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IMPACT OF BILL C-22

FROM 1969 to 1983



Consommation  
et Corporations  
Canada

Consumer and  
Corporate Affairs  
Canada

IMPACT OF BILL C-22

FROM 1969 to 1983

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IMPACT OF BILL C-22  
FROM 1969 TO 1983

**RESUMÉ**

The Department of Consumer and Corporate Affairs has conducted a study of the impact of Bill C-22 on the cost of drugs had those proposals been in place since 1969. This study used the same methodology, assumptions and data as the Eastman Report.

Two major features of the Government's proposals would have had a bearing on drug costs. These features are: i) the proposed 10-year and 7-year periods of exclusivity against licences to import and licences to manufacture respectively; and ii) the Drug Prices Review Board.

This study found that the constrained compulsory licensing of Bill C-22 would have saved consumers \$166 million in 1983 as compared to the Eastman estimates of \$211 million with unconstrained compulsory licensing.

However, the study also found that if the Drug Prices Review Board had been in place since 1969 and had limited drug price increases to a rate equal to the growth in the Consumer Price Index (CPI), then consumers could have saved an additional \$60 to \$200 million in 1983 alone - a saving unavailable under the current law.

As a result, the total impact of Bill C-22 in 1983 would have been to save consumers between \$226 to \$366 million (\$166 million plus \$60 to \$200 million) over what they would have paid if there had been no compulsory licensing. This compares favourably to the \$211 million that Eastman said the current law saved consumers.

The study also reviewed the impact on research and development expenditures and employment in 1983 had the R & D to sales ratio of the pharmaceutical industry reached the levels predicted as a result of Bill C-22.

R & D expenditures would have reached a total of \$144.7 million for 1983, an increase of about \$74 million or more than double the actual 1983 levels. This increase would have created nearly 1100 more jobs in the R & D sector of the pharmaceutical industry.

## SUMMARY OF IMPACT OF C-22 (1969-1983)

The Department of Consumer and Corporate Affairs has conducted a study of the impact of the Government's proposed Patent Act amendments on the cost of drugs had the C-22 proposals been in place since 1969. The Eastman Report calculated that savings of \$211 million in 1983 would accrue as a result of unrestrained compulsory licensing. The results reported here are based on the same methodology, assumptions and data as the Eastman background study. There are two major features of the Government's proposals (Bill C-22) that would have had a bearing on that figure:

### Factor 1: Exclusivity

If the proposed 10 year and 7 year periods of exclusivity (against compulsory licences to import and to manufacture respectively) had been in place since 1969, what would consumers have saved in 1983 over the pre-1969 policy of full patent protection?

We have found that the limited compulsory licensing of C-22 would have saved consumers \$166 million in 1983 as compared to the drug bill in 1983 had the pre-1969 policy continued.

### Factor 2: Impact of Price Review Board

If the Price Review Board had been in place since 1969 and if it had been effective in limiting drug price increases to a rate equal to the growth in the Consumer Price Index (CPI), what would be the savings to consumers in 1983 over prices that would have prevailed had the pre-1969 policy been in effect?

The impact of the Price Review Board in 1983, if it had limited the price increases of all prescription drugs to the CPI since 1969, would have saved consumers up to \$200 million in 1983. If, however, the impact of the Price Review Board had only limited price increases to drugs on the market for less than ten years, then the saving would still be about \$60 million.

### Comparison with Eastman Report

The \$166 million that would have been saved in 1983, had the C-22 exclusivity provisions been in place since 1969, is directly comparable to the Eastman Report estimate of \$211 million in savings from unrestricted compulsory licensing. These estimates, however, do not take into account the savings that would have occurred had the Price Review Board been in place over the same time period. The operation of the Price Review Board over the 1969-1983 period would have added from \$60 million to \$200 million to the value of the savings in 1983 from limited compulsory licensing.

### Impact on Research and Development

R&D expenditures by PMAC companies would have totalled \$144.7 million in 1983 (\$74 million or 104% higher than actual). This would have resulted in nearly 1100 more jobs in the R&D sector of the pharmaceutical industry.

### Conclusion

If the C-22 policy of limited compulsory licensing and a Price Review Board had been introduced in 1969, instead of the amendment to Section 41 of the Patent Act of unrestricted compulsory licensing, Canadian consumers would have benefited by an additional \$15 million to \$155 million in savings in 1983 alone (see the Table below).

In addition, there would have been \$74 million in additional R&D expenditure (an increase of 104%) and 1100 more jobs in R&D than actually existed in 1983.

#### ADDITIONAL CONSUMER SAVINGS FROM BILL C-22 IN 1983

(\$ millions)

	EXCLUSIVITY	PRICE BOARD	TOTAL
Bill C-22 Savings	166	60-200	226-366
Eastman Report Savings	211	0	211
Additional Consumer Savings from Bill C-22			15-155
Additional R&D Expenditure			\$74 M
Additional Jobs			1100



## IMPACT OF C-22 (1969-1983)

### DETAILED ANALYSIS

In order to determine the benefits (costs) of the proposed policy, on consumer expenditures on drugs it was assumed that the C-22 policy had been implemented in 1969.

The following questions were asked:

- A. What would have happened to drug expenditures in 1983 had the Price Review Board been in place since 1969 and it had been effective in limiting drug price increases to a rate equal to the Consumer Price Index?
- B. What would be the benefits to consumers of the limited compulsory licensing scheme of C-22 had it been in effect since 1969 instead of the unrestrained compulsory licensing scheme extant? (i.e. 10 and 7 year periods of exclusivity for licences to import and manufacture respectively or expiry of the first patent if that occurs sooner)
- C. What is the net result of A. and B. combined?
- D. How does this compare to the Eastman estimates of \$211 million in savings to consumers?
- E. What would have been the impact on R&D expenditures and employment had this policy generated the R&D to sales proportions that are predicted?

The details of these calculations and results are described in the following two sections. Except where noted, the same methodology, assumptions and data were used as the Eastman background study.

### CONCLUSION

We have concluded the following:

- A. If price increases for new drugs had been limited to the Consumer Price Index, consumers would have saved a minimum of \$60 million in 1983 alone and, conceivably, saved as much as \$200 million if the Board had been totally effective in limiting all prescription drug price increases to the CPI.
- B. The benefit to consumers of the limited compulsory licensing features of this policy would have been \$166 million in 1983.

- C. The total benefit of the policy vis à vis unrestricted compulsory licensing would have been approximately \$226 million in 1983 and, there could have been a benefit of \$366 million to consumers if the Board were effective in limiting all drug prices.
- D. The net benefit to consumers of the C-22 policy vis à vis the Eastman estimates of the benefits of unrestrained compulsory licensing (\$211 million) is at least \$15 million in 1983 and could be as high as \$155 million.
- E. R&D expenditures would have been about \$144.7 million (\$74 million or 104% higher than actual). This would have resulted in nearly 1100 more jobs in the R&D sector of the pharmaceutical industry.

A. EFFECTS OF PRICE BOARD

Assumptions

- Board permits price increases no higher than increases in CPI.
- volume of drugs and rate of new drug introduction and usage remain unchanged.
- Board influences price of all prescription drug sales.

Results

- In 1983, the cost of prescription drug purchases would have been \$200 M less than actual expenditures had the Review Board been effective in limiting all prescription prices. Many of these drugs, however, do not have any patent protection remaining. It could be argued that since the Board can only set price ceilings for single source drugs on the market less than ten years (which is currently about 30% of the market), therefore the Board could have reduced 1983 drug costs by \$60 M.
- For the period 1969-1985, the Board could have reduced drug costs by a total of \$930 M if it affected all prescription prices. More directly, it could set ceilings for single source drugs on the market less than ten years (about 30% of the market) and thereby have saved about \$280 M over this 16 year period.

### Background

Annex I shows the rate of increase of the Consumer Price Index (CPI) and the CPI for Prescribed Medicines (CPIPM) between the years 1969 and 1985. It also includes the actual sales of ethical (prescription) pharmaceuticals for those same years.

Annex II shows the amount which would have been saved for the years where CPIPM was higher than CPI, and the total for that whole period.

NOTE: It should not be assumed that price increases as high as the CPI rate will necessarily be accepted by the Board without very good reasons.

### B. PERIODS OF EXCLUSIVITY

#### Assumptions

- periods of exclusivity (10 years for importing; 7 years for manufacturing) implemented in 1969
- rate of new drug introduction was unchanged
- rate, timing and effect of generic copying was unaffected except for delays imposed by the policy
- generics enter the market first day after period of exclusivity ends for those drugs that were delayed
- chemicals manufactured in Canada priced at same level as those imported

#### Results

- of 32 drugs in Eastman study 3 were on the market less than 10 years in 1983 and therefore could possibly reduce the Eastman saving of \$211 million;
- however, one of three (Naproxen) would have been copied under compulsory licence to manufacture before 1983, and therefore would contribute to the Eastman savings;
- in addition, one product's first patent (Amoxicillin) expired before 1983 and hence could have been copied via importation or manufacturing licences by 1983 and would also contribute to savings analagous to Eastman's;
- for the third drug (Cimetidine) competition would have been delayed and therefore it does reduce the Eastman savings figure by about \$45 million;
- as a result, savings in 1983 would have been \$166 million versus the \$211 million reported by Eastman.



## Background

Drugs	First Patent Expiry	Orignator NOC	Actual Generic NOC	Available for Licence to Import	Manufacture
Naproxen	July 88	July 74	June 82	July 84	July 81
Amoxicil- lin	Oct. 79	Feb. 74	Jan. 78	(1)	(1)
Cimetidine	June 91	June 77	Sept. 81	June 87	June 84

(1) licences available in October 1979 because of 1st patent expiry

- Naproxen licence to manufacture available in 1981

° because of large market for this drug and relative simple chemical processes required it would probably have been manufactured here - thus no impact.

- Amoxicillin's first patent expired in October 1979 and hence could be copied - There is no price effect.

- Cimetidine available for copy under importation licence in June 1987 and under manufacture licences in June 1984 - thus price estimate affected, and thus it would reduce the Eastman savings figure.

## C. COMBINED IMPACT OF THE PRICE BOARD AND EXCLUSIVITY

The effects described in A and B above do not exist separately but rather sum together to give the combined effect of the total policy.

The value of ethical sales in 1983 in the absence of any compulsory licensing was estimated as being the total of actual recorded ethical sales (\$1,599.9 million) plus the value of the savings from compulsory licensing estimated in the Eastman Report. This produced an estimate of \$1,810.9 million for the value of ethical sales in the absence of compulsory licensing. From this amount the savings which the two factors of Bill C-22 would have generated were subtracted to arrive at estimates of the value of ethical sales in 1983 had Bill C-22 been in place since 1969. This procedure showed that Bill C-22 would have produced a minimum total savings of \$226 million and a maximum total savings of \$366 million in 1983 (see the table below).

MINIMUM AND MAXIMUM TOTAL SAVINGS FROM BILL C-22 IN 1983

Total Ethical Sales in 1983 without any compulsory licensing		\$1,810.9 million
Less: Savings from Price Review Board	- minimum	\$ 60.0 million
	- maximum	\$ 200.0 million
Less: Savings from limited Compulsory Licensing		<u>\$ 166.0 million</u>
Estimated Total Ethical Sales in 1983 had Bill C-22 been in place since 1969	- minimum	\$1,444.9 million
	- maximum	\$1,584.9 million
Estimated Total Savings	- minimum	\$ 226.0 million
	- maximum	<u>\$ 336.0 million</u>

D. COMPARISON WITH EASTMAN ESTIMATE OF SAVINGS

The savings of \$211 million estimated by the Eastman study for 1983 are inherently accounted for in the value of actual ethical sales given above (\$1,599.9 million). That is, in the absence of all compulsory licensed drugs actual ethical sales would have been some \$211 million greater than the actual recorded value in 1983. The \$45 million difference between compulsory licence savings under the Eastman assumptions (\$211 million) and under the assumption of limited exclusivity (\$166 million) reduces the total savings to the consumer while the effect of the Price Review Board is to increase the total savings. The total additional savings to the Canadian consumer would have been from \$15 million to \$155 million (see the Table below).

ADDITIONAL CONSUMER SAVINGS  
FROM BILL C-22 IN 1983

\$ millions

	Exclusivity	Price Board	Total
Bill C-22 Savings	166	60-200	226-366
Eastman Report Savings	211	0	211
Additional Consumer Savings from Bill C-22			15-155

E. ESTIMATE OF IMPACT ON R&D EXPENDITURES AND EMPLOYMENT

In order to determine the impact on R&D expenditures it was assumed that the PMAC R&D to PMAC sales ratio would have been 10% in 1983 rather than the approximately 4.9% at which it actually stood. PMAC sales for 1983 were estimated as \$1,447.1 million by applying the proportion PMAC sales in 1984 were of all 1984 sales (90.5%) to the total of Drug Store and Hospital Purchases in 1983. This gives an estimate of \$144.7 million in total PMAC R&D expenditure. This is an increase of \$73.8 million or 104% over the \$70.9 million that a 4.9% R&D to sales ratio would have brought about.

To estimate the impact in terms of additional R&D jobs the increase (\$73.8 million) was pro-rated between salary and non-salary expenditures. Statistics Canada estimates that about 47% of such R&D is actually salaries, therefore the increased salary expenditure would have been about \$34.7 million. This was then divided by the average 1983 salary in pharmaceutical R&D (Statistics Canada estimates this as \$32,258) to arrive at an estimate of nearly 1100 new jobs.

Annex I

CPIPM, CPI and Actual Ethical Sales  
1969-1985

	<u>CPIPM</u> <u>(1981=100)</u>	<u>% CHANGE</u>	<u>CPI</u> <u>(1981=100)</u>	<u>% CHANGE</u>	<u>ACTUAL</u> <u>ETHICAL</u> <u>SALES</u>
					(\$000)
1969	56.1	-	39.7	-	262,049
1970	56.2	0.2	41.0	3.3	283,034
1971	55.1	-2.0	42.2	2.9	335,255
1972	55.1	0.0	44.2	4.7	363,843
1973	56.1	1.8	47.6	7.7	396,056
1974	58.4	4.1	52.8	10.9	443,411
1975	62.7	7.4	58.5	10.8	500,529
1976	66.7	6.4	62.9	7.5	570,535
1977	69.4	4.0	67.9	7.9	628,386
1978	72.2	4.0	73.9	8.8	717,359
1979	79.2	9.7	80.7	9.2	839,300
1980	87.5	10.5	88.9	10.2	942,700
1981	100.0	14.3	100.0	12.5	1,119,700
1982	115.8	15.8	110.8	10.8	1,338,900
1983	130.6	12.8	117.2	5.8	1,599,900
1984	139.6	6.9	122.3	4.4	1,856,500
1985	148.8	6.6	127.2	4.0	2,088,100

CPIPM: Consumer Price Index for Prescribed Medicines

CPI: Consumer Price Index

SOURCES: - Statistics Canada, catalogue 62-010  
- Statistics Canada, Inquiry desk  
- IMS Canada

Annex II

Impact of Price Review Board  
1979-1985<sup>1</sup>

	ACTUAL ETHICAL SALES	SAVINGS-TOTAL PRESCRIPTION MARKET <sup>2</sup>	SAVINGS-30% OF PRESCRIPTION MARKET <sup>3</sup>
	(\$000)	(\$000)	(\$000)
1979	839,300	3,577	1,073
1980	942,700	6,690	2,007
1981	1,119,700	25,504	7,651
1982	1,338,900	87,140	26,142
1983	1,599,900	196,667	59,003
1984	1,856,500	266,648	79,994
1985	2,088,100	344,032	103,209
TOTAL	9,785,100	930,258	279,079

NOTES

- (1) Prior to 1979 the drug price index rose more slowly than the Consumer Price Index and hence the Board would have had no effect on prices during the pre-1979 period.
- (2) These are the savings if it is assumed that the Review Board influences the prices of all prescription drugs.
- (3) These are the savings if it is assumed that the Review Board influences the prices of drugs on the market less than 10 years.

Source: IMS (Ethical drugs relate closely to prescription drugs).

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