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An Analysis of US International Competitiveness in Pharmaceuticals

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An analysis of international competitiveness is undertaken from several perspectives. The US industry is currently the leader in worldwide pharmaceutical sales, R&D activity and new drug candidates under development. During the 1980s the Japanese pharmaceutical industry surpassed the US one in terms of total worldwide new drug introductions. However, the US industry was found to have significantly more commercially important new drugs and 'consensus' introductions worldwide. The paper considers what factors are likely to influence future international competitiveness in pharmaceuticals.

Competition in the multinational pharmaceutical industry centres around the discovery and development of important new drug therapies. The United States has been the acknowledged world leader in pharmaceutical innovation for the past several decades. This has resulted in significant health advances, rapid output growth and positive contributions to the US balance of trade.[1]

However, international competition in pharmaceutical innovation in recent years has markedly intensified, posing a challenge to the US industry's continued leadership. A study by the National Academy of Engineering (1983) has documented several potentially significant developments in this regard. It points out that pharmaceutical R&D expenditures in Europe and Japan have been growing faster than in the United States. This has led to a significant decline in the US industry's share of worldwide R&D activity for new drugs. The rapid evolution of the research segment of the Japanese pharmaceutical industry is particularly highlighted in the NAE's analysis, which indicates that Japan may very well pose the greatest challenge to the United States in pharmaceuticals over the next few decades.

In this paper an analysis of international competitiveness in pharmaceuticals is undertaken from several perspectives. The next section examines various indicators of competitive position utilizing additional, and more recent, data to that considered in the NAE study. The following section considers current policy developments that are likely to have an important bearing on future international competitiveness in pharmaceuticals.

INTERNATIONAL COMPETITION IN PHARMACEUTICALS

Research and Development Expenditures

The NAE study appropriately focused on R&D activity as a key dimension of future competitive performance. Competition in pharmaceuticals is clearly dynamic in nature. Market position can shift significantly in the wake of successful product innovations, both at the individual firm level and internationally. Moreover, deterioration in competitive position at the R&D stage can occur for many years before becoming visible in new product introductions. The average new drug now takes over a decade from discovery to marketing (Grabowski and Vernon, 1983).

The NAE study emphasized the fact that the US share of world pharmaceutical R&D expenditure has fallen from greater than 60% during the 1950s to less than 30% by the end of the 1970s. In addition, it found that the number of self-originated drug candidates from US firms entering clinical trials in the United States have steadily declined since the mid-1960s. By contrast, the number of foreign-owned drug candidates entering US trials has remained relatively constant.[2]

One basic explanation for the declining US position in drug R&D is that it is a natural adjustment to the depleted condition by European and Japanese firms after World War II. In particular, the US industry had a great advantage in the immediate post-war period that one would have expected to erode with time. While this is plausible, it is difficult to attribute all the observed change to this factor. The adjustment to post-war conditions should have been largely completed by the 1970s. The NAE study observes that US drug R&D expenditures grew hardly at all in real terms during the 1970s, whereas those in Japan and other major European countries were increasing rapidly over this period (in excess of 8%).

Since the NAE study was completed, additional data have become available on R&D expenditures during the 1980s. Table 1 provides comparative information on growth rates in R&D in the United States and three other major research-intensive countries in pharmaceuticals. The first column in Table 1 shows the real growth in R&D expenditures for the 1973–9 period as computed by the NAE study. Column 2

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Table 1. Comparative Growth Rates in R&D Expenditures by Country (Location)

Country	Annual growth rates (%)[a] 1973 9	1980 85
United States	1.1	14.3
United Kingdom	13.1	8.7
West Germany	7.9	9.8
Japan	8.1	11.5

[a] Data represent expenditures for both human and veterinary R&D and are computed in terms of constant values of each currency. Deflator is wholesale price in each county as compiled by the International Monetary Fund. The growth rates for 1973–79 are from Table 2-2 of the National Academy of Engineering Study (1983).

Sources: Pharmaceutical Manufacturers Association, *Annual Survey Report*, Washington, DC, 1985–6: Association of the British Pharmaceutical Industry, Annual Report, *ABPI*, London, 1985–6: Bundesverband der Pharmazeutischen Industrie, *Pharma Jahresbericht*, BPI, Frankfurt, 1986–7: Japan Pharmaceutical Manufacturers Association, *Data Book*, 1986: National Academy of Engineering (1983).

shows the growth in R&D expenditures for the period 1980–85 utilizing the same sources and deflators as the NAE study. Obviously, there has been a significant shift between these two periods. After little growth in the 1970s, US R&D expenditures have grown at a very rapid rate in the first half of the 1980s (14.3% in real terms). Moreover, they increased faster in the 1980s than any of the major competitive countries shown in Table 2.[3]

What explains the turnabout in US R&D performance between the 1970s and 1980s? While a full explanation is beyond the scope of this study some important factors can be cited here. First, the late 1970s and early 1980s saw the introduction of several important new drug therapies by US firms. The most publicized of these was Tagamet, the anti-ulcer compound that revolutionized the medical treatment of this disease. In addition, significant drugs of major commercial importance were also introduced in other therapeutic categories, including cardiovasculars, anti-infectives and anti-inflammatories.

Breakthrough new drugs like Tagamet and Capoten (a cardiovascular therapy) were not only large commercial successes but also created a new period of optimism about technological opportunities and the ability of firms to exploit accumulating knowledge emerging from basic biomedical research. In this regard both Tagamet and Capoten were examples of the new 'discovery by design' approach to R&D that utilized biomedical research knowledge to target R&D efforts more directly than in the past. The United States has also been at the forefront of pharmaceutical applications of biotechnology, a growing area of R&D outlays during the 1980s.[4]

The 1980s have not only been a period of increased optimism for the US pharmaceutical industry concerning technological opportunities but also one of rising cash flows to support increased R&D. Past studies have pointed to the importance of cash flow availability as a significant determinant of US R&D expenditures in pharmaceuticals.[5] The product successes of the late 1970s provided significantly increased cash flows during the 1980s. In addition, beginning in the early 1980s, drug firms began increasing their prices faster than product costs. This reversed a general pattern in the 1970s of lagging prices on costs and declining profit margins for established products. This change in drug pricing patterns also contributed to increased cash flow availability in the 1980s.

New Product Development

Another measure of innovational activity is the number of new products under development. In recent years a survey has been conducted by 'Pharmaprojects' on self-originated and total drugs under development by pharmaceutical firms on a worldwide basis. Table 2 shows summary information on the number of self-originated drugs under development by corporate nationality. This is based on data for the top one hundred pharmaceutical firms ranked by the number of drugs under development in 1986. While some bias may be introduced by focusing on the top one hundred firms, this group includes those that have made most of the significant innovations in the pharmaceutical industry in recent years.

Data on new products under development have some advantages over R&D expenditure data since the latter include outlays for improvements in existing products (i.e. new dosage forms, combination products, defensive R&D etc.). Furthermore, the data in Table 2 on self-originated product candidates allow

Table 2. Drugs under Development by Corporate Nationality for the Top Hundred Ranked Firms in 1986

Country	Number of firms	Self-originated drugs under development	Percentage of total
United States	27	938	36.5
Japan	24	462	17.8
West Germany	11	350	13.5
United Kingdom	5	182	7.0
Switzerland	4	164	6.3
France	6	157	6.0
Italy	6	94	3.6

Source: *Script* (1986).

one to measure the development activities of US firms on a worldwide basis and similarly for foreign firms. By contrast, R&D expenditure data are collected on a location-specific basis and may obscure the shares of the respective national industries, given the multinational character of the pharmaceutical industry.

Table 2 shows that the US industry is the worldwide leader in new drug candidates in 1986 with 938 self-originated drugs under development (36.5% of the total for the top one hundred firms). The United States had a comparable percentage of the sum of self-originated plus licensed drugs under development.[6] The data further show that US firms had twice the number of self-originated drugs under development as Japanese firms, the country ranked second. Moreover, the United States had approximately as many self-originated drugs under development as the five major research oriented countries in Europe shown in Table 2.

The data in Tables 1 and 2 provide a much more optimistic picture of future US innovative capacity than that presented in the NAE study. Of course, R&D input data, measured either in terms of dollar outlays or projects under development, do not provide information on the productivity or the quality of R&D being performed in various countries. In this regard a number of prior studies have shown that new products in pharmaceuticals tend to vary greatly in terms of commercial importance.[7] A relatively small number of drug products account for a disproportionate share of global sales. The next two sections provide information on pharmaceutical introductions and the significance of new drugs emerging from different countries.

New Product Introductions

Data on worldwide new chemical entities (NCEs) by corporate nationality are presented in Table 3. This table shows that the US pharmaceutical industry has originated 23–4% of the world's NCEs since 1962. In addition, the US share has remained remarkably stable over the three decades for which data are assembled. By contrast, the percentage of NCEs originating from European firms generally exhibit a declining trend over the three periods.

The most striking finding in Table 3, however, is the significant increase in the number of NCEs originating from Japanese firms. The Japanese industry originated approximately 10% of the world's NCEs during the 1960s and 1970s. Its share increased to 27% during the 1980s, making it the worldwide leader in NCE introductions. This is particularly remarkable given the fact that the Japanese only began carrying out drug R&D in any real sense in the 1960s and its R&D inputs have been much smaller in size than those of US industry.

The data in Table 3 involve only simple counts of NCE introductions originating in each country. In Table 4 data are presented which provides some information on the importance or quality of NCEs originating in different countries. In particular, this table focuses on worldwide introductions that were subsequently adopted in at least a majority of eleven major industrialized countries.[8] These drugs have been categorized as internationalized or consensus NCEs in the literature. There is also evidence of a significant statistical correlation between the international acceptance of a drug and its therapeutic and commercial importance.[9]

The sample of consensus NCEs in Table 4 are drawn from a broader sample of 723 total NCEs first introduced in the eleven industrialized countries over the period 1970–83. Only 170 NCEs, or less than one in four, are subsequently marketed in a majority of the eleven countries and become consensus NCEs. It generally takes at least two years for an NCE to diffuse across a majority of these eleven countries.

The data on consensus NCEs in Table 4 give a very different picture than those on total NCE introductions in Table 3. They show that US drug firms accounted for 41.7% of the 170 consensus NCEs introduced since 1970. Hence US firms account for a much larger share of consensus NCEs than overall NCEs. The same is true of Switzerland and the United Kingdom. On the other hand, Japan, France and Italy have a noticeably smaller share of consensus NCEs compared to their total NCEs. In this regard Japan had only 4.1% of the consensus NCEs, well below it share of total NCEs or product candidates under development.

What accounts for these striking differences observed in Tables 3 and 4? In particular, what does it tell us about Japan's ability to enhance its future competitive position in pharmaceuticals? One interpretation of these results is that the Japanese drug firms

Table 3. Worldwide New Chemical Entity Introductions by Nationality of Originating Firm, 1961–86

Period	Numbers of new entities	Share distribution (%)						
		USA	Japan	West Germany	France	Italy	Switzerland	UK
1961–70	863	24	9	13	20	6	7	5
1971–80	635	23	12	14	16	11	7	5
1981–6	281	23	27	10	8	8	6	3

Notes Classification is based on the country where company discovering the drug is headquartered rather than that where first synthesis of the drug occurred.

Sources: 1961–80 NCE introductions: E. Reis-Arndt (1982). The twenty year decline in worldwide drug development. *Medical Marketing and Media* August. 1981–6 NCE introductions: *Script* (various issues)

Table 4. Distribution of Consensus NCEs by Nationality of Originating Firm, 1970–83

Country	Number of NCEs	(%)
United States	71	41.7
Switzerland	22	12.9
West Germany	17	10.0
United Kingdom	17	10.0
Sweden	12	7.1
Italy	8	4.7
Japan	7	4.1
France	4	2.4
Others	12	7.1
	170	100

Note: Consensus NCEs are defined as new drugs introduced in at least six of eleven major markets over the period 1970–83.

Source: Data appendix in Coppinger and Hass (1986).

have largely concentrated on imitative rather than innovative research, and this in turn has produced a high quantity of new introductions that are not widely adopted in other countries. This certainly appears to be characteristic of the Japanese industry during its initial evolutionary period from a largely generic type industry in the 1950s and 1960s to a more research-oriented one today. Yamamoto (1986) observes in this regard that, until very recently, the Japanese drug industry largely concentrated on improvements of predecessor drugs using known parmacological concepts. This is consistent with the findings of Table 4.

There is evidence, however, that this situation may be changing. Yamamoto (1986) has recently surveyed the research projects being undertaken by Japanese drug companies and finds that they are performing R&D projects utilizing new pharmacological concepts in a number of therapeutic areas.

The data on consensus NCEs also provide some indication that the Japanese share of these innovative compounds is likely to be greater in the future. In this regard it is instructive to consider the source of consensus NCEs whose first introduction in the eleven-country sample occurred between 1979 and 1981. This is necessarily a very small sample (nineteen introductions).[10] Nevertheless, the data indicate that in this period the United States accounted for nine of the introductions (47%), followed by Japan with three (16%) and several other countries with two or fewer. Hence there is at least fragmentary evidence suggesting that the Japanese share of consensus NCEs has been increasing in accordance with its current emphasis on more innovative research. This is an issue on which further analysis is currently being performed.

Another factor accounting for the lower rate of internationalization of Japanese drugs is the fact that its pharmaceutical industry is the least multinational of the leading R&D countries in pharmaceuticals. Japanese drugs generally are licensed in foreign countries rather than being marketed by Japanese subsidaries. This leads to additional transactions costs, time delays and other potential disincentives in the drug-diffusion process. By contrast, US and Swiss firms, with their extensive multinational structure, can obtain regulatory approval and introduce new drugs worldwide more rapidly through their foreign subsidaries. There has been speculation that the next phase in the evolution of the Japanese pharmaceutical industry will be direct investment in the United States and other major markets. This is considered further below.

New Product Sales

Another common measure of the significance of new drug introductions in the literature involves weighting an NCE by its market sales after introduction. Given the fact that the sales distribution of new NCEs is highly skewed, it is appropriate to examine the national origins of the most significant commercial products introduced over recent periods. An analysis of the most important commercial products introduced into the US market between 1970 and 1982 was undertaken to analyze this issue.

There were fourteen new drug introductions in the United States between 1970 and 1982 that achieved $100 million sales (measured in constant 1986 dollars) by their fifth year of market life.[11] These are the 'big winner' drugs that generate a disproportionate share of the sales and profits for the firms developing and marketing these compounds. Of these fourteen economically important NCEs, nine were discovered and marketed by US firms (approximately two-thirds of these drugs on a sales-weighted basis). Of the five foreign-originated NCEs, two emanated from the United Kingdom, while one each came from West Germany, Japan and Switzerland. Three of the five foreign-originated drugs were marketed in the United States by US firms under licence and only two by subsidaries of foreign-owned firms.

Data on the timing of these 'blockbuster' NCEs also illustrate a point discussed earlier. In particular, there was only one such product introduced by US firms for the period 1970–75. By contrast, US firms originated eight 'big winner' drugs between 1976 and 1982. Hence, this latter period witnessed a significant turnabout in new product sales for US firms, as discussed above. These introductions led to large increases in the available cash flows for the industry, and this has presumably also contributed to the rapid rate of growth in US R&D since 1980.

Total Worldwide Sales

A final indicator of international competitive performance that is considered here is the global sales and market shares by corporate nationality during the 1980s. This, of course, will reflect, the R&D activities and innovations of the respective national industries over earlier periods, given the lags in the pharma-

Table 5. Worldwide Sales by Corporate Nationality

	1980	1984	1986
World wide sales ($ billion)	44.3	51.3	70.9
SHARES (%)			
US companies	34.6	40.3	36.5
Japanese companies	13.3	15.1	17.6
West German companies	15.3	12.5	12.7
Swiss companies	9.3	8.4	7.9
UK companies	5.6	6.3	7.0
All others	21.9	17.4	18.3

Notes: Sales are expressed in billions of US dollars using average annual exchange rates. Worldwide market sales consists of 33 countries covered by International Medical Statistics Inc. (IMS) audit data surveys.

ceutical innovation process. Table 5 provides data on worldwide pharmaceutical sales and market shares by corporate nationality for three points in time during the 1980s. These are based on audit data for 33 countries, including all the major developed ones. Sales are computed in terms of US dollars.

The data on worldwide sales in Table 5 also confirm the leadership position of the United States. The US drug industry had 37% of worldwide sales in 1986. The second-ranked country is Japan, with 18% of global sales, followed by West Germany (13%), Switzerland (8%) and the United Kingdom (7%). Collectively, these countries account for just over 80% of worldwide sales.

The data for the three years shown in the 1980s do not reveal any tendency for US firms market shares to decline over time, as was feared in the NAE study. Rather, the variations in these are more or less in line with currency fluctuations.[12] The market share data in Table 5 also show a rising trend in the share of worldwide sales accounted for by Japan and a generally declining trend for the European pharmaceutical industries. The increasing shares accounted for by the Japanese industry reflects the growing importance of the Japanese market as a percentage of global sales together with the fact that their firms hold a dominant 75% share of their domestic market.[13]

The US industry's strong current competitive position is also reflected in terms of individual firm rankings on the basis of estimated worldwide pharmaceutical sales. In particular, this is shown in a ranking from the trade journal *Script* (1986). The top 25 firms includes 13 US firms, four British, three West German, three Swiss and two Japanese.

The Japanese industry accounts for the most firms in the top two hundred ranked firms (50 from Japan versus 35 from the US drug industry in 1985). The more fragmented character of the Japanese drug industry relative to other research-oriented countries has also received attention in the literature. The industry may very well be headed for a consolidation phase in line with the Japanese government's objective that it focus more on foreign markets (Yamamato, 1986). Recent government measures in drug pricing and other policy areas may lead to greater consolidation of the domestic Japanese drug industry in the future.

CONCLUSIONS AND FACTORS INFLUENCING FUTURE COMPETITIVE PERFORMANCE

All the data examined in this paper indicate that the competitive position of the US pharmaceutical industry is decidedly better now than at the start of the decade, when the NAE report was undertaken. After little real growth during the 1970s, US pharmaceutical R&D activity has been increasing at a rapid rate since 1980, both absolutely and relative to foreign competitors. At the output stage, the US drug industry has been the source of an impressive number of significant new drug introductions, beginning in the late 1970s. It has also maintained 35–40% of worldwide sales during the 1980s. This is more than double the size of Japan, the nearest ranked foreign competitor.

Nevertheless, it is still the case that foreign competitors could provide a strong challenge to US leadership in pharmaceuticals over the next few decades. The Japanese industry, in particular, has evolved rapidly from the early 1960s, when it was an essentially a generic type one. Beginning in the late 1960s, R&D programs in drugs were initiated which concentrated on imitative type drugs using known pharmacologic concepts. The result was many new product introductions but few world-class drugs. Recently, however, the Japanese have been emphasizing a more innovative approach to biomedical R&D. The most recent data on NCE introductions suggest that they are likely to account for a much larger share of important or consensus NCEs in the future than in the past. Moreover, one can expect that some of the leading Japanese firms will enter the US and other major markets, probably following a period of industry consolidation that already appears to be in process.

The data on competitive performance indicate that the European pharmaceutical industries have generally exhibited a declining position in the 1980s. This is most evident in the case of worldwide market sales and the number of new product introductions emanating from these countries. One of the factors underlying this decline *vis-à-vis* the United States has been the fall in drug sales and earnings in their domestic markets. Over the past several years drug prices increases in Europe have been constrained by national health insurance programs, and profit margins have correspondingly declined. One strategic response has been a wave of entry by European firms into the US market through mergers with smaller US firms as well as direct investment in the United States, starting in the mid-1970s.[14] This will provide a direct outlet for European firms to market their innovations in the United States. It will also reduce licensing opportunities for US firms and make self-originated drug innovation even more important to retaining high domestic market shares in the future.

Future competitive performance in a dynamic Schumpeterian industry like pharmaceuticals will be significantly affected by national policies influencing the technological and economic opportunities for drug innovation. While a full analysis of this issue is beyond the scope of this paper, it is instructive to conclude by highlighting a few of the major developments affecting the US environment.

In terms of scientific opportunities, R&D directors in the United States (and other research-oriented countries) have been optimistic about the growing biomedical scientific base for the technological advances in pharmaceuticals. The support for basic biomedical research at the NIH remains strong, and this provides a rich source of knowledge and leads for new pharmarceutical therapies (Grabowski and Vernon, 1983). The US industry is also pursuing a number of promising paths at the discovery phase of the innovational process.

At the same time, the future economic environment in the United States for new drug innovation is more uncertain. The US market has been traditionally characterized as having the most stringent regulatory controls for new drug introductions but the most open and attractive market environment once FDA approval was obtained. However, the latter situation is changing. Generic drug products have obtained increasing shares of US pharmaceutical sales as a result of 1984 legislation and other factors.[15] In recent years there has also been a number of health sector cost-containment measures impacting on pharmaceutical sales and innovation incentives (Grabowski, 1986a, 1987). Under pending legislation, outpatient drugs consumed by the elderly are likely to be covered soon under the Medicare program. This would lead to a considerable increase in the US drug market subject to government reimbursement and cost control.

Consequently, the market situation in the United States for new drug candidates now beginning the R&D process may be very different when these drugs are introduced a decade or more from now. A more stringent economic environment for new drugs would adversely affect both domestic and foreign firms competing in this country. However, US firms would be disproportionately influenced by such a development.

In sum, there is considerable good news to report in terms of the present US international position in pharmaceuticals. The US drug industry is currently the world leader in innovation and sales and US firms are also at the forefront of expanding biomedical research opportunities. At the same time, however, current US policies in the health sector are increasingly driven by priorities that could result in a less favorable economic environment for new product candidates currently entering the R&D pipeline.

NOTES

1. For specific analyses of industry performance along these dimensions, see Grabowski (1982) and Grabowski and Vernon (1983).
2. These trends are documented in Chapter Two of NAE (1983). See, in particular, Tables 2-1 and 2-7 of this study.
3. The use of the average wholesale price index to deflate R&D expenditures undoubtedly overstates the real growth of R&D expenditures in the United States and these other countries. This is because research employee salaries and laboratory equipment have been rising faster than overall wholesale prices, especially during the 1980s. Some indication of this is provided by deflating US R&D data by the NIH Biomedical Research and Development Index rather than the wholesale price index. Deflation by this index results in a real growth rate of 8.5% for the period 1980–86 rather than the 14.3% given in Table 1. However, a similar phenomenon would presumably hold in the case of other countries given in Table 1, leaving the United States in the same relative position as before.
4. For a further discussion of the changing research process in pharmaceuticals see Grabowski and Vernon (1983, Chapter 2). In addition, the US Office of Technology Assessment (1983, Chapter 5) provides a survey of biotechnology research applications to pharmaceuticals .
5. See Grabowski and Vernon (1981) for a statistical analysis of this question and further references. This study finds that research opportunities and cash flow availability are two primary determinants of R&D expenditures in pharmaceuticals.
6. In 1986 the data from Pharmaprojects indicate that the United States had 36.1% of total drugs under development. The percentage on total drugs for the other countries in Table 2 were similar to that given for self-originated drugs.
7. See, for example, Joglekar and Patterson (1986), Grabowski and Vernon (1982) and Virts and Weston (1980).
8. The eleven countries are Australia, Canada, France, West Germany, Italy, Japan, Norway, Sweden, Switzerland, the United States and the United Kingdom. For a further discussion of the data sample see Coppinger and Hass (1986).
9. Barral (1985), using a different sample period (1975–84) and a smaller sample of countries, calculated shares with weights based on therapeutic importance (expert rankings) and commercial importance (sales in country of origion). He found that country rankings were very similar using the alternative criteria of internationalization, therapeutic or commercial importance. His results are summarized in *Script*, 23 December 1985, pp 20–21.
10. This is so because it takes two or more years for an NCE to diffuse across a majority of the eleven countries in our sample. The last year for which data were available on new drug introduction approvals for all eleven countries is 1983, and the last year which a consensus NCE was recorded was 1981. Hence one is observing a somewhat truncated sample for this three-year period.
11. The analysis here is based on the drug store and hospital audits of IMS Incorporated located in Ambler, Pennsylvania. The eleven products achieving $100 million in sales or more by their fifth year are as follows: Capoten, Cardizem, Clinoril, Feldene, Keflex, Lopressor, Mandol, Mefoxin, Motrin, Naprosyn, Procardia, Tagamet, Tenormin and Xanax.
12. The rising dollar in the early 1980s will cause the US market sales to be weighted higher relative to other countries. Given that the US drug industry's overall market shares are much greater for the domestic market than in foreign countries, their worldwide market share will tend to increase with a rising dollar and vice versa. Hence the observed pattern of a rising market shares between 1980 and 1984 and declining market shares between 1984 and 1986 is consistent with currency movements.
13. The rising importance of the Japan drug market was based on a rapid rate of growth in sales until 1984, when the government instituted widespread price declines for pharmaceutical products. At this point in time the Japanese rate of drug consumption per capita was much higher than any other country and proportion of national healthcare expenditures devoted to drugs was over 30% (compared to approximately 7% in the United States). While total drug sales in Japan have declined in the last few years, the

importance of the Japanese market has continued to grow in terms of global market shares because of the rapid appreciation of the yen against the dollar since 1984.

14. This is documented in the NAE (1963) study. See, for example, Table 2-15.
15. The 1984 Drug Price Competition and Patent Restoration Act (the Waxman–Hatch Bill) removed regulatory requirements for generic products, facilitating their rapid entry onto the market when patents expire. At the same time, for future new drug products this legislation restored some of the patent time that is lost during clinical testing and regulatory approval. Average patent life in pharmaceuticals had declined to about half the nominal 17-year life by the early 1980s. Since passage of this Act in 1984, generic products have obtained much greater market sales in pharmaceuticals. An initial analysis of the expected economic effects of the 1984 Act on drug innovation indicates that the typical new drug product will experience negative effects (Grabowski and Vernon, 1986).

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