Chapter 5

Market Behaviour

The three principal characteristics of the pharmaceutical industry examined this chapter, sales promotion, research and development, and vertical and horizontal integration, are at once descriptive both of industrial structure and also of the behaviour of firms in response to more fundamental elements of market structure. In this context, the instability of market shares, the frequent reliance of firms on the sales of one or a few products, and the diverse and complex nature of buying/demand decisions can be thought of as setting the framework within which firms respond with the activities of sales promotion, new product development, integration, and diversification.

Sales and Promotion Activities

Given the nature of the markets for pharmaceutical products implicit in the discussion of the preceding chapter and in particular given the reliance of firms on the sales of a fairly small number of products, it is perhaps to be expected that the industry is characterized by a relatively high level of sales promotion and advertising. In the first part of this section, the number of persons allocated to these functions is considered. In the second part, expenditures on advertising and related items are examined. In the third part, comparative information for other countries is briefly considered.

Manpower Allocated to Sales and Promotion Activities

A principal source of information on the extent to which manufacturers of pharmaceuticals and medicines employ sales persons is the dicennial census of Canada. Information from the last three such censuses, 1961, 1971, and 1981, is presented in Table 5.1. Unfortunately, the classification systems of occupations and of industries are not always precisely similar from one census to the next. More importantly, however, the commonly held view as to who is and who is not a "sales person" can change quite significantly over a decade and especially over two decades. The information presented in Table 5.1 is probably more valuable for considering the extent to which in a given year manufacturers of pharmaceuticals and medicines rely on sales personnel in comparison to other industries than as an indicator of the extent to which such reliance changes over time.

Table 5.1

Sales Labour Force as a Percentage of the Total Labour Forces for Manufacturers of Pharmaceuticals and Medicines: Canada, 1961, 1971, and 1981

	1961		1971		1981*	
All Industries	6.35 = 100.0		9.46 = 100.0		9.55 = 100.0	
Manufacturing Industries	3.94	62.1	6.52	68.9	4.38	45.9
Chemical and Chemical Products Industries	12.17	191.7	12.01	126.9	8.30	86.9
Manufacturers of Pharmaceuticals and Medicines	21.58	339.8	17.83	188.5	10.59	110.9
Manufacturers of Soap and Cleaning Compounds	10.43	164.3	15.26	161.3	14.17	148.4
Manufacturers of Toilet Preparations	50.96	802.6	25.82	272.9	11.52	120.6
Manufacturers of Industrial Chemicals	3.51	55.3	5.10	53.9	3.69	38.6
Scientific and Professional Equipment Mfrs	3.80	59.9	6.13	64.8	4.70	49.2
Wholesale Trade: Drugs and Toilet Preparations	34.98	550.9	43.91	464.1	32.70	342.4
Retail Trade: Drugstores	46.03	725.0	47.34	500.4	34.76	364.0

* 1981 data are based on the 1971 Classification System for Occupations and Industries.

Source: Statistics Canada, *Decennial Census*, 1961, 1971, and 1981.

Of the total labour force of manufacturers of pharmaceuticals and medicines in 1961, those who were referred to as sales persons accounted for 21.6 per cent. This figure was 3.4 times larger than that for all industries and more than five times larger than that for all manufacturing industries. Indeed, for the industries considered in Table 5.1, only manufacturers of toilet preparations, the wholesale trade in drugs and toilet preparations, and the drugstore retail trade were characterized by higher levels of employment of sales persons.

By 1971 the reliance of manufacturers of pharmaceuticals and medicines on sales persons relative to all manufacturing industries, or indeed all industries, had fallen sharply. The number of sales persons represented 17.8 per cent of their labour force; this was only three times larger than the percentage for all manufacturing industries and not quite twice that for all industries. The sales force in toilet preparations was again higher than that found in pharmaceuticals and medicines but relatively less so than it was in 1961. In contrast, the sales force found in the wholesale trade in drugs and toilet preparations and in the drugstore and pharmacy retail trade increased relative to that found in pharmaceuticals and medicines.

The picture for pharmaceuticals and medicines relative to all manufacturing in 1981 indicates the continuation of the earlier trend. The sales force in all industries in 1981 accounted for 9.6 per cent of the total labour force, whereas

in pharmaceuticals and medicines it was only somewhat higher at 10.6 per cent. The wholesale trade in drug and toilet preparations and the retail drugstore and pharmacy trade continued to rely heavily on sales persons.

Yet another source of information on the extent to which the pharmaceutical industry relies on sales and promotion is provided by the information set forth in Table 5.2 on production and sales distribution employees as a percentage of all employees. This information, gathered from the annual census of manufacturers, indicates that from 1962 to 1974 there was a fairly stable 24 to 25 per cent of all employees in the pharmaceutical industry devoted to sales and distribution activities, a fairly stable 42 to 43 per cent devoted to production, and the remainder devoted to the administration and head office activities. This is in some contrast to the other industries for which similar information is available. For example, with respect to soap and cleaning compounds, the reliance on sales and distribution employees increases over this period; with respect to the manufacturers of toilet preparations and opthalmic goods, such reliance appears to fall.

A major problem in assembling information on sales and distribution employees is the frequent need to arbitrarily allocate the total work time of individual employees to more than one category, for example, to selling and to general administration. This problem is more likely to occur with non-production employees. Accordingly, it is of interest to consider the information on production and related employees presented in Table 5.2.

The percentage of employees described as production workers remains fairly stable over the entire 21-year period. There is a slight peaking towards the middle to late 1970s, much the same as occurred with manufacturers of soap and cleaning compounds and of toilet preparations. All manufacturing reveals a similar trend. However, manufacturers of orthopaedic and surgical appliances and opthalmic goods are seen to place an increasing reliance on production workers over this period.

Of equal interest to the time trends is information on the relative numbers of production workers as a percentage of all employees. At some 42 per cent over much of the period since 1962 the pharmaceutical industry is seen to have the smallest proportion of work force accounted for by production workers of all the industries and industry groups considered. In particular, all manufacturing industries are characterized by work forces of which over 70 per cent are classified as production workers. Even in toilet preparations and soap and cleaning compounds, the percentage of production workers is greater than it is for pharmaceuticals and medicines. The corollary is of course that the pharmaceutical industry involves more effort directed towards the combination of selling and distribution and general head office activities than do any of the other industries considered in Table 5.2.

Yet another source on the extent to which pharmaceutical firms devote resources to sales promotion is the Pharmaceutical Manufacturers Association of Canada (PMAC). Information from the PMAC describing the total cost of

Table 5.2

Production and Sales and Distribution Employees as a Percentage of All Employees in the Pharmaceutical Industry in Canada, 1962-82

	1962	1963	1964	1965	1966	1967	1968	1969	1970	1971	1972	1973	1974	1975	1976	1977	1978	1979	1980	1981	1982
Production Workers as a % of Total:																					
Pharmaceuticals	42.3	41.1	40.0	39.9	42.3	42.2	42.6	43.3	41.9	41.9	41.0	43.2	42.9	45.3	44.9	46.3	47.0	40.1	43.3	43.4	42.3
Soap and Cleaning Compounds	44.0	43.7	43.7	43.3	43.5	43.7	44.0	42.9	45.2	44.5	44.7	44.9	47.5	47.9	54.6	54.0	51.6	49.8	49.0	46.0	47.5
Toilet Preparations	51.2	50.8	52.8	51.3	51.1	51.7	52.1	51.9	52.6	52.6	52.4	51.4	50.1	54.1	54.9	52.1	51.5	51.9	52.5	48.3	48.1
Orthopaedic and Surgical Appliances	68.0	67.4	69.5	69.3	71.0	70.8	72.3	70.0	72.2	72.2	71.9	n.a.	68.2	79.9	76.3	78.2	81.1	72.9	72.7	78.2	76.3
Opthalmic Goods	68.6	67.8	71.0	70.0	72.8	72.5	71.0	69.2	69.6	68.6	69.2	69.6	70.4	70.4	71.5	69.1	71.3	72.3	75.1	74.1	75.1
Chemical and Chemical Products	—	—	—	—	50.6	50.4	50.4	50.7	—	49.9	50.3	51.0	—	—	—	—	—	—	—	—	—
All Manufacturing	70.1	70.4	70.9	71.1	71.3	70.7	70.6	71.0	71.3	71.7	72.4	72.9	72.8	73.0	73.3	72.9	73.2	73.4	72.8	72.1	71.0
Sales and Dist. Workers as a % of Total:																					
Pharmaceuticals	24.0	23.8	24.0	25.6	24.5	23.7	23.5	23.6	24.6	25.3	26.6	24.4	23.9	—	—	—	—	—	—	—	—
Soap and Cleaning Compounds	16.4	16.8	16.7	17.0	16.6	16.8	16.4	17.2	22.1	23.8	24.8	24.7	23.5	—	—	—	—	—	—	—	—
Toilet Preparations	22.4	23.6	22.3	23.7	24.6	23.9	22.7	21.3	20.7	19.8	20.5	19.5	19.3	—	—	—	—	—	—	—	—
Orthopaedic and Surgical Appliances	7.1	7.2	7.3	7.6	5.5	5.8	6.2	6.1	5.7	7.1	6.3	n.a.	8.5	—	—	—	—	—	—	—	—
Opthalmic Goods	10.4	8.7	6.2	7.2	7.7	7.1	7.0	7.0	7.1	7.4	6.9	9.2	9.0	—	—	—	—	—	—	—	—

Source: Statistics Canada, *Manufacturing Industries of Canada* (Catalogue 31-203), and similar catalogues for the three- and four-digit industries.

sales promotion, including both external expenditures on advertising and the internal cost of maintaining the force of detail persons, is set out in the last column of Table 5.3 for 1964 to 1983. It is clear from this information that the proportion of total expenses devoted to sales promotion declines with minor fluctuations from 1964 to 1980. It has subsequently begun to rise and by 1983 was back at the level it was in the early 1970s.

The census data presented in Table 5.1 is not strictly comparable from one census period to another and therefore cannot be relied upon by itself to indicate the trend in the extent to which sales persons are employed in any particular industry. There is, however, a rough consistency in the trend shown by these census data with that from the PMAC data. The census data for 1971

Table 5.3

Sales Promotion and Advertising Expenditures as a Percentage of Sales in the Pharmaceutical Industry: Canada, 1964-83

Year	Total Net Sales[a] ($000)	A + B[b] Total Promotion as % of Sales	A Total Advertising as % of Sales	B Pharmaceuticals Representation Expense as % of Sales
1964	107,784	26.3	10.6	15.7
1965	125,054	24.3	9.9	14.4
1966	160,066	23.7	9.9	13.8
1967	176,597	22.9	9.2	13.7
1968	189,854	21.3	8.4	12.9
1969	200,442	19.3	7.6	11.7
1970	223,917	18.6	7.5	11.1
1971	236,173	17.8	6.9	10.9
1972	268,601	16.0	6.4	9.6
1973	291,479	15.7	6.2	9.5
1974	345,315	15.8	6.1	9.7
1975	345,011	15.2	5.6	9.6
1976	441,588	15.5	5.9	9.6
1977	347,489	17.0	6.1	10.9
1978	545,131	14.9	5.6	9.3
1979	634,664	15.6	5.9	9.7
1980[c]	822,903	14.6	6.0	8.0
1981	995,421	15.4	6.5	8.9
1982	1,153,927	15.5	6.6	8.9
1983	1,250,449	16.7	7.5	9.2

[a] The size of Net Sales in any given year varies amongst other reasons according to the number of firms in the sample.

[b] Excludes in-house market administration.

[c] The largest sales increase recorded in recent times occurred in 1980.

Source: The Pharmaceutical Manufacturers Association of Canada, *The Pharmaceutical Industry and Ontario* (Ottawa: PMAC, 1978), p. 34, and for 1976-83, Mr. R. Everson, PMAC.

indicate that 17.8 per cent of the total labour force in pharmaceuticals and medicines was devoted to sales, whereas the PMAC data indicate the figure was 10.9 per cent. Since the salaries of sales persons are not generally less than those of production employees on average, it is clear that there are major differences in the definitions of sales labour force on the one hand and representation expense on the other. Startingly, the figure for overall promotion set out in Table 5.3 for 1971 is 17.8 per cent. This figure is precisely that found in the 1971 census for the relative size of the sales labour force.

With regard to the most recent five-year period for which data were available as assembled by the Commission from the annual reports of individual firms, the number of persons employed as sales persons is somewhat higher than the estimates that have been described above. The results of this survey of pharmaceutical firms as they pertain to relative sales promotion employment are presented in Table 5.4. For the 52 firms surveyed for 1979 to 1982 and for the 56 firms surveyed in 1983, the overall sales-weighted average ratio of sales personnel to total employed labour force was in the order of 32 per cent. Moreover, over the five years in question it has been slowly increasing from 31.8 per cent in 1979 to 33.9 per cent in 1983.

Much the same trend over these five years is revealed by the unweighted average of the sales to total labour force ratios. The unweighted average was 40.4 in 1979 and had risen to 43.5 by 1983.

The variation amongst these more than 50 pharmaceutical firms is exceedingly large. Even if the five firms with the lowest, and the five with the highest, ratios are excluded, some firms at the lower end (excluding the outriders) have a sales to total labour force ratio of just under 19 per cent; whereas at the upper end, again excluding the five outriders, some firms have a sales to total labour force ratio of 70 per cent or more. If ten outriders at the lower end and ten at the upper end are excluded, the range though narrowed is still large, extending from approximately 26 per cent to over 61 per cent.

Table 5.4

Ratio of Selling and Marketing Employees to Total Employees in Surveyed Pharmaceutical Firms: Canada, 1979-83

Year	# of Surveyed Firms	Sales-weighted Average Ratios of Selling Employees to Total Employees	Unweighted Average Ratios of Selling Employees to Total Employees
1983	56	33.9	43.5
1982	52	32.9	41.1
1981	52	32.4	41.0
1980	52	31.8	41.4
1979	52	31.8	40.4

A firm conclusion to be drawn from these several sources of information on the relative size of the sales labour force is that the leading 50 or more firms, and indeed the pharmaceutical industry in Canada, taken as a whole, are characterized by a heavy emphasis on sales promotion and marketing.

Expenditures on Advertising

A second approach to considering the degree to which pharmaceutical firms rely on sales promotion, marketing, and advertising is the consideration of advertising expenses as a percentage of net sales. Information gathered by the PMAC for 1964 to 1983 as presented in Table 5.3 above indicates the relative size and trend in such expenditures on advertising (such advertising costs do not include the major cost component of the salaries and support of detail persons and/or sales field forces). These advertising expenditures display a similar trend to those for expenditures on the sales field forces and, in general, are about two-thirds the level of expenditures on the sales field forces.

Comparative data on ratios of advertising expenditures to the value of factory shipments are presented in Table 5.5 not only for pharmaceuticals and medicines but also for selected other industries. Manufacturers of phar-

Table 5.5

Advertising Ratios in Manufacturing for Selected Industries: Canada, 1954 and 1965

	Ratio of Advertising Expenditures* to Value of Shipments	
	1954	1965
All Manufacturing	1.07	1.25
Chemicals and Chemical Products	3.24	3.85
Pharmaceuticals and Medicines	6.07	8.65
Soap and Cleaning Compounds	11.26	10.85
Toilet Preparations	15.86	15.22
Industrial Chemicals	—	.41
Miscellaneous Manufacturing	1.59	2.17
Scientific and Professional Equipment	1.32	2.06
Food and Beverages	1.62	2.03
Breweries	2.19	6.56
Distilleries	3.50	2.74
Soft Drink Manufacturers	—	8.20
Wineries	2.89	3.99
Breakfast Cereal Manufacturers	11.76	12.12
Tobacco: Tobacco Product Manufacturers	—	6.13

*Excludes expenditures on sales promotion.

Source: Statistics Canada, *Advertising Expenditures in Canada*, 1954 and 1965 (Catalogues 63-501 and 63-216).

maceuticals and medicines are characterized by fairly high advertising ratios in both 1954 and 1965. In fact, the advertising ratios are nearly six times higher than those for all manufacturing firms. At the same time, however, the advertising ratios for a few other industries, in particular for soap and cleaning compounds and breakfast cereals, are substantially higher. Nevertheless, it seems clear that advertising expenditures by manufacturers of pharmaceuticals and medicines in Canada were relatively high in 1954 and had become greater in absolute terms and relative to all manufacturing industries by 1965.

A further framework for considering the extent to which the pharmaceutical industry in Canada relies on advertising and sales promotion is provided indirectly by information on the cost of containers and packaging supplies as a percentage of the cost of all materials and supplies. Such information, presented in Table 5.6, reveals that the pharmaceutical industry is characterized by a fairly heavy reliance on containers and packaging supplies. For 1982 such supplies represented 16.8 per cent of the cost of all materials and supplies. The comparable figure for all manufacturing industries was 3.7 per cent and that for all chemicals was 6.4 per cent.

There are of course some industries in which containers and packaging supplies have a greater prominence. Such supplies represented 19.5 per cent of the cost of all materials and supplies used by soap and cleaning compound manufacturers and 49.9 per cent for manufacturers of toilet preparations.

The trend in the reliance on containers and packaging supplies by manufacturers of pharmaceuticals and medicines has, however, fallen quite steadily over the 15-year period considered in Table 5.6. In the late 1960s and early 1970s, containers and packaging supplies accounted for approximately a quarter of the cost of all materials and supplies used in this industry. Interestingly, this downward trend is characteristic of every industry considered in Table 5.6.

International Comparisons of Sales, Promotion, and Advertising Activities

International comparisons of the extent of sales, promotion, and advertising activities are characterized by difficulties in establishing common definitions of what constitutes a sales person, advertising expenditures, or overall sales promotion expenditures. In spite of these problems, some comparative information from various sources can be usefully examined.

Comparative information on the extent of sales promotion activities in several countries in the mid 1970s is presented in Table 5.7. Canada is seen to have one of the higher levels of sales promotion, but three countries have yet higher levels. Amongst the well-developed countries considered in Table 5.7, the United Kingdom is clearly in a league apart with sales promotion activities accounting for 15 per cent of total sales; this level is in the order of three-quarters of the level in the other well-developed countries.

Table 5.6

The Cost of Containers and Packaging Supplies as a Percentage of the Cost of All Materials and Supplies Used in Pharmaceuticals and Selected Industries: Canada, 1967-82

Year	All Manufacturing	All Chemicals	Pharmaceuticals	Soap and Cleaning Comp.	Toilet Preparations	Industrial Chemicals
1982	3.7	6.4	16.8	19.5	49.9	.7
1981	3.5	7.1	17.5	22.4	48.3	.9
1980	3.6	8.0	17.6	23.1	54.3	1.3
1979	3.5	8.3	16.3	23.1	55.4	1.5
1978	3.7	7.2	16.5	25.1	54.4	1.3
1977	3.9	9.6	18.2	27.2	56.9	1.8
1976	4.0	7.9	17.1	26.8	58.6	1.4
1975	4.0	10.4	18.2	24.1	55.2	1.9
1974	4.0	11.8	21.6	27.5	56.2	2.6
1973	4.2	13.3	22.5	30.8	56.7	3.0
1972	4.5	14.0	24.4	29.5	59.8	3.0
1971	4.7	14.0	24.6	28.4	59.0	3.0
1970	4.7	14.3	25.6	27.1	57.6	3.4
1969	4.5	14.5	25.7	29.3	60.5	3.6
1968	4.6	14.4	25.1	29.2	62.8	3.9
1967	4.6	14.0	24.4	29.0	62.9	4.1

Source: Statistics Canada, *Manufacturing Industries of Canada* (Catalogue 31-203).

Table 5.7

Promotional Expenditures as a Percentage of Total Sales in Selected Countries

Country	Percentage
United States	22
West Germany	22
Italy	22
Belgium	21
Canada	21
Australia	19
Sweden	18
India	18
France	17
Turkey	16
Indonesia	16
United Kingdom	15

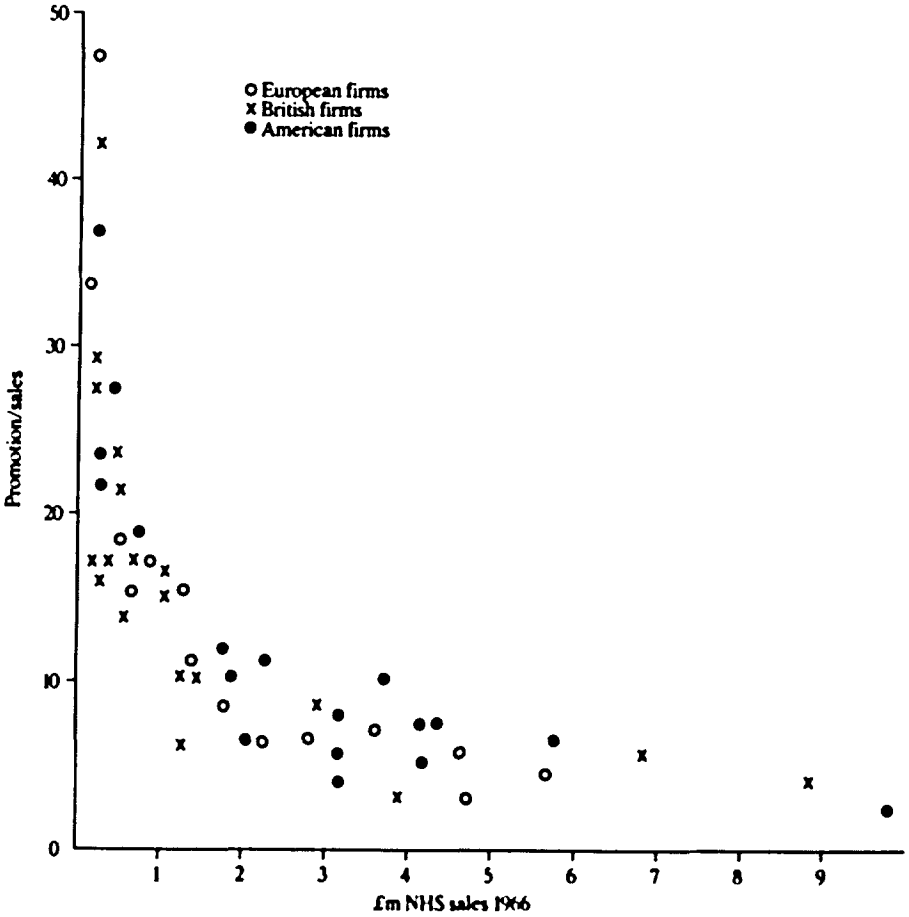
Source: S. Slatter, *Competition and Marketing Strategies in the Pharmaceutical Industry* (London: Croom Helm, 1977), p. 102.

Information on the relationship between size of firm and the level of sales promotion expenditure in the United Kingdom in 1966 is presented in Chart 5.1. The strong relationship between these two magnitudes is evident. The smallness of the Canadian market, especially as subdivided geographically, may well explain some part of the relatively high levels of sales promotion activities found in Canada. Other countries not geographically dispersed, however, have similarly high levels of advertising. Accordingly, other factors, such as very large numbers of competing products, must also be considered.

With respect to the United Kingdom, the Prescription Price Regulation Scheme (PPRS) includes a limitation on the extent to which sales promotion activities can be included in the statements of costs incurred by firms as part of the elaborate calculation of actual and target profit levels. Currently the

Chart 5.1

The Economics of the Pharmaceutical Industry in the U.K.
(Promotion to Sales Ratios Compared with Firm Size)



Source: Duncan Reekie, *The Economics of the Pharmaceutical Industry* (London: Methuen, 1975).

limitation on sales promotion expenditures is set at 10 per cent for all but the smallest firms. Against this background, information for 1981 indicates that sales promotion expenditures thus calculated were some 3 percentage points in excess of the 10 per cent limitation. This implicit level of sales promotion expenditures of approximately 13 per cent must be interpreted carefully because of the inherent incentives for individual firms to limit sales promotion expenditures for the purposes of accounting under the PPRS scheme.

Research and Development and New Products

The discussions of seller concentration and market share instability (Chapter 4) and sales promotion (above) lead naturally to a consideration of the sources of new products. This is especially so since the overall level of competition of the pharmaceutical industry seems to be a function of competition for market share through new product innovation and the sales promotion of existing products rather than through price competition on existing products.

Consideration is first given to the extent to which pharmaceutical firms direct resources towards research and development activities. Subsequently, an examination is made of the sources of new products in terms of whether they originate from firms which are already dominant in a particular therapeutic class or whether new product innovations come from firms either outside the class entirely or whose market shares are not that high.

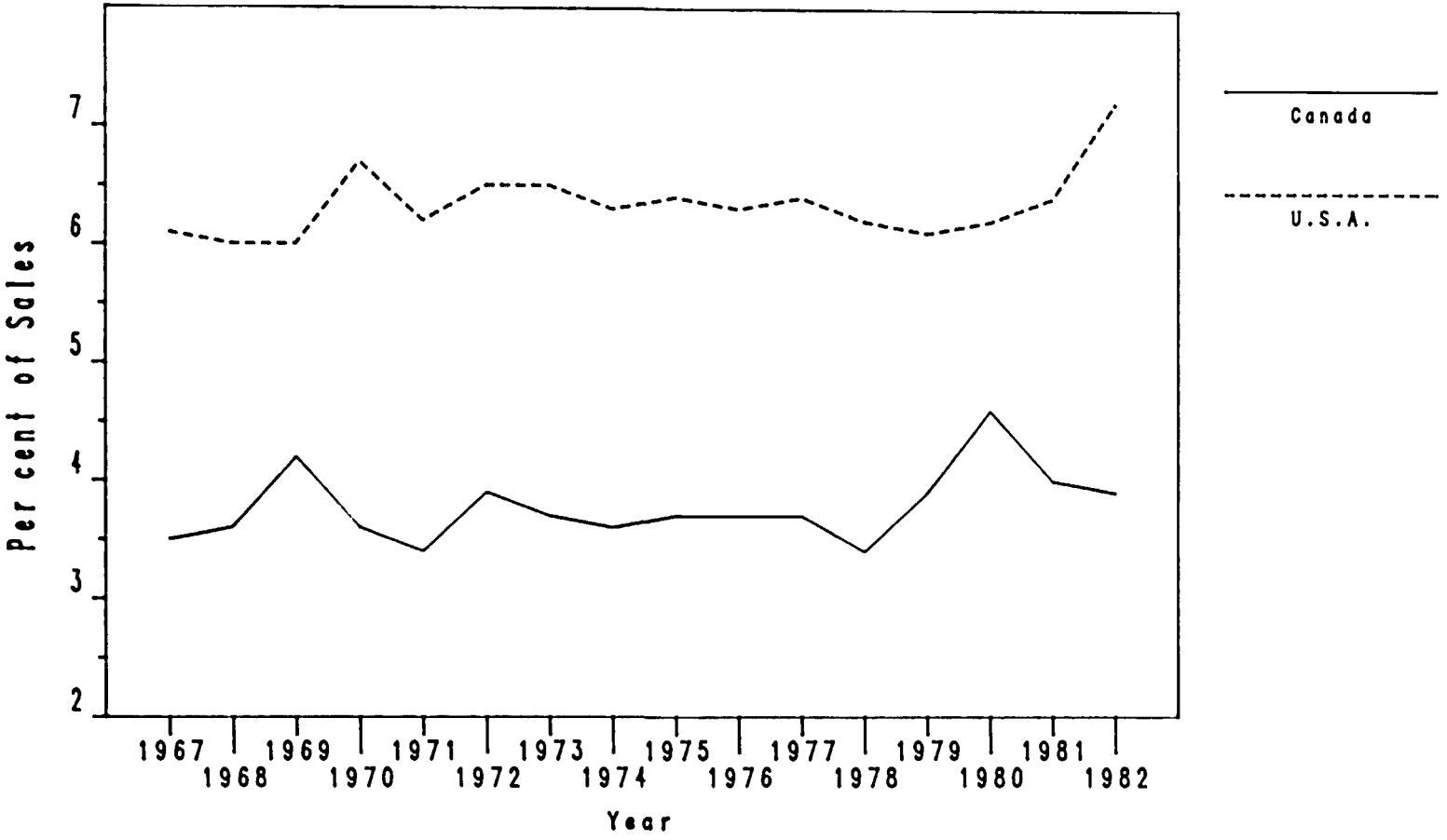
A third part of this section is devoted to a consideration of the judged therapeutic value of new product introductions. The classification of such introductions according to whether the drugs in question are thought to represent major therapeutic advances, modest therapeutic advances, or little or no therapeutic advance is important in evaluating whether expenditures on research and development are directed principally towards the maintenance of market shares or principally towards the discovery of a major new drug. In this latter instance, the ultimate outcome is of course enhanced market share for the firms responsible for discovery and introduction. At the same time, however, to the extent that the vast bulk of new drug introductions are classified as having little or no therapeutic advance over existing drugs, there would be support for the argument that research and development activities serve principally as a market strategy for the maintenance and/or enhancement of market shares rather than for the discovery of major new drugs.

Expenditures on Research and Development Relative to Sales

In Chapter 2, information was provided on the extent to which firms in Canada devote resources towards intramural research and development activities. These were set out in Chart 2.12 for the period 1967 to 1982. This information for Canada is juxtaposed with similar information for the United States in Chart 5.2.

Chart 5.2

Comparison of Research and Development Costs as a Percentage of Sales in the Pharmaceutical Industry: Canada and United States, 1967-82



Expenditures on research and development relative to sales in the United States are substantially higher than those characterizing the pharmaceutical industry in Canada. The ratio of these expenditures to sales in the United States is in the range of 6 to 7.2 per cent from 1967 to 1982. Moreover, this ratio, after remaining relatively stable for the first 14 years or so, begins to rise sharply in the last two years under consideration. This trend for the United States is thus somewhat dissimilar from that for Canada, for which the ratio is generally in the range of 3.5 to 4.5 per cent. It is also fairly stable over much of the period. However, for the last three years under consideration it actually falls rather than rises as does the United States ratio.

Though these data for the United States have been collected systematically for more than two decades and are comparable with similar data for other manufacturing industries in the United States as well as with Canadian data, they may underestimate the magnitude of research and development. This results from the methodology used to assemble the data. Corporations, rather than the individual establishments of the company, are assigned to an industry. Research and development expenditures and sales for firms in the pharmaceutical industry thus include total company activities. Since research and development activities are generally larger in the pharmaceutical divisions, overall ratios of research and development expenditures to sales underestimate the relative size of these in the pharmaceutical industry.

Data available from the Pharmaceutical Manufacturers Association in the United States (PMA) confirm the trend revealed by the data summarized in Chart 5.2. After being in the range of 10.3 to 12.1 per cent from 1965 to 1981, the ratio of research and development expenditures to sales rises sharply in the last three years: from 12.1 in 1981, to 13.8 in 1982, and 14.4 per cent in 1983.

In order to use these PMA data for comparative purposes, it is necessary to adjust them in order to account for foreign sales. Since U.S. domestic sales by the companies surveyed were in the order of $15 billion while global sales were some $25.6 billion in 1982, the ratio of 13.8 per cent referred to above should properly be adjusted downwards to 8.1 per cent. When this is done, the estimate of 7.2 per cent implicit in Chart 5.2 for 1982 is seen to be too low, but yet not as low as appears initially to be the case.

Information for the United Kingdom on research and development expenditures related to ethical drugs (prescribed, over-the-counter, and veterinary medicine) and on sales, both under the auspices of the NHS and also exports, is available for selected years since 1953.[1] In that year the ratio of research and development expenditures to sales was 3.4 per cent; it rose to 5.1 per cent in 1960, to 7.9 per cent in 1970, to 9.5 per cent in 1975, and to 13.6 per cent in 1980. This explosive rise in the magnitude of research and development activities is no doubt strongly associated both with the substantial incentives to investing and carrying out research in the United Kingdom that

[1] *Scrip*, "The Pharmaceutical Market in the United Kingdom" (February, 1982).

are central to the Prescription Price Regulation Scheme (PPRS) in that country and also with the entrance of the United Kingdom into the European Economic Community.

Information on the size of research and development expenditures for the three major Swiss pharmaceutical companies is available from their annual reports.[2] For Hoffmann-La Roche, the ratio of the entire company's research and development expenditures to sales was 13.0 per cent in 1982 and 13.2 per cent in 1983. Pharmaceuticals accounted for 41.8 per cent of this company's total sales in 1983. For Ciba-Geigy, the ratio of group research and development expenditures to group sales was in the range of 7.5 to 8.5 per cent from 1974 to 1983. It was at a peak of 8.5 per cent in 1978, 1982, and 1983. Pharmaceuticals accounted for approximately 30 per cent of Ciba-Geigy's total sales in 1983. For Sandoz, the research and development expenditures to sales ratio for the group has been 8 to 9 per cent since 1974. It was 8 per cent in 1983 and in the preceding three years. Pharmaceuticals accounted for 47 per cent of the Sandoz group's sales in both 1982 and 1983.

Information for 20 of the largest Japanese companies for 1983 and 1984 indicates that the research and development to sales ratio was 8.3 per cent.[3] Similarly, information on a sample of companies in West Germany indicates that the research and development to sales ratio was 12.4 per cent in 1979.[4] In Italy the ratio was 6.4 per cent in 1983.[5]

Information for several other countries on the ratio of research and development expenditures to sales is available in a recent publication from *Scrip* entitled *Pharmaceutical Companies: League Tables, 1982-83.* Briefly, the ratio of research and development expenditures to total sales for 65 companies (a combination of firms that are wholly pharmaceutical and the pharmaceutical divisions of more broadly based companies) is 11.5 per cent. The corresponding ratio for 118 pharmaceutical firms for which only overall company data were available was 5.1 per cent. The sales-weighted average ratio for the entire 183 companies was 5.6 per cent. Once again, the effect of combining the research and development expenditures and sales of all divisions of a company is to reduce the estimate of the relative size of research and development.

With respect to several major firms for which information was also available for their pharmaceutical divisions and for all product divisions combined, the ratio for the pharmaceutical division was not in every case greater than that for the overall company. Indeed, for E. Merck, B. Ingelheim, and Lek the ratio for the pharmaceutical division was actually less than that for the overall company. For other companies, these ratios were similar. In

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[2] Annual reports, 1983, for Ciba-Geigy, Hoffmann-La Roche, and Sandoz

[3] *Scrip*, No. 914 (July 16, 1984), p. 16.

[4] Pharmaceutical Manufacturers' Trade Association of the Federal Republic of Germany. *Pharmadata 1983.*

[5] *Scrip*, No. 945 (October 31, 1984), p. 9.

general, however, the ratio for the pharmaceutical division was substantially in excess of that for the overall company.

Though the degree to which pharmaceutical firms allocate resources to research and development activities differs significantly from one country to another, it seems clear that these expenditures are substantially higher in the five countries in which the vast majority of the world's leading pharmaceutical firms are headquartered than is the case for Canada. The levels found in Canada are similar to those found in several other countries that are roughly similar in size and have roughly similar standards of living but whose economies do not include significant activities by home-based pharmaceutical firms. There are of course yet other countries with substantial markets for pharmaceuticals and medicines in which there is substantially less research and development than is currently carried out in Canada.

With regard to the ratio of research and development expenditures to sales throughout the world, information from disparate sources for a variety of firms and countries suggests that the ratio is probably in the order of 6 per cent. As discussed above, for the leading countries it is substantially higher than 6 per cent. In the United States it is 7.2 to 8.1 per cent. In the United Kingdom it is some 13 to 14 per cent. In West Germany it is approximately 12.4 per cent; in Japan it is 8.3 per cent; in Switzerland 9.5 per cent; and in Italy 6.4 per cent.

Given the substantial role of U.S.-owned firms in the Canadian market and the smaller but significant role of firms from the United Kingdom, Switzerland, and West Germany, a reasonable sales-weighted estimate of the level of research and development expenditures associated with the sales of pharmaceuticals and medicines in Canada is 10 per cent. In other words, the firms whose sales constitute the market in Canada appear to spend on average some 10 per cent of their world-wide sales on research activities. These activities are predominantly located in the home country of the firm or in one of the four countries mentioned above.

A ratio as high as even 6 per cent would nevertheless indicate that the pharmaceutical industry, world-wide, had one of the highest levels of research and development activity of any industry. Similarly, the ratio of 4 per cent in Canada indicates that the pharmaceutical industry in Canada has a relatively high allocation of resources to research and development.

Sources of New Pharmaceutical Products

This part considers the role played by currently dominant firms in a therapeutic class in introducing new products to this class. Whether such firms are the principal sources of new products or not should help clarify the extent to which dominant firms employ research and development strategies and the introduction of new products as a method of reinforcing and enhancing their market share. At the same time, to the extent that this is so, it may also shed light on the nature and extent of the specialization of pharmaceutical firms in

the production and sale of a particular class of pharmaceutical products and thereby the extent and possible impact of specialization in research and development activities.

Set out in Table 5.8 are the results of an analysis of the source of new products in each of 14 therapeutic classes and for the total ethical market for the period 1964 to 1975 and for each of two sub-periods, 1964-69 and 1970-75. The new products introduced on the market in each of these therapeutic classes are classified according to whether they came from one of the top ten firms already in the class, came from any firm already producing a drug in the class, or came from firms that at the beginning of the period did not produce any drug in the class.

With regard to ethical analgesics, some 42 drugs were introduced within the 12-year period. Of these, 31 per cent were introduced by firms that ranked in the top ten in the therapeutic class in 1964, 62 per cent by all firms producing a drug in the class, and 38 per cent by firms that were not producing in the therapeutic class in 1964.

Though there is a fairly wide variation in the percentage of new drugs introduced by the top ten firms of a particular therapeutic class, on average just under 50 per cent of new drugs seem to come from such firms. Some 70 per cent or so of new products come from firms that are already selling in the particular therapeutic class. Lastly, just over 30 per cent of new product innovations come from firms that were not producing for sale in the particular therapeutic class at the beginning of the period.

Therapeutic classes in which existing firms appear to have been the principal sources of new products include hematinics and nutrients. In contrast, classes in which new drugs more commonly are introduced by firms outside the therapeutic class at the start of the period include other hypotensives and oral and other penicillins.

This same information is recast in terms of the rank of firms in the final year of the overall period and each of the two sub-periods. The results presented in Table 5.9 are similar to those described above with the exception that a larger percentage of the products are seen to originate from firms inside a class. This is to be expected. Being in, and having a particular rank in, the class is determined by information on the final year of each period after successful product introductions have occurred rather than by the situation at the beginning of the period.

This information on the sources of new product introductions is suggestive of a fairly high degree of competition coming both from firms already in a particular therapeutic class but not amongst the leading ten firms judged by sales and also from firms not in the particular therapeutic class. There is also information that is consistent with the view that at least with respect to some therapeutic classes there may well be specialization in research and development activities such that new product introductions are more likely to come from leading firms already in the class rather than from other firms.

Table 5.8

Source of New Products in the Ethical Drug Market by Major Therapeutic Class and by Rank of the Initial Year: Canada, Selected Periods, 1964-69, 1970-75, and 1964-75

Therapeutic Class	1964-69				1970-75				1964-75			
	No. of New Products	% by Top Ten* Firms in Class	% by All Firms in Class	% by Firms Outside Class	No. of New Products	% by Top Ten* Firms in Class	% by All Firms in Class	% by Firms Outside Class	No. of New Products	% by Top Ten* Firms in Class	% by All Firms in Class	% by Firms Outside Class
Ethical analgesics	25	28	52	48	17	35	82	18	42	31	62	38
Antibiotics: broad and medium spectrum	23	48	52	48	29	55	69	31	52	46	56	44
Antibiotics: oral and other penicillins	11	64	64	36	14	57	71	29	25	48	48	52
Ataractics	27	48	70	30	25	28	68	32	52	38	62	38
Bronchial dilators	20	45	65	35	9	56	78	22	29	34	55	45
Ethical cough and cold preparations	27	52	74	26	27	59	70	30	54	39	61	39
Hematinics	11	64	100	0	10	30	70	30	21	48	76	24
Sex hormones	28	43	61	39	15	60	80	20	43	44	60	40
Hormones: plain corticoid	18	67	72	28	18	56	67	33	36	61	64	36
Hormones: corticoid combinations	28	36	68	32	6	67	67	33	34	35	68	32
Other hypotensives	2	50	50	50	6	17	83	83	8	25	25	75
Ethical laxatives	7	71	86	14	9	22	56	44	16	44	63	37
Vitamins	26	35	81	19	27	30	59	41	53	36	68	32
Nutrients	14	71	79	21	12	83	83	17	26	69	73	27
Total	267	48	69	31	224	47	69	31	491	47	69	31

* Ranked according to order in the first year of the period in question.

Source: IMS Canada.

Table 5.9

Source of New Products in the Ethical Drug Market by Major Therapeutic Class and by Rank of Firm in the Final Year: Canada, Selected Periods, 1964-70, 1970-75, and 1964-75

Therapeutic Class	1964-69				1970-75				1964-75			
	No. of New Products	% by Top Ten* Firms in Class	% by All Firms in Class	% by Firms Outside Class	No. of New Products	% by Top Ten* Firms in Class	% by All Firms in Class	% by Firms Outside Class	No. of New Products	% by Top Ten* Firms in Class	% by All Firms in Class	% by Firms Outside Class
Ethical analgesics	25	48	88	12	17	47	88	12	42	40	83	17
Antibiotics: broad and medium spectrum	23	39	70	30	29	59	90	10	52	44	75	25
Antibiotics: oral and other penicillins	11	73	100	0	14	64	93	7	25	60	84	16
Ataractics	27	56	85	15	25	40	76	24	52	44	67	33
Bronchial dilators	20	60	100	0	9	36	67	33	29	52	72	28
Ethical cough and cold preparations	27	52	81	19	27	63	78	22	34	57	72	28
Hematinics	11	64	100	0	10	60	90	10	21	62	95	5
Sex hormones	28	71	93	7	15	80	100	0	43	63	91	9
Hormones: plain corticoid	18	67	78	22	18	61	89	11	36	64	81	10
Hormones: corticoid combinations	28	29	86	14	6	83	83	17	34	44	79	21
Other hypotensives	2	50	50	50	6	100	100	0	8	88	88	22
Ethical laxatives	7	71	71	29	9	33	100	0	16	38	81	19
Vitamins	26	42	92	8	27	22	74	26	53	25	77	23
Nutrients	14	64	93	7	12	92	100	0	26	73	88	12
Total	267	54	87	13	224	56	86	14	491	50	79	21

* Ranked according to order in the first year of the period.

Source: IMS Canada.

Information on the extent to which a few of the largest world-wide pharmaceutical firms account for the lion's share of new products introduced is presented in Table 5.10. Several major companies in terms of sales (as indicated by the data presented above in Table 4.11) are also characterized by high levels of involvement in research and development as is clearly shown by the number of new drugs currently being researched. For example, nine of the top ten companies in terms of their share of world markets are also in the top ten in the world in terms of the number of drugs under development. As a general proposition, the relationship between share of market and involvement in developing new drugs is a positive and close relationship. There are, however, some exceptions. Some firms have a relatively high ranking in terms of market share but have a significantly lower ranking in terms of their involvement in the development of new drugs. In quite the opposite way, some firms appear to have a disproportionately heavy involvement in research and development activities as shown by the number of new drugs under development, but less success in terms of their share of the world market. The rankings must of course be interpreted with care. As discussed above, research and development activities may be directed towards a large number of drugs similar to ones already on the market, that is, to "me-too" drugs. Thus, a company that concentrated on a small number of potentially major new drugs should be judged to have a higher commitment to worthwhile research. The rankings contained in Table 5.10 do not permit evaluation of this matter.

With regard to the source of new drugs by country, the information presented in Table 5.11 indicates that new chemical entities appear to come disproportionately from some ten countries. These ten countries accounted for 2,987 new products or 83.5 per cent of all the new products being developed in 1984. The United States, Japan, West Germany, France, Italy, Switzerland, and the United Kingdom clearly had the dominant position in terms of the number of new products under development.

Much the same result holds when the sources by country of all new single-product chemicals are evaluated for the years 1940 to 1977 as shown by the information presented in Table 5.12. With the United States the overwhelming leader with 53.4 per cent of such new chemicals, the remaining leading countries are the same as for the 1984 picture presented in Table 5.11. Interestingly, the dominant position of the United States has declined while the position of Japan has risen dramatically.

Therapeutic Value of New Pharmaceuticals and Medicines

An indication of the flow of new products onto the Canadian market for pharmaceuticals and medicines is available from IMS Canada. Of $60 million of sales of new products in 1984, an estimated $14.2 million were for drugs that represented new chemical entities and the remaining $45.8 million were for product line extensions (as in new formulations, new dosage strengths, and new package sizes) and for new generic brands. Though the flow of new

Table 5.10

The Leading Pharmaceutical Companies Ranked by Number of New Drugs Under Development: The World, 1981 and 1982

Mkt. Share Rank 1982	New Drug Rank 1982	New Drug Rank (1981)	Company	No. of R&D Drugs	No. of Own Develop.	No. Under Licence
9	1	(1)	Roche	100	84	16
10	2	(2)	Bristol-Myers	82	44	38
3	3	(7)	Hoechst	73	63	10
1	4	(3)	Merck & Co.	72	57	15
4	5	(5)	American Home Prod.	66	52	14
15	6	(4)	Upjohn	64	54	10
8	7	(8)	J & J	56	50	6
7	8	(9)	Lilly	56	48	8
2	9	(26)	Ciba-Geigy	49	36	13
	10	(6)	Roussel Uclaf	48	24	24
			Subtotal: top 10	666(18.9%)	512(18.5%)	154(20.3%)
11	11	(15)	Sandoz	47	40	7
12	12	(10)	Boehringer Ing.	45	39	6
	13	(20)	Rhône-Poulenc	43	28	15
14	14	(13)	Bayer	42	36	6
	15	(14)	Schering-Plough	42	33	9
	16	(12)	Meiji Seika	42	32	10
	17	(16)	Dow Chemical	41	34	7
18	18	(19)	Takeda	41	33	8
13	19	(17)	Warner-Lambert	41	27	14
20	20	(18)	Beecham	40	36	4
			Subtotal: top 20	1090(30.9%)	850(30.7%)	240(31.7%)
5	21	(21)	SmithKline	40	29	11
6	22	(11)	Pfizer	38	32	6
	23	(28)	Syntex	36	32	4
	24	(25)	Farmitalia C-E	34	32	2
	25	(31)	Sterling Drug	34	31	3
16	26	(33)	Schering AG	34	26	8
	27	(24)	Kyowa Hakko	33	27	6
	28	(29)	Wellcome	32	28	4
	29	(27)	Fujisawa	32	24	8
19	30	(43)	Squibb	30	26	4
			Subtotal: top 30	1433(40.7%)	1137(41.1%)	296(39.1%)
	31	(22)	Astra	29	24	5
	32	(34)	Akzo Pharma	26	25	1
	33	(32)	Sankyo	26	22	4
	34	(30)	Sanofi	26	22	4
21	35	(37)	Amer Cyanamid	25	22	3
	36	(36)	Banyu Pharma	24	9	15
	37	(51)	Degussa	22	18	4
	38	(62)	Green Cross	22	12	10
24	39	(66)	ICI	21	17	4
	40	(46)	Yamanouchi	21	14	7
			Subtotal: top 40	1675(47.5%)	1322(47.8%)	353(46.6%)
17	41	(23)	Abbott	21	10	11
25	42	(63)	G D Searle	21	10	11
	43	(55)	Boehringer Man.	20	13	7
	44	(42)	Glaxo	19	18	1
	45	(58)	BASF	19	17	2
	46	(41)	Tanabe Seiyaku	19	17	2
	47	(40)	Yoshitomi	19	17	2
	48	(64)	Chugai	19	16	3
	49	(56)	Ono	19	15	4
	50	(65)	Teijin	18	14	4
			Subtotal: top 50	1869(53.0%)	1469(53.1%)	400(52.8%)

Table 5.10 (continued)

The Leading Pharmaceutical Companies Ranked by Number of New Drugs Under Development: The World, 1981 and 1982

Mkt. Share Rank 1982	New Drug Rank 1982	New Drug Rank (1981)	Company	No. of R&D Drugs	No. of Own Develop.	No. Under Licence
	17	(67)	SRI Internat.	17	16	1
	52	(38)	Daiichi Seiyaku	17	14	3
	53	(49)	E. Merck	17	12	5
	54	(61)	Otsuka	17	10	7
	55	(35)	Dainippon	17	9	8
	56	(45)	Shionogi	17	8	9
	57	(48)	Kaken Pharma	16	12	4
	58	(44)	Morton-Norwich	16	11	5
	59	(52)	Ajinomoto	16	9	7
	60	(50)	Chinoin	15	15	0
			Subtotal: top 60	2034(57.7%)	1585(57.3%)	449(59.3%)
	61	(85)	Byk Gulden	15	12	3
	62	(39)	Sumitomo	15	11	4
	63	(74)	Revlon	15	8	7
	64	(54)	A.H. Robins	14	12	2
	65	(77)	Solvay	14	12	2
	66	(60)	ISF	14	11	3
	67	(53)	Eisai	14	9	5
	68	(89)	Mochida	14	6	8
	69	(71)	Elan	13	13	0
	70	(84)	SISA	13	13	0
			Subtotal: top 70	2175(61.7%)	1692(61.1%)	483(63.8%)
	71	(83)	Pharmuka	13	12	1
	72	(68)	Taisho	13	11	2
	73	(47)	Sanraku Ocean	13	10	3
	74	(73)	Mitsubishi Chem.	13	5	8
	75	(-)	Alza	12	12	0
	76	(82)	Asahi Chemical	12	12	0
	77	(-)	Genentech	12	12	0
	78	(69)	Pierre Fabre	12	10	2
	79	(72)	Richter	12	10	2
	80	(-)	Kanebo	12	9	3
			Subtotal: top 80	2299(65.2%)	1795(64.9%)	504(66.6%)
	81	(-)	Kay Pharma	12	8	4
	82	(70)	Toyo Jozo	12	8	4
	83	(88)	Mitsubishi Yuka	12	5	7
	84	(-)	Angelini	11	11	0
	85	(-)	KV Pharma	11	11	0
	86	(-)	Rotta Research	11	11	0
	87	(75)	Servier	11	11	0
	88	(-)	Ausonia	11	10	1
	89	(76)	Delalande	11	10	1
	90	(96)	Sigma Tau	11	8	3
			Subtotal: top 90	2412(68.4%)	1888(68.2%)	524(69.2%)
	91	(91)	Selvi	10	10	0
	92	(78)	Du Pont	10	9	1
	93	(80)	Reckitt & Colman	10	9	1
	94	(59)	Synthelabo	10	9	1
	95	(81)	Nippon Kayaku	9	6	3
	96	(-)	Crinos	9	5	4
	97	(-)	Institut Pasteur	9	5	4
	98	(-)	Adria	9	3	6
	99	(98)	Grunenthal	9	3	6
	100	(57)	UCB	9	2	7
			Total: top 100	2506(71.7%)	1949(70.4%)	557(73.6%)

Source: *Scrip*, Nos. 755, 756 (December 20, 22, 1982), p. 23.

Table 5.11

Country of Origin of New Chemical Entities Under Development: 10 Leading Countries, 1984

Country	No. of Products	% Dist.	No. of Originating Companies
U.S.	1,013	33.9	97
Japan	619	20.7	94
West Germany	321	10.7	31
France	248	8.3	30
Italy	232	7.8	54
Switzerland	203	6.8	13
U.K.	187	6.3	11
Sweden	60	2.0	7
Hungary	55	1.8	5
Spain	49	1.6	20
Subtotal	2,987	100.0	

Source: *Scrip*, No. 959 (December 19, 1984), p. 40.

chemical entities, estimated to be 15 in number, seems high, it accounted for only a small percentage of the total number of pharmaceuticals and medicines being sold in Canada and in value accounted for less than 1 per cent of total sales.

Unfortunately, there is no readily available source by which all the drugs that have been introduced into the Canadian market can be systematically evaluated according to whether they represent a major therapeutic gain or whether they represent little more than an altered package size or formulation of an existing product with little or no increased benefits to the patient.

Limited information of this kind is, however, available for the United States, the United Kingdom, Norway, and a number of other countries. Presented in Table 5.13, for example, is information for the United States on the classification of new drug introductions in both 1982 and 1984 according to whether they represented a "significant therapeutic advantage," a "modest therapeutic gain," or "little or no therapeutic gain over existing products." As is clearly indicated, the majority of new chemical entities approved in both 1982 and 1984 were judged to have little or no therapeutic gain over existing products. Indeed, only six of the 50 drugs approved in both 1982 and 1984 were expected to represent significant therapeutic gain.

Information on the distribution of applications for investigational new drug status (IND applications) on file at the end of 1982 in the Federal Drug Administration in the United States indicated that by far the overwhelming percentage, some 87 per cent, or 802 of the 902 such applications, were for drugs that were judged to have little or no likely therapeutic gain. Only 23 drugs, or 2.5 per cent of the total, were thought to represent potential significant therapeutic gains.

Table 5.12

Distribution by Country of New Single Chemical Products Introduced, 1940-77

Rank	Country	Total Number of Products	Percentage of Total
1	United States	658.5	53.36
2	West Germany	84.0	6.80
3	Switzerland	78.0	6.33
4	France	70.0	5.67
5	United Kingdom	62.0	5.02
6	Japan	46.0	3.73
7	Italy	34.0	2.75
8	Denmark	18.5	1.50
9	Sweden	18.0	1.46
10	Belgium	16.0	1.30
11	Holland	11.0	0.90
12	Mexico	11.0	0.90
13	Austria	6.0	0.48
14	Hungary	4.0	0.32
15	Canada	3.0	0.24
16	Czechoslovakia	1.5	0.12
17	Argentina	1.0	0.08
18	Australia	1.0	0.08
19	India	1.0	0.08
20	Poland	1.0	0.08
	Other	108.5	8.80
	Total	1,234.0	100.00

Note: Sometimes credit for introduction of a new product may be divided between two countries. Total number of products includes credit attributed to a country for developing products in other countries. Total number of new products differs from deHaen listing as this includes biological products as well, and in some cases there was a difference in actual count.

A similar evaluation of applications for product licences in the United Kingdom was carried out by J.P. Griffin and G.E. Diggele.[6] For 103 such applications made between 1973 and 1977, four were judged to be "fully innovative," 32 were judged to be "semi-innovative," and 67 were judged to be "non-innovative."

Several other countries not only classify drugs in this way but also refuse to give approval for the introduction of a new pharmaceutical or medicine on the basis of the judged need for the product given the existence of substitute products already on the market. For example, in 1982, Norwegian authorities refused to approve 30 products for human use. Of these, 18 were rejected on the "need" clause.

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[6] J.P. Griffin and G.E. Diggele, "A Survey of Products Licensed in the United Kingdom from 1971-1981," *British Journal of Clinical Pharmacology*, Volume 12 (1981), pp. 453-63.

Table 5.13

Estimated Therapeutic Value of New Chemical Entities Approved and IND Applications on File: United States, 1982 and 1984

Category	New Chemical Entities Approved				IND Applications for New Molecular Entities on File at the End of 1982	
	1982		1984			
	No.	%	No.	%	No.	%
A-Significant therapeutic gain	4	14.3	2	9.1	23	2.5
B-Modest therapeutic gain	5	17.9	8	36.4	97	10.5
C-Little or no therapeutic gain	19	67.9	12	54.5	802	87.0
Total	28	100.0	22	100.0	922	100.0

Source: *Scrip*, No. 763 (January 26, 1983), p. 10 and No. 969 (January 30, 1985), p. 22.

Tackling the problem from a somewhat different angle is the use of selective or negative lists in several Scandinavian and European countries. Such lists are used currently in many of these countries and are proposed for use in still others. They effectively reduce by up to a half or more the number of pharmaceuticals and medicines for which the government or non-profit voluntary sickness funds will be responsible for reimbursement.

Though information on the judged therapeutic value of the various pharmaceuticals and medicines that are currently sold in Canada, especially with respect to those that are being newly introduced into the Canadian market, is not readily available, the world-wide nature of the pharmaceutical market suggests that the experience of these other countries probably characterizes the Canadian market. This experience suggests that a substantial proportion of the outcome of research and development activities is the production of a pharmaceutical or medicine whose therapeutic value is not significantly better than existing products on the market.

If it were the case that such "like" products could be brought to the market to compete with existing products at little or no cost for research and development, the existence of these products would be supportive of a competitive market. On the other hand, it is not clear that the development and introduction of such new products, which are very little different from existing products, can be accomplished at costs any lower than the costs of inventing and introducing a new drug that represents a major therapeutic advance.

In spite of the fact that the majority of new drug introductions are of little or no therapeutic value over and above that of existing drugs, some existing and new drugs do indeed represent major therapeutic advances. The value of some of these, though difficult to quantify completely, is generally thought to be enormous. Attributing the decline in a particular illness to the introduction of a particular drug or class of drugs is difficult because many factors influence the health of individuals, including factors not directly related to the health care sector, and because many illnesses affect a population in a cyclical fashion that may be as long as several years or even decades. At the very least, however, it is worth briefly describing the strong associations that exist and that many hold to be causal between drugs and the incidence and severity of diseases over the past several decades.

Notifiable, Communicable Diseases. The decline in the severity of scarlet fever and streptoccal sore throat is strongly associated with the introduction of sulfa drugs and antibiotics. The incidence of these diseases has declined considerably, and death as a result of them has all but disappeared. Much the same picture describes tuberculosis. Though the pasteurization of milk appears to have been a major factor in reducing its incidence, the decline in deaths is likely very much a function of the introduction of drugs such as streptomycin, para-amino-salicylic acid, and isoniazid.

Venereal disease represents yet another example of the major success of drug therapy. In this case, while the incidence has actually increased significantly (presumably as a result of changes in lifestyle), the death rate per population unit and per case have fallen dramatically and become negligible. Drugs such as salvasan and penicillin must be given most of the credit.

The advent of vaccines and antibiotics must similarly be given much of the credit for the decline in the severity of diseases such as diptheria, typhoid and para-typhoid fever, and whooping cough. Moreover, prevention has also been facilitated by these drugs and thus incidence of these diseases has also declined dramatically.

Perhaps the best example of how the discovery and use of drugs has prevented a disease is the case of poliomyelitis. The introduction of the Salk and Sabin vaccines has made it possible to prevent almost every case of polio. Prevention can now be almost complete if the population is prepared to make use of the vaccines at the appropriate time.

Mental Health. The association of prescribed drugs and the decline in the percentage of the population institutionalized in order to be treated for mental ill health yields more ambiguous results. It appears that drugs such as chlorpromazine and reserpine have indeed made it possible to treat substantial and significant groups of the mentally unwell on an ambulatory rather than institutionalized basis. Direct mental hospital costs fall sharply at least in the first instance. However, these changes are so recent that it is not yet possible to judge the full impact on the long-term mental health of those so treated.

Respiratory Diseases. Associated with antibiotics is yet another major success. Influenza and pneumonia, though still serious diseases, are characterized by steadily falling death rates since 1950. The same is true of respiratory diseases taken together.[7]

Hypertension. The death rate from hypertension without mention of heart disease has fallen dramatically since 1950. Again this can be associated with the introduction of drugs such as hexamthonium, hydralazine, rauwolfia, and methylopa.

Heart Disease. Of the major causes of death, heart disease stands out for two reasons. It is the most frequent and it has been declining steadily over the last two decades.[8] It constrasts with cancer and accidents for which the age-standardized death rate is either increasing (cancer) or remaining relatively stable (accidents). Cardiovascular drugs, especially those described as "beta blockers," are said to play a prominant role in reducing deaths from heart disease.

The flip side of falling death rates is increased life expectancy. Since deaths from heart disease constitute such a major portion of total deaths, a reduction in them translates directly into increased life expectancies. Information on increasing life expectancies,[9] which since 1956 at least have been positively associated with age, can be roughly correlated with the use of drugs such as cardiovasculars. These, as indicated by Table 3.11 in Chapter 3, are utilized heavily by persons over 45 years and especially by those over 65 years.

Negative Outcomes

As with almost every health good and service, some risk is associated with the use of drugs including those that represent major therapeutic advances. Almost every well-developed country has some system of reporting adverse drug reactions for both new and existing products. These are usually known in the case of existing drugs to be inherent in the (widespread) use of the drug and accepted because the expected benefits are sufficiently positive on average to offset them. In the case of new drugs, adverse drug reactions are monitored and as the information on them increases, changes may be made in the way in which the drug is described and/or the diseases for which it is indicated.

In addition to adverse drug reactions, there are the misadventures associated with the process of delivering a manufactured drug through to use by the ultimate consumer/patient. The best-publicized of these are errors in administering drugs in the hospital setting. Besides improved procedures in

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[7] See Appendix Table A5.1.

[8] See Appendix Table A5.1.

[9] See Appendix Tables A5.1 (males) and A5.3 (females) for information on life expectancy at various ages for selected years 1956 to 1981.

hospitals, packaging and labelling by the manufacturer are potentially important avenues for avoiding these "misadventures."

Vertical and Horizontal Integration

The discussion in Chapter 4 on market share instability and the reliance on the sales of one or a few products, and that above on the nature of research and development activities, leads to an expectation that individual firms may well succeed only if they are able to spread their risks. This spreading of risks can take a number of forms. In particular, it can involve a type of geographic horizontal integration such that a given pharmaceutical firm attempts more or less to blanket the world market with divisions or subsidiaries of the parent firm. Horizontal integration can also be of a kind that involves the firm in producing a variety of products other than pharmaceuticals in an effort to diversify its activities. The risk of the varied processes of discovering, developing, and ultimately introducing new products also provides a strong incentive in pharmaceutical firms to integrate vertically. Similarly, the nature of the ultimate market and the instability inherent in the sometimes volatile demand for a particular product may provide yet an additional incentive for firms to integrate over a wide variety of activities.

Geographic Horizontal Integration

The growth and development of the world-wide pharmaceutical industry is very much characterized by multinational pharmaceutical and related corporations that have a large number of subsidiaries throughout the world. Presented in Table 5.14 is information on 58 of the world's largest pharmaceutical firms ranked in order of their sales of pharmaceutical products in 1975. Taken together these firms accounted for just over 60 per cent of world-wide sales of pharmaceuticals in 1975. These firms, with headquarters principally in the United States, the United Kingdom, West Germany, Japan, Switzerland, and France, are recognized firms in almost every well-developed country and many developing countries throughout the world. Approximately 40 of these 58 firms are amongst the leading pharmaceutical firms in Canada.

Another way of considering the impact of these multinational pharmaceutical firms is to consider information on the percentage of output in several countries that is accounted for by domestic firms. Such information, as presented in Table 5.15, reveals that the percentage of output accounted for by domestic firms is fairly high in countries such as the United States, West Germany, Japan, Switzerland, and France. These are countries that have a disproportionately large number of the world's major pharmaceutical firms headquartered in their countries. In the 25 countries listed, however, 17 have less than 50 per cent of the domestic market supplied by domestically-owned firms. Indeed, in 11 of the 25 countries the share of the domestic market held by domestically-owned firms is 25 per cent or less.

Quite clearly the geographic integration of pharmaceutical firms is quite high.

Table 5.14

Size and Origin of Leading Multinational Pharmaceutical Companies

Rank 1975	Firm	Origin	Total Group Sales ($ U.S. Millions) 1975	1976	1977	1978	1979	1980	1981	Pharmaceutical Sales as % of Total Group Sales 1975	1977	1979	Pharmaceutical Sales (U.S. $ Millions) 1975	1978	1979	As % of Total World Sales 1975	1978
1	Hoechst	W.Ger.	8,520	9,333	10,042	12,068	14,785	16,481	15,292	14	16	16	1,193	2,200	2,300	3.14	3.8
2	Hoffmann-La Roche	Sch.	1,847	2,047	2,291	2,728	3,123	3,496	3,461	56	51	44	1,034	1,380	1,374	2.72	2.4
3	Ciba-Geigy	Sch.	3,510	3,797	4,152	5,029	5,950	7,113	7,061	29	28	28	1,018	1,355	1,595	2.68	2.4
4	Merck	U.S.	1,490	1,662	1,724	—	2,385	2,734	2,929	67	84	84	998	1,355	2,004	2.63	2.4
5	Foremost-McKesson	U.S.	2,378	—	—	—	—	—	—	39	—	—	928	—	—	2.44	—
6	American Home Prod.	U.S.	2,258	2,472	2,685	—	3,401	3,798	4,131	38	39	43	858	1,279	1,448	2.26	2.2
7	Pfizer	U.S.	1,665	1,888	2,032	—	2,746	3,029	3,249	50	50	52	833	1,193	1,430	2.19	2.1
8	Sandoz	Sch.	1,522	1,644	1,993	2,420	2,673	2,926	2,946	53	48	48	806	1,242	1,289	2.12	2.2
9	Bayer	W.Ger.	7,273	8,298	9,220	11,392	14,196	15,881	14,985	11	13	13	800	1,890	1,850	2.11	3.2
10	Warner-Lambert	U.S.	2,172	2,349	2,543	—	3,217	3,479	3,379	35	40	32	780	971	1,045	2.00	1.7
11	Boehringer Ingelheim	W.Ger.	709	884	713	878	1,016	1,148	1,018	100	77	77	709	1,027	1,092	1.87	1.8
12	Eli Lilly	U.S.	1,234	1,341	1,518	—	2,206	2,559	2,773	57	53	45	703	1,063	1,003	1.85	1.9
13	Akzo	Nth.	3,869	4,069	4,253	4,983	5,992	6,272	5,826	18	11	—	696	—	—	1.83	—
14	Bristol-Myers	U.S.	1,828	1,986	—	—	2,753	3,158	3,496	35	30	34	640	745	946	1.68	1.3
15	Upjohn	U.S.	891	1,026	1,134	—	1,508	1,760	1,898	69	66	63	615	859	956	1.62	1.5
16	Squibb	U.S.	1,111	1,215	1,341	—	1,783	1,846	1,846	54	50	50	600	723	900	1.58	1.3
17	Richardson-Merrell	U.S.	659	746	836	—	1,090	1,212	1,291	88	28	—	580	—	—	1.53	—
18	Schering-Plough	U.S.	793	872	941	—	1,434	1,740	1,808	73	63	53	579	690	757	1.52	1.2
19	Rhône-Poulenc	Fr.	4,184	4,554	4,805	5,655	7,944	7,155	6,649	13	13	16	544	907	1,242	1.43	1.6
20	Sterling Drug	U.S.	957	1,096	1,184	—	1,501	1,701	1,792	56	14	58	536	861	768	1.41	1.2
21	Takeda	Japan	924	1,033	1,084	1,360	1,939	1,916	2,081	57	65	59	527	1,062	1,092	1.39	1.9
22	Glaxo	U.K.	784	819	836	994	1,080	1,379	1,626	65	72	68	510	670	955	1.34	1.2
23	Beecham	U.K.	1,267	1,203	1,250	1,558	1,792	2,243	2,795	38	36	31	481	635	711	1.27	1.1
24	Roussel Uclaf	Fr.	725	—	—	—	—	—	—	63	48	—	457	—	—	1.20	—
25	Wellcome	U.K.	476	560	582	710	847	996	1,101	95	65	—	452	—	—	1.19	—
26	Baxter Labs	U.S.	564	681	844	—	1,191	1,374	1,503	80	42	—	451	—	—	1.19	—
27	Cyanamid	U.S.	1,928	2,094	2,412	—	3,187	3,455	3,649	21	20	—	405	—	—	1.07	—
28	Abbott Labs	U.S.	941	1,085	1,245	—	3,187	3,455	3,649	40	47	49	376	680	830	0.99	1.2
29	Searle	U.S.	712	1,085	1,245	—	984	1,082	1,049	43	51	—	306	—	—	0.81	—
30	Dow Chemical	U.S.	4,888	—	—	—	—	—	—	6	5	—	293	—	—	0.77	—

Rank 1975	Firm	Origin	Total Group Sales ($ U.S. Millions) 1975	1976	1977	1978	1979	1980	1981	Pharmaceutical Sales as % of Total Group Sales 1975	1977	1979	Pharmaceutical Sales (U.S. $ Millions) 1975	1978	1979	As % of Total World Sales 1975	1978
31	SmithKline	U.S.	589	674	780	—	1,351	1,772	1,785	48	53	64	283	671	862	0.74	1.2
32	Astra	Sweden	311	—	—	—	—	—	—	69	73	—	215	—	—	0.57	—
33	Syntex	U.S.	246	—	—	—	—	—	—	70	69	—	172	—	—	0.45	—
34	Montedison	Italy	5,429	5,826	6,184	6,875	8,199	9,104	7,945	3	8	—	163	—	—	0.43	—
35	Rorer-Amchem	U.S.	272	—	—	—	—	—	—	58	—	—	158	—	—	0.42	—
36	Morton-Norwich	U.S.	538	—	—	—	—	—	—	29	—	—	156	—	—	0.41	—
37	Miles Labs	U.S.	414	—	—	—	—	—	—	36	—	—	149	—	—	0.39	—
38	Banyu	Japan	145	—	—	—	—	—	—	100	—	—	145	—	—	0.38	—
39	Yamanouchi	Japan	169	—	—	—	—	—	—	85	—	—	143	—	—	0.38	—
40	ICI	U.K.	—	—	—	—	—	—	—								
41	Johnson & Johnson	U.S.	543	—	—	—	—	—	—	24	18	—	130	608	760	0.34	1.1
42	Soc.Nat.Pet d'Aquitaine	Fr.	892	—	—	—	—	—	—	13	—	—	16	—	—	0.31	—
43	Fisons	U.K.	481	443	481	631	847	927	—	23	—	—	110	—	—	0.29	—
44	Chemie Linz	Austria	436	—	—	—	—	—	—	23	—	—	100	—	—	0.26	—
45	Pechiney-Uguine	Fr.	1,084	—	—	—	—	—	—	9	—	—	98	—	—	0.26	—
46	Sumitomo	Japan	1,620	—	—	—	—	—	—	6	—	—	97	—	—	0.26	—
47	Asahi Chemical	Japan	1,545	—	—	—	—	—	—	6	—	—	93	—	—	0.24	—
48	Am.Hospital Supply	U.S.	1,143	—	—	—	—	—	—	8	—	—	92	—	—	0.24	—
49	Degussa	W.Ger.	877	—	—	—	—	—	—	10	—	—	88	—	—	0.23	—
50	UCBSA	Belg.	420	—	—	—	—	—	—	20	—	—	84	—	—	0.22	—
51	ICN Pharm.	U.S.	108	—	—	—	—	—	—	73	—	—	79	—	—	0.21	—
52	Taisho	Japan	169	—	—	—	—	—	—	40	—	—	68	—	—	0.18	—
53	A.H. Robins	U.S.	241	—	—	—	—	—	—	27	69	—	65	—	—	0.17	—
54	Marion Labs	U.S.	84	—	—	—	—	—	—	69	—	—	58	—	—	0.15	—
55	Reckitt & Coleman	U.K.	639	—	—	—	—	—	—	9	—	—	58	—	—	0.15	—
56	BASF	W.Ger.	8,208	—	—	—	—	—	—	0.7	2	—	58	—	—	0.15	—
57	Dart Industries	U.S.	387	—	—	—	—	—	—	7	—	—	27	—	—	0.07	—
58	Kali Chemie	W.Ger.	337	—	—	—	—	—	—	7	—	—	24	—	—	0.06	—
													22,856			60.2	

Source: Surest Pradhan, *International Marketing of Pharmaceuticals*, 1983; IT&C — *Chemical Age*, July 23, 1976; OECD, *An Industry Like No Other*, Pharma Information, 1982.

Table 5.15

Pharmaceutical Market Shares Held by Domestic Firms in 25 Selected Countries, 1975 and 1985

Country	Estimated 1975	Expected 1985
Argentina	30%	32%
Australia	15	20
Belgium	10	12
Brazil	15	20
Canada	15	18
France	55	45
India	25	30
Indonesia	15	20
Iran	25	32
Italy	40	45
Japan	87	77
Mexico	18	20
Netherlands	40	40
Nigeria	3	10
Philippines	35	35
Saudi Arabia	0	10
South Africa	40	40
Spain	55	45
Sweden	50	43
Switzerland	72	68
United Kingdom	40	45
United States	85	73
U.S.S.R.	100	100
Venezuela	12	17
West Germany	65	60

Source: Leif Schaumann, *Pharmaceutical Industry Dynamics and Outlook to 1985* (Menlo Park, Ca.: Health Industry Research Departments, Stanford Research Institute, 1976) p. 13. Note: Domestic firms are defined as those that are more than 50 per cent nationally owned facilities or interests.

Horizontal Product Integration

The horizontal integration of pharmaceutical firms across product lines is also indicated in part by data presented in Table 5.14 on pharmaceutical sales as a percentage of the total group sales of the multinational pharmaceutical companies considered. In 1975, of the 58 companies listed only 24 had 50 per cent or more of the total sales accounted for by the sales of pharmaceutical products. In other words, more than half of the companies considered had more than half of their sales in product lines other than pharmaceuticals and medicines. This is also true of the ten leading firms. Of these only four had 50 per cent or more of their total sales accounted for by the sales of pharmaceutical products for 1975. By 1979, only two of these ten leading firms had 50 per cent or more of their total sales accounted for by pharmaceuticals and medicines.

This involvement in the manufacture of products other than pharmaceuticals is quite consistent with the early development of the pharmaceutical industry. In many instances, it developed in companies that were major producers of chemicals, dyes, and food stuffs. Several of the initial pharmaceutical firms have retained their activity in these other product lines.

More recently, some of the largest of the multinational pharmaceutical firms have combined production of pharmaceuticals and medicines with activity in a wide range of toilet preparations, cosmetics, and personal care goods. Examples of such companies among the leading pharmaceutical firms in the world are American Home Products, Warner-Lambert, and Bristol-Myers.

It is of interest to consider the geographic spread of three major Swiss companies. With regard to the overall group activities of the firm Ciba-Geigy, production activities occur in 42 countries and selling activities in 57 countries. Similarly, for the overall group activities of Sandoz production occurs in 34 countries and selling and marketing in 40 countries. With regard to Hoffmann-La Roche and its pharmaceutical divisions only, production takes place directly in its own establishments in 26 countries, but in 13 additional countries production is carried out for Hoffmann-La Roche by subcontractors. Hoffmann-La Roche sells directly in 46 countries and its research and development activities associated with pharmaceuticals and medicines are carried out in five countries. The geographic coverage of these three major Swiss companies is illustrative of the coverage of the world by almost all of the world's major multinational pharmaceutical companies.

Vertical Integration

There is almost complete vertical integration of the entire range of activities associated with the invention, production, and distribution of pharmaceutical products in almost every major multinational pharmaceutical firm. A substantial number of these firms are fully engaged in basic, applied, and developmental research on new chemical entities. They are almost all involved in the clinical testing of new pharmaceuticals and medicines both for their own purposes in demonstrating the safety and efficacy of the products as well as for the purposes of governments who have their own regulations on the same matters.

In turn, these leading pharmaceutical firms are engaged in the production of the active ingredients for the patented pharmaceuticals and medicines that they sell. This production of fine chemicals appears to be done by firms other than the patent-holding firms only in some of those instances in which the patents have expired. For that part of the world market in which patent protection is not available and for those pharmaceuticals and medicines whose patents have expired, the production of fine chemicals is carried out by a fairly large number of non-vertically or non-horizontally integrated firms who specialize in fine chemical production. Countries such as Italy, Israel, Finland, and Hungary have a significant number of such fine chemical producers.

With regard to the mixing of active ingredients with inactive ingredients and excipients, the ultimate formulation of the pharmaceutical or medicine, and its packaging, all leading pharmaceutical firms are heavily involved in their own product lines.

The same is true of the activities involved in marketing and/or selling these products either to hospitals, drugstores, pharmacies, and other health care agencies or facilities in the country in question or to the same institutions or government buying agencies in other countries.

With regard to wholesaling or distribution activities, there is some variation amongst the leading pharmaceutical firms. In the main, however, each of these firms both does some wholesaling and direct distribution itself and also sells to wholesalers who are at arm's length.

The vertical integration almost always stops at the wholesaling level; that is, few pharmaceutical firms are directly involved in the retail market as an owner of drugstores, pharmacies, hospitals, or other stores or health care facilities in which pharmaceutical products are sold or dispensed to final consumers/patients. A major exception to this general rule is Boots, which is heavily involved in retailing.

The extent of vertical integration is therefore quite comprehensive and almost complete. When this characteristic of the world-wide pharmaceutical industry is considered along with information on the sources of new chemical entities, the economies of scale inherent in research and development activities, and the risk reduction inherent in geographical horizontal integration and product line integration, the ultimate outcome is an industry that may well have adapted to inherent risk in such a way as to eliminate substantial portions of that risk.

Another characteristic of the world-wide pharmaceutical industry is that there are clearly major constraints to the large-scale development of this industry in any particular country short of decreeing that all pharmaceuticals and medicines manufactured and sold in a particular country must be manufactured and sold by domestic firms.

With regard to the characteristics of countries that are thought to facilitate the further development of a domestic pharmaceutical industry, a recently completed work by Burstall, Dunnings and Lake for the OECD has suggested a three-fold classification of the majority of the well-developed countries in the world. These classifications are high capacity, medium capacity, and low capacity countries for the further development of the pharmaceutical industry in them. The criteria used to determine the extent of the potential capacity include a consideration of:

1. The level of pharmaceutical production, which should constitute a significant portion of world output;
2. A significant and positive ratio of net exports to total production (that is, the existing domestic industry can service a substantial portion of its entire domestic demand);

3. Positive net exports of intermediate drugs (that is, active ingredients);
4. A strong successful record of drug innovation.

As a result of an assessment of the world-wide market for pharmaceuticals and the existing nature of multinational firms in this industry, Burstall, Dunning and Lake generate the following classification of countries:

High Capacity	Medium Capacity	Low Capacity
U.S.A	Italy	Canada
W. Germany	Japan	Australia
Switzerland	Netherlands	Spain
U.K.	Sweden	Norway
France	Austria	Finland
	Belgium	Portugal
	Denmark	

Though this is but one set of judgements on capacity for potential development, it is nevertheless the case that countries judged to have low capacity are not arbitrarily so judged. There are indeed major characteristics of these countries that represent major barriers to the development of a domestic pharmaceutical industry. In contrast, a country like Japan that has a substantial population and can also satisfy some of the other criteria may well be shifting to the list of high capacity countries. Similarly, some of the countries in the European Common Market may well be capable of further development if some of the current barriers to trade of pharmaceuticals and medicines is reduced by the European Economic Commission.

Given these several characteristics of the world-wide pharmaceutical industry and its leading firms, the potential for entry of a new firm is not high. Indeed, entering is probably only possible within the confines of a national market if the government in that country is prepared to introduce specific legislation designed to encourage, if not indeed guarantee, an entry of a particular firm or a small group of firms.

Summary of Chapter

Pharmaceutical firms in Canada devote substantial resources to sales promotion. In so doing they presumably reduce what would otherwise be major swings in the demand for particular products. Even with these heavy sales promotion expenditures the variation in sales of leading products is high from one year to the next.

The examination of research and development activities also leads to the conclusion that these activities are very important to pharmaceutical firms in their attempts to retain and enhance their share of the overall ethical market and of particular sub-markets. In this regard the large number of new product introductions judged to represent little or no therapeutic advance is consistent with these activities being used for the purpose of maintaining market share

rather than primarily for the purpose of the developing drugs that would represent major therapeutic advances.

The discussion of vertical and horizontal integration leads to a fairly complete picture of the world-wide pharmaceutical industry as one that is populated by fairly comprehensively integrated firms. The leading firms are integrated geographically across several major product lines and are also vertically integrated to cover almost all activities from the discovery of a new chemical entity to the wholesaling of finished products. Only final retailing is not generally a part of a leading multinational pharmaceutical firm's activities.

Chapter 6

Market Performance: Profits

Introduction

Profits serve as one of the principal indicators of market performance. This is true both at the level of the individual firm as well as for the industry as a whole. At the level of the individual firm, profits relative to the average for the industry are probably the best indicator of the performance of that firm and its employees. For example, if profits remain consistently high relative to the industry average, it is usually possible to attribute them to performance and deliberate planning rather than to accident.

At the industry level, profits are also an indicator of performance "on average." At the same time, however, profits "on average" are influenced by a wide variety of factors. Excessively high or low profit levels may be more indicative of the failure or success of government policies than of the collective success of individual firms. Similarly, high or low profits may reflect short-run market conditions as opposed to long-run conditions and thus will not trigger the otherwise expected entry or exit of firms from the industry. Finally, high or low profits may reflect relatively high or low degrees of risk within the industry.

In the case of an individual firm, consistently high relative profits indicate high performance. In contrast, at the industry level, performance "on average" cannot necessarily be said to be better the higher the overall profits, since these are affected by several factors not wholly under the control of individual firms. Such factors include demand side, market conditions, risk, and the degree of protection and/or subsidy that is afforded firms in a particular industry as a result of what is usually a rather complex and comprehensive set of government policies within which an industry must operate. In this light, consistently high levels of profit over a long period of time may indeed indicate that some or a combination of government policies are much too generous as they relate to firms in a particular industry.

There are three objectives for this chapter. The first is to describe the overall profitability in the pharmaceutical industry in Canada, and especially the historical stability of profits. The second is to describe the variability of profit levels amongst individual firms. The third objective is to inquire about the magnitude of any possible impact of compulsory licensing both on overall industry profit levels as well as on those of individual firms.

In pursuing these objectives, a fairly simple methodology is employed. Several alternative indicators of profit for the pharmaceutical industry in Canada are considered in comparison with those for all manufacturing industries and for selected industries that are similar either in production or marketing. The pharmaceutical industries in Canada and in the United States are also compared in some detail, and additional comparisons are made with yet other countries.

Encountered in this examination are several technical problems. One of these is the lack of precise information on the profits of pharmaceutical firms related directly to the sale of ethical products in contrast to profits related to proprietary drugs and the wide variety of other commodities produced by these companies such as toilet preparations, personal care goods, chemicals, and so forth.

A second problem, related to the preceding one, is the shifting number of firms that are said to be manufacturers of pharmaceuticals and medicines. In allocating firms to a particular industry class, Statistics Canada follows the criterion of allocating a firm to the industry according to which product group accounts for the largest percentage of a firm's sales in a particular year. Though Statistics Canada attempts to avoid rapid shifts in classification from one year to the next, it is possible that from 1968 to 1982 some technical shifts have occurred. Accordingly, the annual estimates of profit do not in every year apply to a consistent set of firms. At the same time it should be noted that the extent and magnitude of this problem is probably less for the pharmaceutical industry in Canada than it is for a number of other industries because of the international nature of the pharmaceutical industry and the specialization of the subsidiaries of foreign-owned firms in pharmaceuticals and medicines.

Industry Profits

The first of the three approaches pursued in this section is to indicate the trend in profits in the pharmaceutical industry in Canada from 1968 to 1982 according to each of several different measures of profitability. Secondly, profitability in the pharmaceutical industry is explored relative to that in other Canadian industries. Variation in profits over time is also considered as is the response of potential entrants to high levels of profit. The third approach is the comparison of profits in Canada relative to those found in the United States.

Alternative Measures of Profits in the Pharmaceutical Industry in Canada, 1968-82

Set out in Table 6.1 and Chart 6.1 are profit rates for the pharmaceutical industry from 1968 to 1982. Each of the four different measures of profitability, namely, after tax profits on total income, after tax profits on equity, before tax profits on capital employed, and after tax profits on capital employed, give roughly the same picture of profit trends. Several general characteristics can be

Table 6.1

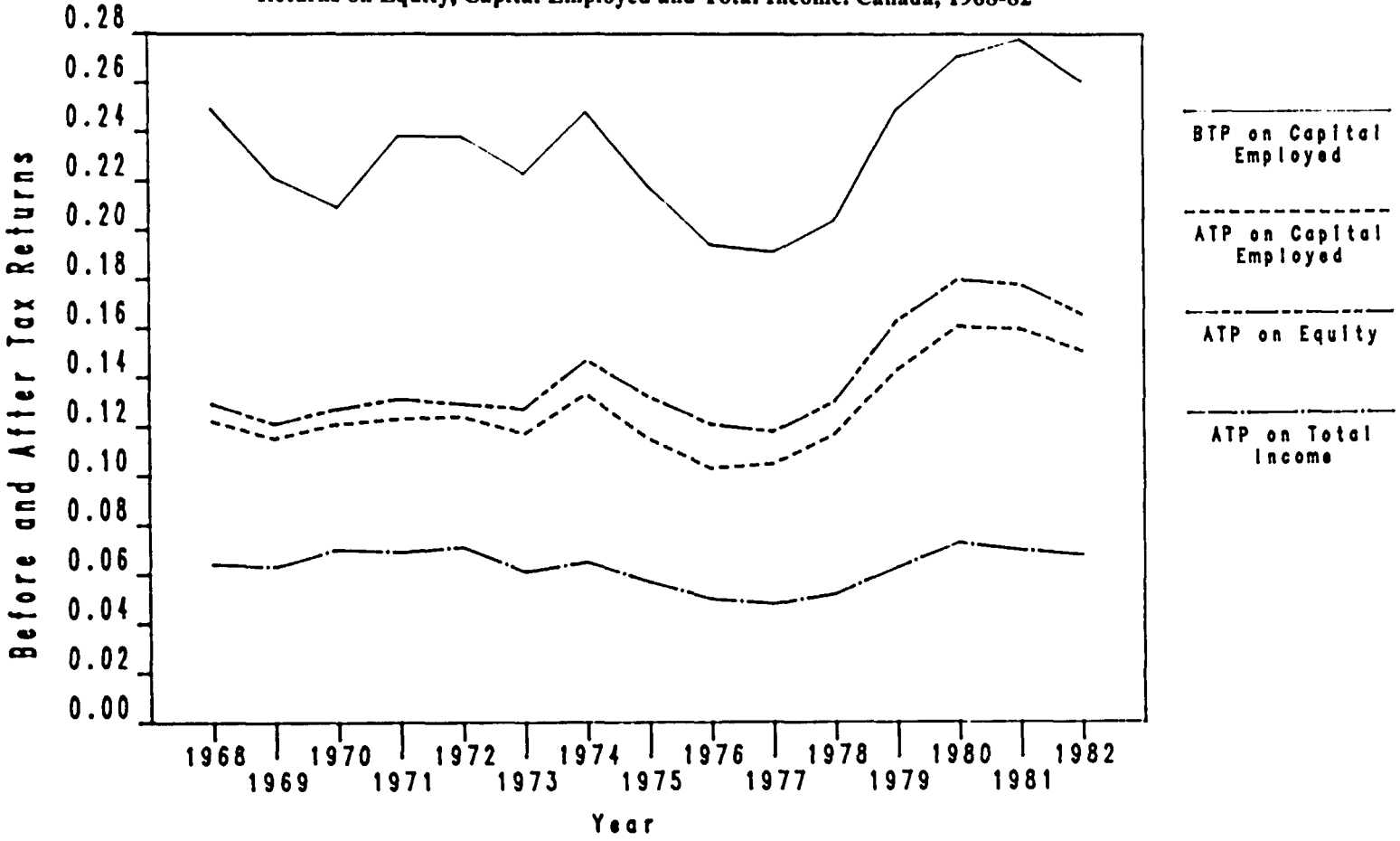
Alternative Measures of Profits in the Pharmaceutical Industry: Canada, 1968-82

Ratio/Year	1968	1969	1970	1971	1972	1973	1974	1975	1976	1977	1978	1979	1980	1981	1982	Average	Variance	St. Dev.
Number of Firms Reporting	148	142	155	134	153	154	157	152	153	140	132	134	130	150	145	145.2667	80.3289	8.9626
Profit Before Tax on Capital Employed	.249	.221	.209	.238	.238	.223	.248	.218	.194	.191	.204	.249	.271	.278	.261	.2328	.0007	.0261
Profit After Tax on Capital Employed	.122	.115	.121	.123	.124	.117	.133	.115	.103	.105	.117	.143	.161	.160	.151	.1273	.0003	.0178
Profit After Tax on Equity	.129	.121	.127	.131	.129	.127	.147	.132	.121	.118	.130	.163	.180	.178	.166	.1399	.0004	.0205
Profit After Tax on Total Income	.064	.063	.070	.069	.071	.061	.065	.057	.050	.048	.052	.063	.070	.070	.068	.0629	.0001	.0077

Source: Statistics Canada, *Corporation Financial Statistics* (Catalogue 61-207).

Chart 6.1

Alternative Measures of Performance of the Pharmaceutical Industry—Returns on Equity, Capital Employed and Total Income: Canada, 1968-82



discerned. First, profits seem to be fairly consistent over the 15 years with only two significant variations. The first of these is a slight dip in profitability centred on the years 1976 and 1977. The second major variation is the significant increase in profitability for the three years, 1978, 1979, and 1980. The trend in the last two years is back down to the long-term average. Also noteworthy is the relatively low variability of profits as indicated by the variance and standard deviation of profits over this period as shown in Table 6.1. This is especially true of after tax profits on total income. Similarly, the relative consistency of the number of corporations (as reported for tax purposes), some 145 firms, that are said to be principally in the pharmaceutical industry in Canada is of interest. Given the remarkable stability of this number in association with the general stability of profits, it may well be that the variations in the number of firms reporting is more a function of the technical data problems noted earlier than a reflection of movement into and out of the industry in response to current or expected profits.

These historical trends indicate that profitability did not fall after the 1969 amendments to the Patent Act. Profits are, however, the resultant of a wide variety of sometimes quite complex factors. Hypothetically, downward pressure on profits resulting from the change in compulsory licensing might well have led to lower profits had not a number of offsetting positive influences on profits not occurred. Principal amongst these might be the steady growth in the coverage of the population by third-party pharmicare insurance, whether organized privately or by government, and the slow but steady growth of the portion of the population aged 65 or more, who are known to have disproportionately high levels of consumption of pharmaceutical products.

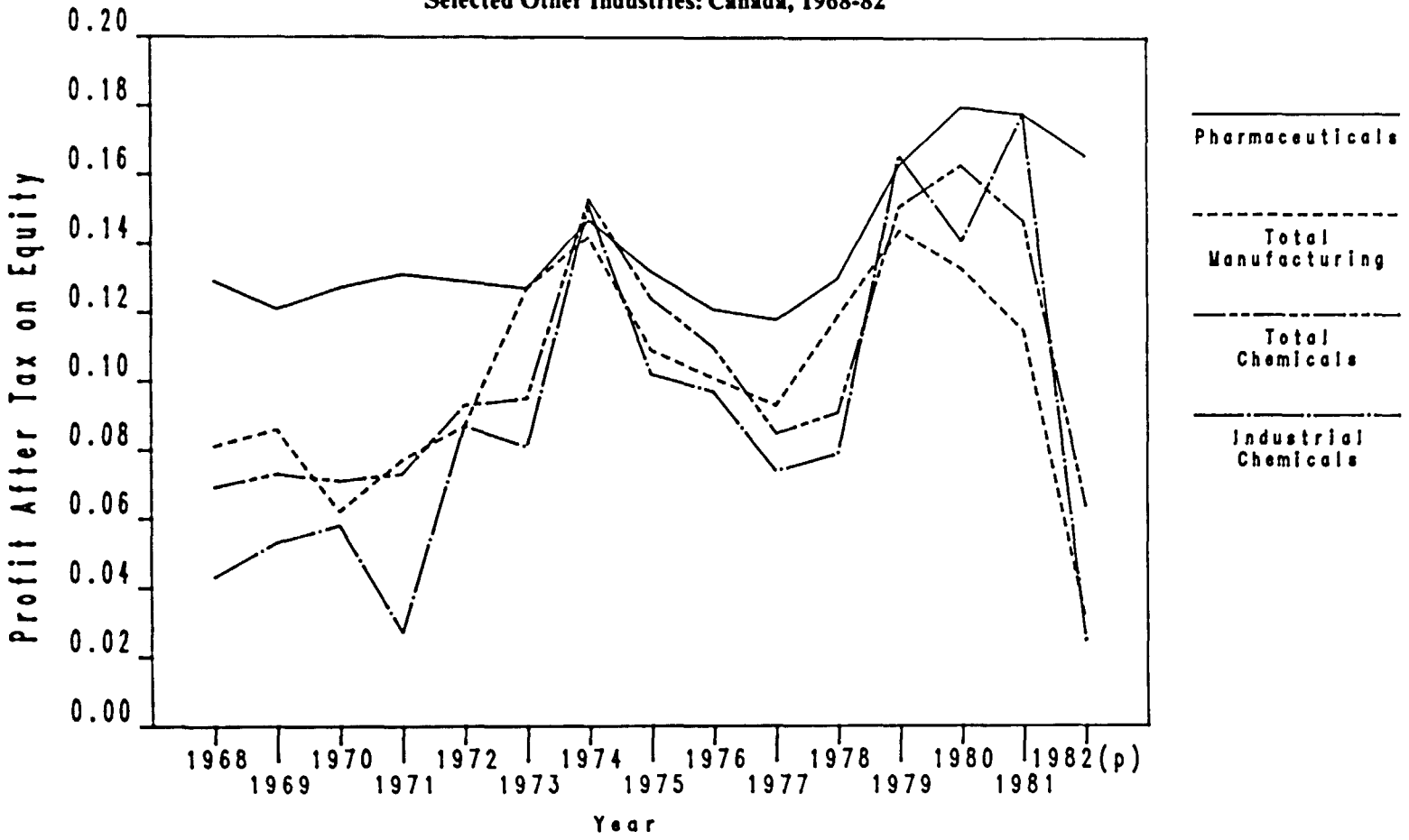
Pharmaceutical Profits Relative to Other Canadian Industries

The data presented in Charts 6.2 and 6.3[1] on after tax profits on equity illustrate relative profits in the pharmaceutical industry. In the first of these, pharmaceuticals are compared with all manufacturing industries, all chemical and chemical products industries, and with industrial chemicals. The last of these, like pharmaceuticals, is one of the major sub-classes of chemical and chemical products industries. In Chart 6.3, the pharmaceutical industry is compared with four other selected industries: scientific and professional

[1] The detailed data on which these charts are based is presented in Tables A6.1 to A6.10 in the Appendix. In the first of these, the number of corporations reporting financial data for each of the industries and for each of the years 1968 to 1982 is set out. In the second, this same information is presented in index form: the number of firms in 1968 is referred to as 100 and subsequent changes are represented by movements of the index up or down from 100. Set out in Tables A6.3 and A6.4 are annual profits after taxes on total income for pharmaceuticals in selected industries for 1968 to 1982 and secondly the presentation of this same information in ratio form. Two sets of ratios are presented: first ratios formed by taking pharmaceutical profits relative to those in each of the industry subgroups and second ratios formed by taking profits in each selected industry group, including pharmaceuticals, relative to profits in all manufacturing. In the succeeding pairs of tables, similar information is presented for each of the other three measures of profitability.

Chart 6.2

Profit After Tax on Equity, Comparison of Pharmaceutical Industry to Selected Other Industries: Canada, 1968-82



equipment manufacturers, wholesale drug and toilet preparations, retail drugstores and pharmacies, and toilet preparations manufacturers.[2]

It is clear from Chart 6.2 that profitability in the pharmaceutical industry in Canada is relatively high and has remained so over the entire period from 1968 to 1982. The profitability of pharmaceuticals clearly exceeds that for all manufacturing industries, and also that for all chemicals and chemical products, except in 1974. It is relatively stable for the first 11 years and then moves sharply higher for the last four years. Moreover, pharmaceutical profits are seen to be less variable than those of the other industry groups.[3]

With regard to the comparison industries, as presented in Chart 6.3, pharmaceutical profits, though relatively high, by no means dominate. Again, they appear to be relatively stable.

Much the same picture of relatively high and stable profits is indicated by the other measures of profitability. These are presented in Charts A6.1 to A6.4 in the Appendix for the same set of industries considered in Charts 6.2 and 6.3.

In spite of these relatively high and stable profit levels, the number of firms that are said to be manufacturers of pharmaceuticals and medicines has actually declined, as described in Chapter 2.[4] In contrast, the number of firms in scientific and professional equipment manufacturing, also characterized by high profits, has grown from 240 firms to 1,042, a 434 per cent increase. In all manufacturing firms the overall growth is 82 per cent.

Of special interest is the significant increase in the number of firms in those industries with relatively high profit levels that have been discussed briefly above. In addition to professional and scientific equipment manufacturers, the industries of toilet preparations, wholesale drug and toilet preparations, and retail drugstores and pharmacies have all exhibited significant growth in the number of firms, the figures being, respectively, 52 per cent, 51.6 per cent, and 74.4 per cent. Such growth is consistent with normal expectations about the response to high profits. Manufacturers of pharmaceuticals and medicines thus stand out as an industry in which there does not appear to be this same sensitivity to high profit levels.

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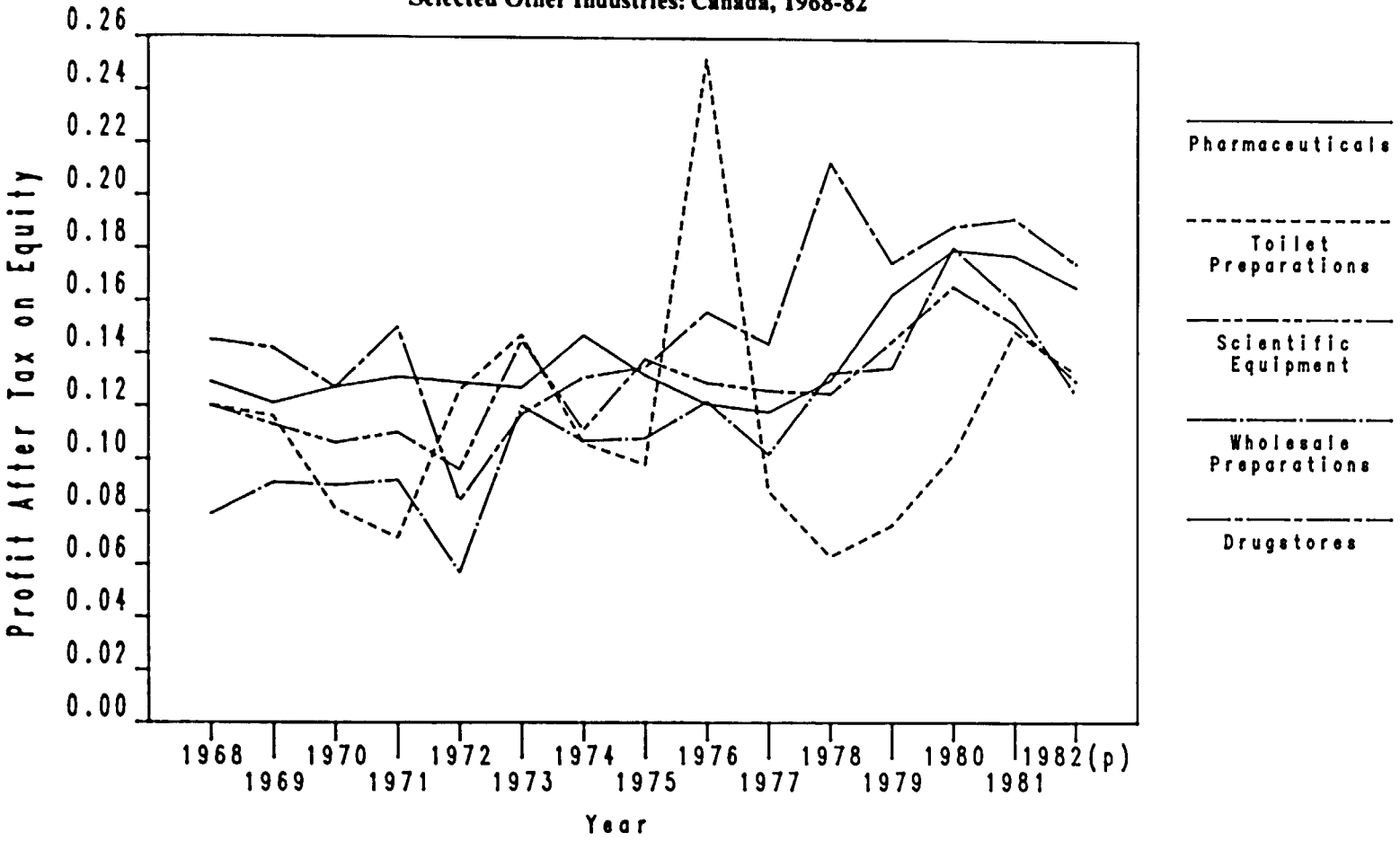
[2] In various ways, these industries can serve as comparable industries. Scientific and professional equipment involves a similar high level of technical expertise both in selling and in research and development and is sold to professionals rather than to the general public. The wholesale and retail trade in ethical and proprietary products are the vertical extensions to the final market of the pharmaceutical industry itself. As noted in Chapter 3, toilet preparations are a major other product line of the pharmaceutical industry and the toilet preparations industry produces pharmaceuticals and medicines as its second product line after toilet preparations themselves. These industries are therefore comparable to pharmaceuticals on the production side and/or on the selling/marketing side.

[3] The variance and standard deviation for each of the profit measures for each of the industries is also presented in Tables A6.3 to A6.10 of the Appendix.

[4] Information on changes in the number of firms reporting financial data for each of the industries is presented in Tables A6.1 and A6.2 of the Appendix.

Chart 6.3

Profit After Tax on Equity, Comparison of Pharmaceutical Industry to Selected Other Industries: Canada, 1968-82



Against this background, the question of whether there is any indication that relative profits fell after the 1969 amendments to the Patent Act might again be posed. Facilitating this comparison is the information presented in Charts 6.4 and 6.5.

Since the changes to the Patent Act were specific to the pharmaceutical industry, any major impact on profitability associated with these changes should be indicated by the comparison of profitability in pharmaceuticals to that for each of the industries considered in these two charts. Any such impact would probably be seen by a falling ratio of profits in pharmaceuticals to those in the other industries.

Relative profitability in pharmaceuticals for the period 1968 to 1972 does seem to be higher than for the succeeding four years, as shown by the ratios in Chart 6.4. For the later years, however, profitability in pharmaceuticals is generally as high as it was in the earlier period. It is thus difficult to draw any firm conclusions from the information presented in Chart 6.4 as to whether the changes in the Patent Act had an impact on profitability in the pharmaceuticals industry.

The comparisons shown in Chart 6.5 again lead to no general conclusion about the impact on profitability of the change in 1969 in the Patent Act. Indeed, with regard to toilet preparations, scientific and professional equipment, and wholesale and drug preparations, there appears to be a slight increase in the relative profitability of pharmaceuticals over the first four or five years of the period 1968 to 1982. The data from 1972 onwards show no particular trend in relative profits.

Accordingly, without a comprehensive analysis of all the factors that influence profitability of all the industries considered, it is not possible to infer from the information on comparative levels of profit that the 1969 change in the patent system resulted in lower relative profitability for manufacturers of pharmaceuticals and medicines.

Pharmaceutical Profits in Canada Compared to Pharmaceutical Profits in the United States

Roughly comparable information on the profitability of the pharmaceutical industry in the United States has been gathered for the period 1968 to 1982. It is assembled to provide a benchmark of a somewhat different kind than that considered in the preceding subsection. The preceding comparisons permit account to be taken of possible factors specific to the pharmaceutical industry rather than the general influence of the Canadian economy. In addition to changes in the patent system of 1969, such factors include changes on the demand side of the market as the result of increased levels of third-party pharmicare insurance and the number of persons over the age of 65.

Chart 6.4

Profit After Tax on Equity, Ratios of Returns by Pharmaceutical Industry to Total Manufacturing, Total Chemical and Industrial Chemical Industries: Canada, 1968-82

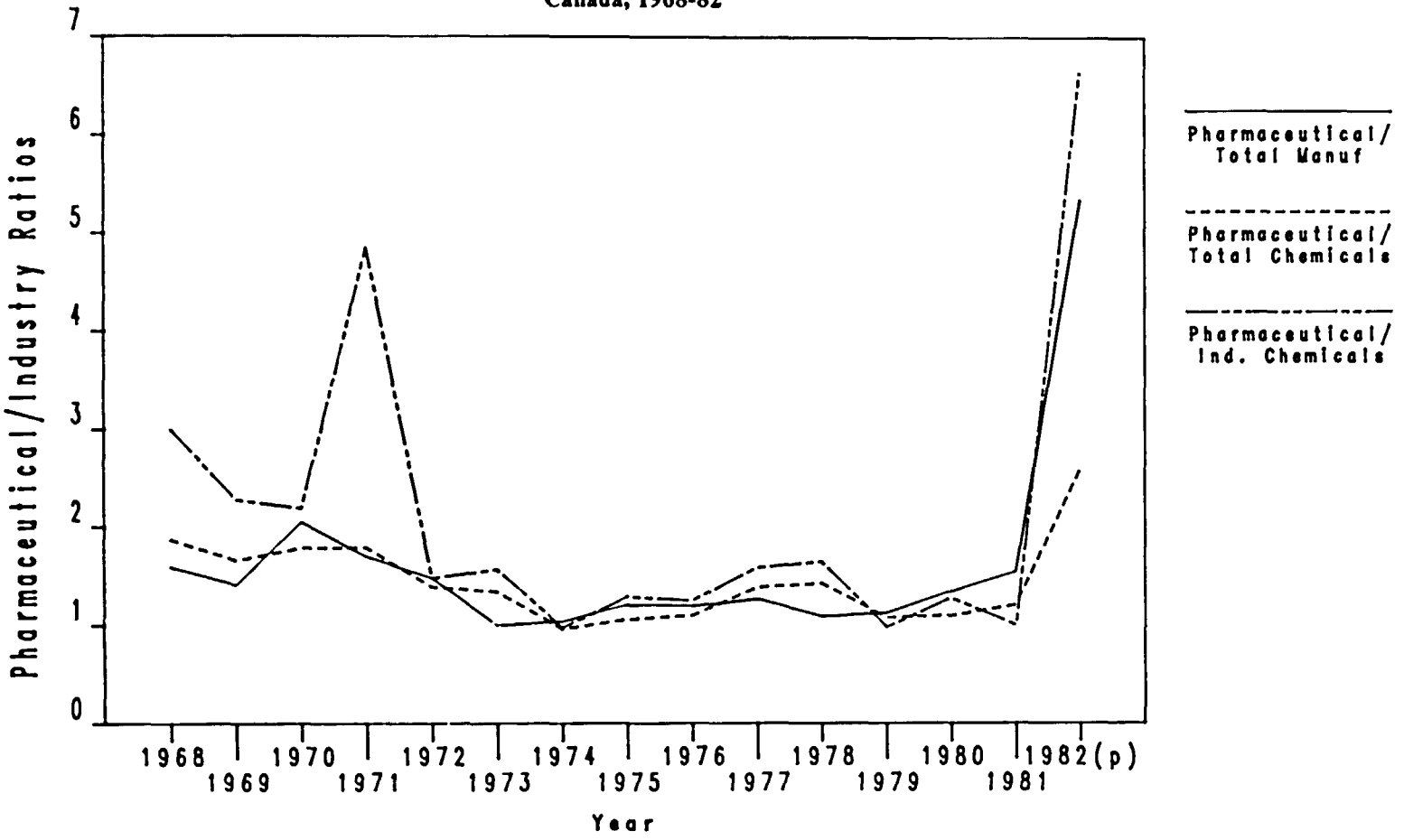
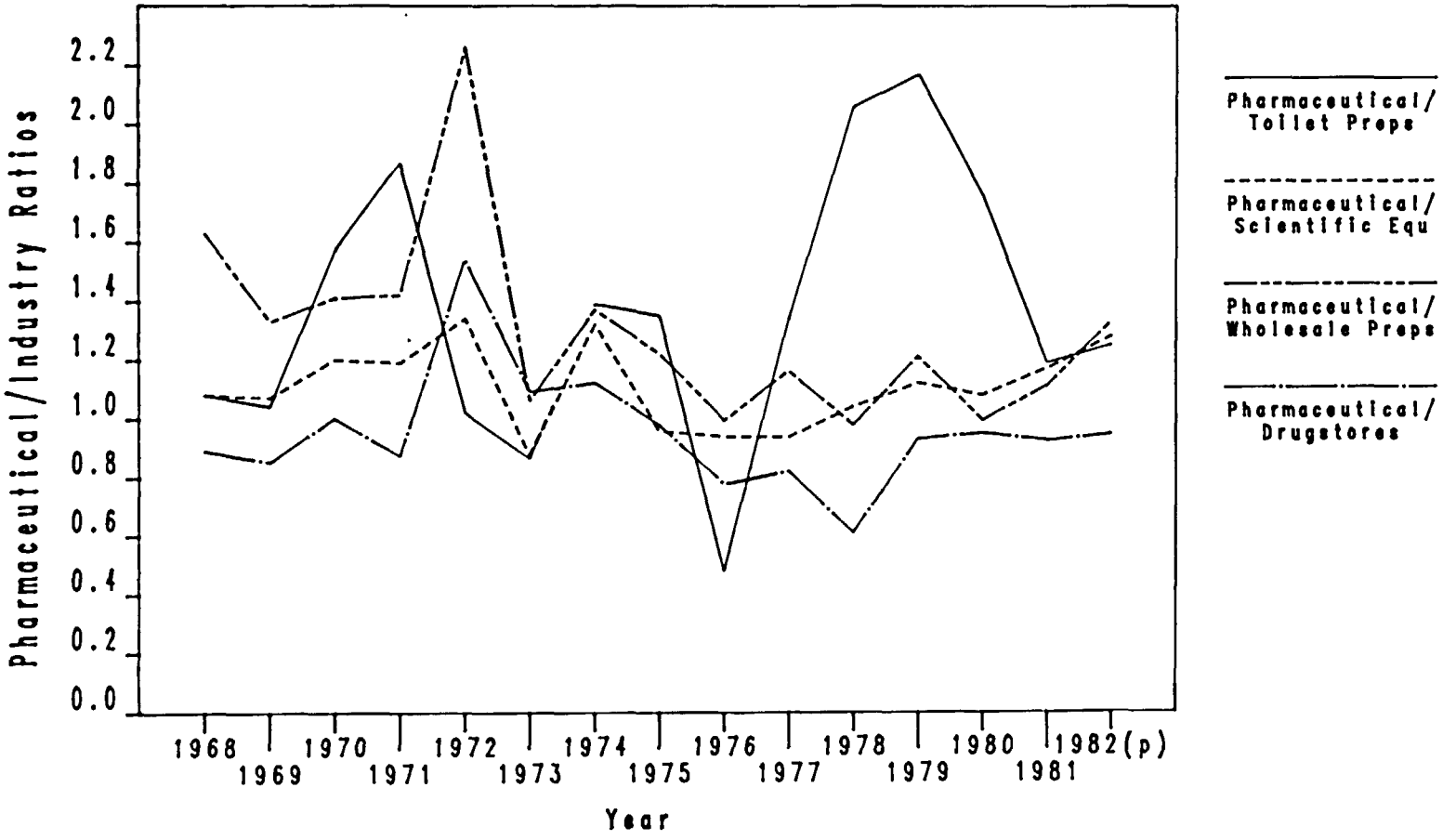


Chart 6.5

Profit After Tax on Equity, Ratios of Returns by Pharmaceutical Industry to Toilet Preparations, Scientific Equipment, Wholesale Preparations and Retail Drugstore Industries: Canada, 1968-82



Comparing profits in Canada and the U.S. for not only pharmaceuticals but also a selected number of industries, provides an alternative framework for considering the "reasonableness" of profits in the pharmaceutical industry in Canada. In particular, differences in the trends of these profits can likely be more directly related to the 1969 change in the Patent Act rather than to either broad changes in the economy at large or to changes in the market for pharmaceuticals. Though a detailed comparison of the nature of the market in each country and especially of third-party insurance has not been attempted, there are similarities. For example, the number of persons aged 65 and over, who as a class are disproportionately heavy consumers of pharmaceuticals, is slowly but steadily growing in both countries. Similarly, the coverage by third-party insurance has been growing steadily and significantly in both the United States and Canada. Moreover, the growth is very much of the same kind, with government associated with insurance for persons over the age of 65 and for persons receiving social assistance in both countries.

In Chart 6.6 information is provided on the profits after taxes on equity for pharmaceuticals and for all manufacturing industries for both Canada and the United States separately for the period 1968 to 1982.[5] In Chart 6.7 information is portrayed for both countries in the form of the ratio for each year of profits after taxes on equity for pharmaceuticals compared to profits after taxes on equity for all manufacturing.

As indicated by Chart 6.6, there has been a substantial difference between the profits after taxes on equity for pharmaceuticals in the United States as compared to Canada in all years including those before any impact of the change in compulsory licensing would have been felt. With the exception of one year, namely 1981, profits in the U.S. pharmaceutical industry are always greater than those of the pharmaceutical industry in Canada. Indeed, for the first 11 years of the comparison, profits in the United States are seen to be proportionately higher than those in Canada by about the same amount for each one of the years in question. Only in the last five years of the comparison period does the profitability of the pharmaceutical industry in Canada increase relative to that in the United States.

The information presented in Chart 6.7 permits a more ready comparison of profitability of the pharmaceutical industries of the two countries in the sense that it provides for a comparison within the framework of the overall health of the manufacturing industry in each of the two countries. As can be readily seen, relative profitability of the pharmaceutical industry in Canada is higher for the first five years of the comparison period than for the succeeding six or seven years and subsequently is again higher for the last three years.

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[5] The detailed information on profits in the United States is presented in Appendix Tables A6.11 to A6.18. The information in the first pair of these tables relates to profits after taxes on sales and is provided for all manufacturing industries, all chemical and chemical products industries, pharmaceuticals, industrial chemicals, and for instruments and their related products. In the first part of the second table of each pair, pharmaceutical profits are set out relative to profits in the other selected industries; and in the second part, profits of the selected industries are set out relative to profits in all manufacturing. The subsequent three pairs of tables refer to profits after taxes on equity, profits before taxes on total assets, and profits after taxes on total assets.

Chart 6.6

Profit After Tax on Equity, Comparison of Returns of Pharmaceutical and Total Manufacturing Industries: Canada and United States, 1968-82

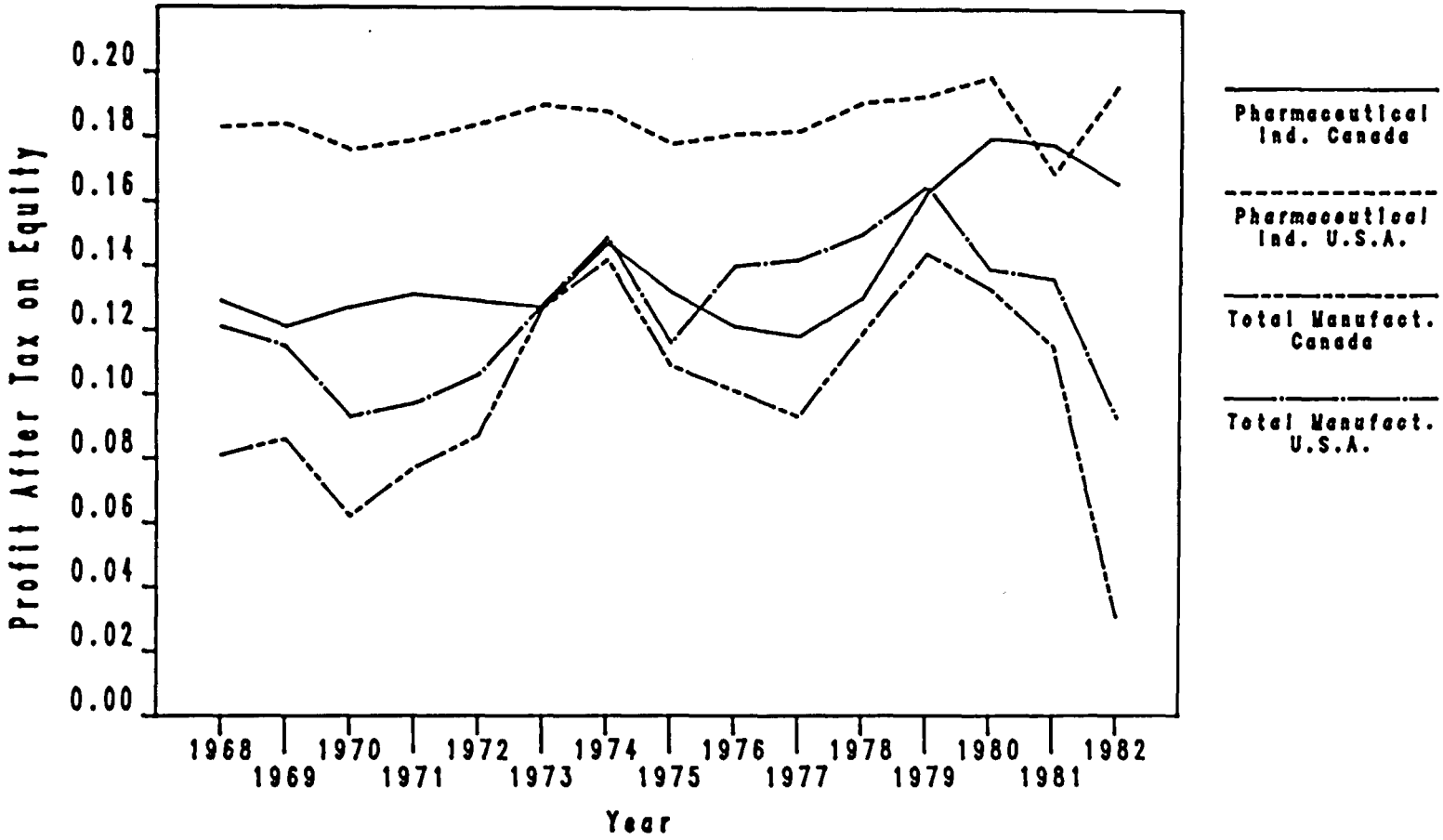
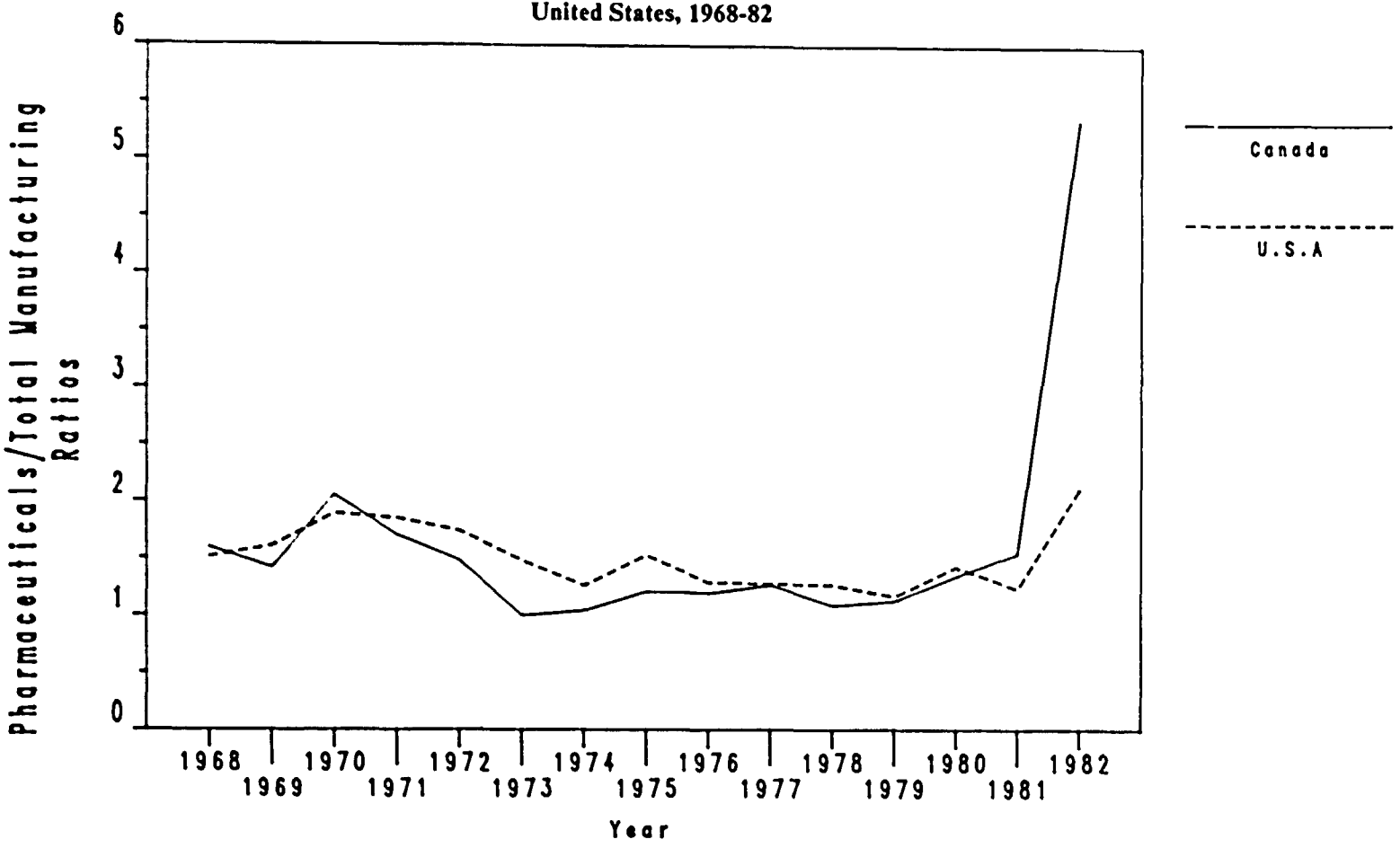


Chart 6.7

Profit After Tax on Equity, Comparison of Ratios of Returns by Pharmaceutical Industry to Total Manufacturing Industry: Canada and United States, 1968-82



With not quite so much volatility, the relative profitability of the pharmaceutical industry in the United States follows very much the same pattern.

With regard to the variability of pharmaceutical profits in the United States, information on variances and standard deviations presented in the Appendix Tables A6.11 to A6.18 indicates that profits are sometimes less variable in pharmaceuticals than in the other industries; but this is by no means always the case.

A direct comparison of pharmaceutical profit variability in Canada and the United States reveals it to be lower in the United States. This is so, as indicated by three of the four measures of profitability. In the case of "profits after taxes on sales/total income," it appears to be somewhat lower in Canada.

In spite of the obvious differences between pharmaceutical profit levels in Canada and the United States, they seem to follow roughly similar trends. This further supports the conclusion that changes in the Patent Act have had little observable impact on profitability.

Profits at the Level of the Individual Firm

The apparent relationship between the level of profit for the individual firm and certain characteristics is briefly discussed in this section. The first of these characteristics is the size of firm, the second, the extent to which the firm is engaged in pharmaceuticals, and the third is the direct impact of compulsory licensing on firm profitability. Variations in profits of individual firms are also considered. Finally, limited comparisons of profit rates for parent and subsidiary firms in Canada are considered.

Profitability and Firm Size

Limited information on the relationship between profitability and size of firm can be gleaned from the analysis, carried out by Statistics Canada in 1983, of profitability for some 20 firms in the pharmaceutical industry for each of the years 1975 to 1982. The principal statistics on the financial returns of these 20 firms allow for the calculation of a wide variety of profitability figures including net income, profits before taxes, and profits after taxes all as measures of profit, level of activity, sales, equity, total assets, and net assets. In order to carry out the analysis and yet maintain the confidentiality of the firms included in the sample, the 20 firms were classified according to size into four groups.

For before and after tax profits on each of sales and total assets, there was generally a negative relationship between profits and firm size for all the years considered. Seldom do the smallest sized firms have lower profits than the next largest size. The same negative relationship was also often indicated by profits on fixed assets.

A general conclusion from the analysis of profits for this sample of 20 firms from 1975 to 1982 is that profit rates generally decline the larger the size of firm, but that not infrequently firms of the smallest size also exhibit relatively low profits.

Profitability and Specialization in the Production of Pharmaceuticals and Medicines

Using the same sample of 20 firms for the same period discussed above, it is possible to look at the level of profitability for firms according to the extent to which they specialize in the production of pharmaceuticals as opposed to other goods such as toilet preparations, soaps, and/or a wide variety of other chemical products. The sample includes two groups: 14 firms whose sales of pharmaceuticals accounted for 50 per cent or more of total sales and six firms whose pharmaceutical sales accounted for less than 50 per cent of total sales.

The general conclusion that follows from this exercise is that the firms with less than 50 per cent of sales in the pharmaceutical industry appear to be in general somewhat more profitable than the 14 firms whose pharmaceutical sales account for more than 50 per cent of total sales. This is especially true of the information on profit margins as related to total sales and with respect to profit margins related to equity. The results pertaining to profit margins as a function of total assets and net assets are somewhat less consistent over the period of years and for the alternative measures of profit margin. Nevertheless, even with respect to these latter two categories of profit margins, a general summary would suggest that firms more heavily concentrated in pharmaceutical sales are somewhat less profitable than those with less than 50 per cent of their total sales in the pharmaceutical market.

The Impact of Compulsory Licensing on Firm Profitability

Considered in this part is the impact of compulsory licensing on the profits of firms that account for the overwhelming percentage of output of generic pharmaceuticals and medicines in Canada as well as the impact on the profits of individual patent-holding firms. In much of the discussion in the earlier section of this chapter, the profits under consideration were average profits for the entire pharmaceutical industry. Though these were seen to be both high and relatively stable over long periods of time, there have been substantial changes in profitability of individual firms that appear to be related to the change in the Patent Act but that are masked by the profit picture for the majority of firms.

There was a significant change in the number of firms that are commonly referred to as generic firms following the 1969 changes in the Patent Act. For example, of several firms who presented briefs in the mid to late 1960s on the prospects of the generic firms and who at that time appeared to be viable firms, only a very few remain today. Several of the smaller firms have indeed either

gone out of business entirely or have been merged with one of the remaining four major generic firms. The changes to the Patent Act in 1969 thus had a significant impact on the viability of some generic firms.

With regard to the current status of the generic firms, some of them appear to be highly profitable.

The change in the Patent Act in 1969 also appears to have had a significant impact on the profitability of a limited number of patent-holding firms. As demonstrated in Chapter 4, a large number of patent-holding firms rely on a single product or at most a few products for the bulk of their sales and profits. For firms that rely on a single product that is subject to competition by generic firms using compulsory licences, there could be a major negative impact on profits. This outcome appears to describe some 10 to 12 patent-holding firms. In turn, for several of these the impact has been felt only in the most recent years, but it clearly has the potential to grow as generic prescribing increases and the sales of generic products grow.

As has been indicated in Chapter 2, generic firms currently constitute only a small part of the total market for pharmaceuticals and medicines at the manufacturing level and further this growth has not been especially rapid in the last two or three years. Nevertheless, the potential for significant gains by generic firms clearly exists.

In order for overall industry profits to have remained as high as they have and indeed to have grown, it clearly must be the case that some patent-holding firms have profits that are sufficiently high so as to offset the negative impact of compulsory licensing on the profits of other firms.

As an example of the extent of the negative impact of compulsory licensing, the results of the Commission's survey of firms for the last five years indicated that at least one firm recorded losses in each one of the years 1979 to 1983. Indeed in 1982, six firms reported losses measured by after tax profits on sales, and five indicated losses as indicated by after tax profits on equity.

Variation in Firms' Profits

Consistent with the discussion in Chapter 4 on the instability of market shares that appears to be a function of the reliance of pharmaceutical firms on the sales of a few products, if not a single product, is information presented in Table 6.2 on the ratio of after tax profits to sales for 16 firms from 1972 to 1981.

An indication of the variation in profits amongst firms is given by the calculated averages for the entire period. These run from an average after tax return on sales of minus 2.9 per cent to a high of 16.2 per cent and probably understate the overall variation of profits amongst firms in any given year.

The variation in profits for a particular firm over a period such as that from 1972 to 1981 is for some firms quite large. But in the main, it is moderate to low as judged by the information presented in Table 6.2 on the minimum,

Table 6.2

Variations in After Tax Profits on Sales
For Selected Pharmaceutical Companies: Canada, 1972-81

Company	1972-81 Average	1972-81 Minimum	1972-81 Maximum	1972-81 St. Dev.	1972-81 Variation
Allergan Canada Ltd.	4.167%	−6.168%	9.363%	4.824%	.233%
Astra Pharmaceuticals Canada Ltd.	3.187	−4.041	7.242	3.658	.134
Burroughs Wellcome Inc.	10.915	7.877	12.616	1.496	.022
Cyanamid Canada Inc.	6.958	3.618	13.382	3.229	.104
Eli Lilly Canada Inc.	6.845	−.963	10.968	3.434	.118
Hoechst Canada Inc.	3.198	.749	5.536	1.485	.022
Hoffmann-La Roche Limited	−2.875	−14.486	2.346	4.963	.246
Pennwalt of Canada, Limited	6.748	5.157	8.005	.818	.007
Rhône-Poulenc Pharma Inc.	10.558	7.583	28.210	6.018	.362
Riker Canada Inc.	5.787	1.507	9.110	2.431	.059
Roussel Canada Inc.	4.653	.934	9.282	2.936	.086
Sandoz (Canada) Limited	2.423	.178	4.808	1.660	.028
Schering Canada Inc.	13.465	10.748	17.020	2.068	.043
Smith Kline & French Canada Ltd.	6.559	.453	11.373	3.308	.109
Squibb Canada Inc.	4.216	.914	8.123	2.072	.043
Wyeth Ltd.	16.157	12.307	22.752	3.126	.098

Source: Company annual reports.

maximum, standard deviation, and variance for each firm's profit rate from 1972 to 1981. For most firms, for example, the standard deviation is less than half the average profit rate. There are, however, six of the 16 firms for which the standard deviation is very close to the average, if not greater. For such firms, the variation in profits from one year to the next is indeed quite large.

Profitability of Parent Versus Canadian Subsidiary Firms

Information on ratios of after tax profits to sales and to capital employed for 23 multinational firms and for at least one each of their Canadian subsidiaries is presented in Table 6.3 for 1982. In the case of the ratio of after tax profits to sales, profitability in the Canadian subsidiary exceeds that for the

Table 6.3

Ratios of After Tax Profits to Sales and to Capital Employed for Parent and Subsidiary Pharmaceutical Firms: Canada, 1982

Company	After Tax Profits	Capital Employed	Sales	Country	Profits/ Sales	Profits/ Capital
Akzo	$ 63,000,000	$ 3,844,600,000	$ 5,404,400,000	Nether.	1.166%	1.639%
Organon Canada Ltd.	392,530	6,559,076	9,858,275		3.982	5.985
American Home Products	560,100,000	2,832,000,000	4,582,100,000	U.S.	12.224	19.778
Ayerst, McKenna Harrison, Inc.	9,011,804	44,087,790	72,946,038		12.354	20.441
Wyeth Ltd.	14,259,545	22,540,627	62,988,986		22.699	63.262
Astra	49,660,000	455,300,000	377,500,000	Sweden	13.155	10.907
Astra Pharmaceuticals Canada Ltd.	1,162,299	10,169,407	19,783,549		5.875	11.429
B. Ingelheim	24,520,000	1,008,900,000	982,200,000	W. Ger.	2.496	2.430
Boehringer Ingelheim (Canada) Ltd.	1,466,113	6,915,511	14,887,804		9.848	21.200
Beecham	180,200,000	1,583,700,000	2,494,000,000	U.K.	7.225	11.378
Beecham Laboratories Inc.	538,471	4,298,632	8,699,629		6.190	12.527
Bristol Myers	294,800,000	2,756,200,000	3,599,900,000	U.S.	8.189	10.696
Bristol-Myers Canada Limited	18,691,000	151,198,000	253,213,000		7.382	12.362
Ciba-Geigy	312,880,000	9,477,900,000	6,945,700,000	Switz.	4.505	3.301
Ciba-Geigy Canada Ltd.	(778,356)	105,214,027	159,709,143		−.487	−.740
Cyanamid	132,130,000	2,977,400,000	3,453,700,000	U.S.	3.826	4.438
Cyanamid Canada Inc.	1,843,547	198,875,060	274,765,279		.671	.927

Table 6.3 (continued)

Ratios of After Tax Profits to Sales and to Capital Employed for Parent and Subsidiary Pharmaceutical Firms: Canada, 1982

Company	After Tax Profits	Capital Employed	Sales	Country	Profits/ Sales	Profits/ Capital
Dow Chemical	$399,000,000	$11,807,000,000	$10,618,000,000	U.S.	3.758%	3.379%
Merrell Pharmaceuticals Inc.	589,335	13,777,562	13,120,214		4.492	4.277
Eli Lilly	411,800,000	3,155,100,000	2,962,700,000	U.S.	13.899	13.052
Eli Lilly Canada Inc.	7,918,835	50,327,619	112,559,497		7.035	15.735
Fisons	31,540,000	355,100,000	569,900,000	U.K.	5.534	8.882
Fisons Corporation Limited	(518,514)	4,356,904	6,223,296		−8.332	−11.901
Fortia AB	39,260,000	288,200,000	256,600,000	Sweden	15.300	13.622
Pharmacia Canada Inc.	(138,460)	5,146,084	10,773,692		−1.285	−2.691
Hoechst	134,000,000	11,029,100,000	14,792,000,000	W. Ger.	.906	1.215
Hoechst Canada Inc.	3,172,819	77,302,528	132,101,822		2.402	4.104
Revlon	60,100,000	2,272,500,000	2,351,000,000	U.S.	2.556	2.645
USV Canada Inc.	763,163	1,604,420	4,466,293		17.087	47.566
Roche	141,440,000	5,453,200,000	3,573,100,000	Switz.	3.958	2.594
Hoffmann-La Roche Limited	(3,749,076)	38,896,251	55,869,175		−6.710	−9.639

Table 6.3 (continued)

Ratios of After Tax Profits to Sales and to Capital Employed for Parent and Subsidiary Pharmaceutical Firms: Canada, 1982

Company	After Tax Profits	Capital Employed	Sales	Country	Profits/ Sales	Profits/ Capital
Rorer	$ 36,300,000	$ 345,400,000	$ 402,400,000	U.S.	9.021%	10.510%
Rorer Canada Inc.	662,098	6,384,115	9,229,011		7.174	10.371
Roussell UCLAF	21,070,000	981,500,000	1,161,800,000	France	1.814	2.147
Roussel Canada Inc.	461,365	5,478,852	17,583,342		2.624	8.421
Sandoz	137,320,000	3,330,500,000	3,044,800,000	Switz.	4.510	4.123
Sandoz (Canada) Limited	3,458,000	35,807,000	44,729,000		7.731	9.657
Schering-Plough	183,500,000	2,428,900,000	1,817,900,000	U.S.	10.094	7.555
Schering Canada Inc.	4,493,278	24,170,935	36,470,779		12.320	18.590
SmithKline	455,160,000	2,858,000,000	2,968,700,000	U.S.	15.332	15.926
Smith Kline & French Canada Ltd.	(558,024)	40,470,837	66,477,471		−.839	−1.379
Squibb	153,640,000	1,930,000,000	1,660,800,000	U.S.	9.251	7.961
Squibb Canada Inc.	602,450	24,631,373	39,089,821		1.541	2.446
Syntex	149,320,000	468,600,000	870,200,000	U.S.	17.159	31.865
Syntex Inc.	3,023,806	38,483,913	45,378,627		6.664	7.857
Wellcome	97,230,000	799,400,000	1,045,600,000	U.K.	9.299	12.163
Burroughs Wellcome Inc.	3,010,294	36,846,700	30,160,165		9.981	8.170

Source: Annual reports compiled by Price Waterhouse and *Scrip, Pharmaceutical Company League Tables, 1982/83.*

parent in 11 of the 23 cases. Similarly for the ratio of after tax profits to capital employed, profitability in the Canadian subsidiary exceeds that in the parent in 14 of the 23 cases considered. For this particular year, a sales-weighted ratio of profitability would indicate a further advantage to the Canadian subsidiary in terms of its profitability relative to the parent. Exchange rate problems clearly complicate the making of these comparisons amongst countries as do differences in the way in which assets are valued, for example, and possible differences amongst countries in intercorporate pricing policies. In spite of these several problems, the data presented in Table 6.3 suggest at the very least that pharmaceutical operations in Canada are no less profitable than they are in the other countries in which these multinational corporations operate.

International Comparisons of Pharmaceutical Profitability

Apart from data for the United States, there is limited information on profitability in the pharmaceutical industry in other major countries in the world. Comparisons with Canada are characterized by sometimes insurmountable problems on the definition of the financial terms, the adjustment of national data to account for differences in changing exchange rates, and in general differences in the extent to which the majority of firms in the pharmaceutical industry of a particular country are covered by the available data.

Information presented in Table 6.4 sheds some light on the profits of the pharmaceutical industry in the United Kingdom for the two years 1981/82 and 1982/83. These U.K. data are classified according to the country of the multinational company whose subsidiary operates in the United Kingdom. Because the information for the two years in question relates to different numbers of firms, inferences should not be drawn on the trend over the two years. For comparison purposes, information is also provided for the two profit ratios in question for Canada.

With a high degree of caution it may be concluded that at the very least, profitability of pharmaceutical firms in Canada appears to be at least as high if not higher than it is for the firms in the United Kingdom. This conclusion appears to hold for both measures of profitability.

Because of the operation of the Prescription Price Regulation Scheme (PPRS), there is also available for the United Kingdom a set of profit figures that relate to the total sales of National Health Service medicines, including both home sales and export sales. These figures thus relate only to that part of the total output of the pharmaceutical industry that is recognized by the National Health Service for eligibility under its program. The profit figures for this component of the activities of pharmaceutical firms in the U.K. are higher than those describing their overall activities presented in Table 6.4. For example, with regard to before tax profits on capital employed, the PPRS

Table 6.4

Ratio of Before Tax Profits to Sales and to Capital Employed in the Pharmaceutical Industry: United Kingdom, 1981/82 and 1982/83

	Ratio of Before Tax Profits to Sales		Ratio of Before Tax Profits to Capital Employed	
	1981/82	1982/83	1981/82	1982/83
United Kingdom:	8.3	9.9	23.9	15.8
U.K. Subsidiaries	13.1	13.0	23.1	21.0
Other Foreign Subsidiaries	6.2	5.0	10.1	n.a.
Total: 1981/82 — 41 companies	10.3			
1982/83 — 32 companies		7.8		
Canada	12.2[a,c]	11.7[b,c]	27.8[a]	26.1[b]

[a] 1981. [b] 1982. [c] Profit before tax to total income.

Source: United Kingdom: *Scrip*, No. 811 (July 13, 1983), p. 6 for 1981/82 and No. 955 (December 5, 1984), p. 12 for 1982/83. Canada: Statistics Canada, *Corporation Financial Statistics* (Catalogue 61-207), 1982.

figures were in the order of 27 per cent in 1977, fell to 18.5 per cent in 1980, and then recovered to 24.5 per cent in 1982.[6] Accordingly, even with respect to this particular component of the activities of pharmaceutical firms in the United Kingdom, profitability is nevertheless seen to be higher in Canada than in the United Kingdom.

On the other hand, for the more narrowly defined National Health Service medicines, the ratio of before tax profits to sales in the U.K. is substantially higher than the level of profits for all firms in the pharmaceutical industry in Canada and for their entire output of prescribed and non-prescribed drugs and of other goods such as toilet preparations. The trend of the profit sales ratio in the United Kingdom is from 20.5 in 1977 down to 15.0 in 1980 and rising somewhat to 17.8 in 1982.

With the recently announced further reduction in the target level of profits in the United Kingdom under the PPRS scheme, these profit levels should decline even further. This reduction in target profit levels will be the third in the last few years and will have brought the target rate of return down from what was once 23 per cent to 18 per cent or less. These rates of return are for profits before taxes on capital employed.[7] They would thus indicate profit rates substantially below the before tax return on capital employed that has characterized the industry in Canada over the 15 years since 1968.

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[6] Information supplied by the Association of the British Pharmaceutical Industry, 1984.

[7] *Scrip*, No. 969 (January 30, 1985), p. 1, and No. 971 (February 6, 1985), p. 3.

Information for 234 pharmaceutical firms throughout the world for 1982/83 is presented in Table 6.5. As with the information for the United Kingdom just discussed, this information is based on net profits before tax relative to sales. The overall unweighted return is 7.7 per cent for the 234 firms. In turn, however, these firms can be classified into those whose profits and sales are reported for pharmaceutical divisions only and those reporting on all group activities of the firm. Profits for the former at 20.6 per cent of sales are substantially in excess of profits for the latter at 4.3 per cent of sales as shown in Table 6.5.

Also presented in Table 6.5 is information for four countries not previously discussed: France, Japan, Switzerland, and West Germany. As can be readily seen, for these countries profit rates are low both for firms that are wholly pharmaceutical firms and for firms with pharmaceutical divisions as well as for firms reporting on total group activities. Left out of Table 6.5 is information on companies in the United Kingdom and the United States. The profit rates for these two countries are presumably sufficiently high as to offset the rates found in the four countries described in Table 6.5. Indeed, all but three of the leading firms that are wholly pharmaceutical or for which pharmaceutical division activities only are recorded are multinational companies headquartered in these two countries.

Information is available from another source[8] for 44 leading Japanese pharmaceutical firms ranked in order of sales. The sales-weighted ratio of after tax profits to sales in 1983 was 4.8 per cent. It was slightly lower than this in

Table 6.5

Ratio of Net Profits Before Taxes to Sales of Pharmaceutical Firms: France, Japan, Switzerland, and West Germany, 1982/83

Country	Pharmaceutical Divisions Activities			Firm's Total Group Activities		
	Number of Firms	Ratio		Number of Firms	Ratio	
		Unweighted	Sales-weighted		Unweighted	Sales-weighted
France	5	5.6	8.4	10	2.1	1.9
Japan	12	4.2	3.8	41	5.4	3.9
Switzerland	n.a.	n.a.	n.a.	5	4.2	4.2
West Germany	2	1.7	2.4	14	1.9	0.8
Firms Overall[a]	82	n.a.	20.6	152	n.a.	4.3

[a] For all 234 firms, which include U.K. and U.S. firms, unweighted average is 7.7.

Source: *Scrip, Pharmaceutical Company League Tables, 1982/83*, pp. 58-77.

[8] *Scrip*, No. 882 (March 26, 1984), p. 14.

1982. The corresponding figure for the pharmaceutical industry in Canada in 1982 was 6.8 per cent. Thus profit levels in Canada would appear to be substantially higher than those in Japan. It might be noted that the Japanese pharmaceutical firms are similar to those in Canada in that they specialize to a high degree in the production of pharmaceuticals and medicines.

The review of information on profitability in several countries indicates that profit levels in Canada are likely lower than they are in the United States, but are generally higher than they are in most other well-developed countries in the world. In particular they appear to be higher than corresponding profit rates for pharmaceutical firms in the five countries other than the United States that are host to a disproportionate share of the world's multinational pharmaceutical firms: France, Japan, Switzerland, the United Kingdom, and West Germany.

Table A6.1

Number of Corporations Reporting for Pharmaceuticals and Selected Industries: Canada, 1968-82

Industry/Year	1968	1969	1970	1971	1972	1973	1974	1975	1976	1977	1978	1979	1980	1981	1982(p)	Average
Total Manufacturing	20,800	21,000	22,100	22,000	23,000	24,600	26,500	27,500	29,300	30,000	31,900	34,100	36,500	38,300	38,000	28,373
Total Chemicals and Chemical Products	904	915	922	872	917	939	959	971	990	946	931	964	964	1039	1012	950
Fertilizers	45	42	42	37	37	36	37	39	40	35	37	43	48	49	50	41
Pharmaceuticals	148	142	155	134	153	154	157	152	153	140	132	134	130	150	145	145
Paint and Varnish	110	119	118	121	122	121	120	115	120	116	116	114	110	117	113	117
Soap and Cleaning Comp.	79	74	82	81	82	80	83	82	80	69	71	78	80	93	90	80
Toilet Preparations	69	70	76	76	78	81	81	87	89	86	90	104	103	107	105	87
Industrial Chemicals	139	168	167	157	153	162	157	170	180	180	154	161	153	161	160	161
Other Chemicals	314	300	282	266	292	305	324	326	328	320	331	330	340	362	349	318
Scientific and Professional Equipment	240	256	239	232	270	292	333	386	474	535	636	684	774	948	1042	489
Wholesale: Drug and Toilet Preparations	386	422	433	468	422	430	447	448	463	469	484	507	539	601	585	474
Retail: Druggists	1,880	2,007	2,055	2,074	2189	2,346	2,470	2,548	2,708	2,834	2,982	3,135	3,306	3,186	3,279	2,600

Source: Statistics Canada, *Corporation Financial Statistics* (Catalogue 61-207).

Table A6.2

Index of Number of Firms Reporting for Pharmaceuticals and Selected Industries: Canada, 1968-82 (1968 = 100)

Industry/Year	1968	1969	1970	1971	1972	1973	1974	1975	1976	1977	1978	1979	1980	1981	1982(p)	Average	Variance	St.Dev.
Total Manufacturing	100	100 80	106 08	105 60	110 40	118 08	127.20	132 00	140 64	144 00	153.12	163 68	175.20	183.84	182.40	136	836	28.9215
Total Chemicals and Chemical Products	100	101 20	101 97	96 44	101 42	103 85	106 07	107 39	109 49	104 63	102.97	106 62	106 62	114.91	111.93	105	21	4.6099
Fertilizers	100	93 33	93 33	82 22	82 22	80 00	82 22	86 67	88 89	77.78	82.22	95.55	106.67	108.89	111.11	91	114	10.6687
Pharmaceuticals	100	95 95	104 73	90 54	103 38	104 06	106 08	102.71	103.38	94 60	89.19	90.54	87.84	101.36	97.98	98	37	6.0560
Paint and Varnish	100	108 18	107 27	110 00	110 91	110 00	109 09	104 55	109 09	105.46	105.46	103.64	100.00	106.36	102.73	106	11	3.3887
Soap and Cleaning Comp	100	93 67	103 80	102 53	103 80	101 26	105 06	103 80	101 26	87.34	89.87	98.73	101.26	117.72	113.92	102	57	7.5449
Toilet Preparations	100	101 45	110 15	110 15	113 05	117 39	117.39	126 09	128 99	124 64	130.44	150.73	149.28	155.08	152.18	126	321	17.9090
Industrial Chemicals	100	120 86	120 14	112 95	110 07	116 54	112 95	122.30	129 49	129 49	110.79	115.82	110.07	115.82	115.10	116	54	7.3822
Other Chemicals	100	95.55	89 82	84 72	93 00	97.14	103 19	103 83	104 47	101.92	105.42	105.11	108.29	115.30	111.16	101	61	7.8376
Scientific and Professional Equipment	100	106 68	99 59	96 67	112 51	121 68	138.76	160 85	197 52	222.93	265.02	285.02	322.53	395.03	434.20	204	11880	108.9945
Wholesale Drug and Toilet Preparations	100	109 34	112 19	121 26	109 34	111 41	115 82	116 08	119 96	121.52	125.40	131.36	139.65	155.72	151.57	123	234	15.2885
Retail Drugstores	100	106 77	109 33	110 34	116 45	124 81	131 40	135 55	144 07	150.77	158.64	166.78	175 88	169.50	174.44	138	660	25.6931

Source: Statistics Canada, *Corporation Financial Statistics* (Catalogue 61-207)

Table A6.3

Profit After Tax on Total Income for Pharmaceuticals and Selected Industries: Canada, 1968-82

Industry/Year	1968	1969	1970	1971	1972	1973	1974	1975	1976	1977	1978	1979	1980	1981	1982(p)	Average	Variance	St. Dev.
Total Manufacturing	.041	.041	.03	.036	.039	.053	.053	.042	.038	.035	.042	.050	.047	.040	.011	.0399	.0001	.0099
Total Chemicals and Chemical Products	.043	.045	.043	.042	.054	.054	.075	.064	.053	.043	.041	.062	.069	.060	.0287	.0517	.0001	.0122
Fertilizers	- .096	- .106	- .061	- .063	.021	.042	.082	.068	.003	.058	.021	.030	.049	.056	.009	.0075	.0034	.0584
Pharmaceuticals	.064	.063	.070	.069	.071	.061	.065	.057	.050	.048	.052	.063	.073	.070	.068	.0629	.0001	.0077
Paint and Varnish	.025	.020	.017	.041	.028	.033	.047	.037	.028	.025	.020	.041	.041	.040	.027	.0313	.0001	.0090
Soap and Cleaning Comp.	.058	.059	.052	.059	.050	.044	.048	.077	.056	.053	.054	.053	.060	.057	.056	.0557	.0001	.0071
Toilet Preparations	.049	.058	.037	.035	.054	.060	.047	.048	.085	.029	.020	.026	.030	.041	.036	.0437	.0003	.0159
Industrial Chemicals	.042	.047	.051	.022	.068	.065	.102	.078	.070	.057	.049	.084	.073	.087	.014	.0606	.0005	.0231
Other Chemicals	.043	.045	.035	.048	.046	.050	.077	.061	.044	.033	.038	.060	.082	.040	.018	.0480	.0003	.0160
Scientific and Professional Equipment	.049	.053	.049	.053	.044	.066	.045	.053	.049	.049	.045	.048	.055	.052	.046	.0504	.0000	.0053
Wholesale: Drug and Toilet Preparations	.019	.019	.013	.016	.010	.020	.018	.017	.019	.014	.019	.017	.022	.018	.012	.0169	.0000	.0032
Retail: Druggists	.036	.037	.031	.034	.018	.025	.024	.023	.026	.023	.035	.029	.031	.028	.023	.0282	.0000	.0055

Source: Statistics Canada, *Corporation Financial Statistics* (Catalogue 61-207)

Table A6.4

Ratios of Profit After Tax on Total Income for Pharmaceuticals and Selected Industries: Canada, 1968-82

Industry/Year	1968	1969	1970	1971	1972	1973	1974	1975	1976	1977	1978	1979	1980	1981	1982(p)	Average	Variance	St. Dev.
Pharm/Total Man	1.56	1.54	2.33	1.92	1.82	1.15	1.23	1.36	1.32	1.24	1.26	1.55	1.55	1.75	6.18	1.8382	1.4426	1.2011
Pharm/Tot Chem	1.49	1.40	1.63	1.64	1.31	1.13	.87	.89	.94	1.12	1.27	1.02	1.06	1.17	2.43	1.2905	.1498	.3870
Pharm/Fertilizers	- .67	-.59	-1.15	-1.10	3.38	1.45	.79	.84	16.67	.83	2.48	2.10	1.49	1.25	7.56	2.3551	18.9908	4.3578
Pharm/Pharm	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.0000	.0000	.0000
Pharm/Paint	2.56	3.15	4.12	1.68	2.56	1.85	1.38	1.54	1.79	1.92	2.60	1.54	1.78	1.75	2.52	2.1806	.5093	.7137
Pharm/Soap	1.10	1.07	1.35	1.17	1.42	1.39	1.35	.74	.89	.91	.96	1.19	1.22	1.23	1.21	1.1465	.0375	.1937
Pharm/Toilet Prep	1.31	1.09	1.89	1.97	1.31	1.02	1.38	1.19	.59	1.66	2.60	2.42	2.43	1.71	1.89	1.6302	.3128	.5593
Pharm/Ind Chem	1.52	1.34	1.37	3.14	1.04	.94	.64	.73	.71	.84	1.06	.75	1.00	.80	4.86	1.3835	1.2123	1.1011
Pharm/Oth Chem	1.49	1.40	2.00	1.44	1.54	1.22	.84	.93	1.14	1.45	1.37	1.05	.89	1.75	3.78	1.4864	.4712	.6865
Pharm/Scie Equip	1.31	1.19	1.43	1.30	1.61	.92	1.44	1.08	1.02	.98	1.16	1.31	1.33	1.35	1.48	1.2602	.0368	.1919
Pharm/Wholesale Prep	3.37	3.32	5.38	4.31	7.10	3.05	3.61	3.35	2.63	3.43	2.74	3.71	3.32	3.89	5.67	3.9248	1.4010	1.1837
Pharm/Drugstores	1.78	1.70	2.26	2.03	3.94	2.44	2.71	2.48	1.92	2.09	1.49	2.17	2.35	2.50	2.96	2.3212	.2207	.5751
Tot Man/Tot Man	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.0000	.0000	.0000
Tot Chem/Tot Man	1.05	1.10	1.43	1.17	1.38	1.02	1.42	1.52	1.39	1.23	.98	1.24	1.47	1.50	2.55	1.3628	.1315	.3626
Fertilizers/Tot Man	-2.34	-2.59	-2.03	-1.75	.54	.79	1.55	1.62	.08	1.66	.50	.60	1.04	1.40	.82	.1256	2.1426	1.4638
Pharm/Tot Man	1.56	1.54	2.33	1.92	1.82	1.15	1.23	1.36	1.32	1.37	1.24	1.26	1.55	1.75	6.18	1.8382	1.4426	1.2011
Paint/Tot Man	.61	.49	.57	1.14	.72	.62	.89	.88	.74	.71	.48	.82	.87	1.00	2.45	.8657	.2127	.4611
Soap/Tot Man	1.41	1.44	1.73	1.64	1.28	.83	.91	1.83	1.47	1.51	1.29	1.06	1.28	1.43	5.09	1.6136	.9362	.9676
Toilet Prep/Tot Man	1.20	1.41	1.23	.97	1.38	1.13	.89	1.14	2.24	.83	.48	.52	.64	1.03	3.27	1.2240	.4715	.6866
Ind Chem/Tot Man	1.02	1.15	1.70	.61	1.74	1.24	1.92	1.86	1.84	1.63	1.17	1.68	1.55	2.18	1.27	1.5035	.1607	.4009
Oth Chem/Tot Man	1.05	1.10	1.17	1.33	1.18	.94	1.45	1.16	.94	.90	1.20		.74	1.00	1.64	1.2174	.0616	.2482
Scie Equip/Tot Man	1.20	1.29	1.63	1.47	1.13	1.25	.85	1.26	1.29	1.40	1.07	.96	1.17	1.30	4.18	1.4300	.5757	.7587
Wholesale Prep/Tot Man	.46	.46	.43	.44	.26	.38	.34	.40	.50	.40	.45	.34	.47	.45	1.09	.4589	.0323	.1797
Drugstores/Tot Man	.88	.90	1.03	.94	.46	.47	.45	.55	.68	.66	.83	.58	.66	.70	2.09	.7931	.1518	.3896

Source: Statistics Canada, *Corporation Financial Statistics* (Catalogue 61-207).

Table A6.5

Profit After Tax on Equity for Pharmaceuticals and Selected Industries: Canada, 1968-82

Industry/Year	1968	1969	1970	1971	1972	1973	1974	1975	1976	1977	1978	1979	1980	1981	1982(p)	Average	Variance	St. Dev.
Total Manufacturing	.081	.086	.062	.077	.087	.127	.142	.109	.101	.093	.119	.144	.133	.115	.031	.1005	.0009	.0302
Total Chemicals and Chemical Products	.069	.073	.071	.073	.093	.095	.153	.124	.110	.085	.091	.151	.163	.147	.064	.1041	.0011	.0336
Fertilizers	-.205	-.219	-.122	-.178	.049	.092	.234	.074	.004	.123	.046	.095	.220	.304	.038	.0370	.0237	.1540
Pharmaceuticals	.129	.121	.127	.131	.129	.127	.147	.132	.121	.118	.130	.163	.180	.178	.166	.1399	.0004	.0205
Paint and Varnish	.048	.041	.036	.090	.064	.084	.141	.095	.078	.075	.056	.131	.134	.131	.077	.0854	.0011	.0338
Soap and Cleaning Comp	.135	.129	.104	.119	.067	.062	.091	.164	.116	.117	.120	.124	.143	.133	.138	.1175	.0007	.0264
Toilet Preparations	.120	.116	.081	.070	.126	.147	.106	.098	.252	.088	.063	.075	.102	.149	.133	.1151	.0020	.0449
Industrial Chemicals	.043	.053	.058	.027	.087	.081	.151	.102	.097	.074	.079	.166	.141	.178	.025	.0908	.0022	.0471
Other Chemicals	.084	.082	.070	.096	.097	.110	.191	.151	.110	.077	.097	.157	.198	.100	.043	.1109	.0018	.0428
Scientific and Professional Equipment	.120	.113	.106	.110	.096	.145	.111	.138	.129	.126	.125	.145	.166	.152	.130	.1275	.0003	.0185
Wholesale: Drug and Toilet Preparations	.079	.091	.090	.092	.057	.120	.107	.108	.122	.102	.133	.135	.181	.160	.125	.1135	.0009	.0305
Retail: Druggists	.145	.142	.127	.150	.084	.117	.131	.135	.156	.144	.213	.175	.189	.192	.175	.1517	.0010	.0318

Source: Statistics Canada, *Corporation Financial Statistics* (Catalogue 61-207)

Table A6.6

Ratios of Profit After Tax on Equity for Pharmaceuticals and Selected Industries: Canada, 1968-82

Industry/Year	1968	1969	1970	1971	1972	1973	1974	1975	1976	1977	1978	1979	1980	1981	1982(p)	Average	Variance	St. Dev.
Pharm/Total Man	1 59	1 41	2 05	1 70	1 48	1 00	1 04	1 21	1.20	1.27	1.09	1.13	1.35	1.55	5.35	1.6284	1.0661	1.0325
Pharm/Tot Chem	1 87	1 66	1 79	1 79	1 39	1 34	.96	1 06	1.10	1.39	1.43	1.08	1.10	1.21	2.59	1.45	.1737	.4168
Pharm/Fertilizers	- 63	- 55	-1 04	- .74	2 63	1.38	63	1.70	30 25	.96	2.83	1.72	.82	.59	4.37	2.993	55.1207	7.4243
Pharm/Pharm	1 00	1 00	1 00	1 00	1 00	1 00	1 00	1 00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.0000	.0000	.0000
Pharm/Paint	2 69	2 95	3 53	1 46	2 02	1 51	1 04	1 39	1.55	1.57	2.32	1.24	1.34	1.36	2.16	1.8753	.4818	.6941
Pharm/Soap	96	.94	1 22	1 10	1 93	2 05	1 62	80	1.04	1.01	1.08	1.31	1.26	1.34	1.20	1.2573	.1183	.3440
Pharm/Toilet Prep	1 08	1 04	1 57	1 87	1 02	.86	1 39	1 35	.48	1.34	2.06	2.17	1.76	1.19	1.25	1.3630	.1987	.4458
Pharm/Ind Chem	3 00	2 28	2 19	4 85	11 48	1 57	.97	1 29	1.25	1.59	1.65	.98	1.28	1.00	6.64	2.1353	2.3951	1.5476
Pharm/Oth Chem	1 54	1 48	1 81	1 36														
Pharm/Scie Equip	1 08	1 07	1 20	1.19	1.34	.88	1.32	.96	.94	.94	1.04	1.12	1.08	1.17	1.28	1.1071	.0195	.1397
Pharm/Wholesale Prep	1 63	1 33	1 41	1 42	2 26	1 06	1.37	1 22	.99	1.16	.98	1.21	.99	1.11	1.33	1.2989	.0996	.3156
Pharm/Drugstores	89	85	1 00	87	1 54	1 09	1 12	.98	.78	.82	.61	.93	.95	.93	.95	.9534	.0385	.1961
Tot Man/Tot Man	1 00	1 00	1 00	1 00	1 00	1 00	1 00	1 00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.0000	.0000	.0000
Tot Chem/Tot Man	.85	.85	1 15	.95	1.07	.75	1 08	1.14	1.09	.91	.76	1.05	1.23	1.28	2.06	1.0807	.0932	.3054
Fertilizers/Tot Man	-2 53	-2 55	-1 97	-2 31	.56	.72	1 65	.68	.04	1.32	.39	.66	1.65	2.64	1.23	.1460	2.6245	1.6200
Pharm/Tot Man	1 59	1 41	2 05	1 70	1 48	1 00	1 04	1.21	1.20	1.27	1.09	1.13	1.35	1.55	5.35	1.6284	1.0661	1.0325
Paint/Tot Man	.59	48	.58	1 17	.74	.66	.99	.87	.77	.81	.47	.91	1.01	1.14	2.48	.9113	.2218	.4709
Soap/Tot Man	1 67	1 50	1 68	1.55	.77	.49	.64	1.50	1.15	1.26	1.01	.86	1.08	1.16	4.45	1.3835	.7997	.8942
Toilet Prep/Tot Man	1 48	1 35	1 31	.91	1 45	1.16	.75	.90	2.50	.95	.53	.52	.77	1.30	4.29	1.3428	.8434	.9184
Ind Chem/Tot Man	.53	62	.94	.35	1 00	.64	1 06	.94	.96	.80	.66	1.15	1.06	1.55	.81	.8705	.0801	.2830
Oth Chem/Tot Man	1 04	.95	1 13	1 25	1.11	.87	1.35	1.39	1.09	.83	.82	1.09	1.49	.87	1.39	1.1097	.0457	.2137
Scie Equip/Tot Man	1 48	1 31	1 71	1 43	1.10	1.14	.78	1 27	1.28	1.35	1.05	1.01	1.25	1.32	4.19	1.4453	.5841	.7643
Wholesale Prep/Tot Man	98	1 06	1 45	1 19	.66	.94	.75	.99	1.21	1.10	1.12	.94	1.36	1.39	4.03	1.2779	.5879	.7667
Drugstores/Tot Man	1.79	1 65	2 05	1.95	.97	.92	.92	1.24	1.54	1.55	1.79	1.22	1.42	1.67	5.65	1.7546	1.2030	1.0968

Source: Statistics Canada, *Corporation Financial Statistics* (Catalogue 61-207)

Table A6.7

Profit Before Tax on Capital Employed for Pharmaceuticals and Selected Industries: Canada, 1968-82

Industry/Year	1968	1969	1970	1971	1972	1973	1974	1975	1976	1977	1978	1979	1980	1981	1982(p)	Average	Variance	St. Dev.
Total Manufacturing	.106	.107	.082	.095	.108	.152	.173	.134	.117	.108	.128	.162	.147	.119	.033	.1181	.0011	.0335
Total Chemicals and Chemical Products	.109	.107	.094	.096	.106	.135	.203	.161	.118	.091	.097	.155	.173	.150	.071	.1244	.0013	.0355
Fertilizers	- .086	- .084	- .042	- .055	.027	.117	.298	.100	- .003	.041	.023	.048	.088	.123	.020	.0410	.0090	.0949
Pharmaceuticals	.249	.221	.209	.238	.238	.223	.248	.218	.194	.191	.204	.249	.271	.278	.261	.2328	.0007	.0261
Paint and Varnish	.075	.072	.052	.100	.096	.128	.175	.179	.152	.135	.104	.186	.220	.198	.106	.1319	.0024	.0493
Soap and Cleaning Comp.	.207	.204	.172	.193	.111	.095	.134	.161	.160	.166	.161	.158	.174	.182	.181	.1639	.0009	.0301
Toilet Preparations	.234	.214	.177	.136	.194	.227	.165	.166	.148	.139	.108	.128	.158	.203	.197	.1729	.0013	.0365
Industrial Chemicals	.063	.071	.060	.038	.051	.101	.174	.126	.099	.066	.061	.131	.137	.129	.021	.0885	.0018	.0419
Other Chemicals	.128	.111	.091	.104	.122	.151	.257	.189	.115	.079	.106	.170	.195	.125	.044	.1325	.0026	.0511
Scientific and Professional Equipment	.237	.203	.173	.179	.151	.219	.165	.218	.205	.194	.185	.215	.251	.228	.194	.2011	.0007	.0268
Wholesale: Drug and Toilet Preparations	.150	.149	.163	.139	.112	.173	.192	.197	.201	.198	.183	.238	.267	.226	.184	.1848	.0015	.0387
Retail: Druggists	.171	.146	.155	.170	.109	.146	.138	.166	.201	.170	.192	.213	.220	.200	.180	.1718	.0009	.0293

Source: Statistics Canada, *Corporation Financial Statistics* (Catalogue 61-207)

Table A6.8

Ratios of Profit Before Tax on Capital Employed for Pharmaceuticals and Selected Industries: Canada, 1968-82

Industry/Year	1968	1969	1970	1971	1972	1973	1974	1975	1976	1977	1978	1979	1980	1981	1982(p)	Average	Variance	St. Dev.
Pharm/Total Man	2.35	2.07	2.55	2.51	2.20	1.47	1.43	1.63	1.66	1.77	1.59	1.54	1.84	2.34	7.91	2.3231	2.3672	1.5386
Pharm/Tot Chem	2.28	2.07	2.22	2.48	2.25	1.65	1.22	1.35	1.64	2.10	2.10	1.61	1.57	1.85	3.68	2.0049	.3260	.5386
Pharm/Fertilizers	-2.90	-2.63	-4.98	-4.33	8.81	1.91	.83	2.18	-4.67	4.66	8.87	5.19	3.08	2.26	13.05	-1.9105	305.6515	17.4829
Pharm/Pharm	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.0000	.0000	.0000
Pharm/Paint	3.32	3.07	4.02	2.38	2.48	1.74	1.42	1.22	1.28	1.41	1.96	1.34	1.23	1.40	2.46	2.0490	.7189	.8479
Pharm/Soap	1.20	1.08	1.22	1.23	2.14	2.35	1.85	1.35	1.21	1.15	1.27	1.58	1.56	1.53	1.44	1.4776	.1304	.3611
Pharm/Toilet Prep	1.06	1.03	1.18	1.75	1.23	.98	1.50	1.31	1.31	1.37	1.89	1.95	1.72	1.37	1.32	1.3988	.0861	.2935
Pharm/Ind Chem	3.95	3.11	3.48	6.26	4.67	2.21	1.43	1.73	1.96	2.89	3.34	1.90	1.98	2.16	12.43	3.6558	7.1705	2.6778
Pharm/Oth Chem	1.95	1.99	2.30	2.29	1.95	1.48	.96	1.15	1.69	2.42	1.92	1.46	1.39	2.22	5.93	2.0738	1.2402	1.1136
Pharm/Scie Equip	1.05	1.09	1.21	1.33	1.58	1.02	1.50	1.00	.95	.98	1.10	1.16	1.08	1.22	1.35	1.1740	.0337	.1836
Pharm/Wholesale Prep	1.66	1.48	1.28	1.71	2.13	1.29	1.29	1.11	.97	.96	1.11	1.05	1.01	1.23	1.42	1.3136	.0982	.3133
Pharm/Drugstores	1.46	1.51	1.35	1.40	2.18	1.53	1.80	1.31	.97	1.12	1.06	1.17	1.23	1.39	1.45	1.3954	.0852	.2918
Tot Man/Tot Man	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.0000	.0000	.0000
Tot Chem/Tot Man	1.03	1.00	1.15	1.01	.98	.89	1.17	1.20	1.01	.84	.76	.96	1.18	1.26	2.15	1.1056	.0966	.3108
Fertilizers/Tot Man	-.81	-.79	-.51	-.58	.25	.77	1.72	.75	-.03	.38	.18	.30	.60	1.03	.61	.2580	.4741	.6886
Pharm/Tot Man	2.35	2.07	2.55	2.51	2.20	1.47	1.43	1.63	1.66	1.77	1.59	1.54	1.84	2.34	7.91	2.3231	2.3672	1.5386
Paint/Tot Man	.71	.67	.63	1.05	.89	.84	1.01	1.34	1.30	1.25	.81	1.15	1.50	1.66	3.21	1.2019	.3772	.6142
Soap/Tot Man	1.95	1.91	2.10	2.03	1.03	.63	.77	1.20	1.37	1.54	1.26	.98	1.18	1.53	5.48	1.6635	1.2364	1.1119
Toilet Prep/Tot Man	2.21	2.00	2.16	1.43	1.80	1.49	.95	1.24	1.26	1.29	.84	.79	1.07	1.71	5.97	1.7477	1.4640	1.2099
Ind Chem/Tot Man	.59	.66	.73	.40	.47	.66	1.01	.94	.85	.61	.40	.81	.93	1.08	.64	.7245	.0397	.1992
Oth Chem/Tot Man	1.21	1.04	1.11	1.09	1.13	.99	1.49	1.41	.98	.73	.83	1.05	1.33	1.05	1.33	1.1180	.0401	.2004
Scie Equip/Tot Man	2.24	1.90	2.11	1.88	1.40	1.44	.95	1.63	1.75	1.80	1.45	1.33	1.71	1.92	5.88	1.9580	1.1983	1.0947
Wholesale Prep/Tot Man	1.42	1.39	1.99	1.46	1.04	1.14	1.11	1.47	1.72	1.83	1.43	1.47	1.82	1.90	5.58	1.7837	1.1057	1.0515
Drugstores/Tot Man	1.61	1.36	1.89	1.79	1.01	.96	.80	1.24	1.72	1.57	1.50	1.31	1.50	1.68	5.45	1.6935	1.1038	1.0506

Source: Statistics Canada, *Corporation Financial Statistics* (Catalogue 61-207).

Table A6.9

Profit After Tax on Capital Employed for Pharmaceuticals and Selected Industries: Canada, 1968-82

Industry/Year	1968	1969	1970	1971	1972	1973	1974	1975	1976	1977	1978	1979	1980	1981	1982(p)	Average	Variance	St. Dev.
Total Manufacturing	.062	.067	.048	.059	.066	.098	.108	.082	.075	.068	.087	.107	.097	.079	.021	.0749	.0005	.0225
Total Chemicals and Chemical Products	.054	.058	.053	.057	.074	.079	.125	.095	.075	.055	.061	.103	.116	.101	.045	.0769	.0006	.0244
Fertilizers	- .089	- .085	- .050	- .064	.025	.076	.198	.069	.001	.036	.016	.037	.081	.115	.018	.0256	.0057	.0754
Pharmaceuticals	.122	.115	.121	.123	.124	.117	.133	.115	.103	.105	.117	.143	.161	.160	.151	.1273	.0003	.0178
Paint and Varnish	.043	.035	.032	.078	.058	.074	.126	.083	.067	.063	.047	.108	.115	.110	.063	.0735	.0008	.0288
Soap and Cleaning Comp	.113	.111	.091	.105	.061	.053	.078	.138	.096	.096	.097	.100	.113	.106	.109	.0978	.0004	.0205
Toilet Preparations	.117	.113	.076	.065	.116	.139	.101	.09	.223	.08	.059	.065	.092	.127	.117	.1053	.0015	.0394
Industrial Chemicals	.033	.039	.041	.019	.064	.065	.118	.074	.062	.042	.045	.096	.09	.108	.016	.0608	.0009	.0303
Other Chemicals	.065	.066	.056	.077	.074	.087	.150	.107	.070	.052	.066	.112	.146	.070	.029	.0818	.0011	.0325
Scientific and Professional Equipment	.115	.102	.089	.096	.083	.127	.096	.126	.117	.115	.116	.129	.148	.135	.116	.1140	.0003	.0174
Wholesale: Drug and Toilet Preparations	.075	.085	.082	.078	.05	.108	.097	.102	.115	.095	.124	.123	.161	.142	.107	.1029	.0007	.0271
Retail: Druggists	.125	.126	.110	.13	.072	.101	.116	.117	.142	.118	.184	.155	.160	.160	.138	.1303	.0007	.0267

Source: Statistics Canada, *Corporation Financial Statistics* (Catalogue 61-207)

Table A6.10

Ratios of Profit After Tax on Capital Employed for Pharmaceuticals and Selected Industries: Canada, 1968-82

Industry/Year	1968	1969	1970	1971	1972	1973	1974	1975	1976	1977	1978	1979	1980	1981	1982(p)	Average	Variance	St. Dev.
Pharm/Total Man	1.97	1.72	2.52	2.08	1.88	1.19	1.23	1.40	1.37	1.54	1.34	1.66	1.66	2.03	7.19	2.0314	2.0323	1.4256
Pharm/Tot Chem	2.26	1.98	2.20	2.16	1.68	1.48	1.06	1.21	1.37	1.91	1.92	1.39	1.39	1.58	3.36	1.7965	.3035	.5509
Pharm/Fertilizers	1.37	-1.35	-2.42	-1.92	4.96	1.45	.67	1.67	103.00	2.92	7.31	3.86	1.99	1.39	8.39	8.7089	644.5301	25.3876
Pharm/Pharm	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.0000	.0000	.0000
Pharm/Paint	2.84	3.29	3.78	1.58	2.14	1.58	1.06	1.39	1.54	1.67	2.49	1.32	1.40	1.45	2.40	1.9904	.6004	.7748
Pharm/Soap	1.08	1.04	1.33	1.17	2.03	2.21	1.71	.83	1.07	1.09	1.21	1.43	1.42	1.51	1.39	1.3679	.13305	.3647
Pharm/Toilet Prep	1.04	1.02	1.59	1.89	1.07	.84	1.32	1.28	.46	1.31	1.98	2.20	1.75	1.26	1.29	1.3539	.1991	.4462
Pharm/Ind Chem	3.70	2.95	2.95	6.47	1.94	1.80	1.13	1.55	1.66	2.50	2.60	1.49	1.79	1.48	9.44	2.8965	4.6841	2.1643
Pharm/Oth Chem	1.88	1.74	2.16	1.60	1.68	1.34	.89	1.07	1.47	2.02	1.77	1.28	1.10	2.29	5.21	1.8330	.9671	.9834
Pharm/Scie Equip	1.06	1.13	1.36	1.28	1.49	.92	1.39	.91	.88	.91	1.01	1.11	1.09	1.19	1.30	1.1352	.0352	.1875
Pharm/Wholesale Prep	1.63	1.35	1.48	1.58	2.48	1.08	1.37	1.13	.90	1.11	.94	1.16	1.00	1.13	1.41	1.3159	.1445	.3801
Pharm/Drugstores	98	.91	1.10	.95	1.72	1.16	1.15	.98	.73	.89	.64	.92	1.01	1.00	1.09	1.0146	.0548	.2340
Tot Man/Tot Man	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.0000	.0000	.0000
Tot Chem/Tot Man	.87	.87	1.15	.97	1.12	.81	1.16	1.16	1.00	.81	.70	.96	1.20	1.28	2.14	1.0788	.1077	.3282
Fertilizers/Tot Man	-1.44	-1.27	-1.04	-1.08	.38	.78	1.83	.84	.01	.53	.18	.35	.84	1.46	.86	.2146	.9360	.9675
Pharm/Tot Man	1.97	1.72	2.52	2.08	1.88	1.19	1.23	1.40	1.37	1.54	1.34	1.34	1.66	2.03	7.19	2.0314	2.0323	1.4256
Paint/Tot Man	.69	.52	.67	1.32	.88	.76	1.17	1.01	.89	.93	.54	1.01	1.19	1.39	3.00	1.0643	.3329	.5770
Soap/Tot Man	1.82	1.66	1.90	1.78	.92	.54	.72	1.68	1.28	1.41	1.11	.93	1.16	1.34	5.19	1.5642	1.0982	1.0479
Toilet Prep/Tot Man	1.89	1.69	1.58	1.10	1.76	1.42	.94	1.10	2.97	1.18	.68	.61	.95	1.61	5.57	1.6687	1.4078	1.1875
Ind Chem/Tot Man	.53	.58	.85	.32	.97	.66	1.09	.90	.83	.62	.52	.90	.93	1.37	.76	.7889	.0637	.2523
Oth Chem/Tot Man	1.05	1.52	1.85	1.63	1.26	.89	1.39	1.30	.93	.76	.76	1.05	1.51	.89	1.38	1.0989	.0521	.2283
Scie Equip/Tot Man	1.85	1.52	1.85	1.63	1.26	1.30	.89	1.54	1.56	1.69	1.33	1.23	1.53	1.71	5.52	1.7591	1.0751	1.0369
Wholesale Prep/Tot Man	1.21	1.27	1.71	1.32	.76	1.10	.90	1.24	1.53	1.40	1.43	1.15	1.66	1.80	5.10	1.5712	.9636	.9816
Drugstores/Tot Man	2.02	1.88	2.29	2.20	1.09	1.03	1.07	1.43	1.89	1.74	2.11	1.45	1.65	2.03	6.57	2.0302	1.6333	1.2780

Source: Statistics Canada, *Corporation Financial Statistics* (Catalogue 61-207)

Table A6.11

Profit After Tax on Sales for Pharmaceuticals and Selected Industries: United States, 1968-82

Industry/Year	1968	1969	1970	1971	1972	1973	1974	1975	1976	1977	1978	1979	1980	1981	1982	Average	Variance	St. Dev.
Total Manufacturing	0.051	0.048	0.04	0.042	0.043	0.047	0.055	0.046	0.054	0.053	0.054	0.057	0.049	0.047	0.035	0.0481	0.0000	0.0060
Total Chemicals and Allied Products	0.068	0.065	0.059	0.061	0.064	0.068	0.084	0.076	0.075	0.072	0.073	0.075	0.071	0.069	0.055	0.0690	0.0001	0.0072
Pharmaceuticals	0.097	0.096	0.094	0.095	0.101	0.102	0.122	0.122	0.122	0.121	0.128	0.129	0.132	0.109	0.131	0.1134	0.0002	0.0141
Industrial Chemicals	0.063	0.06	0.05	0.05	0.055	0.065	0.084	0.069	0.069	0.065	0.068	0.067	0.054	0.058	0.033	0.0607	0.0001	0.0112
Instruments and Related Products	0.081	0.078	0.073	0.072	0.082	0.084	0.093	0.076	0.079	0.09	0.093	0.087	0.093	0.09	0.08	0.0834	0.0000	0.0070

Source: United States Bureau of the Census, Federal Trade Commission, *Quarterly Financial Report for Manufacturing*

Table A6.12

Ratios of Profit After Tax on Sales for Pharmaceuticals and Selected Industries: United States, 1968-82

Industry/Year	1968	1969	1970	1971	1972	1973	1974	1975	1976	1977	1978	1979	1980	1981	1982	Average	Variance	St. Dev.
Pharm/Total Man	1.90	2.00	2.35	2.26	2.35	2.17	2.22	2.65	2.26	2.28	2.37	2.26	2.69	2.32	3.74	2.3890	.1686	.4106
Pharm/Total Chem	1.43	1.48	1.59	1.56	1.58	1.50	1.45	1.61	1.63	1.68	1.75	1.72	1.86	1.58	2.38	1.6527	.0508	.2253
Pharm/Pharm	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.0000	.0000	.0000
Pharm/Ind Chem	1.54	1.60	1.88	1.90	1.84	1.57	1.45	1.77	1.77	1.86	1.88	1.93	2.44	1.88	3.97	1.9518	.3408	.5838
Pharm/Instr	1.20	1.23	1.29	1.32	1.23	1.21	1.31	1.61	1.54	1.34	1.38	1.48	1.42	1.21	1.64	1.3160	.0202	.1420
Tot Man/Tot Man	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.0000	.0000	.0000
Tot Chem/Tot Man	1.33	1.35	1.48	1.45	1.49	1.45	1.53	1.65	1.39	1.36	1.35	1.32	1.45	1.47	1.57	1.4422	.0084	.0915
Pharm/Tot Man	1.90	2.00	2.35	2.26	2.35	2.17	2.22	2.65	2.26	2.28	2.37	2.26	2.69	2.32	3.74	2.3890	.1686	.4106
Ind Chem/Tot Man	1.24	1.25	1.25	1.19	1.28	1.38	1.53	1.50	1.28	1.23	1.26	1.18	1.10	1.23	.94	1.2555	.0190	.1378
Instr/Tot Man	1.59	1.63	1.83	1.71	1.91	1.79	1.69	1.65	1.46	1.70	1.72	1.53	1.90	1.91	2.29	1.7532	.0373	.1931

Source: United States Bureau of the Census, Federal Trade Commission, *Quarterly Financial Report for Manufacturing*.

Table A6.13

Profit After Tax on Equity for Pharmaceuticals and Selected Industries: United States, 1968-82

Industry/Year	1968	1969	1970	1971	1972	1973	1974	1975	1976	1977	1978	1979	1980	1981	1982	Average	Variance	St. Dev.
Total Manufacturing	0.121	0.115	0.093	0.097	0.106	0.128	0.149	0.116	0.14	0.142	0.15	0.165	0.139	0.136	0.093	0.1260	0.0005	0.0216
Total Chemicals and Allied Products	0.133	0.128	0.114	0.118	0.129	0.148	0.183	0.152	0.155	0.151	0.156	0.167	0.154	0.148	0.111	0.1431	0.0004	0.0197
Pharmaceuticals	0.183	0.184	0.176	0.179	0.184	0.19	0.188	0.178	0.181	0.182	0.191	0.193	0.199	0.169	0.196	0.1849	0.0001	0.0078
Industrial Chemicals	0.11	0.105	0.085	0.087	0.1	0.13	0.176	0.132	0.143	0.135	0.145	0.152	0.119	0.132	0.065	0.1211	0.0008	0.0283
Instruments and Related Products	0.166	0.156	0.143	0.135	0.149	0.159	0.163	0.135	0.147	0.169	0.179	0.168	0.175	0.169	0.143	0.1571	0.0002	0.0138

Source: United States Bureau of the Census, Federal Trade Commission, *Quarterly Financial Report for Manufacturing*

Table A6.14

Ratios of Profit After Tax on Equity for Pharmaceuticals and Selected Industries: United States, 1968-82

Industry/Year	1968	1969	1970	1971	1972	1973	1974	1975	1976	1977	1978	1979	1980	1981	1982	Average	Variance	St. Dev.
Pharm/Total Man	1.51	1.60	1.89	1.85	1.74	1.48	1.26	1.53	1.29	1.28	1.27	1.17	1.43	1.24	2.11	1.5111	.0724	.2691
Pharm/Total Chem	1.38	1.44	1.54	1.52	1.43	1.28	1.03	1.17	1.17	1.21	1.22	1.16	1.29	1.14	1.77	1.3157	.0353	.1879
Pharm/Pharm	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.0000	.0000	.0000
Pharm/Ind Chem	1.66	1.75	2.07	2.06	1.84	1.46	1.07	1.35	1.27	1.35	1.32	1.27	1.67	1.28	3.02	1.6287	.2229	.4721
Pharm/Instr	1.10	1.18	1.23	1.33	1.23	1.19	1.15	1.32	1.23	1.08	1.07	1.15	1.14	1.00	1.37	1.1848	.0100	.1001
Tot Man/Tot Man	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.0000	.0000	.0000
Tot Chem/Tot Man	1.10	1.11	1.23	1.22	1.22	1.16	1.23	1.31	1.11	1.06	1.04	1.01	1.11	1.09	1.19	1.1452	.0065	.0809
Pharm/Tot Man	1.51	1.60	1.89	1.85	1.74	1.48	1.26	1.53	1.29	1.28	1.27	1.17	1.43	1.24	2.11	1.5111	.0724	.2691
Ind Chem/Tot Man	.91	.91	.91	.90	.94	1.02	1.18	1.14	1.02	.95	.97	.92	.86	.97	.70	.9531	.0119	.1091
Instr/Tot Man	1.37	1.36	1.54	1.39	1.41	1.24	1.09	1.16	1.05	1.19	1.19	1.02	1.26	1.24	1.54	1.2703	.0242	.1554

Source: United States Bureau of the Census, Federal Trade Commission, *Quarterly Financial Report for Manufacturing*.

Table A6.15

Profits Before Tax on Total Assets for Pharmaceuticals and Selected Industries: United States, 1968-82

Industry/Year	1968	1969	1970	1971	1972	1973	1974	1975	1976	1977	1978	1979	1980	1981	1982	Average	Variance	St. Dev.
Total Manufacturing	0.119	0.111	0.085	0.089	0.099	0.114	0.125	0.101	0.122	0.124	0.128	0.131	0.109	0.105	0.068	0.1087	0.0003	0.0172
Total Chemicals and Allied Products	0.145	0.14	0.119	0.12	0.13	0.147	0.173	0.138	0.141	0.135	0.132	0.135	0.121	0.115	0.078	0.1313	0.0004	0.0198
Pharmaceuticals	0.238	0.235	0.207	0.202	0.202	0.203	0.194	0.179	0.179	0.18	0.181	0.171	0.169	0.142	0.159	0.1894	0.0006	0.0253
Industrial Chemicals	0.109	0.105	0.079	0.08	0.094	0.122	0.162	0.116	0.124	0.113	0.113	0.112	0.085	0.09	0.035	0.1026	0.0007	0.0272
Instruments and Related Products	0.198	0.188	0.16	0.15	0.174	0.177	0.171	0.136	0.155	0.192	0.192	0.172	0.175	0.163	0.129	0.1678	0.0004	0.0188

Source: United States Bureau of the Census, Federal Trade Commission, *Quarterly Financial Report for Manufacturing*

Table A6.16

Ratios of Profits Before Tax on Total Assets for Pharmaceuticals and Selected Industries: United States, 1968-82

Industry/Year	1968	1969	1970	1971	1972	1973	1974	1975	1976	1977	1978	1979	1980	1981	1982	Average	Variance	St. Dev.
Pharm/Total Man	2.00	2.12	2.44	2.27	2.04	1.78	1.55	1.77	1.47	1.45	1.41	1.31	1.55	1.35	2.34	1.7898	.1374	.3707
Pharm/Total Chem	1.64	1.68	1.74	1.68	1.55	1.38	1.12	1.30	1.27	1.33	1.37	1.27	1.40	1.23	2.04	1.4671	.0567	.2382
Pharm/Pharm	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.0000	.0000	.0000
Pharm/Ind Chem	2.18	2.24	2.62	2.53	2.15	1.66	1.20	1.54	1.44	1.59	1.60	1.53	1.99	1.58	4.54	2.0263	.6154	.7845
Pharm/Instr	1.20	1.25	1.29	1.35	1.16	1.15	1.13	1.32	1.15	1.02	.94	.99	.97	.87	1.23	1.1353	.0200	.1415
Tot Man/Tot Man	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.0000	.0000	.0000
Tot Chem/Tot Man	1.22	1.26	1.40	1.35	1.31	1.29	1.38	1.37	1.16	1.09	1.03	1.03	1.11	1.10	1.15	1.2160	.0159	.1260
Pharm/Tot Man	2.00	2.12	2.44	2.27	2.04	1.78	1.55	1.77	1.47	1.45	1.41	1.31	1.55	1.35	2.34	1.7898	.1374	.3707
Ind Chem/Tot Man	.92	.95	.93	.90	.95	1.07	1.30	1.15	1.02	.91	.88	.85	.78	.86	.51	.9314	.0279	.1672
Instr/Tot Man	1.66	1.69	1.88	1.69	1.76	1.55	1.37	1.35	1.27	1.43	1.50	1.31	1.61	1.55	1.90	1.5677	.0367	.1916

Source: United States Bureau of the Census, Federal Trade Commission, *Quarterly Financial Report for Manufacturing*.

Table A6.17

Profits After Tax on Total Assets for Pharmaceuticals and Selected Industries: United States, 1968-82

Industry/Year	1968	1969	1970	1971	1972	1973	1974	1975	1976	1977	1978	1979	1980	1981	1982	Average	Variance	St. Dev.
Total Manufacturing	0.069	0.063	0.05	0.052	0.057	0.067	0.08	0.062	0.075	0.076	0.078	0.084	0.069	0.067	0.045	0.0663	0.0001	0.0111
Total Chemicals and Allied Products	0.079	0.075	0.066	0.068	0.074	0.084	0.106	0.086	0.086	0.083	0.084	0.09	0.082	0.078	0.057	0.0799	0.0001	0.0110
Pharmaceuticals	0.124	0.122	0.113	0.113	0.116	0.116	0.122	0.114	0.115	0.114	0.119	0.119	0.12	0.099	0.116	0.1161	0.0000	0.0057
Industrial Chemicals	0.062	0.058	0.046	0.047	0.055	0.07	0.097	0.071	0.075	0.07	0.073	0.076	0.059	0.065	0.031	0.0637	0.0002	0.0151
Instruments and Related Products	0.104	0.097	0.086	0.082	0.096	0.1	0.106	0.085	0.091	0.106	0.113	0.106	0.111	0.107	0.092	0.0988	0.0001	0.0095

Source: United States Bureau of the Census, Federal Trade Commission, *Quarterly Financial Report for Manufacturing*

Table A6.18

Ratios of Profits After Tax on Total Assets for Pharmaceuticals and Selected Industries: United States, 1968-82

Industry/Year	1968	1969	1970	1971	1972	1973	1974	1975	1976	1977	1978	1979	1980	1981	1982	Average	Variance	St. Dev.
Pharm/Total Man	1.80	1.94	2.26	2.17	2.04	1.73	1.53	1.84	1.53	1.50	1.53	1.42	1.74	1.48	2.58	1.8045	.1068	.3268
Pharm/Total Chem	1.57	1.63	1.71	1.66	1.57	1.38	1.15	1.33	1.34	1.37	1.42	1.32	1.46	1.27	2.04	1.4808	.0453	.2128
Pharm/Pharm	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.0000	.0000	.0000
Pharm/Ind Chem	2.00	2.10	2.46	2.40	2.11	1.66	1.26	1.61	1.53	1.63	1.63	1.57	2.03	1.52	3.74	1.9500	.3417	.5845
Pharm/Instr	1.19	1.26	1.31	1.38	1.21	1.16	1.15	1.34	1.26	1.08	1.05	1.12	1.08	.93	1.26	1.1856	.0140	.1182
Tot Man/Tot Man	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.0000	.0000	.0000
Tot Chem/Tot Man	1.14	1.19	1.32	1.31	1.30	1.25	1.33	1.39	1.15	1.09	1.08	1.07	1.19	1.16	1.27	1.2156	.0094	.0968
Pharm/Tot Man	1.80	1.94	2.26	2.17	2.04	1.73	1.53	1.84	1.53	1.50	1.53	1.42	1.74	1.48	2.58	1.8045	.1068	.3268
Ind Chem/Tot Man	.90	.92	.92	.90	.96	1.04	1.21	1.15	1.00	.92	.94	.90	.86	.97	.69	.9524	.0137	.1171
Instr/Tot Man	1.51	1.54	1.72	1.58	1.68	1.49	1.33	1.37	1.21	1.39	1.45	1.26	1.61	1.60	2.04	1.5190	.0401	.2003

Source: United States Bureau of the Census, Federal Trade Commission, *Quarterly Financial Report for Manufacturing*.

Table A6.19

Significant Statistics on After Tax Income to Shareholders' Equity for Selected Pharmaceutical Companies: Canada, 1972-81

	1972-81 Average %	1972-81 Minimum %	1972-81 Maximum %	1972-81 St. Dev. %	1972-81 Variation %
Allergan Canada Ltd.	12.256	−66.122	39.781	28.874	8.337
Astra Pharmaceuticals Canada Ltd.	7.164	−23.180	26.348	13.341	1.780
Burroughs Wellcome Inc.	19.157	15.060	23.261	2.689	.072
Cyanamid Canada Inc.	14.387	6.073	27.595	6.769	.458
Eli Lilly Canada Inc.	25.366	−5.703	47.986	14.766	2.180
Hoechst Canada Inc.	19.896	4.049	42.172	11.50	1.325
Hoffmann-La Roche Limited	−15.961	−112.330	3.005	33.391	11.150
Pennwalt of Canada, Limited	18.214	11.853	26.362	4.821	.232
Rhône-Poulenc Pharma Inc.	24.138	14.089	48.894	10.294	1.060
Riker Canada Inc.	19.591	4.868	41.894	9.574	.917
Roussel Canada Inc.	27.865	4.829	61.510	18.404	3.387
Sandoz (Canada) Limited	6.868	.479	14.053	4.620	.213
Schering Canada Inc.	26.633	19.409	50.306	8.884	.789
Smith Kline & French Canada Ltd.	16.803	.803	35.165	11.906	1.418
Squibb Canada Ltd.	11.814	3.061	22.527	5.846	.342
Wyeth Ltd.	54.119	33.293	91.704	15.595	2.432

Source: Company annual reports.

Chart A6.1

Profit After Tax on Capital Employed, Comparison of Pharmaceutical Industry to Selected Other Industries: Canada, 1968-82

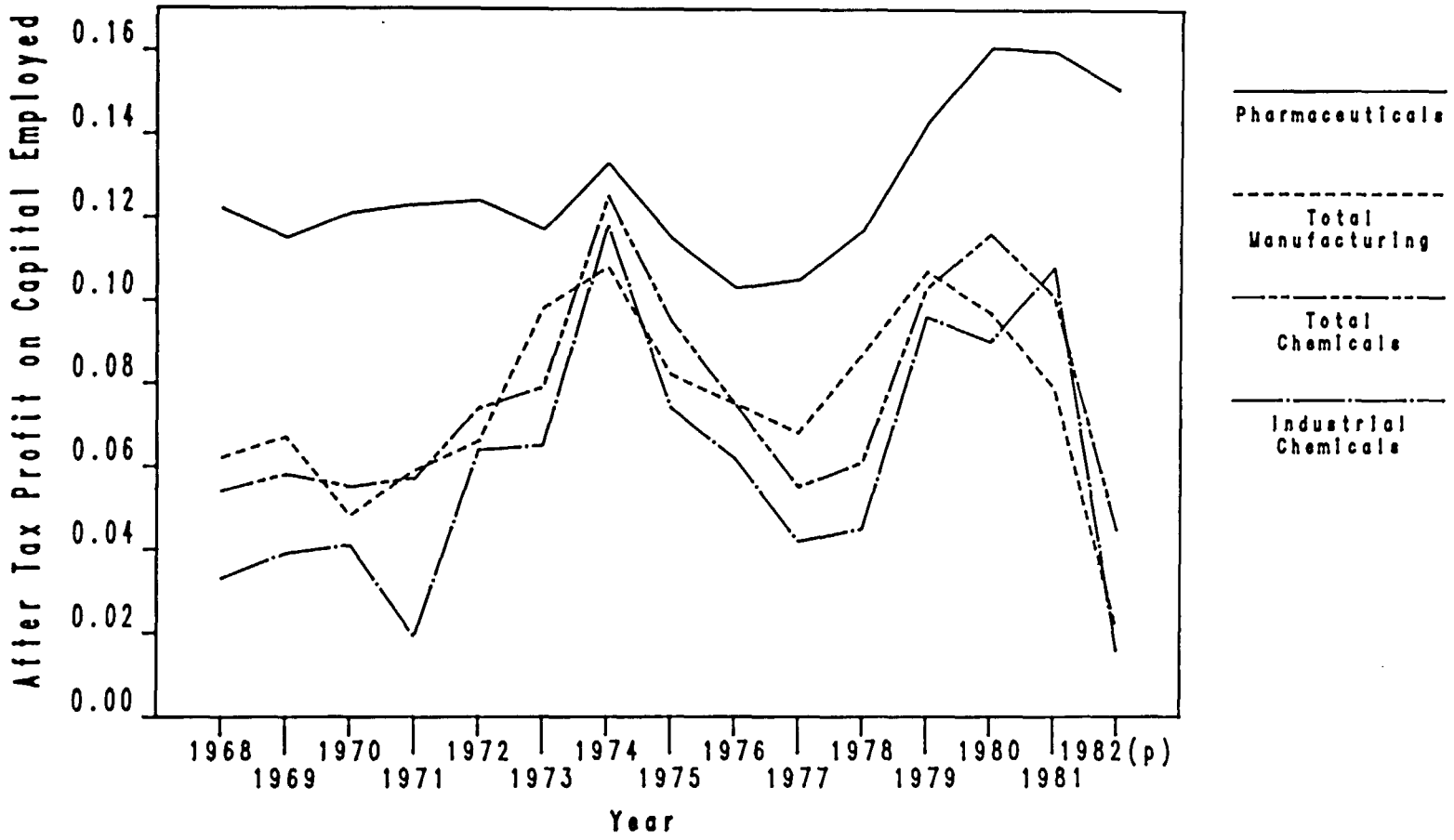


Chart A6.2

Profit After Tax on Capital Employed, Comparison of Pharmaceutical Industry to Selected Other Industries: Canada, 1968-82

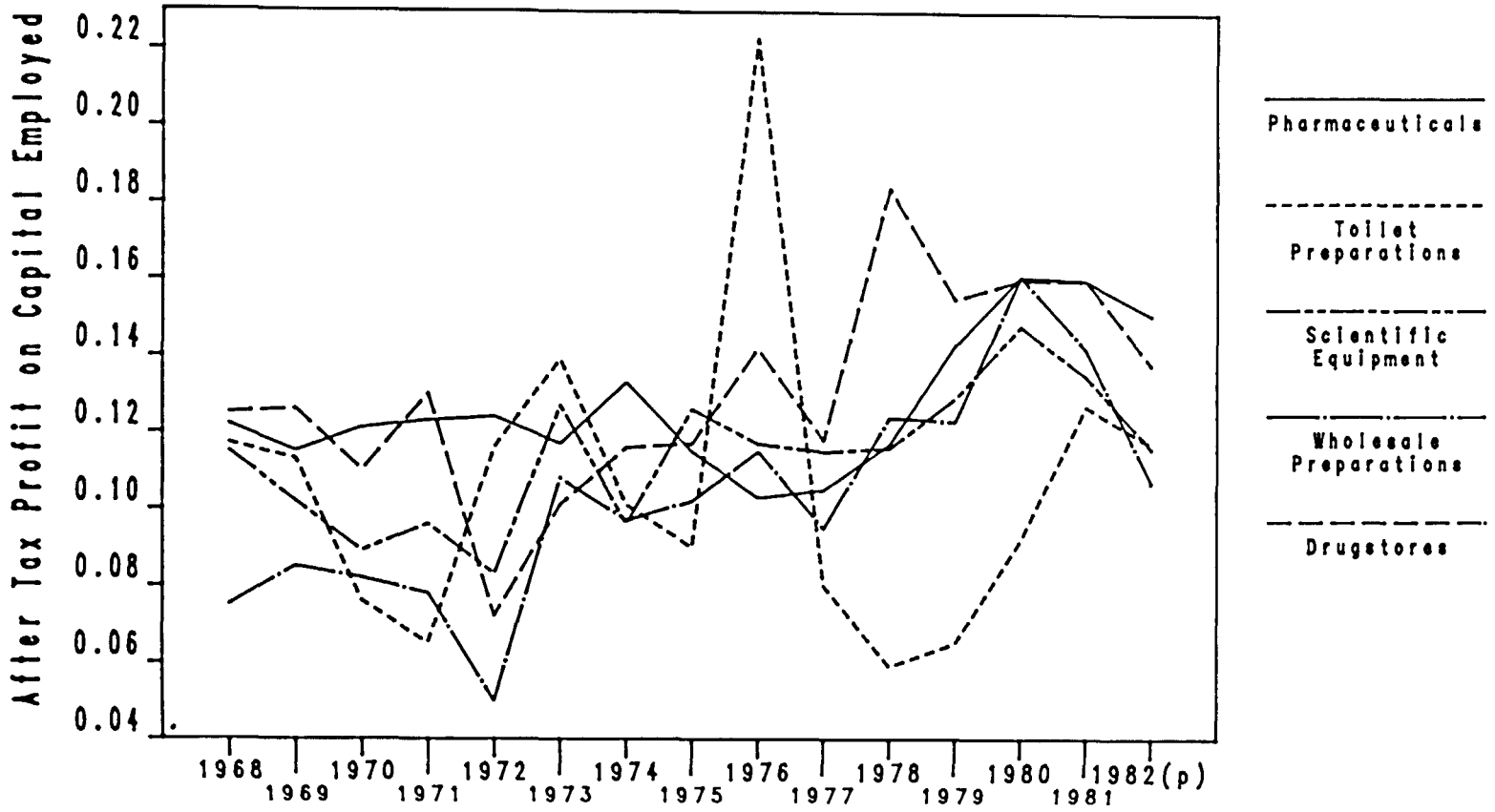


Chart A6.3

Profit After Tax on Total Income, Comparison of Pharmaceutical Industry to Selected Other Industries: Canada, 1968-82

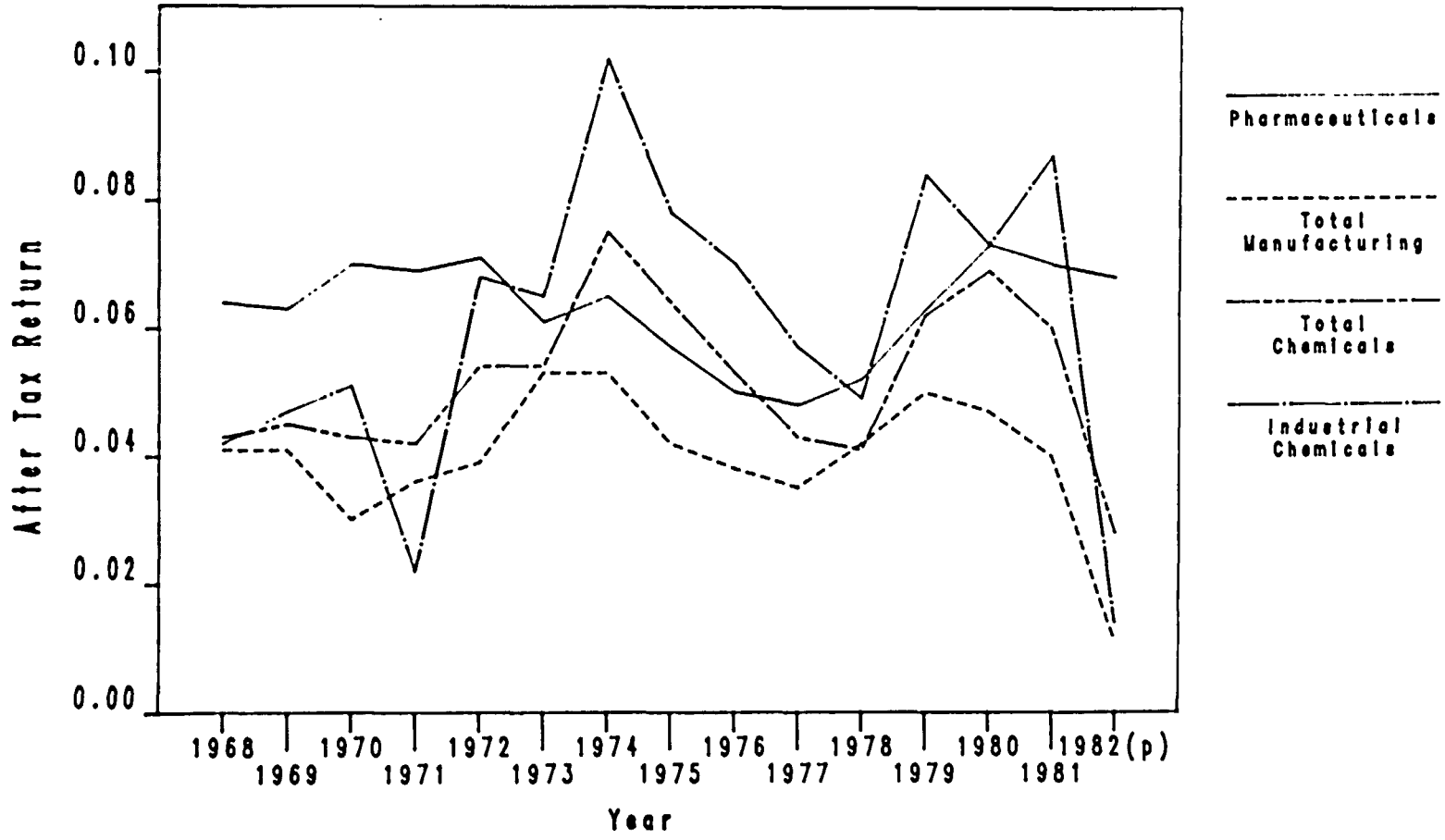
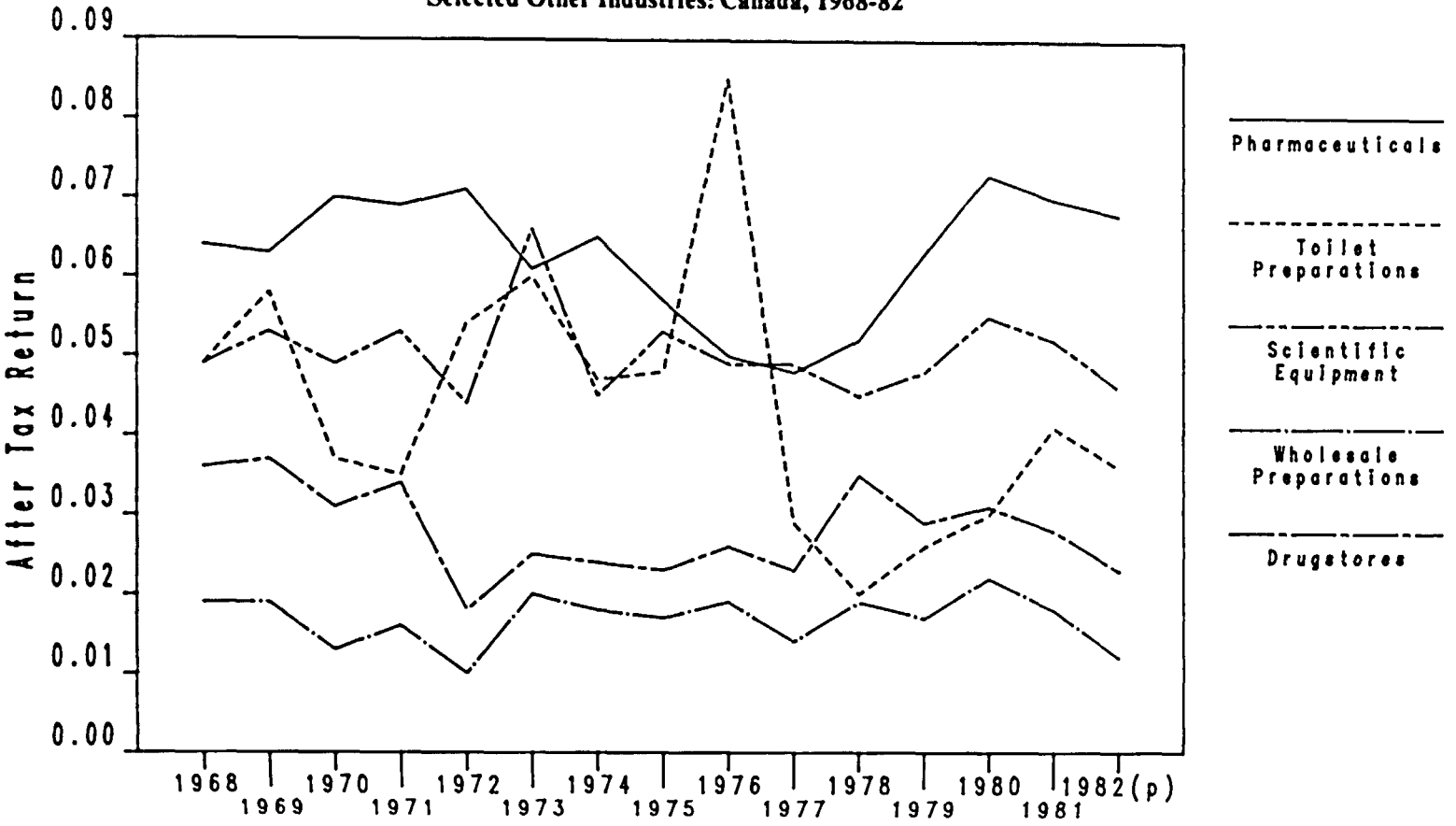


Chart A6.4

Profit After Tax on Total Income, Comparison of Pharmaceutical Industry to Selected Other Industries: Canada, 1968-82



Chapter 7

Market Performance: Prices

Introduction

A second major indicator of an industry's performance is the level of prices. As a general case, given the quality and range of products, performance is judged to be better should prices be constant or falling. Such changes in prices cannot of course be judged in a vacuum. Prices can be considered relative to historical prices, relative to those in other industries, and relative to prices in other countries for the products and services of a particular industry.

In the first section of this chapter, price changes over the last two decades are considered. This is done both for the pharmaceutical industry and other selected industries in Canada, and also for the industry in other countries, especially in the United States.

A major problem with the price indices for a large number of commodity groups is the difficulty of accounting for changes in the quality of products. This is an especially troublesome problem for the pharmaceutical industry in which each year several new products are introduced in the marketplace as fairly direct competitors with an existing array of products. In Canada, as well as in most countries, the normal procedure for constructing the pharmaceutical price index treats such newly introduced products as distinctly new products. Thus, the price index does not capture any increase in the price of the new product relative to the old product even in those frequently encountered situations in which the old and the new drug have roughly the same therapeutic value to the prospective patient and thereby are for practical purposes the same product. This problem of product replacement and potential product upgrade is considered in the second section of this chapter.

The third major section of this chapter reports on the results of two major studies in which prices of pharmaceutical products in Canada are compared with those found in the United States over the period 1968 to 1983. An indication of the potential impact of compulsory licensing as seen in reduced expenditures for pharmaceuticals in Canada is provided by the results of these studies.

Subsequently examined are a number of other studies and sets of data that permit a comparison of international prices with those found in Canada.

In the examination of price changes and comparative prices in Canada relative to those found in other countries, a principal concern is whether the evidence is consistent with, if not suggestive of, a significant impact of the change in compulsory licensing that was introduced in 1969. A policy objective of the government in introducing the change in compulsory licensing regulations in 1969 was that of reducing what were then seen to be relatively high drug prices. Indeed, the nature of the changes that were made would lead one to expect fairly significant reductions in prices throughout the Canadian pharmaceutical industry, other things being equal.

As shown in the preceding chapter on profits, compulsory licensing is not the only factor that must be considered. In particular there are those demand-side factors of significantly increasing proportions of the population covered by third-party insurance for pharmicare and also a rising percentage of the population over 65 who are disproportionately large consumers of pharmaceutical products. Both of these factors can make the market a fairly bouyant one. Indeed, were it not for changes in compulsory licensing or any other similar change in government regulation, a general expectation would be that prices would rise relatively sharply, at least until patent expirations permitted the entry of new firms, as a result of these strong demand-side pressures.

General Price Level Changes

General changes in prices can be seen at both the manufacturing and retail level. However, the 1969 policy regarding compulsory licensing would be expected to bear most directly on manufacturing and therefore on prices at this level. In contrast, retail prices comprise several components in addition to manufacturers' costs which by themselves account for less than 50 per cent of final retail prices. Thus movements in retail prices may result from changes in the market structure of retail pharmacies and drugstores and in the purchasing behaviour of hospitals. Such changes may or may not be consistent with changes at the manufacturing level and thus the expected impact of compulsory licensing on retail price levels will be much less direct than that at the manufacturing level. Nevertheless, price changes at the retail level are examined.

Prices in Manufacturing

Set out in Table 7.1 is a summary of prices at the manufacturing level in the form of the Industry Selling Price Index for pharmaceuticals and for the products and services of selected other industries and industry groups. This information is provided for three periods, 1961 to 1971, 1971 to 1981, and 1980 to September 1984.

The first major inference that can be drawn is the difference in relative price movements in the three periods shown. For the first of these periods, 1961 to 1971, pharmaceuticals and medicines and the component of these described as "patented pharmaceuticals and medicines" are characterized by substantially lower changes in prices than those for all manufacturing. Indeed, prices

Table 7.1

Summary of Industry Selling Price Indices for Pharmaceuticals and Selected Other Industries: Canada, 1961-71, 1971-81, and 1980 to Sept. 1984

Industry and Industry Group	1961-71 (1961=100)	1971-81 (1971=100)	1980-Sept. 1984 (1980=100)
All Manufacturing	121.4	272.4	126.2
Chemicals and Chemical Products	102.6	286.4	131.4
Manufacturers of Pharmaceuticals and Medicines	107.8	189.8	149.4
Patented Pharmaceuticals and Medicines	104.2	209.2	157.7
Antibiotics: Penicillin Preparations		89.2	138.5
Antibiotics: Other		139.0	134.8
Vitamins		163.3	110.0
Sex Hormones		211.3	189.9
Oral Antiseptics		242.0	135.2
Ethical Preparations for Human Use n.e.s.		196.9	158.5
Manufacturers of Soap and Cleaning Compounds		209.9	127.3
Manufacturers of Toilet Preparations		204.8	153.4
Medicinal and Pharmaceutical Preparations		203.9	148.4

Source: Statistics Canada, *Industry Price Indexes* (Catalogue 62-011), various issues, 1961-84.

for all manufacturing goods advance some 13 per cent more rapidly than those for all pharmaceuticals and medicines for this period and some 17 per cent more rapidly than is the case for patented pharmaceuticals and medicines. As judged by these overall changes in the Industry Selling Price Index, the performance of the pharmaceuticals and medicines industry group is clearly superior to that of all manufacturing.

A consideration of price performance over the second period from 1971 to 1981 again reveals a superior price performance. Over this period, the prices of all manufacturing goods advance some 44 per cent faster than those for all pharmaceuticals and medicines and some 38 per cent faster than ethical preparations for human use n.e.s.

The sharply increased price performance of pharmaceuticals and medicines for this period relative to that for the preceding period (1961 to 1971) is clearly consistent with the expected and desired impact of the change in compulsory licensing.

The most recent four-year period reveals a somewhat different picture. This is of course a period during which the overall Canadian economy has gone through a fairly serious recession. The Industry Selling Price Index for all pharmaceuticals and medicines and for patented pharmaceuticals and medicines reveals that the prices of these commodities are advancing more rapidly than those of all manufacturing goods. Indeed the prices of manufacturing goods advanced only 80 per cent as fast as those for ethical preparations for human use n.e.s. and 84 per cent as fast as all pharmaceuticals and medicines.

The historical picture of the relationship between price level changes for pharmaceuticals and medicines relative to all manufacturing goods and indeed many other industry groups is thus sharply reversed in this last four-year period. Such a reversal is consistent amongst other things with the near recession-proof nature of much of the health care sector: expenditures by third-party insurers, especially governments, for such things as pharmicare are thought to be sufficiently important as to not be cut during a recession.

An additional framework within which to compare the price performance of pharmaceutical manufacturers in Canada is provided by information on prices at the manufacturing level for pharmaceuticals and medicines and selected other industries and industry groups in the United States. This information is presented in Table 7.2.

There is clearly a marked similarity between Canada and the United States in trends in relative price level changes. As in Canada, so in the United

Table 7.2

Summary of Producer Price Indices for Drugs and Pharmaceuticals and Selected Industries: United States, 1971-81 and 1980 to Sept. 1984

Industry and Industry Group	1971-81 (1971=100)	1980-Sept. 1984 (1980=100)
All Commodities	257.6	115.1
All Industrial Commodities	266.8	117.3
All Chemicals and Allied Products	276.0	115.8
Drugs and Pharmaceuticals	189.0	139.1
Pharm. Prep. Ethical (Prescription)	173.4	151.7
Pharm. Prep. Proprietary (Over the Counter)	207.7	141.3
Industrial Chemicals	356.2	104.4
Agricultural Chemicals	309.1	110.9

Source: United States Bureau of Labour Statistics, *Producer Prices and Price Indexes*, selected issues, 1971-84.

States, prices advanced much more rapidly in the general economy over the late 1960s and 1970s than was the case for pharmaceuticals and medicines, either taken as a whole or for the sector described as prescription drugs. In contrast, in the last four-year period, from 1980 to September 1984, prices of prescription drugs and of all drugs and pharmaceuticals have advanced much more rapidly than the prices of all commodities.

Such similarities are probably closely associated with similarities in the demand side of the market for pharmaceuticals and medicines. These similarities include a similar change in the age distribution of the population, especially over the age of 65, and similar trends in the coverage of the population with third-party insurance programs such as pharmicare.

From 1971 to 1981, the prices of all commodities in the United States advanced more rapidly than those of all drugs and pharmaceuticals by some 36 per cent. Correspondingly, as noted above, the prices of all manufacturing goods in Canada advanced more rapidly than those of all pharmaceuticals and medicines by some 44 per cent. Alternatively, in the United States, all drugs and pharmaceuticals had price increases that were some 73 per cent of those for all commodities; whereas in Canada, pharmaceuticals and medicines had price level changes that were some 70 per cent of the price level changes for all manufacturing goods. These comparisons are consistent with the expectation that the change in compulsory licensing in 1969 would have had some retarding effect on relative price changes in Canada as compared to those in the United States.

Looking at the most recent four-year period, the prices of all pharmaceuticals and medicines in Canada advanced some 18 per cent more rapidly than the prices of all manufacturing goods; in the United States, the comparable figure is 21 per cent. Similarly, whereas in Canada the prices of ethical preparations for human use n.e.s. advanced 26 per cent more rapidly than the prices of all manufacturing goods, the comparable figure for prescription drugs in the United States is some 32 per cent. Accordingly, the price level data for the most recent four-year period are once again consistent with the proposition that compulsory licensing has had a retarding effect on price level changes in Canada as compared to those in the United States pharmaceutical market.

Price Level Changes in the Retail Market

Changes in the Consumer Price Index for pharmaceuticals and for selected other items in Canada for the periods 1961 to 1971, 1971 to 1981, and 1980 to September 1984 are described in Table 7.3. As in the case of prices at the manufacturer's level, consumer prices display quite distinctly different patterns over the 1960s and 1970s from those of the most recent four-year period. For both the 1960s and 1970s, prices of all items advanced some 30 to 40 per cent more rapidly than did those for all pharmaceuticals and the subcategory, prescribed medicines. In contrast, from 1980 to September 1984, the prices of all items in the Consumer Price Index advanced only about 85 per cent as fast as did the prices of prescribed medicines.

Table 7.3

Summary of Consumer Price Indices for Pharmaceuticals and Selected Other Items: Canada, 1961-71, 1971-81, and 1980 to Sept. 1984

Item	1961-71 (1961=100)	1971-81 (1971=100)	1980-Sept. 1984 (1980=100)
All Items	133.4	237.0	138.4
All Goods		245.7	136.9
Health and Personal Care	142.4	221.2	137.3
Health Care	143.0	217.2	145.5
Dental Care	171.4	245.5	143.5
Medical Supplies and Pharmaceuticals	97.0	187.4	156.2
Prescribed Medicines	93.8	181.6	161.9
Non-prescribed Medicines	101.4	200.8	144.4
Personal Care	142.6	222.7	131.7
Personal Care Supplies and Equipment	123.5	180.5	135.2

Source: Statistics Canada, *Consumer Prices and Price Indexes* (Catalogue 62-010), selected issues, 1961-84.

With regard to the comparison of these relative price changes in the 1960s as opposed to the 1970s, the prices of all items relative to prescribed medicines advanced more quickly in the 1960s than did prices of all items relative to prescribed medicines in the 1970s. This is in contrast to the price trends revealed by the Industry Selling Price Index in Table 7.1. However, as noted earlier, compulsory licensing will have a greater impact on manufacturing prices as indicated by the Industry Selling Price Index than on prices at the retail level as shown by the Consumer Price Index. Retail prices (including dispensing fees) of prescribed drugs are roughly twice what they are at the manufacturer's factory gate. Accordingly, structural changes in the retail market may well lead to cost increases that are sufficiently strong to offset any cost reductions stemming from compulsory licensing.

Similar information on consumer prices in the United States is presented in Table 7.4. Once again, price trends are seen to be sharply different as between the 1970s and the most recent four-year period. For the period 1971 to 1981, prices of all items in the United States advanced 32 per cent more rapidly than did the prices of prescribed drugs at the retail level, compared with 31 per cent in Canada. Retail prices of pharmaceuticals were advancing somewhat faster in Canada than in the United States. This difference contrasts with the change at the manufacturer's level, where the prices of all commodities relative to those of pharmaceuticals were advancing more rapidly in Canada than in the United States. It therefore indicates that the non-manufacturing cost components of final retail prescription drug prices have grown more rapidly in Canada than in the United States, and sufficiently so as

Table 7.4

Summary of Consumer Price Indices for Pharmaceuticals and Selected Other Items: United States, 1971-81 and 1980 to Sept. 1984

Item	1971-81 (1971=100)	1980-Sept. 1984 (1980=100)
All Items	224.6	127.4
All Commodities	216.0	120.7
Medical Care	229.4	144.1
Prescription Drugs	170.3	153.8
Non-prescription Drugs and Medical Supplies	n.a.	136.1
Physicians Services	230.4	141.4
Dental Services	207.3	138.2
Hospital Rooms	295.0	162.2
Personal Care	198.6	128.4
Toilet Goods and Personal Care Appliances	199.6	131.8

Source: United States Bureau of Labour Statistics, *Monthly Labour Review and CPI Detailed Report*, selected issues, 1971-84.

to offset the relative slow growth of manufacturing costs in Canada as compared with the United States. This in turn is consistent with a somewhat more competitive retail market in the United States as compared to Canada.

With respect to the most recent four-year period, retail prices of prescribed medicines in Canada are seen to advance about 17 per cent more rapidly than the prices of all items. The corresponding figure for the United States is 21 per cent. That is, pharmaceutical prices at the retail level are advancing more rapidly in the United States than they are in Canada. This is the reverse of the picture describing the period from 1971 to 1981. The recent relative price performance at the retail level in Canada is thus consistent with a measurably more competitive retail market in Canada than in the United States. On the other hand, it is also consistent with the information described earlier of price level changes at the manufacturer's factory gate. Relative prices of prescribed drugs in Canada for this last four-year period are thus seen to be rising more slowly at both the manufacturing and retail levels than in the United States.

Product Replacement and Potential Product Upgrade

A major problem with the price indices discussed in the preceding section is the difficulty of including in them changes in prices that result from the introduction of new products which may be therapeutically equivalent to old

products but whose prices are markedly different from the old product. Accordingly, without a consideration of this matter of product replacement and potential product upgrade, it is exceedingly difficult to reconcile information on price level changes on the one hand with information on total expenditures on pharmaceuticals on the other.

The explanation of changes in the total sales of pharmaceuticals and medicines or any component of them, such as prescribed medicines, must necessarily include a consideration of each of the following items:

1. The price of a particular drug given its particular dosage form and package size.
2. The number of prescriptions.
3. The package size, that is the number of doses included in the prescription.
4. The dosage form.
5. The replacement of old products with relatively more expensive new products.
6. The improvement, if any, in the quality of a given product.

Of these, perhaps the most difficult to evaluate is the last. Separating out changes in the quality of a given drug is so exceedingly difficult that it is rarely accomplished. Some attempt at doing just that, however, is made by the authorities of the Department of Trade and Industry, Business Statistics Office, in the United Kingdom with respect to the Producer Price Index for pharmaceuticals sold at the manufacturing level in the United Kingdom. Clearly a great deal of information and assessment of comparative therapeutic efficacy must be assembled on a consistent and comprehensive basis if price changes resulting from quality changes are to be distinguished from pure price changes. In general, this is not done and recorded price changes may inappropriately register changes in quality.

An evaluation of the separate effects of the first five factors listed should in principle be more easily accomplished. In practice it is done infrequently.

An interesting attempt by the newsletter *Scrip* involves the producing of information on two new indices for pharmaceuticals sold in the United Kingdom which would complement the Producer Price Index (which is quite similar to the Industry Selling Price Index for Canada and the Producer Price Index for the United States described in the preceding section). The two new indices developed by the publishers of *Scrip* are as follows:

1. *Manufacturer's Scrip Revenue Index*: the monthly drug ingredient (pre-bonuses[1]) cost divided by the number of prescriptions in a month.

[1] Bonuses include a variety of goods in hand received by retail chemists.

2. *National Health Service (NHS) Scrip Expenditures Index*: the monthly post-bonuses ingredient cost divided by the number of prescriptions in a month.

These two indices take into account changes in the number of prescriptions and therefore leave unresolved the amalgam of changes in price, package size, the substitution of more expensive alternatives, and the introduction of new and possibly more expensive products.

Price changes, however, can be easily evaluated. Whereas the Producer Price Index for pharmaceutical production in the United Kingdom in April 1984 stood at 127.8 (1980 being set equal to 100), the Manufacturer's Scrip Revenue Index for the same month stood at 168.4 and the NHS Scrip Expenditures Index stood at 161.6.

Thus for the period from 1980 to April 1984, the combined impact of changes in package size and dosage form, new products, and product upgrade account for 37.8 per cent of an increase in the price of a prescription as seen by the Manufacturer's Scrip Revenue Index and for a 26.4 per cent increase in the cost of a prescription as seen by the NHS Scrip Expenditures Index.

A somewhat more detailed analysis of these factors is provided by the U.S. brokerage firm Kidder, Peabody and Company in its annual evaluation of the pharmaceutical industry in the United States.[2] This company has assembled from a number of sources data that permit the change in total sales to be broken down into several components, namely, the change in price, the change in the number of prescriptions, and the change in the number of doses, and as a result, to establish a residual component that accounts principally for product replacement and potential product upgrade. The results of their most recent analysis are presented in Table 7.5. Having accounted for the price changes of given products, changes in the number of prescriptions, and changes in the number of doses per prescription, there is a residual, accumulated change of some 35 per cent in total expenditures on drugs over the period 1976 to 1983 that can be said to be the impact of product replacement and potential product upgrade.

Yet a third interesting exercise in sorting out these differential impacts other than price changes on sales is the work of the German scientific institute called WIdO. It has recently considered the sales of a group of products that account for 75.4 per cent of all spending on medicines by Krankenkassen (sickness funds) in West Germany in 1983. In its analysis, changes in the sales revenues of drugs in particular therapeutic categories are accounted for by the following components: the number of prescriptions, price changes, shifts from one dosage form or package size within the existing basket of drugs in question, and additions to and deletions from the basket of drugs. The effect on sales of new drugs is then determined. By itself, this effect would have led to an

[2] Kidder, Peabody and Co., as reported in *Scrip*, No. 905 (June 1984), p. 15.

Table 7.5

U.S. Pharmacy Market 1976-83 Year-to-Year Percentage Change

Year	Sales Growth[a] (1)	Price Inc. (2)	Unit Growth (1-2)	No. of Prescriptions[b] (3)	No. of Doses (4)	New Prod. Upgrade[c] (3-4)
1976	8.5	6.3	2.2	−1.9	3.8	0.3
1977	7.0	4.2	2.8	−3.3	2.4	3.7
1978	8.3	7.1	1.2	−1.1	0.2	4.0
1979	8.3	7.1	1.2	−2.2	1.1	2.3
1980	4.2	8.9	5.3	2.0	1.4	1.9
1981	12.9	11.7	11.2	3.6	1.1	6.5
1982	25.2	11.1	14.1	5.3	0.7	8.1
1983	25.9	10.6	5.3	1.0	0.5	3.8

[a] Manufacturers' dollars. [b] New + refill prescriptions dispensed.

[c] Residual figure: unit growth less change in number of prescriptions dispensed and number of doses per prescription.

Source: *Scrip*, No. 930 (September 10, 1984), pp.4-5.

estimated 1.9 per cent increase in the sales of analgesics; to a drop of 0.7 per cent for psychotropics; to an increase of 4.9 per cent for coronary agents and of 18.4 per cent for gastro-intestinal agents.

Limited information is available from IMS Canada on the growth in sales of ethical drugs accounted for by "new presentations." These may represent entirely new chemical entities but more commonly represent new presentations of existing chemical entities. For the first six months of 1984, and for 77 companies, estimated changes in sales accounted for by new presentations averaged only 6.9 per cent. For 40 companies the impact was less than 5 per cent and for eight companies it was over 20 per cent. The portion of these increases that represents advances in safety and/or efficacy in the form of either new products or improved products cannot be easily distinguished from the portion that represents a price increase in an existing product accomplished through a "new presentation."

A fairly detailed and comprehensive data base is necessary if the sources of change in total expenditures on a product such as prescribed drugs, either at the manufacturer's level or at the retail level, or both, is to be fully sorted out. Without such a detailed comprehensive data base the possible sources of changes in total expenditures remain speculative. What is clear, however, is that the changes of price of particular products are not at all a satisfactory indicator of expenditure changes that have as their source decisions by the manufacturer. In addition to deciding on the price of particular products, the manufacturer can also quite clearly decide to introduce a new product that is therapeutically little different from the old product, and furthermore, can set a price for the new product significantly higher than that of the old product.

Such a change will not be picked up by either the Industry Selling Price Index or the Consumer Price Index. Such a product introduction will, however, have a significant impact on total expenditures on drugs. From the experience of the three countries just considered, the United Kingdom, the United States, and West Germany, such an impact might well be as high as 18.4 per cent for products of a particular therapeutic class but in general is less than 5 per cent annually.

Estimated Impact of Compulsory Licensing on Expenditures of Multiple-source Drugs

The results of two major studies on drug prices in Canada and the United States are considered in this section. In these, the cost of a sample of drugs in Canada is compared to the costs that would have been incurred on these drugs had they been purchased in the United States. In both of these studies, the sample of drugs is made up of two categories: (1) multiple-source drugs, which are defined as those subject to the competition from generic firms through the compulsory licensing provisions of the Patent Act in Canada, and (2) single-source drugs, which are those entities marketed in some cases by more than one patent-holding firm and marketed on the basis of competition by brand preference more than by price.

In each instance, the choice of drugs in the sample was dictated principally by the criterion of largest sales in Canada. A second criterion was that roughly similar formulations were sold in both countries.

The methodology for estimating the cost of each of these drugs in the United States was fairly straightforward in those cases in which all package sizes and dosage forms were the same as those in Canada. The prices existing in the United States were used to estimate the United States value of each package size and dosage form. In the case of those drugs for which all package sizes and dosage forms were not the same in both countries, a common mass in kilograms was established for sales in Canada and the prices of this common mass in the United States used to estimate the value of the sales in Canada were they to be purchased at the U.S. prices.

In the first of these studies, Study A, expenditures on a sample of single-source drugs and a sample of multiple-source drugs sold in drugstores and pharmacies in Canada are estimated for each of the years 1968, 1976, 1982, and 1983. In the second of these studies, Study B, expenditures on a sample of single-source drugs and multiple-source drugs sold in hospitals as well as in drugstores and pharmacies in Canada are estimated for 1983. In both of these studies, the estimates are first of total expenditures on these samples in Canada, and second of hypothetical expenditures on these same drugs had they been purchased in the United States at U.S. prices in each of the years in question.

Estimated Impact of Compulsory Licensing on Expenditures on a Sample of Drugs Sold to Drugstores and Pharmacies—1968, 1976, 1982, and 1983: Study A

Set out in Table 7.6 are the principal characteristics of the Study A analysis of actual expenditures in Canada on a sample of single- and multiple-source drugs sold to drugstores and pharmacies compared to estimated expenditures on these drugs in the United States (given an exchange rate of $1.20 Cdn). Total sales of the overall sample of 104 drugs in 1976, amounting to some $135 million, accounted for just over 30 per cent of all sales of ethical drugs to drugstores in that year. Similarly in 1982, the sample of 88 drugs represented total sales of $355.5 million, and this amount accounted for almost 33 per cent of total sales of ethical products to drugstores. In 1983, the sample of 89 drugs accounted for some $453.9 million of sales in total, and this sum was about 36.5 per cent of all sales of ethical pharmaceuticals to drugstores.

With regard to the historical trend in prices as revealed by differences in the actual cost in Canada and the estimated cost in the United States, had the same bundle of drugs been purchased in the United States, the trend for single-source drugs from 1968 to 1983 is very stable. Actual expenditures in Canada in 1968 were 84.2 per cent of the estimated cost of these drugs in the United States. In 1976, the comparable figure was 86.8 per cent, in 1982, 83.9 per cent, and in 1983, 86.5 per cent.

The same stable trend is, however, not in evidence with regard to multiple-source drugs. Whereas the actual cost in Canada relative to the estimated cost in the United States was 69.8 per cent in 1968, this figure fell progressively to 46.7 per cent in 1983.

Also set out is the estimated cost in Canada of multiple-source drugs if the Canadian-U.S. differential that applied in each year for single-source drugs were assumed to characterize multiple-source drugs. The actual cost of the sample of drugs is then set out as a percentage of the estimated cost in Canada of this same sample were the Canadian-U.S. differential for single-source drugs applied. This percentage is 82.9 in 1968; it subsequently falls progressively to 54.0 per cent in 1983.

The difference between the actual cost in Canada and the estimated cost in Canada were the Canadian-U.S. differential for single-source drugs assumed to apply to multiple-source drugs, is $1.5 million in 1968, $21.2 million in 1976, $110.2 million in 1982, and $170.4 million in 1983.

We may thus interpret this last set of figures as the estimated minimum potential impact of compulsory licensing on the expenditures in Canada on a sample of multiple-source drugs sold to drugstores and pharmacies. It is a saving of $170.4 million on the 32 drugs in the sample of multiple-source drugs whose combined sales in 1983 amounted to $200 million. Had these drugs been sold at U.S. prices, they would have cost about $428.3 million. In turn, under these assumptions, such drugs would have accounted for some 29 per cent of the total market in Canada. On the other hand, were they to be sold at the

Table 7.6

Estimated Impact of Compulsory Licensing on Expenditures on a Sample of Single-source and Multiple-source Drugs Sold to Drugstores: Canada Compared to the United States, 1968, 1976, 1982, and 1983 (Study A)

	1968		1976		1982		1983	
	Single Source	Multiple Source	Single Source	Multiple Source	Single Source	Multiple Source	Single Source	Multiple Source
Number of Drugs in Sample	97	4	83	21	59	29	57	32
Cost of Canadian Sales ($000)	$32,870	$ 7,220	$ 94,395	$40,843	$176,595	$178,927	$253,843	$200,099
Estimated Cost of Sales in U.S. ($000)	39,017	10,340	108,766	71,436	210,540	344,653	293,511	428,343
Cost in Canada as Percentage of U.S. Percentage	84.2%	69.8%	86.8%	57.2%	83.9%	51.9%	86.5%	46.7%
Difference in Canadian and U.S. Costs ($000)	$ 6,147	$ 3,120	$ 14,371	$30,593	$ 33,945	$165,726	$ 39,668	$228,244
Difference as Percentage of Canadian Costs	18.7%	43.2%	15.2%	74.9%	19.2%	92.6%	15.6%	114.1%
Estimated Cost in Canada of Multiple-source Drugs if Canadian-U.S. Differential for Single-source Drugs is Applied ($000)		$ 8,706		$62,006		$289,164		$370,517
Actual Cost as a Percentage of Estimated Cost in Canada		82.9%		65.9%		61.9%		54.0%
Difference between Actual and Estimated Cost in Canada ($000)		$ 1,486		$21,153		$110,237		$170,418

Source: T. Brogan, G. Roberge and B. Philie, *A Comparison of Pharmacy Drug Costs in Canada and the United States for Selected Years* (Ottawa: Bureau of Policy Coordination, Consumer and Corporate Affairs, 1985).

same Canadian-U.S. price differential that characterizes single-source drugs, the saving of $170.4 million would be relative to a total potential expenditure of $370.5 million. In turn, this latter figure would have constituted some 26 per cent of the overall Canadian market for pharmaceutical products. The $170.4 million thus constitutes the saving on a sample of drugs whose sales in total amount to less than 30 per cent of the Canadian market.

Estimated Impact of Compulsory Licensing on Expenditures on a Sample of Drugs Sold Both to Hospitals and to Drugstores and Pharmacies in 1983: Study B

The second major study referred to earlier, Study B, expands the estimates of the potential savings associated with compulsory licensing to drugs sold in hospitals as well as those sold in drugstores and pharmacies. The detailed results of Study B are set out in Table 7.7. The format for presenting the results is similar to that used for Study A, the results of which were presented in Table 7.6. Because of the rapid change in the exchange rate between Canada and the United States, both the exchange rate actually existing in Canada in 1983, namely, $1.00 U.S. equals $1.30 Cdn, and the rate that existed in the preceding year, namely, $1.20 Cdn, have been considered in the comparison. The sample of drugs considered includes 68 single-source drugs and 32 multiple-source drugs. Together the 100 drugs in the sample accounted for total sales in Canada in 1983 of $523.2 million or 34.3 per cent of the total market for all drugs.

The results are roughly comparable for each of the two exchange rates considered. With regard to single-source drugs, the actual expenditures in Canada are estimated at 81.3 per cent of what they would have been if they had been bought at U.S. prices for the exchange rate $1.30 Cdn. For the second exchange rate the actual cost of the single-source drugs in Canada amounts to 88.1 per cent of the estimated U.S. cost. The corresponding figure from Study A was 86.5 per cent.

For multiple-source drugs the actual cost, about $216 million, amounts to 41.2 per cent of costs estimated on the basis of U.S. prices and assuming the exchange rate of $1.30 Cdn. For the second exchange rate the actual cost of these multiple-source drugs would account for 44.6 per cent of the estimated U.S. cost. The corresponding figure from Study A was 46.7 per cent.

The impact of compulsory licensing on expenditures on pharmaceuticals and medicines can now be estimated. The cost of the 32 multiple-source drugs examined in 1983 has previously been estimated at $524.7 million and $484.4 million using the two different exchange rates. These costs may be re-estimated using a set of hypothetical prices that would obtain if the Canadian/U.S. differential on single-source drugs applied to multiple-source drugs. If this is done the cost of the bundle of 32 drugs is $426.6 million or $426.8 million using the two different exchange rates. The actual cost in Canada of the bundle of 32 drugs was $216 million.

Table 7.7

Estimated Impact of Compulsory Licensing on Expenditures on a Sample of Single-source and Multiple-source Drugs Sold to Drugstores, Pharmacies and Hospitals: Canada Compared to the United States, 1983 (Study B)

	Exchange Rate: $1.00 US = $1.30 Cdn			Exchange Rate: $1.00 US = $1.20 Cdn		
	Single Source	Multiple Source	All Drugs	Single Source	Multiple Source	All Drugs
Number of Drugs in Sample	68	32	100	68	32	100
Cost of Canadian Sales ($million)	$307.2	$216.0	$523.2	$307.2	$216.0	$523.2
Estimated Cost of Sales in U.S.	377.7	524.7	902.4	348.7	484.4	833.1
Cost in Canada as Percentage of U.S. Cost	81.3%	41.2%	58.0%	88.1%	44.6%	62.8%
Difference in Canadian and U.S. Costs ($million)	$70.5	$308.7	$379.2	$41.5	$268.4	$309.9
Difference as Percentage of Canadian Costs	22.9%	142.9%	72.5%	13.5%	124.5%	59.2%
Estimated Cost in Canada of Multiple-source Drugs if Canadian-U.S. Differential for Single-source Drugs is Applied ($million)		$426.6			$426.8	
Actual Cost as a Percentage of Estimated Cost		50.6%			50.6%	
Difference between Actual and Estimated Cost ($million)		$210.6			$210.8	

Source: T. Brogan and G. Roberge, *1983 Drug Store and Hospital Drug Purchase: A Comparison of Canada and the United States* (Ottawa: Bureau of Policy Coordination, Consumer and Corporate Affairs, 1985), Table 1, p. 4.

The absolute dollar difference between the actual cost of Canadian sales of the 32 sample drugs and this newly estimated hypothetical cost is $211 million. Accordingly, the estimated impact of compulsory licensing is at least $211 million.

If these multiple-source drugs had been sold in Canada at prices that were in line with the prices charged for the sample of 68 single-source drugs relative to U.S. prices, the total cost of pharmaceutical products in Canada in 1983 would have been an additional $211 million, and thus the overall expenditures on drugs at the manufacturing level would have increased from $1.527 billion to $1.738 billion. Were this the case, the sample of 32 multiple-source drugs would have accounted for just under 25 per cent of the total cost of all drugs at the manufacturing level in Canada in 1983.

These estimated annual savings of $211 million to Canadians resulting from compulsory licensing are, however, very much underestimated. Instead of 32 multiple-source drugs in 1983 as a result of compulsory licensing, there were actually some 42. Similarly, the total sales of these drugs were approximately $240 million, not just the $216 million examined in Study B.

It should be emphasized that the estimated savings of the sample of multiple-source drugs are actual not potential. This is so because the actual cost of these drugs in Canada includes the sales by generic firms at their prices plus the sales of the patent-holding firms at their prices. The actual cost calculated for the entire sample of multiple-source drugs is thus a combination of the sales of these two different types of firms.

As a final exercise, the results of Study B of comparative costs in Canada for 1983 can be compared with a previous study carried out for 1982. The exchange rate $1.20 Cdn is assumed to hold for both years. If this is done, the results are as those set out in Table 7.8. With regard to single-source drugs, the cost in Canada of the bundle of 53 drugs relative to hypothetical costs using U.S. prices is 83.7 per cent in 1982 and rises to 88.1 per cent with regard to the 68 drugs in the sample in 1983. In contrast, the cost of the 29 multiple-source drugs in the sample in 1982 relative to estimated costs using U.S. prices is 51 per cent in 1982 and this falls to 44.6 per cent with regard to the 32 drugs in the sample in 1983.

These results for the sales both to hospitals and to drugstores and pharmacies can be compared with those from Study A sales to drugstores and pharmacies only. The change from 1982 in the latter case was from 83.9 per cent to 86.5 per cent for the cost of single-source drugs in Canada relative to the hypothetical cost of the samples using U.S. prices. For multiple-source drugs the cost in Canada relative to the estimated cost using U.S. prices fell from 51.9 per cent in 1982 to 46.7 per cent in 1983. The time trends are thus similar for the two comparisons. In each of these the relative cost of single-source drugs appears to be rising in Canada, whereas the cost of multiple-source drugs continues to fall.

It is also possible to look at the trend in the comparative costs for all drugs taken together with the study of drugs sold to hospitals as well as to drugstores and pharmacies (Study B). The actual cost of the complete sample of single-source and multiple-source drugs relative to estimated costs using U.S. prices rises from 58.4 per cent in 1982 to 62.8 per cent in 1983. In contrast, when sales to drugstores and pharmacies only are considered as in Study A, the total cost of both single-source and multiple-source drugs in Canada relative to estimated costs using U.S. prices for these same drugs falls from 64.0 per cent in 1982 to 62.9 per cent in 1983. Though it is difficult to generalize to the entire market for pharmaceutical products in Canada on the basis of these two different types of samples, it should be emphasized that both sets of samples indicate that the prices of single-source drugs have risen from 1982 to 1983. In addition, the prices of multiple-source drugs have fallen in Canada relative to those in the United States from 1982 to 1983. Whether the fall in the costs of

Table 7.8

Comparison of Costs in Canada and the United States, 1982 and 1983 ($millions)

(Exchange rate: $1.20 Cdn=$1.00 U.S.)		
Single-source Drugs	**1982[a]**	**1983[a]**
Number of Drugs in the Sample	53	68
Total Cost of Drugs in the Sample[b]	$187.2	$307.2
Difference between Costs in Canada and U.S.	36.5	$ 41.5
Difference as Percentage of Total Cost	20%	13%
Est. Cost if Bought at U.S. Prices	$223.7	$348.7
Actual Costs as a % of Estimated Cost	83.7%	88.1%
Multiple-source Drugs		
Number of Drugs in the Sample	29	32
Total Cost of Drugs in the Sample[b]	$191.3	$216.0
Difference between Costs in Canada and U.S.	$183.6	$268.4
Difference as Percentage of Total Costs[c]	96.0%	124%
Est. Cost if Bought at U.S. Prices	$374.9	$484.4
Actual Cost as a % of Estimated Cost	51.0%	44.6%
Impact of Compulsory Licensing		
Estimated Cost of Multiple-source Drugs if Canadian-U.S. Differential for Single-source Drugs Applied	$313.8	$426.8
Difference Between Actual and Estimated Cost	$122.5	$210.8

[a] Figures provide difference between cost in United States and in Canada for drugs in sample.

[b] Includes brand name and generic sales of sampled drugs.

[c] Percentage is based on total sales of compulsorily licensed drugs.

Source: Study B, and Consumer and Corporate Affairs, Ottawa, unpublished study, 1983.

multiple-source drugs has been sufficiently sharp to offset the increases in the prices of single-source drugs as indicated by the different cost estimates is unclear.

Other International Price Comparisons

In this section the results of a variety of international price comparisons are described. These comparisons are of several types, including the comparison of prices of generic products versus patented drugs and comparisons of price levels in different countries.

Generic Prices Versus Prices of Patented Products

For 42 compulsorily licensed drugs sold in Canada in 1983, the sales-weighted average price of the generic products was approximately 51 per cent of the sales-weighted price of the patent-holders' products of these 42 drugs. Together, these drugs accounted for total market sales of approximately $240 million.

Consistent with this result as well as those of the studies described in the preceding section are the results of the comparison of generic prices and the wholesale prices of brand name drugs as presented by the Canadian Drug Manufacturers Association (CDMA) in its brief to the Commission. The prices presented by the CDMA are drawn from the Southwestern Wholesale Price Index in the late spring of 1984 and from price lists of particular firms. They do not necessarily represent actual transaction prices in every sphere of the market. Presumably in the more competitive parts of the market there are a wide variety of discounts and other such practices that generate more transaction costs. On the other hand, in those parts of the market that are less sensitive to price competition, the differences described are probably satisfactory reflections of the differences between the prices of generic and patented drugs.

Of the 62 price comparisons, 14 or some 22.6 per cent had the generic price in the range of 50 to 74.9 per cent of the patentee's price. Twenty-seven observations, or approximately 43.6 per cent, indicated the generic price was in the range of 25 to 49.9 per cent of the patentee's price. The remaining 21 observations, or approximately 33.9 per cent of the total, describe the generic price as in the range of zero to 24.9 per cent of the patentee's price. In no case was the generic price equivalent to 75 per cent or more of the patentee's price.

Somewhat similar information is available for the United States on the relationship between the prices charged by the patent-holding firms with those charged by generic firms. Generic firms in the United States produce drugs that are off patent rather than under compulsory licence. Price comparisons for each of 30 drugs are taken from an advertisement in the Friday, July 17, 1984, issue of the *Washington Post*. The comparisons are for 30 different drugs, and in each case the same dosage form and strength and same package size are considered. Of the 30 drugs and associated price comparisons, two indicate that the generic price is in the range of 75 to 100 per cent of the patentee's price. Four drugs, or approximately 13.3 per cent, have generic prices that are in the range of 50 to 74.9 per cent of the patentee's price. Fourteen drugs, or some 46.7 per cent of the total, have generic prices that are in the range of 25 to 49.9 per cent of the prices of the patented drugs. The remaining ten drugs, or 33.3 per cent of the total, have generic prices that are in the range of zero to 24.9 per cent of the prices of the patented drugs.

This distribution of price comparisons for the United States is thus similar to the one for Canada. The percentage of price comparisons that are in the range of zero to 24.9 per cent is almost identical in the two countries: 33.9 per cent in Canada and 33.3 per cent in the United States. Similarly, the number

of comparisons of generic to brand name prices that fall in the range of 25 to 49.9 per cent is again quite close: 43.6 per cent in Canada and 46.7 per cent in the United States. The combining of the last two classes to create an overall range of 50 to 100 per cent yields the result that 22.6 per cent of the price comparisons in Canada fall in this combined range and a similar 20 per cent fall in this range in the United States.

Data similar to those for the United States are also available for 18 drugs in the United Kingdom.[3] Of the 18 drugs, 10 have generic prices that are in the range of 25 to 49.9 per cent of the prices of the patented drugs. The remaining eight drugs have generic prices that are in the range of zero to 24.9 per cent of the patented drug prices. None of the prices of generic drugs fall in the range of 50 to 100 per cent of the patented drug prices. Such a result is consistent with the very strong and prevalent attitudes against the prescribing of generic drugs in the United Kingdom. As a result, price competition may well have to be even more aggressive if generic products are to be sold. This situation is in some contrast to that found in both Canada and the United States. In both of these countries a large number of central government and provincial or state government regulations are designed to encourage and promote the prescribing of generic drugs. As in the United States, the generic drugs considered in the U.K. are those that are no longer covered by patent protection.

Evidence available from experience with off-patent generic production in both the United States and the United Kingdom is thus seen to be quite consistent with that for generic drugs produced under compulsory licences in Canada. That experience indicates that generic drugs can be and are sold for prices that in the majority of cases are substantially below 50 per cent of the patent holder's price. Over 75 per cent of the price comparisons made in each of the three countries, Canada, the United States, and the United Kingdom, indicated that the generic price was less than 50 per cent of the patented drug price.

Price Comparisons with Europe and Japan

From a disparate set of sources a variety of international price comparisons can be made. Such comparisons are fraught with enormous difficulty because of differences, usually minor, in dosage form, dosage strength, and package size. Changing exchange rates further complicate the matter. In spite of these difficulties, a number of studies, principally for European countries, have been completed.

An example is the recently completed study of the European Consumers Association. Prices at both the retail and wholesale level were compared for seven countries: West Germany, the Netherlands, Denmark, Belgium, the

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[3] The comparisons, published in *Scrip*, No. 873 (February 22, 1984), p. 4, were provided by the U.K. Health Minister, Mr. Kenneth Clark.

United Kingdom, France, and Italy. The detailed results of this study are presented in Table 7.9. West Germany has the highest prices but is followed closely by the Netherlands and Denmark. In contrast Italy has the lowest prices; and those of France and the United Kingdom are also low.

In a similar way the Office of Health Economics in the United Kingdom has recently completed a study of prices in those same European countries as well as in Switzerland and Japan. Its results, presented in Chart A7.1 of the Appendix, are in many ways comparable with those of the European Consumers Association. West Germany, the Netherlands, and Denmark are again seen to have the highest prices. Italy and France are seen to have the lowest prices.

The results of a third recently completed study, conducted by WIdO, might be considered. The detailed results of its study, presented in Tables A7.1 and A7.2 of the Appendix, can be briefly summarized. With West German prices set out in index form as being equal to 100, prices in Switzerland were found to be quite high with an index level of 95.9; those in the United Kingdom are in third rank with an index number of 89.0; prices in Austria are also relatively high with an index of 84.0. Prices in Belgium, France, and Italy are substantially lower, with index numbers of 57.2, 52.4, and 47.4, respectively. The country in which the lowest prices were found is Spain, with Spanish prices having an index number of 38.0.

Another interesting result of this WIdO study might be briefly described. With regard to 15 drugs, but in total some 25 different dosage forms, strengths, and package sizes associated with these 15 drugs, the differential between the West German price and the lowest foreign price was estimated.

The results, set forth in detail as shown in Table A7.2, can be briefly summarized in terms of the distribution of these price differentials. Of the 25 price comparisons, two, or 8 per cent of the total, indicated the lowest foreign price was in the range of 75 to 100 per cent of the German price. For eight price comparisons, or 30 per cent of the total, the lowest foreign price accounted for 50 to 74.9 per cent of the German price. For ten of the price comparisons or 40 per cent of the total, the lowest foreign price was in the range of 25 to 49.9 per cent of the German price. The remaining five price comparisons or 20 per cent of the total, fell in the range of zero to 24.9 per cent. This distribution of price differentials between the German price, typically the highest price in Europe, and the lowest price found amongst the European countries considered, is thus not altogether dissimilar to the distributions discussed earlier of the differentials between the price of patented and generic drugs in Canada, the United Kingdom, and the United States.

There is little question but that prices do vary significantly from one country to another. Further, it seems clear that there is some consistency in these differences over the last five to ten years.

Table 7.9

A Comparison of Prices of Pharmaceuticals and Medicines: Seven European Countries, 1978

Country	W. Ger.	Netherlands	Denmark	Belgium	U.K.	France	Italy
Retail:							
Current exchange rates	100	91	91	62	42	40	30
Purchase power parities	100	99	78	63	58	46	45
Mixed conversion	100	94	86	62	49	42	34
Wholesale:							
Current exchange rates	100	98	102	73	44	46	38

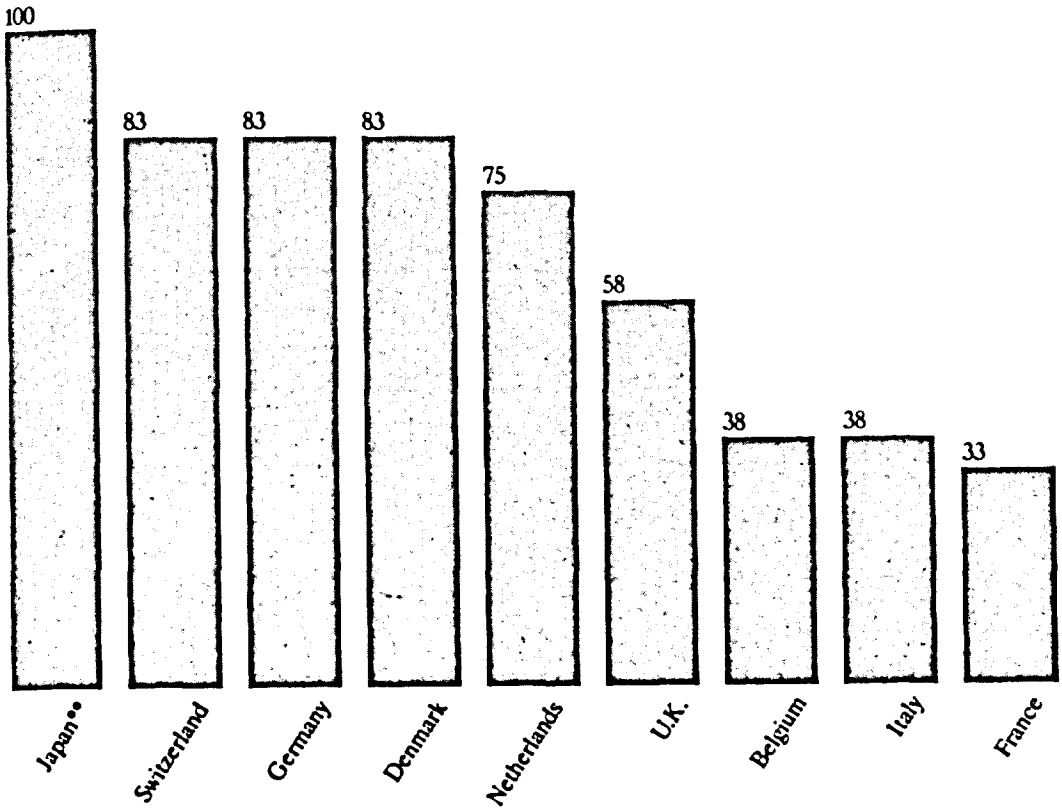
Source: European Consumers Association, *Consumers and the Cost of Pharmaceutical Products* (Brussels: European Consumers Association, 1979).

It is thus not unexpected that there is activity on the part of some firms to exploit these price differentials amongst the European countries. This activity, commonly known as "parallel importing," could conceivably lead ultimately to an equalization of prices amongst the countries of the European Economic Community. The achievement of such a result would of course be possible only if the health authorities in each country in question were prepared to permit, if not facilitate, the free flow of pharmaceutical products amongst the different countries. In turn, this would likely necessitate adoption of a commonly agreed set of criteria by which some EEC agency, that was given the responsibility for the regulatory and clearance procedures for drugs, could assess the principal drugs sold in Europe.

That such international price variations are reasonably stable and consistently estimated by different analysts suggests that a set of more or less systematic factors lead to this outcome. Amongst the more important of these are probably the overall structure of the pharmaceutical industry in each country and the mix of government policies that are brought to bear on it. Of the latter, government policies on administering prices, establishing selective or negative lists as the basis for determining eligibility for reimbursement, and coverage of the population with pharmicare plans may well be at least as important as, if not more important than, adjustments to the Patent Act with provisions such as compulsory licensing. What is absolutely clear is that all of these policies can directly affect the pharmaceutical industry and in turn the level of prices for its products, and further that their combined effect on prices can be substantially greater than that of compulsory licensing by itself.

Chart A7.1

Price Comparison: Japan versus European Wholesalers' Prices, October 1982*



*at current exchange rates
**note: high special rebates

Table A7.1

International Price Comparisons, Part I: For 25 Products with Greatest Price Differential Between West Germany and Other Countries, 1981

German Brand Name	Country of Comparison	German Manufacturer	German Price in DM	Foreign Price in DM	Price Difference in %
Tonoftal	Italy	Byk-Essex	19.85	1.99	997.5
Tavor 25 mg	Italy	Wyeth	15.01	1.62	926.5
Traumanase forte	Italy	Müller-Rorer	19.66	2.29	858.5
Volon 8 mg	Italy	Heyden	25.40	3.13	811.5
Amuno 100 mg	Italy	MSD-Pharma	20.95	2.83	740.3
Volon A 40 mg	Italy	Heyden	50.25	7.00	717.9
Tebonin	Italy	Schwabe	25.00	3.61	692.5
Visken	Italy	Sandoz	21.91	3.40	644.4
Darebon	Spain	Ciba-Geigy	26.10	4.06	642.9
Bellergal	Spain	Sandoz	25.43	4.23	601.2
Adelphan Esidrix	Spain	Ciba-Geigy	20.70	3.46	598.3
Adelphan Esidrix	France	Ciba-Geigy	20.70	3.51	589.7
Tebonin	Italy	Schwabe	11.10	1.89	587.3
Darebon	France	Ciba-Geigy	26.10	4.46	585.2
Zyloric 100 mg	Italy	Wellcome	28.18	4.93	571.6
Alupent Dosier-Aerosol	Italy	Boehringer Ingleheim	25.80	4.55	567.0
Nepresol	Italy	Lappe	11.83	2.10	563.3
Urbason retard	Italy	Hoechst	23.00	4.09	562.3
Trental 5 ml	Italy	Albert-Roussel	19.20	3.44	558.1
Diligan	Spain	UCB-Chemie	9.90	1.80	550.0
Lipostabil forte	Spain	Natterman	44.95	8.22	546.8
Tavor 1 mg	Italy	Wyeth	8.20	1.55	529.0
Aspirin	Spain	Bayer	3.60	0.70	514.3
Lasix 2 ml	Spain	Hoechst	8.86	1.77	500.6
Lanicor 0.25 mg	Spain	Boehringer Mannheim	5.85	1.17	500.0

Source: The Scientific Institute of the Ortskrankenkassen, WldO, as reprinted in *Scrip*, No. 940 (October 15, 1984), p. 8.

Table A7.2

International Price Comparisons, Part II: Products in West Germany with Greatest Savings Potential*

German Brand Name	Country of Comparison	German Manufacturer	German Price in DM	Foreign Price in DM	Price Difference in %
Lexotanil 6	Belgium	Hoffmann-La Roche	24.25	11.04	48.9
Tagamet	France	Smith Kline	65.57	45.07	33.9
Tagamet	Italy	Smith Kline	65.57	45.34	33.4
Tagamet	Belgium	Smith Kline	65.57	49.29	26.9
Adalat	Belgium	Bayer	66.30	36.44	25.5
Lanitop	Belgium	Boehringer Mannheim	12.85	8.76	22.2
Modenol	Austria	Boehringer Mannheim	20.05	8.52	21.2
Euphyllin retard	Austria	Byk-Gulden	30.18	12.58	17.0
Tavor 1 mg	Spain	Wyeth	19.32	5.09	16.8
Tavor 1 mg	France	Wyeth	19.32	5.52	16.5
Berotec	Belgium	Boehringer Ingelheim	28.40	13.84	14.0
Lexotanil 6	Austria	Hoffmann-La Roche	24.25	20.77	12.9
Adelphan Esidrix	Belgium	MSD-Pharma	36.10	23.77	12.3
Adelphan Esidrix	Austria	Sandoz	25.50	18.98	12.3
Euglucon 5 mg	Belgium	Hoffmann-La Roche	10.45	4.79	12.0
Tavor 1 mg	Spain	Ciba-Geigy	20.70	3.46	11.9
Amuno retard	France	Ciba-Geigy	20.70	3.51	11.8
Dociton 40	Spain	B Bannheim/Hoechst	23.90	6.30	11.6
Amuno 100 mg	Spain	Nattermann	44.95	8.22	11.3
Dociton 40	Italy	B Mannheim/Hoechst	23.90	6.83	11.3
Lipostabil forte	Belgium	Wyeth	19.32	9.87	11.1
Tavor 1 mg	Belgium	MSD-Pharma	69.95	28.03	10.7
Aspirin	Italy	Rhein-Pharma	25.65	5.57	10.3
Lasix 2 ml	Italy	MSD-Pharma	20.95	2.83	10.1
Danicor 0.25 mg	Spain	Rhein-Pharma	25.65	7.24	9.5

*On assumption that lowest price found in one of seven European countries could be set in West Germany.

Source: The Scientific Institute of the Ortskrankenkassen, WldO, as reprinted in *Scrip*, No. 940 (October 15, 1984), p. 9.

PART II

POLICY AND RECOMMENDATIONS

Text of Recommendations

There follows, numbered sequentially by chapter, the text of 19 recommendations made by this Commission.

Chapter 8 Patents and Royalties

The Commission recommends:

8.1 *that new drugs should be awarded a period of exclusivity from generic competition of four years after receiving their Notice of Compliance authorizing marketing.*

8.2 *that a Pharmaceutical Royalty Fund be established and be financed by payments made by firms holding compulsory licences, the payments to be determined by the value of the licensee's sales of compulsorily licensed products in Canada multiplied by the pharmaceutical industry's world-wide ratio of research and development to sales, as determined by the Commissioner of Patents, plus 4 per cent (the 4 per cent would reflect the value to compulsory licensees of current promotion expenditures of patent-holding firms); and*

8.3 *that the Pharmaceutical Royalty Fund be distributed periodically to the firms whose patents are compulsorily licensed, each firm's share to be determined by the sales in Canada of its patented products by compulsory licensees multiplied by the firm's ratio of research and development expenditures to total sales of ethical drugs in Canada plus 4 per cent (to reflect promotion), all this as a proportion of the same variables for the entire group of firms with patents under compulsory licence in Canada.*

8.4 *that, conditional on preserving modified provisions for compulsory licensing in the Patent Act as recommended in this Report, limitations on product claims for pharmaceutical products in the Patent Act be removed.*

8.5 *that reverse onus for pharmaceutical patents be abolished.*

Chapter 9 Authorization for Marketing: Safety and Efficacy

9.1 *that Preclinical New Drug Submissions should consist of a summary of information on the new drug, certified in Canada by a qualified health professional, and of a protocol of the proposed clinical studies, and that approvals for Preclinical New Drug Submissions should be automatic within one month of receipt unless the Health Protection Branch finds reason not to grant them or requires further information from the firms concerned. The approval for the PNDS would also apply to the protocols for Phases 1, 2, and 3 which would not require further approval after filing for notification unless by explicit decision of the Health Protection Branch.*

9.2 *that the Health Protection Branch reorder its activities so as to be able to respond to New Drug Submissions and to Supplementary New Drug Submissions without fail within 120 days.*

9.3 *that regulations should permit the Health Protection Branch to impose post-market studies on the manufacturer as a condition of permission for marketing. Such authority does not now exist. It would provide the Branch with greater control over new drugs and perhaps aid in hastening the clearance process itself.*

9.4 *that Notices of Compliance be issued for New Drug Submissions and Supplementary New Drug Submissions for pharmaceutical products and medical devices that have not received them in Canada but which have already received Notices of Compliance in the United States and either France or the United Kingdom without review in Canada until the backlog of submissions has been absorbed and procedures reformed to provide clearance delays no longer than 120 days.*

9.5 *that an expert committee supported by the staff of the Health Protection Branch should be established by statute to make final judgements on the issuance of Notices of Compliance for New Drug Submissions. The Commission also recommends that the various steps in the process of review should make use of statutory advisory committees of outside experts.*

9.6 *that the Minister of Health and Welfare establish an advisory committee of experts from the Health Protection Branch, universities, hospitals, and industry (thus reflecting the many interests affected) to recommend appropriate regulations and guidelines for the evaluation and clearing of drugs for marketing.*

9.7 *that no impediment be placed to the access to and use of Product Monographs, which should be treated as public documents.*

9.8 *that measures be taken to ensure that pharmaceutical products sold to consumers at retail in Canada should be dispensed in the manufacturer's original packages, and further, that complete product information be presented in a way that can be understood by laymen. Indications, administration, dosage, warnings with respect to adverse reactions, a full list of contents, and other relevant information should be included. Provision should be made that physicians could instruct pharmacists to withhold such information from designated patients.*

Chapter 10 The Retail Market

10.1 *that all ethical drugs should be prominently labelled with their generic name, whatever other name may also appear on the label.*

10.2 *that provincial governments should remove restrictions on the advertising of drug prices, dispensing fees, or the sum of both;*

10.3 *that pharmacists should be expressly permitted to provide information on drug prices over the telephone; and*

10.4 *that prescription receipts state both the drug cost and the dispensing fee.*

10.5 *that provincial governments should ensure that public drug reimbursement programs require a significant contribution to each purchase by the consumer arranged in such a way that price competition is induced, and should encourage private drug insurance plans also to have this feature.*

Chapter 12 Pharmaceutical Research in Canada

12.1 *that government departments review their procedures for granting financial support to research in the pharmaceutical industry with a view to improving the access of small research-intensive firms to such support by making such procedures simpler, faster, more stable, and more predictable.*

Chapter 8

Patents and Royalties

Introduction

An examination of the protection afforded by patents and royalties to pharmaceutical firms is central to a consideration of the structure and performance of the industry.

The world-wide operations of pharmaceutical firms are highly dependent on patent protection which allows them to recover the costs of the research and development incurred in introducing new products to the market. The source of this dependency is that research and development is very expensive in this industry and innovative firms have high fixed costs as a consequence, whereas the imitation of new products, once discovered, is relatively easy.

Without patent protection, the prices of new products would soon be depressed by competition between the innovating firms and other firms entering the market with imitative products. The innovating firms would have great difficulty in recovering the costs of research. Patent protection, therefore, provides an incentive to research and development by providing firms with a temporary monopoly during which they can set prices higher than would otherwise prevail and recoup the costs of research and development. The provision of an appropriate amount of patent protection through government regulation is in consequence an important element of policy to stimulate innovation in this industry.

Against the advantage of raising the profitability of research and development by the grant of temporary patent monopolies, governments must balance the needs of consumers and taxpayers. The higher prices charged by innovating firms during the period of patent protection raise the cost of drugs to consumers and delay the full benefit they derive from new products. The goal of governments in extending patent protection to pharmaceutical products is to balance the conflicting objectives of providing appropriate incentives to research and development and of allowing consumers early access to the full benefit of the new drugs through low prices.

Compulsory licensing of pharmaceutical patents is one measure that can be used in attempting to achieve the balance between these conflicting objectives. Under compulsory licensing, an applicant can request the patent

authority to oblige the patent holder to issue a licence to him to manufacture or to import the patented product. The purpose of such a measure is to introduce competition in the sale of the most strongly demanded products so as to temper prices for consumers, while ensuring that the patent-holding firm obtains a return on the investment needed for its innovation in the form of the royalties it receives. Since 1969, in Canada, Section 41(4) of the Canadian Patent Act provides for compulsory licensing to manufacture or import pharmaceutical products in accordance with this objective. Until now compulsory licences to import pharmaceutical products have borne a royalty rate of 4 per cent of the value of licensee sales.

(Compulsory licensing as a central provision of a country's patent act designed to fundamentally affect conditions of competition, as indicated above, is to be distinguished from its nearly universal use as a protection against abuse. In Canada, Section 41(4) of the Patent Act provides for the former objective respecting food and pharmaceutical products; Section 67 is a general protection against abuse.)

Of course, governments have ways of fostering research other than through patent protection. They provide tax incentives to business whereby taxes are reduced in accordance with a firm's research expenditures. They subsidize particular firms or projects, of which some Canadian examples are the Institut Armand Frappier in Montreal and Connaught Laboratories in Toronto. They provide grants to researchers in universities and hospitals in addition to supporting the institutions themselves. Many basic discoveries are made by scientists in such institutions of which the most spectacular Canadian example was the discovery of insulin. Governments also engage in research in their own in-house facilities such as the National Research Council in Canada. Such alternative ways of supporting research have no instrinsic merit beyond their efficacy.

The efficacy of patents and the need for them as a stimulus to innovation varies according to the patentability of the idea and the effectiveness of other impediments to imitation by competitors such as secrecy and the ease with which the method of production can be inferred from the final product itself, which is sometimes referred to as the ease of "reverse engineering." Some ideas, activities, products, or processes are not easily patented. The difficulty of precisely describing a new idea, the cost of enforcing a patent, or the economic sector in which it is used may lead to this unpatentability. New ideas and processes in the service industries are of this kind. In such circumstances other incentives than the patent system should be used to secure the appropriate amount of invention and innovation. Governments should and do choose among alternative sources of innovation and seek to design policies that induce the efficient response.

The variation in patent policies implemented by different countries and by the same countries over time illustrates that governments adapt their patent policies in the light of particular objectives and changing circumstances. Patent life differs internationally from some countries which offer no patent protection

to the 20 years now typical of Europe. Some countries provide product protection; others give patent protection only to processes. The United States' Patent Act does not provide for compulsory licensing under any circumstances; most countries provide for compulsory licensing in the case of abuse, which occurs if a patentee fails to work the invention on which he has a patent and refuses to license it on reasonable terms, or sets exploitative prices. In the past, the Patent Act of the United Kingdom and of some other countries provided for special treatment for food and pharmaceutical products and that of France for pharmaceutical products. Canada continues to do so for pharmaceutical products and food. The United States has recently enacted provisions for special patent treatment for pharmaceutical products.

It is evident therefore that patent protection is simply one type of government intervention to foster innovation and that patent provisions vary internationally. The appropriate form of intervention depends on the circumstances of the case and the efficacy of various measures to address the objective. Patent protection is not an inalienable property right. It is an instrument to stimulate an appropriate amount of innovation. Its terms are variable and should be varied by governments in accordance with needs and opportunities and as the consequences of different patent terms can be gauged.

The fact that greater uniformity exists internationally today between national patent acts is a result of the general movement toward the harmonization of all policies within the European Economic Community. The countries involved are seeking to create a more homogeneous economic area. In that process they are adopting common policies in many fields including that of competition policy and patents. Uniformity of patent protection in Europe is an objective in itself; the particular form of protection may not suit all the needs of each or, indeed, any of the member countries.

Compulsory licensing and related royalties may form part of the most appropriate patent provisions for a government's objectives regarding a particular industry. Compulsory licensing can be an intrinsic part of the structure of patent protection designed to induce the appropriate amount of innovation while protecting consumer interests in an economy or an industry.

General Principles: The Purpose of Patents

The purpose of patents is to seek a balance between creating incentives that encourage firms and individuals to engage in the right amount of research and development, ensuring the diffusion of the results of research and development, and benefiting consumers with lower prices or improved products. This is in principle accomplished by creating a monopoly for the inventor, but one that is temporary and in general limited by any competing products or processes that are already available.

The temporary monopoly creates a financial incentive for research and development, because the patent holder, being the sole supplier, can vary price

and level of sales so as to maximize profits. The innovator thus obtains advantage from his effort. Patents, therefore, are inextricably related to both prices and profits.

A condition of the temporary monopoly is that the patentee divulge information on the nature of the invention. Once the patent is awarded, competitors in innovation are discouraged from duplicating the research and development effort, since no one other than the patentee or his licensee could use the invention even if it were duplicated. Furthermore, duplication in research activity is pointless, because the information is public.

The beneficial effect of patent monopolies in stimulating research does not necessarily avoid the problem of duplication and waste. Duplication in research may take place during the race for discovery before the application for a patent by the winner. The fact that there is a race to patent may lead to costly acceleration of the research process, especially if the rewards of first discovery are very large.

Furthermore, prohibiting competitors from using a patented product or process may encourage them to spend resources in finding products or processes that, while warranting separate patenting, do not constitute a significant improvement but do provide them with access to the market with a closely related product. Such "inventing around a patent" may be entirely wasteful from the standpoint of the effective social use of resources, though it may pay a reward to the imitator. The principle that leads from this observation is that patents should be broad. When a patent is granted, it should preclude close imitation and in that way prevent innovation leading to little or no improvement.

The temporary nature of a patent means that, once the period of exclusivity conferred by it on the inventor has lapsed, consumers benefit from a decrease in price as other producers enter the market. For example, a process might be discovered which significantly lowered the cost of production of some product. During the life of the patent, the patentee could earn high profits by benefiting from lowered costs while the price of the product remained at a relatively high level. This exceptional profit would reward him for the invention. When the process patent lapsed, others would adopt the new cost-reducing process; competition amongst them would increase supplies and push the price down until the rate of return on production again equalled that in other lines of business.

In summary, the objective of patents is to create an advantage for innovators to induce an appropriate level of research and development by creating a limited period of monopoly. The period is then followed by freedom to imitate, expansion of production, and lower prices, to the benefit of consumers.

Effects of Variation of Patent Protection

Because patents both impose costs from monopoly and award benefits from new discoveries and from eventually lower prices, the practical problem is to achieve the best balance between these two opposing sets of effects. This raises the question of the optimal patent life.

Patent life is optimal when the rate of return of innovating firms on the additional expenditures they make on their research and development projects is equal to the value of the improvement in products or processes they create for society as a whole. The improvement may be that the invention is better or more effective as a result of increased spending or that it is developed more quickly or with greater probability of success.

If the patent life is too short, there will be too little innovation through research and development. Such a situation arises when the private investor in research and development receives from his efforts less than the return for society as a whole. It is easy to imagine how this might occur. Heavy investment in some research projects may be required in order to develop a new process or product, but, once the discovery has been made, its imitation may be very cheap. If the inventor could not exclude competitors through a patent or other device when the invention had been made, competitors would immediately enter the field, the price would fall and the inventor would be unable to recover his investment. Faced with this possibility, the investment would not be made even though the increased income for society as a whole would have been sufficient to justify the cost of invention. The social rate of return exceeds the private rate of return on innovation. Useful research will not be undertaken in these circumstances. It is only if the private return to the inventor were raised, perhaps by giving him a temporary patent monopoly, that the investment would be made. It is therefore clear that a patent life may be too short to elicit the right amount of investment in research and development.

Patent protection may also be too long. This occurs when the period of patent protection is such that the innovator expects to earn profits in excess of the minimum necessary to justify the investment. Inventors' profits from innovation might on the average exceed the rate of return obtainable from other uses of the resources invested in research and development.

Patent life also has an effect on the choice of research projects. If the rewards of investment in research from the temporary monopoly are low, investment in marginal research projects, which are the least promising ones innovators carry on, are foregone even though their benefit for society would exceed the resources used. If average patent life is too long, it leads to a reduction in social welfare due to duplication and to overinvestment in marginal projects. The result of excessive patent protection is the attraction of too much investment in research and development and the consequent dissipation of the gains from research. Innovating firms may be induced to compete for the high profits on new inventions by increasing their research activities with the result that the discoveries of research which is marginally

attractive to the firms bring negligible benefits for society. In other words, new products do appear, but the resources that have been spent to produce them would have benefited society more if they had been spent elsewhere. Some of the inventions may be scientifically or economically significant, but have been produced at too great a total cost. Other inventions may be imitative in nature and constitute insignificant progress despite their cost.

Another consequence of excessive patent protection and of the profits to which it potentially gives rise is to induce patent holders to incur excessive costs of promotion through marketing and selling expenditures designed to stimulate demand and maintain their competitive position in the market. Excessive selling costs are those that are greater than necessary to inform consumers of the characteristics of the products; their sole purpose is to persuade. In the absence of collusion and when products are close substitutes, competitors incur excessive promotion costs to push their product. If they did not do so, but their rivals did, they would lose their market share.

From the standpoint of efficiency, it is evident that excessive patent life that gives rise to excess profits is preferable to that which gives rise to imitative research and excessive promotion costs. In the first case, national income is raised by the product of the invention, but the inventor receives such a high return that others are not advantaged. The distribution of the increased income is unnecessarily favourable to the patentee, but the gains from the invention are not dissipated by excessive research of others either in the race to the patent or in seeking to imitate the product. The inventor has a monopoly in inventing. However, where parallel or imitative research and excessive selling costs are induced by the potential high profit, there is considerable wastage of resources, because the resulting benefit to society could have been obtained from a single innovation. The latter outcome is likely when firms can enter the industry relatively easily. They do so if profits from successful innovations are high, and they incur research and development costs and heavy selling costs to which established firms are obliged to respond with greater expenditure as well.

How much research there should be from society's standpoint depends on the increase in social welfare that is expected from the marginal research projects. If the increase in social welfare from the marginal innovation is equal to the cost of the resources used to carry out the innovation, research endeavours are optimized.

This does not imply, of course, that the social value of all past research is only equal to its cost. Quite the contrary, the accumulated value of all research is huge. But that is not the issue. The issue is finding the rate at which new knowledge should be created with present resources. It would be as inefficient to use all society's resources for research and development as it would be to use none of them for that purpose.

The implication of this logic for pharmaceutical research is that the effectiveness of pharmaceutical products in the modern world in reducing suffering, lengthening life, and reducing other health costs, does not of itself

imply that a higher level of expenditures on pharmaceutical research would be beneficial. The question is whether the expected results of more research justify the cost.

A judgement is required as to whether existing incentives to research, of which patents are especially important, result in the right amount of research. Lesser incentives would lead to dropping the less promising projects and investing less in existing projects; greater incentives, to undertaking more projects and investing more in both new and existing research. Therefore, the operative question is to establish the contribution to social welfare that can be expected from the least promising research projects being undertaken.

These principles that determine optimal patent life apply to an invention resulting from a single research project. The optimal patent life varies inversely with the profitability of the particular invention, its probability of success, and the number of competing inventors who may duplicate each other's efforts in the race for the patent or in imitative invention. These factors differ for each project as does, in consequence, the optimal patent grant applicable to each project. There is no single optimal patent grant for the economy as a whole or even for a particular industry.

It is not practicable to apply a different patent term to each invention, because of inadequate information on which to base a judgement and because of administrative complexity. Nevertheless, the inappropriateness of uniform patent terms has often been recognized historically and internationally and attempts have been made to rectify this. The same arbitrary degree of patent protection for all inventions has in many cases been modified in response to the particular characteristics of an industry, notably food and pharmaceutical products, and has led to greater or less protection than the standard.

Compulsory licensing can be used as an instrument to vary the degree of patent protection that would otherwise be uniform. Though it depends on the royalty rates that are set, the likely outcome of compulsory licensing is that projects with low profitability receive long patent protection, but that highly profitable innovations find their patent protection shortened or weakened by the issuance of compulsory licences. The result is that much research finds a reward from patent protection, but that big potential gains are reduced by competition from compulsory licensees. This constitutes a more efficient patent system than one in which the patent grants are undifferentiated, because the inducement to duplicate the research projects that are expected to be most profitable and to seek to invent around the patents of the most profitable innovations is reduced. Furthermore, the danger of awarding too strong a monopoly by giving broad patent protection, the motive for which is also to limit wasteful use of resources in "inventing around" patents, is avoided if compulsory licences can be issued for the patent. The royalty rates applied to the compulsory licences would be no higher than sufficient to reward the costs of innovation and lower than those that would support monopoly pricing and damage the interests of consumers.

The Characteristics of the Pharmaceutical Industry Resulting from Patent Protection

The pharmaceutical industry is one for which patent protection is important. A large part of the cost of pharmaceutical products is in research. Research costs are on average about 10 per cent of sales on a world-wide basis for firms that are active in Canada. This research is used both to discover the product and to test its characteristics before it appears on the market. Once invented, most pharmaceutical products can be produced at low cost and are easily imitated. Some patent protection for pharmaceutical products that act as a barrier to entry is clearly required to induce the appropriate amount of research in discovery. The crucial question is how much patent protection is warranted.

The high front-end costs of research and obtaining authorization to market a product, combined with the low marginal costs of actually producing most pharmaceutical products, are what give the industry its international character under presently prevailing patent conditions. Once discovered, more of a given product can be produced at very low cost. Each unit brings a return to the patentee. The bigger the market, the greater the profitability of that product. Hence the incentive to extend the sale of each product to as many national markets as possible.

Patenting necessarily brings about two characteristics of the industry. These are product differentiation and delay in the appearance of competitive products. Patenting excludes competitors from producing identical products. Competition between firms must be less direct. Two or several firms may produce pharmaceutical products that have the same therapeutic use, but they cannot be identical and perfect substitutes even if their differences are slight from the standpoint of therapeutic effectiveness as is sometimes the case. The product differentiation necessarily enforced by patents provides a basis for the patentee to promote the sale of his product by informing potential consumers and their agents of its effectiveness and to establish his trade name and his firm's identity in their consciousness. Trade name and firm preference constitute in themselves barriers to entry and to competition additional to patent protection.

An effect of the research necessary to differentiate between patented products is that, when a new drug appears on the market and proves to be profitable, potential competitors must engage in research and development activities to produce a similar, but not identical, drug that will compete in the same market. The process of developing drugs that are similar in either composition or purpose is expensive and time is required both to develop and to obtain authorization for marketing. In other words, the patent system creates a delay in the appearance of competitive products and so permits the first firm with a new drug to initially set high prices.

Patents and product differentiation are not the only impediments to the entry of new competitors into the pharmaceutical industry. Research and

development, including the process of testing new drugs for toxicity and therapeutic effectiveness and taking them for approval through the regulatory process, is generally acknowledged to be an expensive undertaking that can only be carried out effectively by large firms. The question of whether a research laboratory can be productive if it is small, say with 75 employees, or need be much larger is a debated question, but is not at issue here. The point is that developing a new drug and putting it on the market is very expensive and that the risk of failure in the development of a particular drug makes it advantageous from a risk avoidance standpoint to carry forward a number of projects simultaneously. Thus the economies of scale for this part of the activities of the pharmaceutical industry are important and create a barrier to the entry of small potential competitors.

On the other hand, the manufacture of finished pharmaceutical products, which involves the blending, mixing, encapsulation, compounding, and other processing of active ingredients and other components, can be carried out in small plants which typically produce a number of different products. Thus economies of scale do not exist as a barrier to the entry of firms into this stage of manufacturing.

It is otherwise with the production of fine chemicals and their synthesis into active ingredients. The average cost of producing active ingredients typically declines over very large outputs so that an efficient plant often supplies a substantial portion of the world market for that ingredient. Nevertheless, these declining costs do not constitute important barriers to entry in the manufacture of components that usually form 25 per cent or less of the total cost of the final product.

The existence of patents leads to the integration of these three aspects of production in the pharmaceutical industry in the control of a single firm. The patent usually resides in the active ingredient, not the finished product. The patentee often carries out himself all three steps in the production of a finished pharmaceutical product though he may, in some cases, license some of the activities. A typical integrated company carries out research and development, obtains patents world-wide, complies with the clearance procedures in many countries, produces the active ingredients in one or a few favourable locations in the world, and manufactures the finished products in many plants in the countries that constitute its major markets. The economies of scale in the research and development stage and the product differentiation arising from heavy brand promotion constitute the chief barriers to entry into the industry.

Competitive Strategies in the Pharmaceutical Industry

When patent protection is available, the question becomes whether the barriers to entry caused by research and development and the regulatory process required to clear drugs for marketing are such as to afford too much protection from competition for the firms in the industry and as a result lead to

either unnecessarily high profits or the dissipation of such potentially high profits by too much investment in research and development and in costs of promotion.

An examination of the pattern of competition and the structure of the international pharmaceutical industry provides only an indication of the degree to which competitive pressure contributes to efficiency in performance. As with many industries, characteristics can be seen that are consistent with the presence of high barriers to entry and competition. Selling costs are amongst the highest of any industry and are comparable to those in cosmetics and cleaning products. Profits are high compared to the average of other industries. Products are highly differentiated.

There are approximately 3,500 different prescription drugs in Canada today and as many in most other countries. Many of them were introduced to compete with innovative new drugs in order to share the high profits that such new drugs often earn. They do not themselves constitute significant therapeutic innovations. Such "me too" drugs may bring advances in treatment, but such progress is often incidental to their introduction. Many drugs have therapeutic effects that are identical or sufficiently similar to make them substitutable in use.

The view that there exists an unnecessary proliferation of drugs is reflected in the policies of many national and provincial governments. They publish formularies identifying equivalent drugs, they issue lists that limit the number of drugs whose cost the government will reimburse to the consumer, or they vary the proportion reimbursed of a drug's cost according to its therapeutic value as judged by an expert body. Many hospitals limit severely the number of drugs they allow for particular therapeutic uses. The Federal Drug Administration in the United States distinguishes between new drugs that bring major new therapeutic advances from those whose therapeutic value is judged of only slight improvement over already approved drugs and provides more rapid clearance procedures for the former.

The principal effects of imitative drugs are to offer competition in the market place for products that are close substitutes, to take a share of the market and to limit prices. In so far as prices are reduced, consumers benefit further from the original innovation. However, this is achieved at the cost of the resources absorbed in developing and clearing the imitative drug for marketing. These costs would not have been incurred, though the benefits would still have been obtained, had the price of the innovative new drug been lower and attracted less imitation. The limitation of price and research to imitate successful new products can be achieved by compulsory licensing, as already discussed.

Evidence of low competitive pressure in the industry additional to high barriers to entry is the reported unwillingness of some patent-holding firms to carry out research and development activities in Canada even when cost conditions in this country are favourable. The Commission was told of a

number of projects for the establishment or expansion of basic research activity in Canada with cost conditions that were favourable in terms of alternative foreign sites, but which were not acted upon because of corporate disapproval of certain public policy measures in Canada especially compulsory licensing, but also the Foreign Investment Review Agency and even the unrelated National Energy Program. In a more competitive context, firms would be obliged to exploit all cost advantages lest competitors undercut them.

Despite this absence of a necessary connection between the profitability of operations and the optimality of locating research in a particular country, multinational firms in an industry with limited competition may refrain from carrying out as much research in that country as costs would justify. If governments rank research and development high amongst their preferences, firms might use the prospect of increasing research and development as a bargaining tool to obtain concessions on other matters.

From the standpoint of the bottom line, the fact that compulsory licensing reduces the profitability of a subsidiary's operations in Canada is irrelevant to whether or not to invest in research in Canada if cost conditions for research are favourable. Indeed, the rationale for multinational firm operation is that this form of business organization permits efficient use of opportunities to minimize costs by producing in the most favourable locations in the world. The conclusion seems inescapable that either costs of research are not in fact relatively favourable in Canada or that firms in the pharmaceutical industry are sufficiently shielded from competitive pressure that they need not take advantage of favourable investment opportunities.

Another example of restraint in competitive strategy is that, with one exception, no patent-holding firm has applied for compulsory licensing of pharmaceutical patents of other firms even though such activity is often clearly highly profitable in Canada.

Nor are customers thought to be well informed and responsive to price: two major firms in Canada, Upjohn and Syntex, have established subsidiaries, Kenral and Syncare, to market their own patented products under generic names in competition with their own brand name products. The same product cannot be sold at two different prices in a market in which customers are knowledgeable.

It should be emphasized that such behaviour is neither irrational nor condemnable. It is the result of informed strategic or tactical decisions of profit-maximizing firms in an industry whose structure is determined by the characteristics of production and marketing within a particular context of which patent protection, the clearance process, and the price insensitivity of final consumers are important elements. It follows that the industry's behaviour and performance can be altered by changing the institutional context.

Costs in the Pharmaceutical Industry

Recognizing that competition is a stimulus to initiative and a source of progress and efficiency, the object should be to create conditions in which competition between present and potential participants in the industry lead to socially beneficial goals. Competition ensures that firms are efficient and that prices are kept close to their costs of production. Canadian industrial development requires that firms should be able to cover the costs they incur, including those of innovation, and be adequately rewarded by profit.

Policies should set the framework for effective competition in an efficient, progressive pharmaceutical industry in Canada without excessive prices or their consequences, excessive profits or wasteful practices.

The costs of hypothetical patent-holding and generic firms in Canada, each producing finished pharmaceutical products and importing the active ingredients, are illustrated in Table 8.1. The sales prices are percentages of the U.S. prices (corrected for the exchange rate) for one unit of the same drug in each country. The cost components in columns 1 and 3 should be thought of as absolute dollar values directly comparable between patent-holding and generic firms. Columns 2 and 4 show the percentage of the final price for the drug that is attributable to the various categories of cost. Table 8.1 reflects the fact that, in 1983, the average price of single-source drugs in Canada (weighted by Canadian consumption) was 80 per cent of U.S. prices, whereas the average Canadian price of generic producers' multiple-source drugs was about 50 per cent of that of patentees. This difference in price level between the two types of drugs accounts for an estimated saving through compulsory licensing of $170 million on pharmacy sales in 1983, a figure that rises to $211 million when sales to hospitals are included.

It must be appreciated that the costs presented in the table are merely illustrative. Cost conditions vary greatly between different drugs.

Table 8.1 suggests that patent-holding firms on the average spend slightly more than generic firms on research and development as a percentage of sales. This translates into an even greater expenditure per physical unit of sales, because of the higher prices that are charged for single-source drugs.

The price of the active ingredients paid by the generic firm is that prevailing in the world market in which firms that are free from patent or other restrictions make purchases. Such firms may hold compulsory licences or may be purchasing unpatented ingredients without intra-corporate restrictions. The suppliers are often chemical producers in countries with little or no effective patent protection. The low prices prevailing in this market often reflect only the cost of manufacturing and not that of research and development. The subsidiaries of patent-holding multinational firms or other firms in some way constrained in their purchases of active ingredients normally pay higher than world prices to the patentees who seek to recover not just the cost of manufacturing but also research and development, central administrative,

Table 8.1

Illustration of Average Costs and Prices
of Hypothetical Patent-holding and Generic Firms

	Patent-holding Firm Single-source Drug		Generic Firm Multiple-source Drug	
	$	Per cent of Canadian price	$	Per cent of Canadian price
Research and Development Costs in Canada	4	5	2	4
Cost of Active Ingredient	18	23	9	23
Cost of Other Materials	6	8	4	10
Other Factory Costs	6	7	5	12
Other Costs	16	21	12	30
Promotion Cost	17	21	2	4
Profit	13	16	6	16
Sales Price	80	100	40	100

medical, and other costs plus a rate of return on these expenditures in the transfer prices that are charged. Transfer prices are the non-arm's-length prices at which related firms do business. The subsidiaries of patent-holding firms in Canada pay a price for active ingredients that is the sum of the world price plus some research and development costs, other costs of central operations, and profits that are allotted to the ingredient by the parent firm. Thus Canadian subsidiaries pay a share of the research and development costs of their parent when they buy active ingredients abroad that they then compound in Canada. They also do so when they buy finished products from their parents.

The costs of manufacturing are shown as somewhat higher by an arbitrary amount for patent-holding than for generic manufacturers, because the latter tend to avoid the more difficult formulations.

The greatest difference illustrated in Table 8.1 is in promotion costs. Patent-holding firms typically engage in extensive marketing and selling effort, notably in making direct contact with physicians by various means of which sales representatives are the most costly, absorbing about half of total promotion expenditures. Generic firms, by contrast, restrict their promotion to hospitals and pharmacies.

Profits in the Pharmaceutical Industry

Profits are the objective of firms and the driving force in a free enterprise economy. Profits in the pharmaceutical industry are very high for the more

successful firms and average profits for the industry are amongst the highest in Canada. Average profits on equity and on capital that are chronically higher than in other industries would not persist in a competitive industry, because large profits attract new firms and an increase in supply pushes down the sales price of the products of the industry. Chronically high profits for an industry are an indication of barriers to entry of potential competitors.

The pharmaceutical industry has both monopolistic and competitive elements. Monopoly resides in the differentiation of the firm's products from those of others by trade name and by physical or therapeutic characteristics. This differentiation gives firms considerable freedom in setting prices. The competitive element resides in the race to introduce new products, some that are close substitutes to the products of others, and in heavy promotion to shift the demand of consumers to their products. This combination of monopoly and competition results in the multiplication of drugs, the heavy promotion, high costs and prices, and healthy profits that are observed. The observed actual profits fall short of the potential profits that would exist if there were no selling costs in excess of those necessary to inform consumers and their agents of the therapeutic characteristics of the drugs and no excess research and development expenditures leading to imitative products. But prices are sufficiently high to cover those excessive costs and provide higher rates of average profits than in most industries.

In its submission to the Commission, the Pharmaceutical Manufacturers Association of Canada stated that profits measured by accounting rates of returns overstate the profits of the pharmaceutical industry in comparison with the average profits for all manufacturing. It claimed that this arises because accounting convention treats expenditures on intangible capital assets as a current expense and not as a capital expense leading to recognition of the larger asset base of the firms. Such understatement of the capital base of the firm and overstatement of profit rate is especially significant for firms with high research and development and promotion expenses which create intangible assets in knowledge, patents, and good will. High expenses of this sort are a characteristic of the pharmaceutical industry.

It is well known that the degree to which profits are overstated when intangible capital is not recognized in the assets of a firm is highly sensitive to the rate at which that capital depreciates. For instance, if the intangible capital created by promotion costs had a life of little more than one year, accounting profits would not be significantly different from an unbiased measure of profit.

It appears to the Commission that the accounting conventions employed in estimating the average rate of profit do overstate those of the pharmaceutical industry in comparison to those for all manufacturing. But research expenditures are low in comparison to promotion expenditures in the pharmaceutical industry and the rate of depreciation of the good will created by promotion is rapid, so that the extent of the overstatement is probably slight.

The argument has been advanced that the high risks involved in the discovery and development of new drugs require a high rate of return to capital in the pharmaceutical industry compared to many other industries. It is undoubtedly true that the degree of uncertainty about the outcome of research in the industry is exceptionally high. Firms may go for years with major research expenditures that result in no important innovations. Adequate incentives for research require in consequence that the successful innovation be rewarded by high profits.

New drug discovery is a risky enterprise for a multinational firm, but investing in Canada is not. The multinational firm sells in Canada drugs that have been developed for the world market. The costs of research and the profit from discovery are recovered in the transfer price, the royalty, or the charges for research paid by the Canadian subsidiary to the parent firm. The profits of the Canadian subsidiary itself reflect only a return on manufacturing the final dosage form and on a selling function which is not especially risky and which does not justify an exceptionally high rate of profits.

Small Country Policies and World-wide Markets

The analysis of patent policy in the section on "Effects of Variation of Patent Protection" above does not distinguish between optimal patent policy in the world as a whole and that which would bring the maximum benefits for a single small country. In principle, if adequate information were available, an optimal patent régime for the world-wide pharmaceutical industry could be established. Does it follow that such patent protection would be optimal for Canada to extend when Canadian consumption accounts for less than 2 per cent of world consumption? What is the right course for Canada to follow in the event that the rest of the world's policy is not optimal?

Canadian consumption is a small proportion of world consumption so that Canadian patent policy has little effect on the world-wide profitability of the pharmaceutical industry, including that of innovation. A decline in prices in Canada by the removal of patents or an increase as a result of longer patent protection would have very slight impact on the profitability and therefore the amount of world-wide innovation. Since the results of research and development are applied to pharmaceutical sales world-wide, a small country is not constrained in its patent policy by its impact on world innovation from which it benefits. In other words, a small country can take an independent course in deciding policies that lead to its paying its share of world research spending. Its share depends on the country's consumption in relation to world sales. Its policies should also reflect where the desirable research takes place and also perhaps the appropriateness of the amount and nature of world-wide research.

It is difficult to form a view about whether total world expenditures on innovation in the pharmaceutical industry are at the right level. It is clear, however, that actual expenditures are in part misdirected to the creation of imitative drugs attracted by the high profits obtained on the infrequent successful new chemical entities. Competition with highly profitable new

products is necessary to lower prices and spread the benefits of innovation to more consumers. But generating such competition by incurring heavy expenditures to create similar products is wasteful of research and development effort. The result can be achieved with less cost by shortening patent life for such major discoveries or by compulsory licensing, because this results in the early appearance of copies of the new drug itself and the avoidance of unnecessary research.

There is also legitimate concern about the location of research and development activity, because of the attractiveness of the occupational opportunities in firms and hospitals it creates and the possibility it offers of stimulating economic growth through various forms of spin-off.

Diplomatic considerations also play a role. Foreign governments represent the interests of owners of the multinational firms and may exert pressure in favour of policies that lead to higher profits for the multinationals even if the small country's policies that are challenged are in conformity with its international obligations.

Compulsory Licensing and the Growth of Generic Production in Canada

The performance of the pharmaceutical industry in Canada does not differ significantly from that in other industrially advanced countries. Its level of research and development is comparable to the disproportionately low level prevailing in such countries as Australia, Austria, Belgium, Denmark, Finland, New Zealand, and the Netherlands. This contrasts with the very high level of research and development expenditures in France, West Germany, Japan, Switzerland, the United Kingdom, and the United States. The structural characteristics of the industry are everywhere similar as are, in consequence, the incentives to which firms are subject, their behaviour, and their performance.

Most countries seek to affect the performance of this industry by policies applicable specifically to it. They chiefly resort to various direct governmental interventions limiting selling costs, prices, or profits and inducing investment, employment, and research and development. Canadian federal policy, on the other hand, is indirect and seeks to affect the industry's performance by altering the conditions of competition at the manufacturers' level. Increased competition has been promoted by easing conditions under which new competitors can enter the market for finished pharmaceutical products. That Canadian policy is currently all but unique among industrially advanced countries does not make it wrong. Indeed it can be thought of as a mechanism to provide socially optimal patent protection in the pharmaceutical industry that other countries might well emulate.

Compulsory licences to import active ingredients or the finished product were introduced by the federal government in 1969 by Section 41(4) of the

Patent Act. This made it possible for new firms to manufacture and sell the finished products without being integrated backward into active ingredient manufacturing and research. The result was a significant reduction in the prices of products against which compulsory licences were taken and used. These multiple-source drugs produced by patent-holding and generic firms together account for a growing proportion (about 14 per cent by value in 1983) of sales of pharmaceutical products in Canada.

The new policy of compulsory licensing to import gave rise to a vigorous and growing generic sector of the industry. The whole of the pharmaceutical industry including patent-holding and generic firms has been doing well since that time in terms of growth and profits compared to the rest of Canadian industry. On the whole, compulsory licensing has caused no decline in the economic health of the patent-holding firms.

From 1969 to 1983 the value of shipments of the entire pharmaceutical industry grew by 400 per cent, whereas all Canadian manufacturing shipments increased in value by 334 per cent. Employment in the pharmaceutical industry rose by 24 per cent between 1969 and 1982 compared to overall manufacturing employment growth of 11 per cent. Profits in relation to sales, capital, and equity have fluctuated, but have been consistently higher than the average for all industries and for manufacturing alone. This general expansion is owing, in part at least, to the aging Canadian population, which consumes more drugs, and to publicly financed purchasing and reimbursement programs, which expand effective demand.

The impact of compulsory licensing and generic drug production in this period can only be estimated, because there is one firm that produces both patented and compulsorily licensed drugs. Nevertheless, it is known that the generic sector was of negligible size in 1968 but contributed about 8 per cent of sales in 1983 and employed about 1,300 persons in 1982. It appears from subtraction, therefore, that the patent-holding firms grew in terms of shipments by about 365 per cent from 1969 to 1983, or about the same as all manufacturing. In terms of employment they grew by 14 per cent.

These numbers overestimate the effect of compulsory licensing, because only about 35 to 40 per cent of the output of generic firms is under compulsory licence and some generic firms produce drugs on which they hold a patent or a voluntary licence. However, it should be kept in mind that the generic sector grew to significance in the industry because of the profitability of compulsory licensing and might well not have obtained a share of the post-patent market without that base.

Compulsory licensing is of acute concern to the patent-holding firms for a number of reasons, despite the relatively satisfactory growth and profitability of their sector of the industry. One is that the introduction of Section 41(4) had an uneven incidence among firms. Some firms were more adversely affected than other patentees, because more of their products were subject to competition from compulsory licences. As a result, the profitability of these

firms declined, in some cases to the point of losses. The Commission was informed at the Hearings that the transfer prices to the Canadian subsidiary of Hoffmann-La Roche were lowered by the foreign parent in response to the subsidiary's losses.

The obverse of this observation is that the decline of the profits of some firms hit hard by compulsory licensing, together with the lack of any overall impact on the profitability of the industry over the last 15 years, implies that some firms have done exceedingly well and their profits have been sufficiently high to offset the low profits and losses of others.

It is also obvious that, however satisfactory the actual performance of patent-holding firms has been, they would have been more profitable had they retained the entire market for patented drugs and avoided the downward pressure on prices exerted by the generic producers.

The profits of the Canadian subsidiaries of foreign firms are directly affected by generic competition. So, too, are the profits of the parent company. These are derived in part from transfer pricing (since the parent sells active ingredients to the Canadian subsidiary at more than the cost of their manufacture) and in part from royalties. Both the royalties and the volume of sales of imported ingredients are a function of the subsidiary's production of the final products in Canada. As the subsidiary's market shares are reduced by generic competition, the profits of both subsidiary and parent are directly reduced.

The present rapid growth of generic firms and the possible increase in their number, especially with the development of the generic sector of the pharmaceutical industry in the United States, threaten further and more rapid losses of market share for patentees in Canada. A particular aspect of these developments that threatens the profitability of the patentee firms' operations in Canada is the intensity of competition between the generic firms themselves.

The most profitable period of operation for a generic firm is when it is the first and sole seller of copies of the patentee's products either with a compulsory licence or after the lapse of patent. At that time, the generic firm can set a price which is not far below that of the brand name product and share in its high profits. As more generic producers enter, they compete for market share by lowering the price, and profitability goes down.

The patentee has some choice as to whether to cut his price too and retain his market share or keep up his price and lose some, but not all, of his sales, protected as he is to some degree by preference for his brand name by price-insensitive consumers. The Commission was told at the Hearings by representatives of Merck Frosst that experience had led that firm to maintain prices in the face of generic competition, because price cuts did not result in proportionate increases in sales. It appears that most brand name firms follow a similar policy of maintaining list prices in such circumstances, but nevertheless reduce the cost of their products to retailers by discounts and other concessions.

The development in size, sophistication, and number of generic firms hastens their application for compulsory licences for promising drugs so as to be the first generic competitor. Some commentators believe that the phenomenon of more intense competition among generic firms is leading to decreasing periods of market exclusivity for newly compulsorily licensed drugs. Their analyses rest on data showing that the most recently patented drugs that have been compulsorily licensed also have a relatively short period of market exclusivity. Projecting this trend into the future leads them to the view that compulsory licensing will soon take place so early as to reduce the average period of exclusivity almost to zero. However, these analyses are incorrect. It is inevitable that *recently introduced* drugs *that are compulsorily licensed* have short periods of exclusivity. How could it be otherwise? The same misleading result would have been obtained if the calculation had been made when the first compulsory licences were issued after 1969. This does not mean that *all* compulsory licences that have recently been issued were for drugs with short periods of exclusivity. The data in Table 8.2 for 29 major drugs that have been compulsorily licensed show that, in fact, the contrary is the case. The eight compulsorily licensed drugs for which NDSs/NOCs were issued in 1981 to 1984 have benefited from periods of market exclusivity averaging 144 months, which exceeds the average of 133 months for the 29 major drugs issued between 1969 and 1984. Setting aside the periods between the date of marketing and 1969 when compulsory licensing to import did not exist, the average period of market exclusivity between the date of introduction on the market and that of generic competition was 122 months for the eight newly licensed drugs and 91 months for the entire sample.

Table 8.2

Duration of Exclusivity Prior to Compulsory Licence: 29 Major Drugs Marketed from 1956 to July 1984

	Average Duration of Exclusivity (months) of New Chemical Entities with Compulsory Licence with NDS/NOC Issued in:	
	1969-July 1984 (29 drugs)	1981-July 1984 (8 drugs)
Patent Exclusivity[a]	108	104
Market Exclusivity[b]	133	144
Patent Exclusivity after 1969	72	84
Market Exclusivity after 1969	91	122

[a] Months between innovator's date of marketing and licence of generic company.

[b] Months between date of innovator's and generic company's dates of marketing.

Source: Table 9.3.

Nevertheless, it is possible to imagine a situation in which early compulsory licensing reduces the potential profits of the patentee who introduces a potential big seller so much as to render the introduction of the drug unattractive, because the costs of clearance are heavier for the patentee than for his generic competitors. A further consideration might militate against introducing a new drug in Canada in these circumstances. A firm obtaining a compulsory licence in Canada might obtain clearance in third-country markets in which patent protection is weak, on the basis of the Canadian clearance. The patentee would then face competition in third-country markets that he might have avoided if the product had not been introduced in Canada. It is conceivable, therefore, that competition between generic firms to obtain compulsory licences might be so early and intense that the patentee would find it unprofitable to introduce a product into the Canadian market.

However remote this possibility, it illustrates the necessity of sheltering patent-holding firms in Canada from competition of generic firms somewhat more than at present.

Since 1969 compulsory licensees have earned high profits because they have been able to apply knowledge generated by patent-holding firms in the development of new drugs and to benefit from the activities of these firms in developing a market demand for the products, while making royalty payments that were less than the expenditures made in developing and marketing the product in Canada. This situation has led to the accumulation of capital and of experience and skill in the generic sector and the rise of effective competition for the dominant patent-holding firms. These developments have greatly benefited consumers, but some drawbacks now threaten.

As the generic sector of the industry has grown in number and size, the prices of multiple-source drugs has continued to fall and the number of compulsory licences, to increase. The possibility now arises that returns may become inadequate to cover the cost of research and development and the introduction of some new drugs in Canada. The present patent legislation does not sufficiently encourage these activities in Canada by either the patent-holding or generic firms. It is now time that the patent legislation or its application, which have brought about such significant change in the performance of the industry to the benefit of consumers, should be altered to correct shortcomings and provide the right incentives, while maintaining the gains that have been made.

In the opinion of the Commission, compulsory licensing to import and to manufacture should be retained, together with appropriate royalty rates, and a short period of exclusivity should be given patentees following the issuance of their Notice of Compliance. Compulsory licensing is necessary to maintain entry and effective competition in the pharmaceutical industry and to ensure that prices are close to costs and that costs are minimized. Appropriate periods of exclusivity and royalty payments for the patent-holding firm together ensure that compulsorily licensed firms (and ultimately the consumer) pay their fair share of the necessary social costs incurred in research and development and in marketing the product in Canada from which they benefit.

Some of the activities of the patent-holding firms are of direct benefit to compulsory licensees. These are principally the research, development, and clearance activities of the patent-holding firms in discovering and putting on the market the pharmaceutical product that is licensed and the dissemination of information about this product, which creates a demand for it. In so far as the demand is caused by the information supplied by the patent-holding firm about the physical and therapeutic properties of the product, the licensee who sells the copied product benefits. In so far as the promotion activities of patentees cause a preference for their brands as against other brands of the same or closely substitutable products, the licensees are disadvantaged.

The objective of policy should be to create conditions under which many firms can potentially compete on a basis of equality. That can be achieved by ensuring that patentees receive a reward for the cost of their activities that are of benefit to their competitors.

Section 41(4) of the Patent Act or its interpretation have not provided such equalization. The section states that licensees should pay their share of costs of ". . .research leading to the invention and for such other factors as may be prescribed." This has resulted in royalty payments that fall substantially short of all the benefits received by the licensees from the activities of patentees. In part at issue is the technical difficulty of estimating the cost of research "leading to the invention"; in part is the insufficient recognition of "other factors," which should be some of the costs of the patentee following the invention.

The Commission believes that compulsory licensing of patents to import and to manufacture should continue, but that they should be issued only after a four-year period of exclusivity, and that royalties should reflect the benefits licensees receive from the patentees' research and development and promotion activities and should provide a reward to patent holders for research in Canada. The sections below indicate how to identify these benefits and estimate their cost. They form the basis for recommendations on the period of exclusivity and on royalty rates on compulsory licences.

The reward to the patentee to be achieved by a combination of exclusivity and royalty arrangements should address two objectives. The first is to ensure that patentees as a group should be compensated for their expenses that benefit licensees, but no barriers to entry should be created by setting exclusivity and royalty payments in excess of the level required for that purpose. The second objective is to reward research and development expenditures for pharmaceutical products that take place in Canada.

It appears from the testimony before the Commission that special encouragement for research activities in Canada is necessary, because research-based firms disregard some cost advantages of doing research in Canada and also because many other countries compete actively with Canada for research and development activities by extending special treatment to firms that do pharmaceutical research on their territory.

It is not the objective to leave the profit position of patent-holding firms unaffected by compulsory licensing. It is not to compensate them for all the consequences of such legislation, but to expose them to fair competition for the benefit of consumers.

Reward to the Patentee

The Period of Exclusivity

The purpose of a period of exclusivity of four years beginning at the date of the issuance of a Notice of Compliance authorizing marketing is to encourage the early introduction of new drugs in Canada by raising the profitability of the firm introducing new products.

The early introduction of a new drug in the Canadian market is of advantage, because it may provide the means to reduce suffering, perhaps lengthen life, and perhaps reduce other health expenditures such as hospitalization and surgery. The introduction of new drugs is expensive because of the direct costs and the time consumed in obtaining a Notice of Compliance from the Health Protection Branch. The introduction may also be delayed if the patent holder is for some reason unwilling to take the drug through the clearance process.

It follows from these considerations that the early introduction of new drugs is desirable and is facilitated if the process of regulatory clearance is efficient and short. Such a process may also encourage international firms to carry out clinical research in Canada with a view to speedy introduction of the drug on the world market by first introducing it in Canada. This is the subject of Chapter 9 of this Report.

An assurance of early introduction of drugs also requires that the patent holder receive sufficient financial incentives. The patent-holding firm is in the best position to go through the clearance process, because it possesses extensive and voluminous proprietary information that must be submitted to the regulatory authorities in order to obtain permission for marketing. Other firms wishing to undertake the clearance process, for instance compulsory licensees, would have to duplicate information already available to the innovating firm. These costs might not be justified for an introduction only into Canada and a few markets without patent protection. Research by other firms to acquire the necessary data would also cause suffering from needless animal experimentation and require clinical tests on human subjects. Hence, adequate incentives for introduction should be given to the patentee.

The pricing behaviour of firms introducing new drugs in the Canadian market and abroad is typically to set high prices initially when the novelty and uniqueness of the drug is greatest so as to maximize its profitability. As competition develops from imitative drugs either with patents of their own or as generics in Canada, prices tend to decline and so increase the benefit of the new drug to consumers and taxpayers.

An assurance of monopoly in the market at the most profitable early period after the introduction of a new drug ensures a satisfactory return and therefore constitutes an inducement to introduce the drug in Canada.

The period accompanying the introduction of a new drug is one of high prices, but also of particularly heavy promotion at a time when the social usefulness of promotion is greatest, because most information is transmitted at that time to physicians and pharmacists. It is at this stage that representatives of the pharmaceutical firms spend the highest proportion of their time on the newly introduced commodity. Physicians allot a part of their valuable time to meeting with sales representatives and obtaining information from them. The physicians believe that this is a low-cost way for them to obtain information, even though it may well contain some bias.

Without a period of exclusivity, competition among generic firms to be the first to introduce a generic copy of a new patented drug might lead to the early introduction of generic competition. This threat to the profitability of the patentee would certainly reduce the patentee's initial promotion and hence the availability of information to physicians and pharmacists about new drugs. It might even inhibit the introduction of the drug. It is thus appropriate to assure patent-holding firms of a period of exclusivity during which they can set high prices without fear of competition and reap a profit that would justify launching the drug in Canada.

The question is to decide on the appropriate length of a period of exclusivity during which the innovating firm can charge prices well above the cost of materials and manufacturing to create a gross profit that covers all other costs including the high initial promotion costs.

The promotion expenditures are used to launch new products and to further the sale of the established brands of the firm. How expenditures are divided between these two objectives depends on the life cycle of the firm's products and the particular position of its new products. The magnitude of expenditures undertaken to launch a new product depends on the timing of the local introduction compared to that of the introduction in foreign markets and on the type of product. For instance, important new chemical entities that have been previously introduced into major foreign markets and are already well known by reputation to local physicians, require less promotion than if the first introduction of the drug on a world-wide basis takes place in the local market. The relatively long period required to introduce drugs in Canada and reliance on foreign clinical data frequently make for earlier introduction abroad than in Canada. Also, drugs whose effectiveness can be judged in a short period of time, such as anti-infectives, acquire a reputation in a shorter period of time than do those which are taken for chronic conditions for which the side effects may appear in the more distant future or those whose effect is necessarily delayed. The common characteristic of promotion costs for a particular drug is that they are very heavy when it is being introduced on the market.

The Commission was told at the Hearings by representatives of Merck Frosst that many drugs achieved large sales in the first year following their introduction and that drugs that took longest to establish themselves required from three to four years after which the growth in their sales slowed. This view is consistent with other information. The four-year period of exclusivity that the Commission believes should be given new drugs reflects these estimates.

Firms holding compulsory licences benefit from some of the patentees' promotion activities, because the knowledge of the patented product already gained by physicians, pharmacists, and the public which results from those activities extends to the licensed product. However, the licensees do not benefit from that element of the promotion that seeks to establish the patentee's brand name in the minds of potential purchasers. Indeed that element reduces the benefit to the licensee as do efforts to cast doubt on the equivalency or quality of his product. Nor does the licensee benefit from efforts to establish the reputation of the patent-holding firm.

The Commission recommends that new drugs should be awarded a period of exclusivity from generic competition of four years after receiving their Notice of Compliance authorizing marketing.

This recommendation of a four-year period of market exclusivity is conditional on no obstacle being placed on the ability of generic firms to complete the requirements for clearance so that a Notice of Compliance can be issued to them immediately the period of exclusivity has lapsed and the compulsory licence is issued.

The Research and Development Component

There is ample evidence to indicate that it is not possible to identify the research and development expenditures that gave rise to a particular discovery, patent, and new drug on the market. This is because research procedures in the industry are still largely empirical and the processes eventually leading to the discovery of a single drug cannot be distinguished from those leading to others or those that fail. Many drugs are tested before a successful one is developed, but most of the processes leading to the successful drug cannot be disentangled from the total research activity.

The unpredictability of the results of research and the impossibility of attributing its costs to a particular drug mean that royalty payments cannot be tied to individual drugs. In consequence, Canadian consumers should contribute to world-wide pharmaceutical research and development expenditures in proportion to their consumption of pharmaceutical products. Total research and development costs in the international pharmaceutical firms in Canada are 10 per cent of their world-wide sales; thus royalty payments for compulsory licences should be 10 per cent of Canadian sales in so far as the research and development component of the reward is concerned. Raising the costs of licensees by higher royalty payments leads to higher prices for

compulsorily licensed drugs and less loss of market share or higher prices for brand name patent-holding firms. Patent-holding firms receive higher incomes from the royalty payments and greater profitability on their own sales.

The Commission takes the view that royalty rates and the period of exclusivity should reward the patent-holding firms for their world-wide research and development and for their promotion expenditures incurred in Canada. Promotion activities abroad have little impact in Canada, but new drugs sold in Canada result from foreign research and development.

Research activities abroad are paid for by Canadian consumers in the high transfer prices for imports of active ingredients and final products paid by subsidiaries in Canada to affiliated firms abroad, in profits, and, to a lesser extent, in royalties and other payments to the parent firm. However, in so far as sales of patent-holding firms are reduced by competition from compulsorily licensed firms, such compensation for research expenses is also reduced. It is to make up this shortfall that licensees should pay for the results of research they use when they produce compulsorily licensed drugs.

The Commission therefore believes that compulsory licensees should pay royalties in proportion to their sales for the research done by patent-holding firms.

The Commission also believes that another major objective of policy, which is the recognition of the varying research efforts of patent-holding firms in Canada, should be addressed in the royalty arrangements. These arrangements should distribute that part of the royalty payments that is based on research and development to patent-holding firms according to their research and development expenditures in Canada.

These objectives can be readily achieved by requiring compulsory licensees to make royalty payments of 10 per cent on their sales, perhaps by way of a levy. This would cover Canada's share of world-wide research. The Pharmaceutical Royalty Fund thus created would periodically be distributed to the owners of the patents that had been compulsorily licensed on the basis of their research and development expenditures in Canada and of the licensee's sales of their compulsorily licensed patented products.

The generic firms are not influenced as to which drug they will apply to license by differences in the royalty payment they make to the Fund, because the payment is the same for all licences. They will thus be guided by considerations of volumes of sales and cost advantage which are also the factors that benefit consumers. On the other hand, the royalty payments to patent-holding firms will be differentiated and may provide incentives to research and development expenditures in Canada, which lead to industrial development.

The Promotion Costs Component

Patent-holding firms incur costs that benefit generic firms and consumers not only from research and development expenditures leading to a new product, but also from promotion activities that provide information to consumers and their agents about the characteristics of the new product. Promotion costs should therefore also be included in the calculation of the needed reward.

Information about new products begins to appear during the period of research, especially when the new product is undergoing clinical trials the results of which are frequently reported in scientific journals. The innovating firm often ensures that some clinical trials take place in countries that will provide future markets so that prominent physicians may become familiar with the product and hasten its acceptability when it is marketed. The costs of such clinical trials are part of total costs of research and development.

Promotion costs are substantial. The innovating firm incurs expenditures in advertising, producing literature on the new product, and providing samples. These are major costs. Another major category of promotion costs is the salaries and travelling expenses of representatives and the cost of their supervision and training. This typically amounts to half the selling costs. In addition, the innovating firm maintains a medical department which provides information to doctors about the characteristics of the firm's drugs and which is responsible for organizing clinical trials and the process of clearance by the regulatory agency. The firm also produces films and exhibits, holds conventions, and undertakes market research on its products.

During the past several years about 15 to 20 new drugs have been introduced each year. These new drugs are single chemical entities or synthesized drugs not previously available. Not all new drugs bring major therapeutic gains or acquire a large volume of sales. Estimates vary about how many such winners have appeared. Representatives of Miles Laboratories told the Commission at its Hearings that probably not more than ten winners have appeared in the last 30 years. Another view is that of the Federal Drug Administration of the United States which classifies new drugs according to its view of their therapeutic merit. Of the 60 new chemical entities introduced into the United States in 1983 and 1984, six (10 per cent) were judged to offer significant therapeutic gains, 13 (22 per cent) to offer modest therapeutic gains, and 41 (68 per cent) to have little or no therapeutic advantages over existing remedies. Drugs drawn from the higher two categories are those that are especially profitable. Some do not become major commercial successes because the incidence of disease for which they are indicated is low. Thus perhaps five new drugs each year will turn out to be money makers. These drugs will be introduced with heavy promotion costs and are also likely to be exposed to applications for compulsory licences in Canada.

Given their importance for earnings, new drugs that are especially therapeutically promising are promoted heavily at the time of launching. This sales effort is chiefly designed to inform physicians and pharmacists about the

therapeutic characteristics of the drug and also has a favourable influence on sales of generic substitutes. Inevitably, a certain amount of brand name promotion takes place at the same time.

The Commission is of the opinion that the four-year period of exclusivity it proposes is sufficient to permit innovating firms to recoup the high promotion costs they incur during this period for the introduction of new drugs that turn out to be successful enough to be subsequently compulsorily licensed. The reason is that new drugs are normally introduced at high prices that are much in excess of materials and manufacturing costs. A substantial positive margin exists for promotion costs. This is indicated by the average difference between the prices of single-source drugs and those of multiple-source drugs. As already reported, using U.S. prices as a reference, the prices of single-source drugs are 68 per cent higher than those of multiple-source drugs, which are also profitable. Thus, a four-year period of exclusivity during the introduction of a drug provides sufficient income to cover the costs of promotion. No provision need be made in the royalty payment of compulsory licensees to compensate the innovating firm for promotion costs incurred in launching new products.

During succeeding years, the patent-holding firm's selling effort in support of an important drug is unlikely to provide significant new information to consumers. It seeks instead to remind and persuade consumers to use that particular brand. Nevertheless, in those provinces where laws require or permit the substitution of pharmaceutical products by pharmacists, compulsory licensees do benefit to some extent from the promotion of a drug through its brand name, because the generic product may be substituted by the pharmacist for the brand prescribed. The importance of this factor varies by province according to the requirements of public reimbursement plans but has had little influence on the 57 per cent of the retail market which is the cash or private reimbursement sector where little substitution takes place.

The sales of compulsorily licensed drugs result chiefly from knowledge of the drug disseminated upon its introduction and from the generic firms' own sales efforts. Nevertheless some indirect influence from the patent holders' continuing promotion activities, though small, exists and should be recognized. The amount of 4 per cent of the licensee's sales would amply cover its value to the licensee.

Calculating the Research and Development Elements of the Pharmaceutical Royalty Fund and Disbursements

A number of practical questions arise in calculating the payments licensees should make to the Pharmaceutical Royalty Fund so as to contribute adequately to world-wide industry research without unduly impeding compulsory licensing which benefits consumers. Others arise in calculating the distribution of the Fund.

The first question concerns the royalty rate. At 10 per cent of licensees' sales it would match the world-wide proportion of total research and development costs to total sales of pharmaceutical firms active in Canada.

A further question arises with respect to the valuation of the licensee's sales. The calculation of the payment into the Royalty Fund is based on the sales of the patented product by the licensee. Royalty calculations are usually based on the actual dollar sales of the licensed drug by the licensee calculated on an arm's-length basis. This basis for the calculation of the royalty has the advantages of being readily identifiable and of encouraging the licensee to set as low a price as possible so as to minimize his royalty payment.

A possible shortcoming of this method of calculation is that the royalty rate is based on the prices charged by the patent-holding firms in world markets, not on the prices that the licensee charges in Canada, which are likely to be less. To base the royalty payment on the Canadian prices of the licensee might lead to a shortfall in this method of reimbursing research and development costs. An attempt might be made to address this possible shortfall by raising the royalty rate in proportion to the difference between the licensees' Canadian prices and average international prices of the patent-holding firms. The Commission recommends against such an adjustment. It would necessarily be arbitrary, because the calculation would depend on which foreign markets were chosen and on the weight given to each drug in each of those markets.

Furthermore, the greater risk is that the 10 per cent payment to the Pharmaceutical Royalty Fund is an excessive contribution to world research, rather than being inadequate. The reason is that the patent system in the rest of the world fosters inefficiency. It gives rise to competition in the pharmaceutical industry by way of high selling costs and heavy research expenditures rather than by price. Some of the research expenditures have the purpose of producing patentable drugs that imitate current big winners. This has led to the existing proliferation of drugs some of which are similar in composition and therapeutic effect and add little or nothing to the improvement of health or comfort. Authoritative judgement of the slight value of many of them is shown in the fact that the health authorities of many countries exclude or limit a substantial number of drugs in their reimbursement programs. Excessive patent life unrelieved by compulsory licensing has provided incentives to use resources in researching around the patents of successful drugs in order to get a share of the high profits such drugs earn for many years of exclusivity. Such research reduces the market share and profits of the real innovators without substantially improving public welfare.

Since the inducements given to duplicative or imitative research in pharmaceuticals by patents are already too high elsewhere, Canadians would not improve the world's allocation of scarce research resources by making disproportionate contributions to that activity.

A decision must also be made as to whether or not licensee export sales should be included in the royalty calculations. The case for their exclusion is to

encourage exports by generic firms. Canadian generic manufacturers typically compete with other suppliers in export markets in countries with little patent protection. Paying royalties on export sales would put them at a disadvantage, while Canadian patent-holding firms are likely to have little access to such markets because of the high transfer prices for active ingredients they pay their parent companies.

It may be argued that multinational firms might find sales of their patented products in such markets eroded by the export competition of compulsorily licensed products of generic firms in Canada. They might seek to prevent access of the generic firms to these new products, and hence competition in these markets, by not introducing the products in Canada in the first place. However, this possibility is unlikely if patent protection is increased as proposed in this Report. Patent-holding firms meet with competition from many sources in markets with weak patent protection. Royalties on the export sales of Canadian licensees would impede their own foreign sales, but not appreciably alleviate the competition faced by brand name firms in these markets, so that compulsory licensees should not pay royalties on export sales.

The distribution of the Pharmaceutical Royalty Fund to individual patent-holding firms depends on how research and development expenditures in Canada are measured and on what sales should be included.

The expenses that should be recognized as research and development expenses in Canada are those that are recognized by Revenue Canada for taxation purposes plus untied grants that are made by firms for research and teaching purposes to other institutions. These expenditures would be verifiable by their tax-exempt status.

The question of how a patentee's total sales should be measured is also important because, for any given level of research and development, high sales reduce the royalty rate and the reward to the patentee. It is in consequence important that the sales figure should be calculated on an arm's-length basis so that the value is not artificially lowered. On the other hand, sales abroad should not be discouraged and patentee exports should be excluded from the value of sales on which the research-to-sales ratio is calculated.

Royalties for Compulsory Licences to Manufacture: The Research and Development Component

Compulsory licences are issued not only to import but also to manufacture. The compulsory licensee to manufacture may not manufacture the final dosage form, but may sell the active ingredient itself. It should be remembered that patents usually apply to the active ingredients in pharmaceutical products, not to the final dosage form. It follows from this that the royalty payment by the licensee appropriate for manufacturing the active ingredient should reflect the costs of research and development in the same way as payments for the right to import the ingredient.

The calculation proposed by the Commission of the payment to the Royalty Fund for compulsory licences to manufacture the active ingredient in Canada is 10 per cent of the value of the active ingredient in the final dosage form valued at its price in the generic market. The physical amount of the active ingredient in the final dosage form varies greatly from one product to another. The result will be widely varying royalties per kilogram of active ingredient.

An example can clarify the calculation and its implications. If a final dosage form of a drug with a manufacturer's unit sales value of $10 contained .001 kilogram of active ingredient, the implied value of the ingredient would be $10,000 per kilogram. Applying the royalty rate of 10 per cent, the royalty payment for a kilogram would be $1,000. But if the content were .01 kilogram, under the same circumstances the implied unit value would be $1,000 per kilogram and the royalty payment $100.

It is evident that both royalty payments would reflect the same research and development costs in the two cases.

It should be recognized that, in the case in which the cost of manufacturing the active ingredient per kilogram is low, and this would be reflected by low prices in the international patent-free market, the appropriate royalty payment might be several times the cost of manufacturing.

Variable Royalty Rates and Incentives to Strategic Behaviour

Variable royalty rates are necessary to reward patentees according to their research and development expenditures in Canada. However, they have the disadvantage of possibly inducing undesirable strategic behaviour in firms to raise their share of the Pharmaceutical Royalty Fund. The larger the patentee's expenditures on research and development in proportion to his sales, the larger the research and development component of his royalty payment will be. The public interest in Canada would be served if firms raised research expenditures in Canada, but not if they decreased their level of sales.

The risk that established firms would reduce the value of their sales to raise their share of the Pharmaceutical Royalty Fund is negligible. The profitability of their own sales is greater than any return that could be obtained from such manipulation, especially because their research-to-sales ratio is calculated on the basis of all their sales, not just their sales of multiple-source compulsorily licensed drugs.

Other possible adaptations of business practices to increase the ratio of research and development expenses to sales can be imagined. For instance, a firm might establish a subsidiary to hold the patent on a compulsorily licensed product and attribute to that subsidiary a disproportionate amount of the firm's research and development expenditures. This would raise the research

and development component of the ratio artificially. Another possibility in such circumstances would be to reduce recorded sales of the firm by issuing voluntary licences to another firm on terms that would keep up the cost and price of the product.

In distributing the Royalty Fund on a compulsory licence to a particular patent-holding firm, the Commissioner of Patents should decide the appropriate corporate entity to which the research and development expenditures and the sales should be attributed so as to ensure that the objectives of the compulsory licensing policy not be frustrated by the strategic response of some firms. For instance, he would ensure that transactions between firms were at arm's length and that sales of pharmaceuticals in Canada under voluntary licence were included in the sales of the patent holder for the calculation of the royalty rate where this appeared to him to be appropriate.

The difficulties that strategic behaviour of firms whose patents are compulsorily licensed might create for the fair functioning of the proposed royalty arrangements are limited, because the payments made by the generic firms holding compulsory licences, and hence the Royalty Fund, would be unaffected by the behaviour. Furthermore, if all the firms receiving payments from the Royalty Fund followed the same strategies, their impact would largely cancel out and shares would not be greatly affected.

The component of the royalty rate attributable to the benefit compulsory licensees derive from the promotion expenses of the patent-holding firms is a flat 4 per cent and is independent of the behaviour of particular firms. Its application requires no analysis of firm behaviour.

The Total Royalty Payments

Royalty payments for compulsory licences should be composed of several elements: the research and development expenditures of the pharmaceutical industry world-wide as a proportion of total sales, sales of compulsorily licensed drugs in Canada, and the ratio of research and development expenditures to total sales in Canada of firms on whose patents compulsory licences have been granted.

The Commission recommends that a Pharmaceutical Royalty Fund be established and be financed by payments made by firms holding compulsory licences, the payments to be determined by the value of the licensee's sales of compulsorily licensed products in Canada multiplied by the pharmaceutical industry's world-wide ratio of research and development to sales, as determined by the Commissioner of Patents, plus 4 per cent (the 4 per cent would reflect the value to compulsory licensees of current promotion expenditures of patent-holding firms); and

that the Pharmaceutical Royalty Fund be distributed periodically to the firms whose patents are compulsorily licensed, each firm's share to be

determined by the sales in Canada of its patented products by compulsory licensees multiplied by the firm's ratio of research and development expenditures to total sales of ethical drugs in Canada plus 4 per cent (to reflect promotion), all this as a proportion of the same variables for the entire group of firms with patents under compulsory licence in Canada.

The Pharmaceutical Royalty Fund and its distribution can be expressed by a formula.

Let ST = value of sales of all ethical drugs
SC = value of sales of compulsorily licensed drugs by generic firms in Canada
A = one firm in Canada with compulsorily licensed patents
I = all firms in Canada with compulsorily licensed patents
R&D = research and development expenditures

The Pharmaceutical Royalty Fund is

[(R&D/ST) for the industry world-wide + .04] x SC

The share of firm A is

$$\frac{[(R\&D/ST)A \text{ in Canada} + .04] \times SC \text{ of A's patents}}{[(R\&D/ST)I \text{ in Canada} + .04] \times SC} \times \text{Fund}$$

At present, with a 10 per cent world ratio of research and development to sales and total sales of compulsorily licensed drugs by generic firms of $46 million, the Pharmaceutical Royalty Fund would be $6.44 million [(.10 + .04) x $46 million = $6.44 million]. A firm in Canada owning patents on which compulsorily licensed sales were $5 million and which had a ratio of research and development costs to sales in Canada of 4.5 per cent (the present industry average) would receive a payment of $700,000 or 14 per cent of the licensee's sales.

$$\left[\frac{(.045 + .04) \times \$5 \text{ million}}{(.045 + .04) \times \$46 \text{ million}} \times \$6.44 \text{ million} = \$700{,}000\right]$$

If a firm did no research, it would receive $329,412 or 6.6 per cent.

$$\left[\frac{(.04) \times \$5 \text{ million}}{(.045 + .04) \times \$46 \text{ million}} \times \$6.44 \text{ million} = \$329{,}412\right]$$

If the research ratio were 10 per cent, the firm would receive $1,152,941 or 23 per cent of the value of licensed sales.

$$\left[\frac{(.10 + .04) \times \$5 \text{ million}}{(.045 + .04) \times \$46 \text{ million}} \times \$6.44 \text{ million} = \$1{,}152{,}941\right]$$

Amongst the 50 largest firms in Canada in 1983, the highest reported ratio of research to sales was 20 per cent. Such a firm would receive a royalty payment of 39 per cent of the licensed sales under the proposed arrangements.

The cost to the consumer of the proposed measures can only be estimated as an increment on the basis of the present situation. In 1983, the value of production of the 32 compulsorily licensed drugs meeting generic competition was $217 million of which generic firms supplied $46 million. If the proposed measures had been applied in that year, licensees would have paid royalties of $6.4 million instead of the 4 per cent or $1.8 million actually paid. There would thus have been an added cost of $4.6 million for licensees and an increase in their prices to cover at least that amount. In addition, the patent-holding firms producing 78 per cent by value of the 32 licensed drugs would have been able either to raise their prices or to retain a larger share of the market for their higher priced products. If they had raised their prices by the full 10 per cent difference implied by the present royalty rate and that proposed for a new régime, this would have raised drug costs by $22 million. These two elements sum to $26.6 million. If they had retained another 10 per cent of the market that would have raised drug costs by $26 million for the same volume of drugs, because their prices were on the average about twice those of the generic products. In this case the sum of the two elements would be $30.6 million.

What the impact of introducing the proposed royalty arrangements would actually be in future is impossible to foretell. This would depend on the responses of firms in the industry to new incentives. Furthermore, present market shares of products and firms, which are the basis of the estimates above, have been changing constantly as new products were introduced, compulsory licences were issued, and market strategies evolved.

But uncertainty is inherent in a market economy. The proper objective of industrial policy is to establish conditions under which firms compete that induce efficiency and are fair. In the opinion of the Commission, such an objective would be furthered by its proposals to retain compulsory licensing to import pharmaceutical products, but to modify its terms.

The Proposed Royalty Arrangements and Canada's International Agreements

Canada should only introduce the proposed new arrangement for royalty payments on compulsory licences if it is not in violation of Canada's international commitments as a member of the International Patent Convention and signatory of the General Agreement on Tariffs and Trade.

In the view of the Commission, the proposed arrangement is consistent with those undertakings. The arrangement does not discriminate between firms on the basis of nationality and so extends national treatment to foreign firms in accordance with Canada's international commitments regarding patents.

The proposed arrangement rewards research and development in Canada, but is entirely neutral with respect to the location of manufacturing. For instance, a firm that did no manufacturing and imported all finished products sold in Canada might yet carry out research in Canada and be duly rewarded.

Hence, the proposed arrangement is consistent with the Articles of Agreement of GATT.

Product and Process Patents

An invention may be of two broad sorts. It may be a process to better produce an existing product and lower the cost of production or improve the quality of the product. Or it may be a new product altogether. Corresponding to these two types of invention are two types of patent claims. Either a patent can be taken out on a process or it can be taken out on a product.

In common with past or present patent acts of some other countries, the Canadian Patent Act restricts the patents that can be taken out on foods and medicines to processes and excludes product claims.

The exclusion of product patents is based on two broad considerations. The first is that the exclusion would encourage invention leading to the development of new processes, because access to the product could be obtained in this way. The second reason is the concern that product patents that have been granted were unreasonably broad. A single patent covered an excessive range of products, and the patent holder could exclude potential competition from his market to an extent unwarranted by the public interest. There is reason to believe that, in many countries, the restriction of patenting in the pharmaceutical industry to processes, by weakening the degree of patent protection that would have been obtained had product patenting been permitted, has encouraged the development and growth of local firms. But that did not happen in Canada. The growth of the Canadian-owned sector only followed the introduction of compulsory licensing to import.

The exclusion of product claims has been criticized on a number of grounds. One is that process-only patenting encourages inventing around existing process patents in order to have access to the product and that this wastes resources. Such efforts would be better devoted to the development of new products. Process patenting also encourages excessive research by the original patent holder to develop other processes of manufacturing his own product as a defensive measure anticipating the research efforts of would-be competitors.

It can be noted that no evidence exists of such wasteful invention on the part of potential competitors and the original patentee in Canada, where very little chemical research occurs. However, a waste has arisen in Canada in the form of multiple applications for compulsory licensing of process patents.

Multiple process patenting has given rise to certain administrative difficulties in the determination of the appropriate royalties to be paid to the patentees against whom compulsory licences have been issued. Characteristically the several process patents existing for a particular drug are of unequal importance. Indeed some may never actually be used. Nevertheless, a generic firm must wisely take out compulsory licences against each of them and pay a

royalty to the owners of the patents who may be several different firms. Fair sharing arrangements for the royalty obviously are difficult to devise, because of the unequal importance of the several process patents limiting imitation of the same drug. Royalty shares combined should not exceed the level that would obtain if there were just one patent.

The main effect of process patents in the Canadian pharmaceutical industry is to indirectly protect the product. In Canada that is virtually their sole effect, because so little active ingredient production occurs. Some patented processes make the production of a new drug possible, and their commercial importance is equivalent to that of a product patent. Other process patents may lower the cost of production or improve the quality of the drug and are less valuable than the first kind. Still other process patents may be trivial. If each of many process patents on a single drug were awarded royalty rates the sum of which exceeded the amount recommended in this Report for a drug covered by a single patent, the drug would receive excess protection and the position of the compulsory licensees would be inappropriately and adversely affected.

The difficulties that arise in sharing the royalty payments would be alleviated if product patents on pharmaceutical products were allowed. During the life of the product patent the full royalty on compulsory licences would be paid to the product patent holder. Any process patents for the product that were licensed during that period would receive zero royalties. After the lapse of the product patent's term, the royalty payable by the licensees would be shared between the holders of the process patents remaining on the product. In this way the inventor of a drug would receive the full reward during the life of his patent. Inventors of improvements in the process for making the drug would be rewarded thereafter.

Process patents granted after the original product or process patent on a drug may lengthen significantly the entire period of effective patent protection for that drug. Indeed progressive firms seek constantly to improve their products and, when their improvements are made, they patent them. This includes numerous processes to prepare the active ingredient, intermediate chemicals used in making the original product, and ways of using the original product. A single drug may be surrounded by a score or more of patents that protect the product for many years beyond the 17 years of the original patent.

When compulsory licensing exists, there appears to be no need to weaken the protection that a product may have by excluding product patents. If a patent-protected product is sufficiently attractive to elicit imitation, this can be achieved more efficiently by giving a compulsory licence to competitors with due compensation to the patent holder rather than by inducing a waste of resources in research to find new processes by which to produce it. Furthermore, exclusion of product patents creates the difficulties indicated above.

In consequence, the Commission recommends that, conditional on preserving modified provisions for compulsory licensing in the Patent Act as recommended in this Report, limitations on product claims for pharmaceutical products in the Patent Act be removed.

Reverse Onus

In cases of alleged infringement of patents, Section 41(2) of the Patent Act places on the compulsory licensee the onus for proving that the process used to produce his drug is the one for which he has a licence and not another one owned by a patentee. This is reverse onus and is an exception to the usual onus in common law that the person making an allegation of wrongdoing must prove it.

Without reverse onus, a patent-holding firm alleging infringement of its patent would be faced with a more difficult task. The firm would be required to prove that the alleged infringer was using the process that it, the patent holder, possessed. The burden of proof of the process by which the alleged infringer had produced the product would rest on the patentee. In the absence of reverse onus, the protection offered by process and product by process claims would be weaker.

Reverse onus in the Canadian Patent Act has faced generic producers with few difficulties, though they import and do not manufacture the active ingredient that is the subject of patents. Foreign manufacturers of active ingredients are sometimes unwilling to provide evidence of the process of production they are using to supply the needs of the Canadian importer, so that the alleged infringer cannot defend himself by providing proof that his product is produced by a process for which he holds a compulsory licence. As a consequence, generic manufacturers have of necessity had recourse to the practice of licensing every process that is patented for the manufacture of a particular drug. This course has been open because of the low royalty rate awarded and its division amongst multiple patent holders. This multiple compulsory licensing is a waste analogous to, but much less important than, the waste that arises from inventing a new process with the intention of producing an existing product.

However, the substantial royalties recommended in this Report would place an undue burden on a generic manufacturer faced with process patents on a product that extended in time beyond the product patent's life. If reverse onus were retained, he would be deemed to infringe were he unable to prove the process actually used, even though the active ingredient he bought was not produced by the new process patented. To avoid this dilemma, he would be forced to licence and to pay the heavy royalty.

The rationale for reverse onus is that the patentee is at a disadvantage in infringement actions, because he has no direct knowledge of the process used by the alleged infringer whereas the latter does. Such a comparative disadvantage often does not hold for compulsory licensees in the pharmaceutical industry. It follows that, when product patenting is allowed to protect the patentee over a normal patent life with either exclusivity or a reasonable royalty on a compulsory licence, the retention of reverse onus on processes awards too much protection.

The Commission recommends that reverse onus for pharmaceutical patents be abolished.

The importance of reverse onus can easily be overstated. Legal precedents indicate that under common law the general rule that he who asserts must prove is usually disregarded where the subject matter of the allegation lies particularly within the knowledge of one of the parties. In such circumstances the party with the special knowledge is required to prove or to deny the allegation. It can be inferred from precedents that, even if reverse onus were removed from Section 41(2) of the Patent Act, the courts might require generic firms to reveal the process used in manufacturing the imported ingredients when they have access to the information.

Conclusion

The Commission's several recommendations to alter the Patent Act and the terms on which compulsory licences for pharmaceutical products are granted have been designed to provide together the right amount of patent protection and the right incentives. These recommendations form a package of interdependent elements. One element is a four-year period of market exclusivity for patentees, which permits them to establish their product and brand name while free from competitive concern. The second is a royalty arrangement for compulsory licences. It requires licensees to pay for the benefits they obtain from the patentees' world-wide research expenditures and from their promotion expenditures in Canada. The royalty payment is the same for all licences and therefore constitutes a flat tax giving the same protection from licensing to all patents. The distribution of the Royalty Fund encourages research in Canada by substantial rewards. The third element is the strengthening of patent claims by permitting product patents, which is justifiable in conjunction with the continuance of compulsory licensing. The final element is the removal of reverse onus which is relevant only to process patents and is, in any event, inappropriate to the particular situation of compulsory licensees in many instances in the Canadian industry.

A change in one of the elements of the policy package would upset the balance sought between safeguarding the interests of patentees and generating the degree of competition in the industry necessary to induce efficient performance and reasonable prices that benefit taxpayers and consumers. If a variation were made in one of the proposed elements, a compensating adjustment would be required in others in order to maintain the balance.

The result of the proposals would be that Canadian consumers and taxpayers would pay their fair share of world-wide pharmaceutical research costs for compulsorily licensed drugs to those firms that do a fair share of world-wide research in Canada. The proposals would also ensure that prices would not be so high as to generate excessive profits or selling costs, thereby protecting the consumer interest.