Containing Health Care Costs in Japan

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Ann Arbor
The University of Michigan Press
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SUMMARY Public policies designed to control health care costs may have substantial, often unintended, effects on the strategy and performance of firms that provide the goods and services that help provide health care. Beginning in 1981, the Ministry of Health and Welfare (MHW) has carried out a series of severe reductions in the reimbursement prices paid for prescription drugs in Japan. There has been extensive discussion of how such price reductions have helped control health care costs (e.g., Yoshikawa 1989, Reich 1990, 1991, University Club 1992). However, whether the price controls have affected the innovativeness of pharmaceutical manufacturers and other health sector firms remains an open question.

In this study, we outline several key trends concerning profitability, R&D growth, and sales growth in the pharmaceutical industry. In addition, we report statistical estimation of relationships between cumulative firm-level price reductions and R&D growth undertaken by fourteen pharmaceutical manufacturers. Although our conclusions are tentative, we identify a possible firm-level relationship between higher price reductions and lower R&D growth during the mid-1980s. In an industry that depends on R&D investment by its members both to provide innovative goods to the domestic market and to compete in international markets, such a negative relationship must concern policy makers and corporate managers.

Health Cost Policy

Based on guidelines established by the Central Social Insurance Medical Council (often referred to by the abbreviated form of its name, Chūkyō), the MHW determines the insurance reimbursement price of each prescription drug in Japan. Under Japan’s national health insurance system, the reimbursement price is standard for all medical institutions and patients. Responding to the desire of the Ministry of Finance to reduce health care costs, the MHW toughened its policy of periodically revising the drug reimbursement price schedule downward. The first of the new round of stringent price revisions occurred in June 1981, when prices were reduced an average of 18.6%. Seven additional rounds of reductions to the schedule of prices reimbursed to medical institutions occurred by April 1992. Table 1 lists the date and average value of the price reductions.

Table 1. Average MHW pharmaceutical price reductions, 1981–92

<table>
<thead>
<tr>
<th>Date</th>
<th>Percent reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jun-81</td>
<td>18.60%</td>
</tr>
<tr>
<td>Jan-83</td>
<td>4.90%</td>
</tr>
<tr>
<td>Mar-84</td>
<td>16.60%</td>
</tr>
<tr>
<td>Mar-85</td>
<td>6.00%</td>
</tr>
<tr>
<td>Apr-86</td>
<td>5.10%</td>
</tr>
<tr>
<td>Apr-88</td>
<td>10.20%</td>
</tr>
<tr>
<td>Apr-90</td>
<td>9.20%</td>
</tr>
<tr>
<td>Apr-92</td>
<td>8.10%</td>
</tr>
</tbody>
</table>

Two factors mitigate the apparent steepness of the reductions. First, the adjustments apply only to drugs on the market at the time of the revisions. Hence, firms can maintain or increase the level of their sales if they introduce new drugs. Many drugs that have been on the market for over ten years have faced price reductions of over 50%, but each new drug to enter the market starts at a new price. New drugs then move down the price schedule with each subsequent price revision. Only those drugs that have been on the price schedule since 1981 have taken the full effect of the price revisions.

The second mitigating factor is that the effect of the reductions differs among different therapeutic classes of pharmaceuticals. During the three price reductions between 1985 and 1990, for instance, the MHW reports that the prices of anti-infective drugs declined by an average of 18.6%, while prices for anti-cancer drugs declined by only 6.3%, and prices for anti-hyperintensives by 10.7%. Firms that have emphasized sales of anti-infective drugs have faced the largest price reductions. During the 1981–92 period, Shionogi and Fujisawa, two firms with high proportions of sales of anti-infective drugs, realized average reductions on the prices of their products of 11.1% and 11.6%, respectively. Daiichi and Sankyo, which have lower proportions of sales for anti-infectives, incurred 6.8% and 7.5% reductions (Merrill Lynch 1992).

Pharmaceutical Industry Trends

Several trends in key industry-average measures of sales, performance, and strategy emerged during the 1980s.
Sales

The price reductions had an immediate impact on pharmaceutical industry revenues. Sales growth of ethical drugs declined sharply following the toughening of the price adjustment policy: falling from a compound annual growth rate of 11.1% between 1975 and 1981, to a 4.5% rate between 1982 and 1989. Given their effect on drug sales revenue, the price reductions might be expected to affect the performance and strategy of the pharmaceutical manufacturers.

Profitability

Influences on performance should emerge in changes in profitability. We calculated operating profit to sales ratios for twenty-three Japanese publicly traded pharmaceutical firms between 1978 and 1992. Together, these companies comprise about half of industry pharmaceutical sales and provide a representative pattern of industry profitability trends. Operating profitability has fluctuated sharply. Profitability grew immediately prior to the 1981 price reductions, fell sharply in the subsequent years, rebounded during 1987–89, and then declined again through 1992. The ratio of net profit to sales, which includes investment activities as well as operating results, follows a similar but more moderate fluctuating pattern. The profitability fluctuation is consistent with the argument that the firms were able to adjust to the first rounds of price reductions but have not yet adjusted their strategies to account for the more recent series of price reductions.

Firm Strategy

Strategic adjustments that the pharmaceutical manufacturers undertook in response to the price reductions between 1981 and 1992 might include changes in the rate of new product introduction, the source of new products, marketing expenditure, and R&D expenditure.

Product introduction. A common assertion by people familiar with the Japanese pharmaceutical industry is that many manufacturers responded to the period of ongoing price reductions by increasing the introduction of new drugs. The new products, which start at higher prices than those of products in the market at the time of the latest price revisions, would then contribute to continued profitability.

Trends in the number of new chemical entities and new drugs approved for the Japanese market between 1975 and 1990 provide at best limited support for this assertion. The number of new drugs and the chemical structures on which they were based approved annually after 1981 was often slightly higher than the numbers approved prior to the first year of the price reductions, but there was no more than a slight upward trend from that in the prerecession period (Japan Pharmaceutical Manufacturers Association 1992, 67). The minimal increase in new drug introductions may stem from the time required to develop and test new drugs, and the high uncertainty associated with new drug development. In any case, firms do not appear to have responded to the price reductions with a strikingly increased rate of new product introduction.

Product sources. The price reductions might also influence the source from which firms obtain new products. Needing new products in order to maintain sales levels, firms might increase their use of in-licensing from domestic or foreign sources in place of internally developed drugs. Such in-licensing offers a quicker way to obtain new products than by internal development. We gathered information concerning the proportion of drugs introduced from pre-and post-1983 that were developed internally, licensed in from Japanese pharmaceutical manufacturers, and licensed in from foreign-owned manufacturers (Nikko Research 1991; Salomon Brothers 1992a). The proportion of internally developed drugs did indeed decline slightly, from 57% prior to 1983 to 42% between 1983 and 1991. Most of the replacement for internally developed drugs came from domestic in-licenses (which rose from 3% to 14%), while foreign in-licenses rose slightly (from 40% to 44%).

At least three issues underlie the product source figures. First, the increased incentives stemming from the price reductions to introduce new drugs may have led to increased use of in-licensing. Second, the growing innovativeness of the domestic Japanese pharmaceutical industry (Halliday, Walker, and Lumley 1992; Hawkins and Reich 1992) provided domestic sources for new drugs. Many such sources were relatively recent entrants to the pharmaceutical industry that had strength in nontraditional drug areas such as products based on biotechnology, but had relatively small pharmaceutical product distribution systems and so had strong incentives to negotiate licenses with established companies that possessed larger distribution coverages. Third, foreign-owned pharmaceutical companies began to establish larger internally owned distribution systems in Japan during the 1980s, planning to gradually decrease the incidence of licensing their products for sale by Japanese-owned companies and increase the incidence of direct distribution. Hence, any increased incentives for Japanese companies to in-license products from foreign-owned companies after the price reductions may have been balanced by a decreased incentive for the foreign companies to negotiate outright licenses.

Marketing expenditure. The price reductions also might influence marketing expenditure. Selling, general, and administrative sales ratio of the top fifteen drug companies increased slightly during the 1980s, from about 29% of sales in 1981 to 31.5% in 1991 (Salomon Brothers 1992a, 149). The increase might stem from a marketing attempt to increase the volume of sales in response to unit price reductions. In addition, though, the increased expenditure may also have been a response to increased foreign competition during the period.

R&D expenditure. The price adjustments also might affect R&D expenditures, leading either to increased expenditure as firms attempt to develop new higher-priced drugs or to decreased expenditure in the face of declining profits. We
calculated R&D/sales ratios for the industry as a whole between 1976 and 1990. The research expenditure figures must be treated cautiously because companies may have substantial expenditure for clinical human trials that take place before drugs are introduced to the market, but the trends are clear.\textsuperscript{9}

R&D intensity rose substantially during the past fifteen years. The industry-average corporate R&D/corporate sales ratio was 5.3% of sales in 1976, rose to 6.6% in 1981, and rose again to 8.6% in 1990 (Japan Pharmaceutical Manufacturers Association 1991, 8, 48). Moreover, R&D intensity rose somewhat more quickly after 1981 than before the price adjustment policy was toughened. Indeed, most major firms had reached the R&D intensity level of their major international competitors by 1990 (Mitchell, Roehl, and Slattery 1993). Although the overall rate of growth of absolute R&D expenditure declined slightly during the 1980s, the sales growth rate declined even more than R&D so that R&D intensity increased. This increased intensity might be attributed, in part, to an increased need to develop new drugs in order to obtain higher prices and to compete with foreign-owned firms in Japan.

Summary of Industry Trends

In summary, several industry-level trends are apparent during the period of severe pharmaceutical reimbursement reductions in the 1980s. Ethical drug sales growth rates declined sharply from growth rates achieved in the second half of the 1970s. On average, firms in the industry experienced fluctuating profitability during the 1980s. In contrast with the profitability fluctuation, R&D intensity grew steadily while selling expenses increased slightly between 1981 and the early 1990s. The firms were slightly more likely to introduce new products after the first round of price reductions and were somewhat more likely to obtain new products from other companies, particularly from domestic firms.

Price-Cut Effects on Firm-Level R&D Growth

Industry-level trends are important but may mask important differences among individual firms. For instance, the degree of price reduction varied markedly among different firms, with differences stemming primarily from differences in the firms' product portfolios. We were able to obtain firm-level estimates for fourteen firms for the eight rounds of price reductions.\textsuperscript{10}

We used the firm-level price cut information as explanatory variables for subsequent firm-level R&D growth. We chose R&D growth as the key dependent variable owing to the importance of research to the continuing vitality of the industry, both to provide new products and to compete with foreign-owned firms. Although one- and two-year periods represent very short horizons in the pharmaceutical industry, where R&D projects often continue for many years, short-term changes in the trend of a firm's R&D expenditure will have substantial long-term impact on the level of its R&D budget. We defined one- and two-year growth ratios equal to \( R\text{D}_t + 1 / R\text{D}_t \) and \( R\text{D}_t + 2 / R\text{D}_t \), where RD is a firm's R&D expenditure in a given year \( t \). We also estimated the effects of corporate sales and operating profits in each year \( t \), which might affect the availability of funds needed for R&D investment.\textsuperscript{11}

The estimates of the relationships between price cuts and R&D growth varied. We found no relationship between individual year price cuts and either one- or two-year growth in R&D. We found a significant relationship between R&D growth and cumulative price cuts, however, where a firm's cumulative price cut is defined as the sum of the price cuts it has incurred up to and including the year \( t \). Table 2 reports the results of ordinary least squares regression estimates of relationships between R&D growth and the cumulative price cuts, while controlling for the level of a firm's sales and operating profit.\textsuperscript{12}

The most conservative conclusion concerning the effects of price reductions reported in Table 2 is that they had little immediate association with one- and two-year R&D growth. Influences between cumulative price cuts and R&D growth with even moderate statistical significance are found only for 1981-86 one-year growth and 1986-88 two-year growth. Nonetheless, although the results are weak, the price cut results in Table 2 do suggest a weak negative relationship between R&D growth and cumulative price cuts during the middle period of the price-cut era.

There may be a link between these results and the earlier discussion of profitability trends. The 1985–88 period during which cumulative price cuts achieved their strongest negative association with R&D growth also was the period during which the industry average operating profit/sales ratio reached its minimum point (8.7% in 1986). Profitability tended to increase during the subsequent period, during which price cuts and R&D growth had no discernible significant relationship. In addition, the mid-1980s decline in R&D growth among firms facing the highest price reductions could represent a downward shift in their R&D budgets, which then had renewed growth during the late 1980s.

The conclusion that price reductions had some effect on firm-level R&D growth during the 1985-88 period is tentative because it is impossible to determine causality from a statistical association. In addition, the sales, profit, and price-cut variables can measure only some of the incentives to invest in research and development. However, the results do suggest a plausible interpretation. Early price cuts during the 1980s had no strong negative association with lower R&D growth, possibly because the firm's R&D expenditure plans had been established during the 1970s. In contrast with the early years, the lower growth of 1985-88 R&D expenditure was more likely to be associated with higher cumulative price cuts, possibly owing to decreasing profitability and consequent adjustment to R&D expenditure. The significant negative relationships disappeared in 1989 and later years, during which time corporate profitability rebounded substantially from the low point of 1986. Hence, there is suggestive evidence that the accumulation of price cuts may have led to some reduction in R&D expenditure during a period in which corporate profitability was lowest.

Whether renewed relationships between higher price cuts and lower R&D...
Table 2. Ordinary least square estimates of cumulative price-cut effects on R & D growth, 1983–92 (fourteen firms)

<table>
<thead>
<tr>
<th>Year</th>
<th>Firm-level explanatory variable</th>
<th>Coefficient</th>
<th>Intercept*</th>
<th>R-square</th>
</tr>
</thead>
<tbody>
<tr>
<td>RD84/RD83</td>
<td>Cumulative price cut to 1983</td>
<td>-0.167</td>
<td>1.182</td>
<td>0.448</td>
</tr>
<tr>
<td></td>
<td>Sales, 1983</td>
<td>0.274</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Operating profit, 1983</td>
<td>-5.144 **</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RD85/RD84</td>
<td>Cumulative price cut to 1984</td>
<td>0.136</td>
<td>1.032</td>
<td>0.231</td>
</tr>
<tr>
<td></td>
<td>Sales, 1984</td>
<td>-0.523 ***</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Operating profit, 1984</td>
<td>5.405 ***</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RD86/RD85</td>
<td>Cumulative price cut to 1985</td>
<td>-0.322 ***</td>
<td>1.229</td>
<td>0.383</td>
</tr>
<tr>
<td></td>
<td>Sales, 1985</td>
<td>-0.209</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Operating profit, 1985</td>
<td>1.793</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RD87/RD86</td>
<td>Cumulative price cut to 1986</td>
<td>-0.318</td>
<td>1.242</td>
<td>0.205</td>
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<tr>
<td></td>
<td>Sales, 1986</td>
<td>-0.005</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Operating profit, 1986</td>
<td>0.367</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RD88/RD86</td>
<td>Cumulative price cut to 1986</td>
<td>-0.980 **</td>
<td>1.686</td>
<td>0.502</td>
</tr>
<tr>
<td></td>
<td>Sales, 1986</td>
<td>0.444</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Operating profit, 1986</td>
<td>-5.749</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RD89/RD88</td>
<td>Cumulative price cut to 1988</td>
<td>0.118</td>
<td>1.002</td>
<td>0.226</td>
</tr>
<tr>
<td></td>
<td>Sales, 1988</td>
<td>-0.198</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Operating profit, 1988</td>
<td>2.448 ***</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RD90/RD88</td>
<td>Cumulative price cut to 1988</td>
<td>0.075</td>
<td>1.100</td>
<td>0.166</td>
</tr>
<tr>
<td></td>
<td>Sales, 1988</td>
<td>-0.463</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Operating profit, 1988</td>
<td>4.739</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RD91/RD90</td>
<td>Cumulative price cut to 1990</td>
<td>0.207</td>
<td>0.982</td>
<td>0.145</td>
</tr>
<tr>
<td></td>
<td>Sales, 1990</td>
<td>-0.216</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Operating profit, 1990</td>
<td>1.493</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RD92/RD90</td>
<td>Cumulative price cut to 1990</td>
<td>0.323</td>
<td>1.023</td>
<td>0.069</td>
</tr>
<tr>
<td></td>
<td>Sales, 1990</td>
<td>-0.272</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Operating profit, 1990</td>
<td>1.900</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* p<.01 (one-tailed tests); ** p<.05; *** p<.10.
Units: sales and profit = yen mln x 1 million; price cuts = sum of % annual cuts (e.g., 10% = 10).

growth will emerge in the future, especially if the current decline in profitability continues, is an open question. Changes to the reimbursement policies that became effective in April 1992 also add caution to projecting future trends from the results. The policy changes limit price reductions in cases where the difference between the company’s price to a doctor and the amount reimbursed to the doctor by MHW would fall below 15%, with the zone being reduced to 10% by 1998. In addition, price premiums will be awarded for drugs that are particularly innovative, with innovation criteria including novelty, safety, and treatment contribution. It is possible that these changes will stem any incipient link between price reductions and R&D growth by raising the incentives for continued innovation.

Conclusion

Japanese pharmaceutical firms are on the verge of either being dominated by international competitors in Japan or being able to compete on equal terms in world markets. Many firms in the industry have become increasingly innovative during the past twenty years, marked by increased inputs of research expenditures and increased output of new drugs. Policy makers must exercise substantial care while achieving the necessary outcome of controlling health care costs, or risk blunting the research-based strength of the pharmaceutical manufacturers.

The findings in this study are only suggestive. Nonetheless, even interpreted cautiously, the results of the analysis are striking. At the minimum, they signal the need for continued monitoring of pharmaceutical R&D investment by those concerned with innovation and competition in the pharmaceutical industry.

NOTES

1. We appreciate comments from Joan Penner-Hahn, Naoki Ikegami, Ron Slattery, and Bernard Yeung.
3. The reimbursement price paid by MHW usually exceeds the price charged by pharmaceutical manufacturers. Prior to regulatory revisions effective April 1992, the actual drug price was determined by a system of rebates and discounts between manufacturer, wholesaler, and customer. The difference between actual and reimbursement prices, which averaged about 20%, is known as yakka saeki. The effect of lowering the reimbursement price is either to reduce the yakka saeki or to put downward pressure on the actual price charged by pharmaceutical manufacturers. The greater the competition between firms, particularly for sales of established drugs with more substitutes, the more likely the latter outcome.
4. An across-the-board 2.4% price increase also was allowed in April 1989 to offset a value-added tax that had recently been created.
5. Ethical drugs realized sales of ¥1,242.8 billion in 1975, ¥2,332.4 billion in 1981, ¥3,108.3 billion in 1982, and ¥4,232.2 billion in 1989 (Japan Pharmaceutical Manufac-
turers Association 1992, 8). These figures represent growth from $6.9 billion to $24 billion at the approximate PPP rate of $1.00 = ¥180.

6. Average operating profit rose from 11.6% of sales in fiscal 1978 (March 1979 year end) to 13.5% in 1981, and then declined to 8.7% in 1986. The ratio rose again to 12.6% in 1989 before declining to 9.7% in 1992. The figures, which are drawn from various editions of the Japan Company Handbook (Oriental Economist 1976–92), address corporate profitability rather than pharmaceutical profitability, but the companies derived a large majority of their sales from the pharmaceutical industry (on average more than 85% in most years).

7. For discussions of the drug development process, including the need for several years of development for most new drugs, see Finch 1989; Grabowski 1990; and Jermigan, Smith, Banahan, and Juergens 1991.

8. As yet, the directly owned distribution systems of foreign-owned firms have achieved relatively little penetration of the Japanese market, reaching a market share of less than 9%, in 1991 (Nakagawa 1992). Foreign-owned firms represent potential competitors more than major current competition.

9. The pharmaceutical R&D process can be categorized in terms of basic biomedical research, drug discovery, and preclinical product development. Basic research identifies opportunities for pharmaceutical therapy. Drug discovery involves the identification and testing of development candidates from existing and newly synthesized chemical entities. Preclinical development requires characterizing a particular drug and carrying out toxicology studies. Following preclinical trials, drugs undergo several rounds of clinical testing on human subjects before being introduced commercially.

10. For instance, the 1990 firm-level price-cut estimates in our sample ranged from 5% to 12.5% (sample average = 9.6%, industry average = 9.2%). The cumulative price cuts for the fourteen firms as of 1990 ranged from 40.5 to 87.5 (sample average = 64.9). We estimated the prices by industry analysts (Merrill Lynch 1992; Nakagawa 1992; Salomon Brothers 1992b). We used the average estimate when we had estimates from more than one source.

11. The relationships between R&D expenditure and profitability, corporate size, and other factors have received extensive study. However, there is little consensus among the studies, likely because changes in R&D expenditure, sales, and profitability usually take place in the context of a changing industry and hence are likely to have changing relationships (Mitchell, Roehl, and Slattery 1995). The data for the R&D growth variables were drawn from the Japan Company Handbook (Oriental Economist 1983–92) and the Yano Research Institute (1991). The 1992 R&D figures are estimates, reported in the Winter 1992 edition of the Japan Company Handbook (Oriental Economist 1992).

12. The statistical analysis reported in Table 2 controls for corporate sales and operating profits as alternative explanations for R&D expenditure growth. Although desirable in order to control for liquidity, the variables introduce a potential bias because the level of a firm’s sales and profits might be a result of past price cuts, so that price reduction effects might be assigned to profits or sales incorrectly. However, the price-cut influences in statistical analyses that omitted the operating profit and sales variables were materially equivalent to those reported in Table 2.

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