tōkei Nenpō* [Annual Statistics on Production in the Pharmaceutical Industry] (Tokyo, Japan, 1953-2005); Ministry of Internal Affairs and Communications, *Kagaku Gijutsu Kenkyū Chōsa Hōkoku* [Survey of Research and Development] (Tokyo, Japan, 1970-2005); and Ministry of Economy, Trade and Industry, *Tsūshō Hakusho* [White Paper on Trade], (Tokyo, Japan, 1970-2005).

<sup>9</sup> Japan Fair Trade Commission, *Shuyō Sangyō ni okeru Ruiseki Seisan Shūchūdo* [Concentration Ratio of Main Industries] (Tokyo, Japan, 1970-1994). Ministry of Health, Labor and Welfare, *Iyakuhin Sangyō Jittai Chōsa Hōkokusho* [Report on the Pharmaceutical Industry] (Tokyo, Japan, 1995-2005).

<sup>10</sup> U.S. Census Bureau, *Concentration Ratios in Manufacturing*. (Washington, D.C., 1947-2002), viewed 25 March 2007. URL: <http://www.census.gov/epcd/www/concentration.html>.

<sup>11</sup> Statistical Survey Department, Statistics Bureau, Ministry of Internal Affairs and Communications, *Kagaku Gijutsu Kenkyū Chōsa Hōkoku* [Survey of Research and Development], (Tokyo, Japan, 1970-2005); and Yakuji Jihosha, ed., *Yakuji Nenkan* [Pharmaceutical Annual] (Tokyo, Japan, 1952, 1957, 1961, 1964).

<sup>12</sup> Ministry of Health and Welfare, *Densenbyō Oyobi Shokuchudoku no Kanjasū to Shibōshasū* [Patients and Deaths of Infectious Diseases and Food Poisoning], (Tokyo, 1876-1999), viewed 20 March 2007. URL: <http://www.stat.go.jp/data/chouki/24.htm>.

<sup>13</sup> Nihon Yakushi Gakkai [The Japanese Society for the History of Pharmacy], ed., *Nihon Iyakuhin Sangyōshi* [The History of the Japanese Pharmaceutical Industry] (Tokyo, Japan, 1995).

<sup>14</sup> Takeda Pharmaceutical Co., *Takeda 200 nen* [A 200-Year History of Takeda] (Osaka, 1984).

Between 1945 and 1952, Allied Occupation forces ruled Japan, mostly U.S. troops under the leadership of Douglas MacArthur. The foundation of the postwar pharmaceutical industry was the product of strong state intervention and government-industry relations during the Occupation. This period witnessed the birth of the modern pharmaceutical industry, as the Occupation authorities developed and bridged the institutions and organizations that would enable antibiotic development, production, and distribution.

The American Occupation authorities had a compelling reason for creating a modern pharmaceutical industry in Japan. For the Americans, enabling Japanese firms to mass-produce antibiotics offered a secure and cost-effective means of public health administration and providing antibiotics to American troops in Japan.<sup>15</sup> With authority over the Japanese government, MacArthur's administration could command an industry into existence. Confectioners and brewers, who had the fermentation capacities to cultivate bacteria and produce antibiotics, were encouraged to do so. Japanese pharmaceutical firms that remain confectioners and brewers reflect this legacy. Morinaga, the first producer of penicillin in Japan, is a confectioner that makes chocolates and other sweets, as is Meiji, which remains a major producer of antibiotics.<sup>16</sup>

The American Occupation authorities contributed to the founding of the postwar industry in various ways. For example, they orchestrated and ensured technology transfers through seminars taught by leading scientists such as Jackson Foster, who had been involved in the commercialization of penicillin at Merck.<sup>17</sup> The Occupation forces also provided effective strains of bacteria and provided on-site consultations at production facilities.<sup>18</sup> The General Headquarters also set up a modern pharmaceutical education system and established regulations such as the Pharmaceutical Affairs Law.<sup>19</sup>

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<sup>15</sup> Supreme Commander for the Allied Powers, *Public Health and Welfare Section, Public Health and Welfare in Japan. Annual Summary: 1949* (Tokyo, 1949), 118.

<sup>16</sup> Morinaga & Co., *Yūkashōken Hōkokusho* [Annual Securities Report] (Tokyo, Japan, 1949-2005); Meiji Seika Kabushiki Kaisha, *Yūkashōken Hōkokusho* [Annual Securities Report] (Tokyo, Japan, 1949-2005).

<sup>17</sup> Crawford Sams, "Address to Tokyo Pharmacists" (speech presented on behalf of the Supreme Commander for the Allied Forces, Public Health and Welfare Section to Tokyo pharmacists, Tokyo, Japan, 7 March 1946), Declassified EO 12065 Section 3-402/NNDG no. 775024, p.3 (NDL).

<sup>18</sup> Nihon Penisirin Kyōkai [Japan Penicillin Association], *Penisirin no Ayumi: 1946-1961* [The History of Penicillin: 1946-1961], (Tokyo, 1961).

<sup>19</sup> See Charles Band, Public Health and Welfare Section, "Meeting of Pharmaceutical Education Committee" (meeting held by the Pharmaceutical Education Committee, Tokyo, Japan, 20 July 1950, Declassified EO 12065 Section 3-402/NNDG no. 775024 (NDL); J. M. Bransky, Public Health and Welfare Section, "Conference Relative to Raising Standards of Pharmaceutical Education" (conference held by Supreme Commander for the Allied Forces, Public Health and Welfare Section in Tokyo, Japan, 11 June 1946, Declassified EO 12065 Section 3-402/NNDG no.

The outcomes of strong state intervention and government-industry collaboration in the early postwar era were mostly positive. After the Occupation, the industry continued to grow under sustained demand from the U.S. Army during the Korean War. Government pharmaceutical policy and historical circumstances, as well as the attributes of antibiotics, including their low-cost, labor-intensive research and development (R&D) and production, benefited the Japanese pharmaceutical environment in the immediate postwar era. Enabling firms to mass produce antibiotics also contributed to significant improvements in health outcomes and solidified the foundations of Japan's postwar pharmaceutical industry.

### The Later Postwar Era

By the 1960s, diseases of affluence had become more common, and in 1981, cancer became the leading cause of death in Japan.<sup>20</sup> With the demographic transition, Japanese firms pursued therapies to treat these newer diseases in the later postwar period.

Unlike the antibiotics sector, strong state intervention, such as the coordination of technology transfers, did not guide the development of anticancer drugs. While the MITI by the 1970s was stimulating industrial growth across various sectors via capital liberalization or the recognition of product patents, the MHW maintained a cautious, developmental health policy that shaped the pharmaceutical industry.<sup>21</sup> In the interests of public access, for example, the government set prices with biannual price reductions. This reduced the incentive to invest in R&D. Smarting from the thalidomide tragedy in the early 1960s, officials valued safety over efficacy in the drug approval process. In addition, the sale of drugs followed traditional medical practices in which physicians both prescribed and dispensed medicines, a system that provided incentives for physicians to profit from the difference between wholesale and retail drug prices. As a result, firms managed to survive without capitalizing on their innovative potential, creating newer, higher-priced, and safe, but largely ineffective, anticancer drugs well into the 1980s. For example, the leading Japanese anticancer drugs for over a decade during the 1970s and 1980s—Krestin and Picibanil—

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775024 (NDL); and B. N. Riordan, Public Health and Welfare Section, "Meeting of Pharmaceutical Education Council" (meeting held by the Pharmaceutical Education Council in Tokyo, Japan, 19 July 1946, 17 Jan., 14 March 1947, 12 Jan., 6 July 1951, Declassified EO 12065 Section 3-402/NN DG no. 775024 (NDL). *Yakujihō* [Pharmaceutical Affairs Law], 1948. See also Public Health and Welfare Section, Memorandum, 7 Oct. 1948, Declassified EO 12065 Section 3-402/NN DG no. 775024. (NDL).

<sup>20</sup> Ministry of Health and Welfare, *Jinkō Dōtai Tōkei* [Population Statistics] (Tokyo, Japan, 1947-2005), viewed 28 April 2007. URL: <http://www.stat.go.jp/data/chouki/02.htm>.

<sup>21</sup> Ministry of Health and Welfare, *Yakumu Kōhō* [Bulletin of Pharmaceutical and Supply Bureau] (Tokyo, 1949-2005).

were not available in the major markets of North America and Europe.<sup>22</sup> The Ministry's decision to reduce the indications for these drugs in 1989 marked a trend toward establishing better drug standards.<sup>23</sup>

The more limited success of the anticancer drug sector sheds light on how government policies and government industry relations were less effective in creating incentives for firms to take advantage of innovative capacities to compete in a more research-intensive, competitive, globalizing industry during the later postwar era. Of course, anticancer drugs are arguably less conducive to government intervention, because only a handful of firms can create a complex product to cater to a small, segmented market. As drugs whose discovery was based largely on technology-intensive and scientifically complex methods of rational drug design, anticancer drugs require high levels of R&D investment and human capital. In addition, unlike antibiotics, where a given therapy is effective for a wide range of infectious diseases without risk of significant side effects, anticancer drugs tend to be effective only as part of a therapy for a particular type and stage of cancer, and they carry the risk of significant side effects. Government policy would be less effective in guiding a high-risk sector with such barriers to entry.

Formally, the government may have become less interventionist toward many firms over the years. However, experiences from the anticancer drug sector suggest that tight-knit relations between select parties in government, industry, and academia (which at times featured significant conflicts of interest) shaped the pharmaceutical sector.<sup>24</sup> The approval of the bestselling anticancer drugs mentioned earlier came under public scrutiny as the media and Diet proceedings revealed that officials involved in regulatory decisions were also involved in drug development or corporate management.<sup>25</sup> Ambiguity between regulators and regulated undermined the industry's

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<sup>22</sup> Masanori Fukushima, "The Overdose of Drugs in Japan," *Nature* 342 (Dec. 1989): 850-51.

<sup>23</sup> See Asahi Shimbun, "Kōgan-zai Krestin, Picibanil, Tandoku de no Yakkō Hobo Hitei" [Krestin and Picibanil Deemed to Have No Effect When Used Alone], 1, 10 Dec. 1989; Yomiuri Shimbun, "Kōgan-zai Krestin Tandoku Shiyō wo Mitomezu" [Ministry No Longer Permits Anticancer Drug Krestin to be Used Alone, Use of Picibanil Also Restricted], 1, 10 Dec. 1989; and Nihon Keizai Shimbun, "Kōgan-zai Kōnō Gentei: Shijō Kakudai ni Kyūbureiki" [Effective Range of Anticancer Drugs Revised: A Severe Impact on Market Growth], 9, 11 Dec. 1989.

<sup>24</sup> Diet, House of Representatives, Committee on Social and Labor Affairs, 94th Diet, 20th sess., 30 July 1981.

<sup>25</sup> Ibid. See also Diet, House of Representatives, Committee on Social and Labor Affairs, 104th Diet, 4th sess., 6th March 1986; Akio Homori, Atsushi Matumura, and Gentaro Yoshino, "Iyaku-hin Shijō: Kyodai naru 20sha no Jōken" [The Pharmaceutical Market: To be the Top 20] *Nikkei Business* (9 Dec. 1985), 6-35; and "Ninki Kōgan-zai Kurestin no Kōnō" [Efficacy of the Popular Cancer Drug, 'Krestin'], *Shūkan Shinchō* (16 Oct. 1986), 44-45; and "Kōgan-zai Icchōen no Kiyasume-ryō" [Cancer Drug Tops One Trillion Yen as Patients Pay for Peace of Mind], *Aera* (7 June 1988), 6-11.

prospects for growth during one phase of its evolution. The non-transparent process of drug approval attenuated incentives to innovate, because it rewarded firms for developing political connections. The harmonization of Japanese standards for drug approval with those of the United States and Europe in the early 1990s not only reduced the cost of duplicating trials, but also helped raise the profile of Japanese firms as they developed more innovative and effective drugs that were recognized and successful in world markets.<sup>26</sup>

The Japanese pharmaceutical industry has experienced an unprecedented and rapid reorganization in recent years. Pressures of globalization, regulatory harmonization with the United States and Europe, rising R&D costs, foreign expansion into the Japanese market, and intensifying domestic competition have fueled dramatic changes in the industry. In addition, the Japanese government recently has demonstrated a more hands-on, managerial approach for industrial development. This more interventionist approach, with greater rewards for innovation and recognition of more flexible forms of corporate organization, may have helped the industry to capitalize on its ability to discover and develop innovative drugs.<sup>27</sup> By 1999, Japanese industry had launched two of the top ten anticancer drugs: Takeda's Leuplin ranked second, with global sales reaching \$1.2 billion, while Yakult and Daiichi's Irinotecan ranked ninth, with global sales of \$294 million.<sup>28</sup>

## Conclusion

During the early postwar period, the Japanese government and industry collaborated successfully in building the foundations of an emerging industry. The industry's rise with antibiotics, for example, bolsters the optimistic views embraced by scholars such as Odagiri and Reich, who have remarked upon the extraordinary growth of postwar Japanese pharmaceuticals and Japan's potential to become a global leader. It is not entirely surprising then, that *The Economist* commented on the potential threat posed by Japanese firms in the global pharmaceutical market in the 1980s.<sup>29</sup>

The Japanese pharmaceutical industry responded only belatedly, however, to expectations of its becoming a global leader. In fact, it realized

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<sup>26</sup> Established in 1990, the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) is a project that aims to harmonize the pharmaceutical regulations of Europe, Japan, and the United States. See the following website, viewed 20 April 2007. URL: <http://www.ich.org>. Yakuji Jihōsha, eds., *Yakuji Handobukku* [Pharmaceutical Affairs Handbook] (Tokyo, 1968-2005).

<sup>27</sup> See Yakuji Nipposha, ed., *Saikin no Shinyaku* [New Drugs in Japan] (Tokyo, 1950-2006).

<sup>28</sup> Rosemary C. Bonney, *SCRIP's Guide to Cancer Therapies: A Biotech Revolution?* (Richmond, U.K., 2001).

<sup>29</sup> "Japanese Drug Companies Pull Ahead in the Race to Innovate," *Economist* 24 (Sept. 1983): 93.



that phase of development only after the mid-1990s with improvements in government policy and government business-relations. As experiences from Japan's anticancer drug sector might suggest, the endurance of developmental policies and ambiguities in the drug approval process long delayed the industry's development. The history of Japan's pharmaceutical industry in the later postwar period is compatible with the more negative views set forth by scholars such as L. G. Thomas or Howells and Neary.

The question of whether government intervention is essential for catch-up or for the development of higher technologies in a late-industrializing economy is beyond the scope of this paper. As a highly regulated, knowledge-intensive industry, the pharmaceutical industry is distinct. Within this context, we conclude that despite earlier success, the endurance of developmental policies and the lack of coherent, transparent, and sector-specific policies long hindered the pursuit of innovative discoveries by Japan's postwar pharmaceutical industry and its achievement of international competitiveness. Recent trends, however, suggest that a more optimistic assessment may be due.