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THE COST PROJECTION OF THE CANADIAN DRUG MANUFACTURER'S ASSOCIATION: A CRITIQUE

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THE COST PROJECTION OF THE CANADIAN DRUG MANUFACTURER'S ASSOCIATION: A CRITIQUE

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ANALYSIS OF CDMA COST ESTIMATES
RE BILL C-22

RESUMÉ

The Canadian Drug Manufacturers Association (CDMA) stated in a brief to provincial Ministers of Health that the cost to consumers in 1995 of the proposed changes in the Patent Act would total $650 million.

However, there are problems with two key assumptions made by the CDMA, which indicate that their assessment is a gross overestimate.

First, the CDMA assume that 100% of all drugs that will be introduced over the course of the next ten years will be copied by 1995. However, no drug on the market for less than 4 years has ever been copied by a generic company. We estimate that currently only about 15% of such drug sales are from copied drugs. It is possible that this ratio could go as high as 30% by 1995, but even this is a generous assumption.

Second, the CDMA assumes that the drug market will grow at 15% per year for each of the next 10 years to get their $650 million cost in 1995. This rate is considered high in relation to recent trends in the growth of this market segment and in relation to the lowering of the inflation rate. For these reasons, it is considered more appropriate to use a 13% growth rate.

The result of modifying only these two CDMA assumptions, to make them more realistic, produces at least a 75% reduction in the CDMA cost forecast of $650 million in 1995: the estimated costs run from $80-$160 million depending on the rate of copying.

However, in addition, the CDMA did not take into account the impact of the earlier availability to the generics of licences to manufacture after seven years. Moreover, the CDMA has ignored the effect of the Drug Price Review Board. Had the Board been in place keeping price increases down, there would have been additional savings. In fact, had the Consumer Price Index grown at only 1 percentage point less than the Drug Price Index (over the past 10 years the CPI has risen an average of 1 percentage point per year less than the index of drug prices) the Board could have saved consumers between $157 and $522 million in 1995.

Combining the savings due to the Price Board with the modified CDMA cost forecast and, assuming a high rate of copying (30%) and the more modest impact of the Price Review Board, produces $3 million in "costs". However, assuming a low rate of copying (15%) and a high impact of the Board results in estimated savings to consumers of $442 million.

NET SAVINGS (COSTS)

	LOW COPY RATE (15%)	HIGH COPY RATE (30%)
	$80 M Cost	$160 M Cost
Low Board Impact ($157 M savings)	$77 M	$ (3) M
High Board Impact ($522 M savings)	$442 M	$362 M

ANALYSIS OF THE CDMA COST PROJECTIONS

SUMMARY

1. In an analysis of the Canadian Drug Manufacturer's (CDMA) cost projections regarding the proposed changes to compulsory licensing, we find that the CDMA have significantly overestimated the "cost" of the policy. They claim it to be $650 million in 1995; we recalculate their estimates to be $80-$160 million at most, based on the CDMA methodology with only 2 changes in assumptions (see Annex). The figure of $80 million is only 12% of the CDMA figure.

2. The CDMA have produced significant overestimates in relation to the following four factors:

   2.1 The CDMA assume 100% of single source drugs that have been on the market less than ten years will be copied, including drugs on the market as little as one year. In reality, no drug on the market 4 years or less has been copied. Therefore, only 75% of the value of the drugs on the market less than 10 years could be subject to copying. In fact, in 1985 only 15% of the total market for drugs under 10 years old was copied (see chart). We estimate, based on recent trends, that about 30% of the value of new drugs could be copied in 1995. This lower copying rate also takes into account the fact that no generic would copy a drug within the first four years of the marketing of the brand-name product.

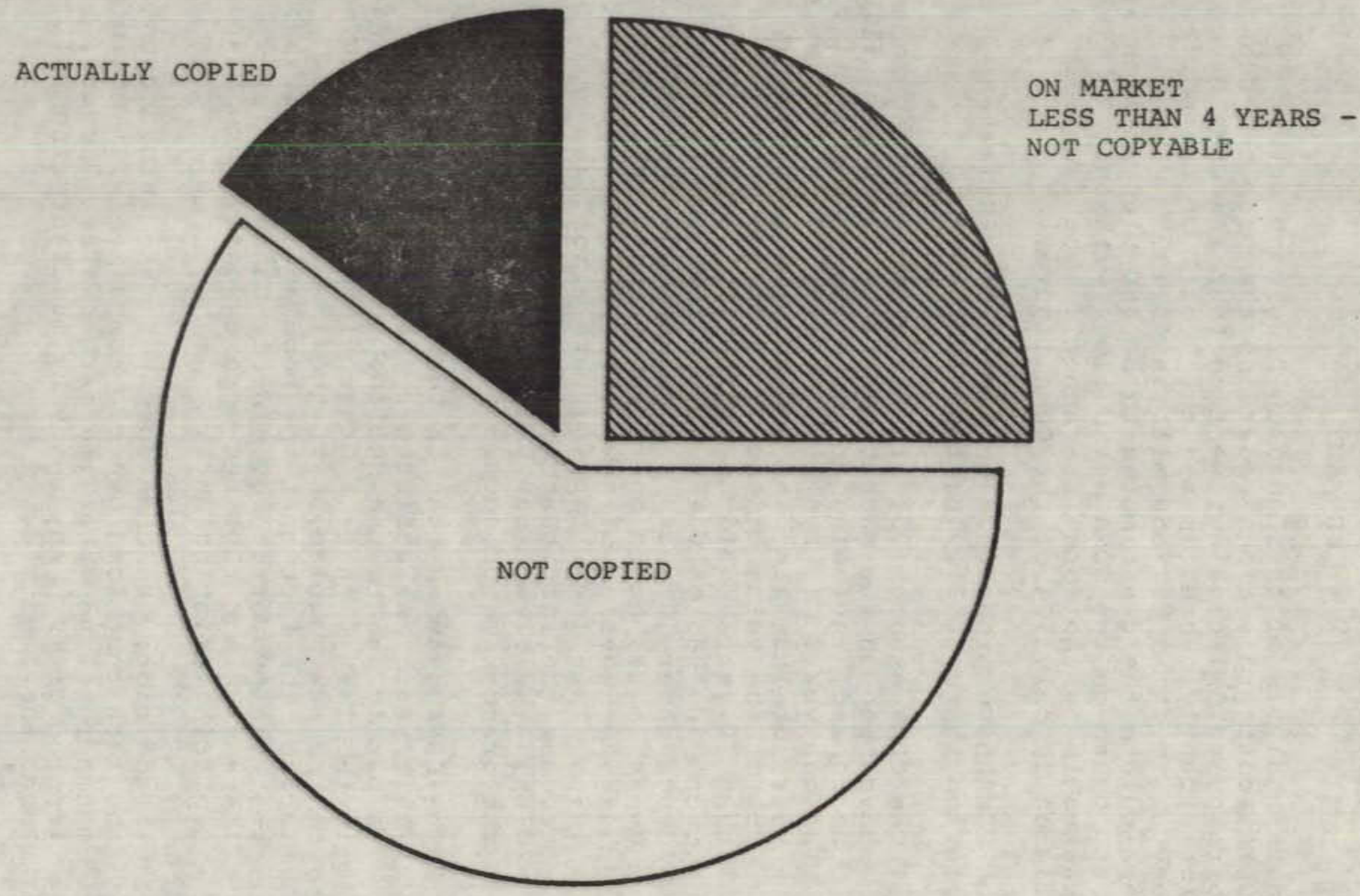
   2.2 The CDMA assumes that the drug market will grow at 15% a year. We estimate a 13% growth rate. This is partly due to the decline in the inflation rate in the last 5 years. Other elements contributing to the reasonableness of the 13% growth rate include the fact that the population is growing, that the proportion of elderly Canadians is increasing and that new more expensive drugs are replacing existing ones.

   2.3 In addition, the CDMA does not take into account the fact that some generic companies will begin to manfacture and enter the market after 7 years, instead of 10. Any entry by manufacturing will lower the "costs".

   2.4 The CDMA has also ignored the effect of the **Drug Price Review Board.** Had the Board been in place keeping price increases down, there would have been additional savings. In fact, had the Consumer Price Index grown at only 1 percentage point less than the Drug Price Index (this is consistent with trends over the past ten years) the Board could have saved consumers between $157 to $522 million in 1995.

1985

RATE OF COPYING OF DRUGS



TOTAL SALES OF DRUGS ON MARKET LESS THAN 10 YEARS

ANNEX

CDMA COST METHODOLOGY	CCAC CRITIQUE
1. 1985 sales of products on the market less than 10 years which could be subject to generic copying = $600M (million)	1. **Agree** is $600M
2. rate of copying of new drugs = **100%**	2* **30%** copying rate is forecast (current rate is only 15%)
3. expected market growth rate = **15%**	3* CCAC forecasts **13%**
4. 1995 sales of products on the market less than 10 years = **$2,500M** ($600M x 100% x 15% for 10 years)	4. Estimated to be **$611** ($600M x 30% x x 13% for 10 years)
5. Brand Name share of 1995 market $2,500M x **.8** (of market) x **.8** (of price)= $1,600M	5. Brand Name share of 1995 market $611M x **.8** (of market) x .8 (of price)=$391M
6. Generic share of 1995 market $2,500M x **.2** (of market) x **.5** (of price)= $250 M	6. Generic share of 1995 market $611M x **.2** (of market) x **.5** (of price) = $61M
7. Assuming generic competition in 1995, the total cost of new drugs under 10 years old = $1,600M + $250M = **$1,850M**	7. Assuming generic competition in 1995, the total cost of new drugs under 10 years old =$391M + $61M = **$452M**
8. Cost without competition less cost with competition= Extra cost of monopoly $2,500M - $1,850M = **$650M** (Step 8 = Step 4 - Step 7)	8. Cost without competition less cost with competition = Extra cost of monopoly $611M - $452M = **$159M** (say $160M)
ADDITIONAL FACTORS	
9. Impact of **licences to manufacture** - omitted	9. Impact of **licences to manufacture** after 7 years -will permit earlier competition
10. Impact of Price **Review Board** - omitted	10. **Price Review Board** possible $522M added savings in 1995.

* changed assumptions

DETAILED ANALYSIS OF CDMA COST ESTIMATES RE: BILL C-22

Introduction

This analysis was undertaken to review the cost estimate the CDMA presented in its brief to Provincial Ministers of Health entitled CDMA Position Re: Proposed Changes to the Patent Act Affecting Pharmaceuticals dated August 27, 1986. This paper claims the cost to consumers in 1995 of the changes in the Patent Act in restricting compulsory licensing would be some $650 million. Several problems were noted with the assumptions used by the CDMA in arriving at this estimate. The assumptions, the problems and their impact on the CDMA estimate are discussed below.

Description of CDMA Estimates

In arriving at this estimate the CDMA used the following assumptions and methods.

CDMA Assumptions:

1) 1985 sales of products on the market for less than 10 years is approximately $600 million at the wholesale level.

2) The pharmaceutical market is projected to grow at 15% a year.

3) New products will continue to occupy approximately the same proportion of the market.

4) Generics usually take 20% of market share.

5) Generics are available to a pharmacist at an average net cost of 50% of the cost of brand name prices.

6) When generic products are introduced, brand name prices usually decrease by 20% due to competitive market forces.

Given assumptions 1, 2, and 3 the CDMA estimated the value of the 1995 market for drugs less than 10 years old in the absence of generic competition as $2.5 billion. The following calculations were then done to estimate the value of the same 1995 market with generic competition given their remaining assumptions:

BRAND NAME SHARE OF MARKET

TOTAL MARKET UNDER 10 YEARS	X	BRAND NAME MARKET SHARE (ASSUMPTION 4)	X	REDUCED BRAND NAME PRICE LEVEL (ASSUMPTION 6)	=	VALUE OF BRAND NAME MARKET SHARE
$2.5 billion	X	.8	X	.8	=	$1.6 billion

GENERIC SHARE OF MARKET

TOTAL MARKET UNDER 10 YEARS	X	GENERIC MARKET MARKET SHARE (ASSUMPTION 4)	X	GENERIC PRICE PRICE LEVEL (ASSUMPTION 5)	=	VALUE OF GENERIC MARKET SHARE
$2.5 billion	X	.2	X	.5	=	$0.25 billion

The estimated values of the brand-name and generic market shares were then subtracted from the estimate of total value of sales in the absence of generic competition to arrive at the estimate of the 1995 cost of the restricted compulsory licensing as follows:

CDMA ESTIMATED COSTS

ESTIMATED TOTAL VALUE WITHOUT GENERIC COMPETITION	-	ESTIMATED TOTAL VALUE WITH GENERIC COMPETITION	=	ESTIMATED EXTRA COST
$2.5 billion	-	$1.85 billion	=	$650 million

Analysis

The methodology employed by the CDMA is not directly comparable to that used for the Eastman Inquiry.

The assumptions made by the CDMA in estimating the extra cost of restricted compulsory licensing, while for the most part acceptable, include two items which must be disputed. Each of the CDMA assumptions and any additional assumptions that are required to perform this type of estimate are discussed individually below.

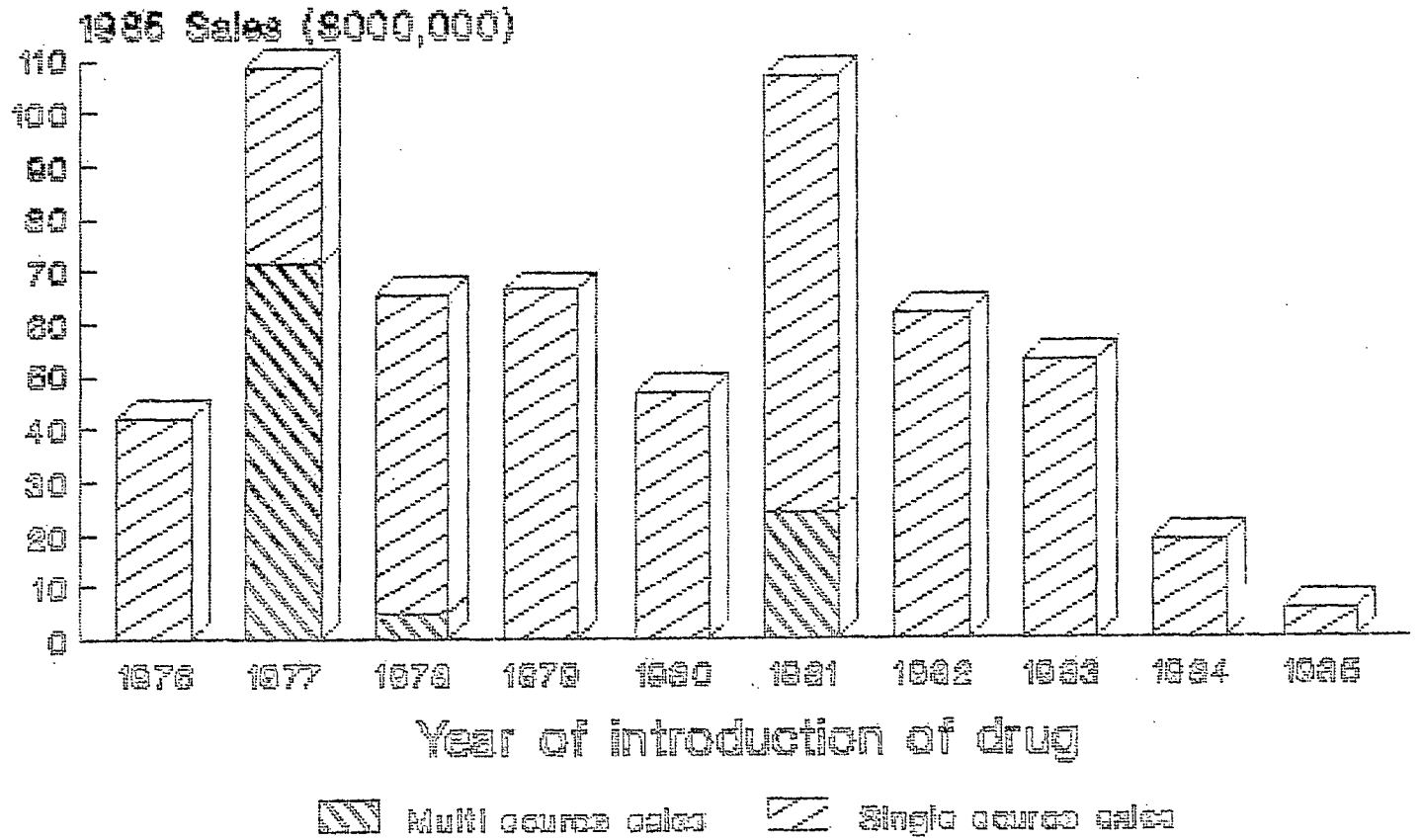
CDMA Assumption #1: 1985 sales of products on the market for less than 10 years is approximately $600 million at the wholesale level.

Comment

The $600 million the CDMA estimated for this value is considered correct (see attached CHART 1). CCAC estimates of 1985 sales for products less than 10 years old, based on IMS data are about $575 million.

CHART 1

Sales in 1985 of drugs introduced since 1975 by year of introduction of the drug



Source: IMS CANADA

CDMA Assumption #2: The pharmaceutical market is projected to grow at 15% a year. (This apparently includes the growth due to inflation).

Comment

The pharmaceutical market is expected to grow at a rate above the rate of inflation as a result of population growth, the increasing proportion of elderly persons, the substitution of drug therapy for other therapies and because some of the newer drugs are more expensive than existing ones. Nevertheless, given the decline in the rate of inflation in recent years (see CHART 2) a 15% growth rate is considered to be too high.

Given the recent trend indicated by the growth of this particular market segment (see CHART 3 and TABLE 1), adjusted for a lowering in the inflation rate, a growth rate of 13% is considered more appropriate. This revision of the growth rate gives an estimate of the total value of the 1995 market for drugs less than 10 years old of $2.037 billion as compared to the CDMA estimate of $2.5 billion.

CDMA Assumption #3: New products will continue to occupy approximately the same proportion of the market.

Comment

This assumption states that the rate of introduction of new drugs will continue at approximately the same rate as in the past and is considered reasonable.

CDMA Assumption #4: Generics usually take 20% of market share (of copied drugs).

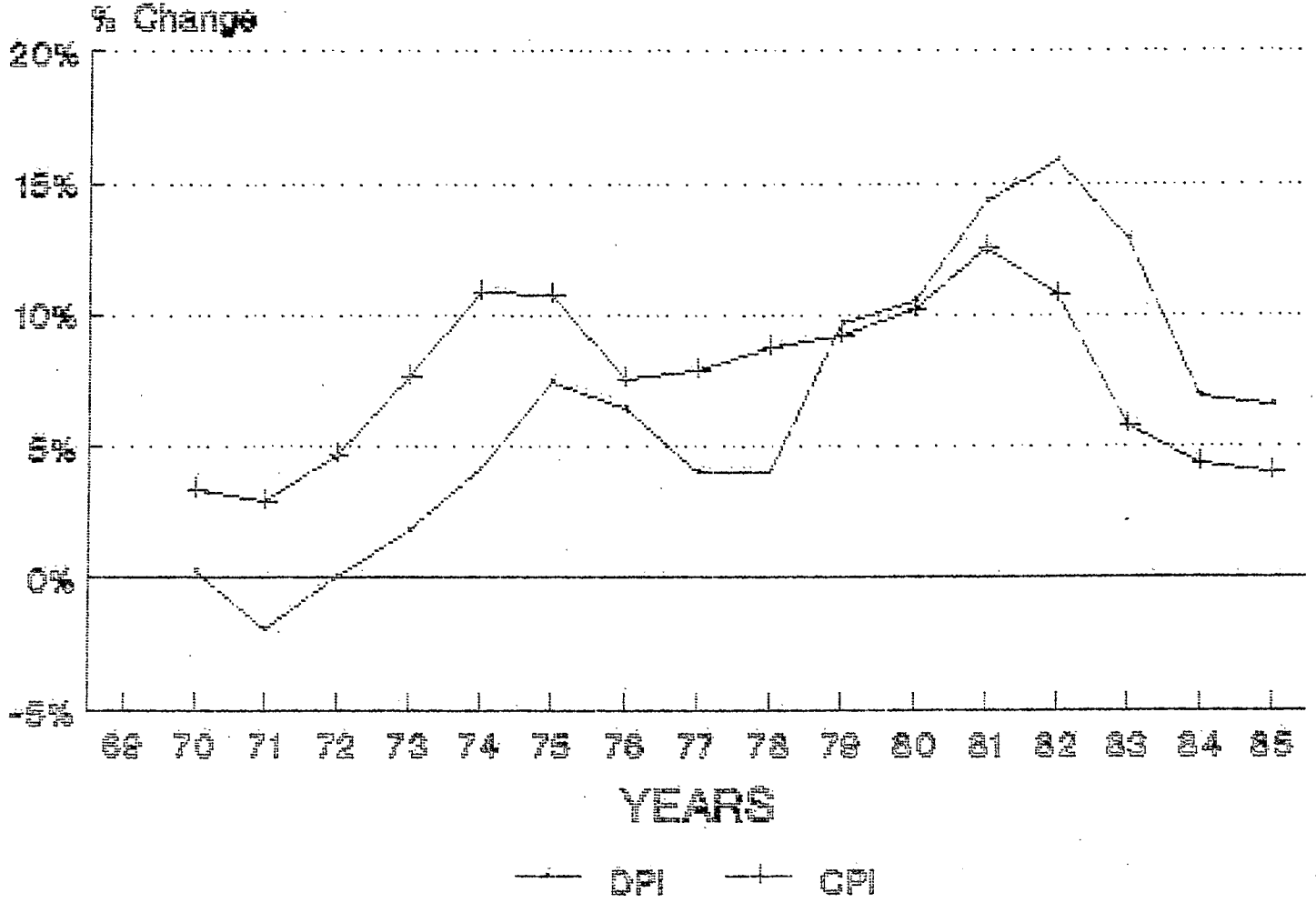
Comment

This assumption is valid as far as it goes. However, it assumes that all of these drugs (those on the market for less than 10 years) would be immediately copied by generic firms by 1995.

Examination of compulsory licensing trends has shown that it is extremely unlikely for a generic copy of a drug to be introduced within four years of the introduction of the brand name drug. If all drugs on the market for less than four years are excluded this would reduce the base value of the calculation by about 25% (see attached CHART 1).

CHART 2

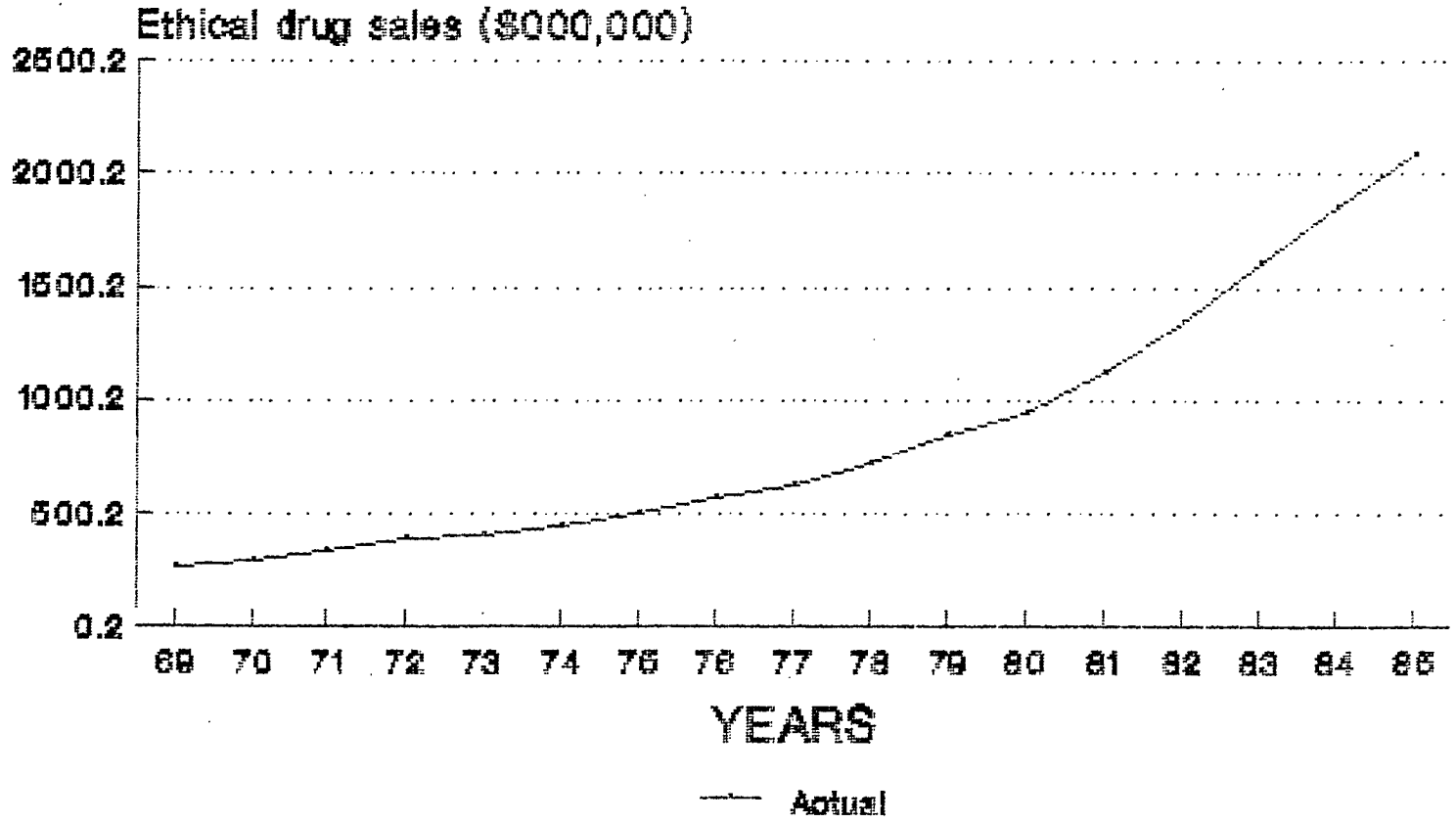
Consumer price index & drug price index
CANADA, 1969-1985



Source: Statistics Canada

CHART 3

Total sales of ethical drugs
Canada, 1969 to 1985



Source: IMS-CANADA
AVERAGE GROWTH 69-85=13.9%

TABLE 1

TOTAL SALES OF ETHICAL DRUGS AND ANNUAL PERCENT CHANGE, CANADA, 1969 to 1985

	Total Sales of Ethical Drugs ($000)	% Change
1969	262,049	--
1970	283,034	8.0
1971	335,255	18.5
1972	363,843	8.5
1973	396,056	8.9
1974	443,411	12.0
1975	500,529	12.9
1976	570,535	14.0
1977	628,386	10.1
1978	717,359	14.2
1979	839,300	17.0
1980	942,700	12.3
1981	1,119,700	18.8
1982	1,338,900	19.6
1983	1,599,900	19.5
1984	1,856,500	16.0
1985	2,088,100	12.5

SOURCE: IMS - Canada

There are also certain types of drugs which the generic companies are not likely to copy. Generic companies have tended to copy only those drugs which have a significant total market value and which are manufactured only in certain dosage forms. This would further reduce the base value of the calculation (i.e. the value of the total market for drugs under 10 years old which would become subject to generic competition).

In fact, only about 15% of the value of the market for drugs under 10 years old has been affected by generic competition (see chart 4). Recent trends do however indicate that this rate will increase because of the earlier copying of new drugs and more generic companies. Taking all of these factors into account a generous assumption would be that, by 1995, about 30% of the market for drugs marketed less than 10 years would have been subject to competition under the current rules. This factor must be applied to the base value of the market before the generic share referred to by the CDMA assumption can be calculated.

Application of this 30% to the 1995 market under an assumed 13% growth rate reduces the base value of the calculation to $611 million. That is, generic competition will affect $611 million in drug sales rather than $2.4 billion calculated in the CDMA analysis.

CDMA Assumption #5: Generics are usually available to a pharmacist at an average net cost of 50% of the cost of brand monopoly prices.

CDMA Assumption #6: When generic products are introduced, brand name prices usually decrease by 20% due to competitive market forces.

Comment

These assumptions are accepted as given.

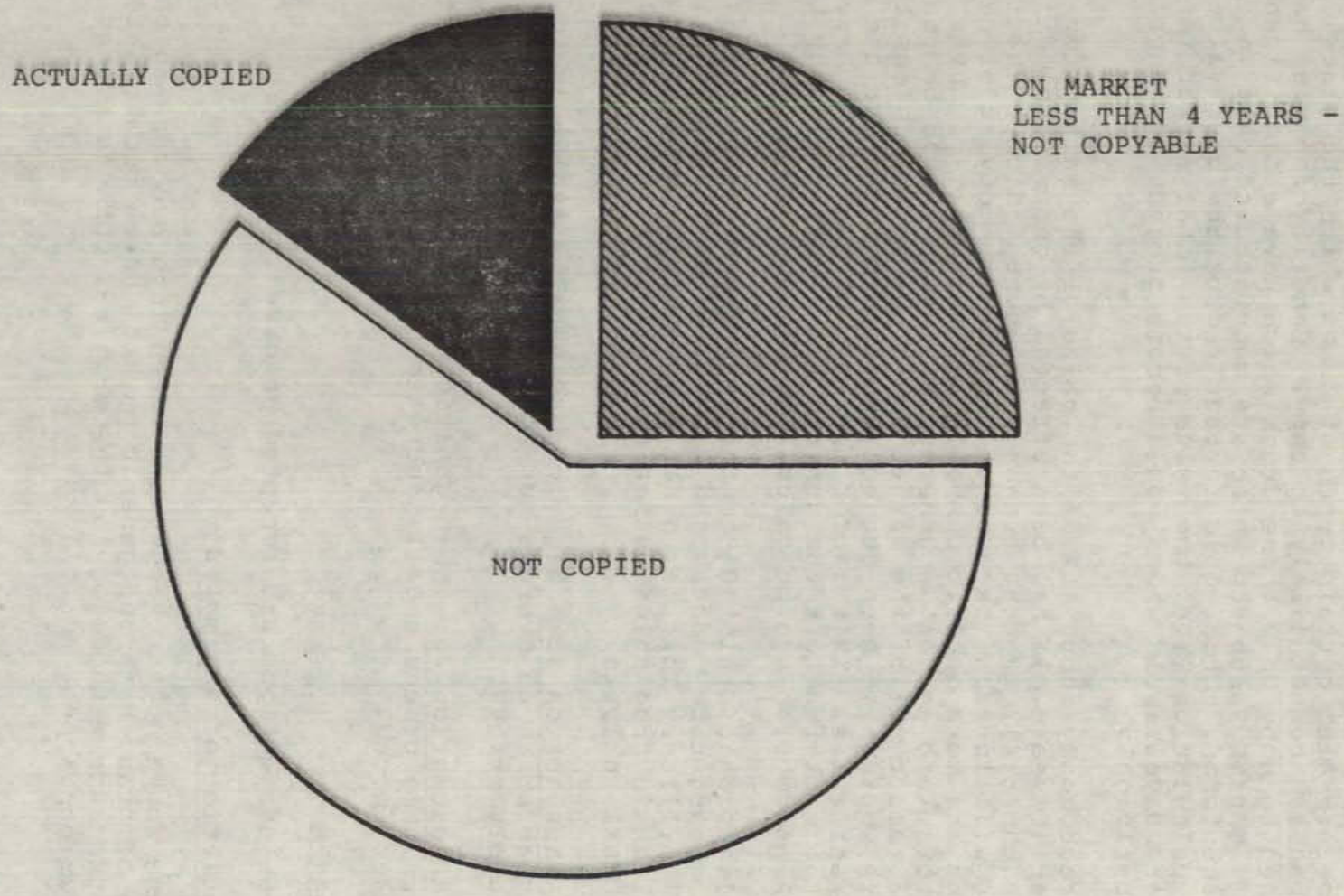
Recalculation of Estimates

When the above noted changes are taken into account and the values of brand name and generic market shares recalculated using the same methodology as the original CDMA estimates the calculations appear as follows:

CHART 4

1985

RATE OF COPYING OF DRUGS



TOTAL SALES OF DRUGS ON MARKET LESS THAN 10 YEARS

BRAND NAME SHARE OF MARKET SUBJECT TO COMPETITION

TOTAL VALUE OF MARKET UNDER 10 YEARS SUBJECT TO GENERIC COMPETITION	X	BRAND NAME MARKET SHARE	X	REDUCED BRAND NAME PRICE LEVEL	=	VALUE OF BRAND NAME MARKET SHARE
$611 million (New Base)	X	.8	X	.8	=	$391 million

GENERIC SHARE OF MARKET SUBJECT TO COMPETITION

TOTAL VALUE OF MARKET UNDER 10 YEARS SUBJECT TO GENERIC COMPETITION	X	GENERIC MARKET SHARE	X	GENERIC PRICE LEVEL	=	VALUE OF GENERIC MARKET SHARE
$611 million	X	.2	X	.5	=	$61 million

ESTIMATED COSTS

TOTAL VALUE OF MARKET SUBJECT TO GENERIC COMPETITION	-	ESTIMATED TOTAL VALUE WITH COMPETITION	=	ESTIMATED EXTRA COST
$611 million	-	$452	=	$159 million

Other Factors not Considered by CDMA Estimates

The CDMA estimates did not take into account the impact of either of the availability of **licences to manufacture** after only 7 years instead of 10 years or of the **Price Review Board.** It is considered that these factors will tend to significantly reduce the "Estimated Extra Cost" as calculated above. Licences to manufacture will permit earlier competition and Price Review Board will moderate price increases. The section that follows demonstrates that signifiant savings could result from the implemation of the Price Review Board.

Impact of the Drug Price Review Board

The impact of the Prices Review Board will depend on the growth of drug prices relative to general prices and the proportion of the pharmaceutial market that the Board will influence.

Bill C-22 invites the Board to use the Consumer Price Index (CPI) as a guideline for price increases and it can be assumed that price increases will not exceed that level. (It should not, however, be assumed that the Board will "automatically" permit increases equal to the CPI.) The major determinant in calculating the savings from the Board is therefore the difference between some estimate of what drug prices would have risen by as compared to the projected CPI.

In order to have some idea of the Boards potential impact, it was assumed that the difference between the drug price index and the CPI would be one percentage point over the next 10 years. The estimated real growth of prescription drug sales was inflated using an assumed drug price index growth of 5% and 4% rate for the CPI. The difference between the two sales projections provides an indication of the potential effect of the Board.

From tables 2 and 3 it can be seen that, had the Board been in place keeping price increases down, there would have been additional savings. In fact, if the Consumer Price Index grows at only 1 percentage point less than the Drug Price Index, the Board will save consumers $522 million by 1995 (Table 2). Even if the Board has an effect on only 30% of the drug market it will save consumers nearly $157M in 1995 alone (see Table 3).

Net Impact of Costs and Savings

The implementation of restricted compulsory licensing on drug costs, which are estimated by using reasonable assumptions in the CDMA model together with an estimate of savings from the Board, yield the results shown below.

	LOW COPY RATE (15%)	HIGH COPY RATE (30%)
	$80 M Cost	$160 M Cost
Low Board Impact ($157 M savings)	$77 M	$ (3) M
High Board Impact ($522 M savings)	$442 M	$362 M

The net impact depends on the assumption used regarding the rate of copying and the scope of the Board's coverage of the market. With a high copy rate of 30%, and if the Board controls the cost of only drugs marketed less than 10 years, the net impact is a cost to consumers of $3 million. However, if we assume that generic companies will have copied only 15% of the market and the Board has an influence on the entire drug market, there is actually a net savings to consumers of $422 million.

Conclusion:

1. By adopting the CDMA methodology but changing only two of their assumptions their estimates of the cost of limiting compulsory licensing is dramatically **reduced by 75%.**

2. Neither the CDMA estimates nor this critique have taken account of the effectiveness of **licenses to manufacture,** which could have the effect of further reducing the cost.

3. The CDMA has ignored the effect of the **Drug Price Review Board.** Had the Board been in place keeping price increases down, there would have been additional savings. In fact, had the Consumer Price Index grown at only 1 percentage point less than the Drug Price Index (this is consistent with trends over the past ten years) the Board could have saved consumers between $157 to $522 million in 1995.

4. Combining the savings due to the Price Board with the modified CDMA cost forecast and, assuming a high rate of copying (30%) and the more modest impact of the Price Review Board produces $3 million in "costs". However, assuming a low rate of copying (15%) and a high impact of the Board results in estimated savings to consumers of $442 million.

TABLE 2

SAVINGS FROM PRICE REVIEW BOARD
(TOTAL DRUG MARKET)
(MILLIONS OF CURRENT $)

Sales Value of Drugs

		1985	1986	1987	1988	1989	1990	1991	1992	1993	1994	1995	1996
A) Assuming no Price Review Board and 8% + 5% = 13%		$2,000.0	$2,260.0	$2,553.8	$2,885.8	$3,260.9	$3,684.9	$4,163.9	$4,705.2	$5,316.9	$6,008.1	$6,789.1	$7,671.7
B) Assuming Price Review Board in 1985 and 8% + 4% = 12%		2,000	2,240.0	2,508.8	2,809.9	3,147.0	3,524.7	3,947.6	4,421.4	4,951.9	5,546.2	6,211.7	6,957.1
C) Difference for Year from 1985	1) Year	-	20.0	45.0	75.9	113.9	160.2	216.3	283.8	365.0	461.9	577.4	-
	2) Cum. Total (Current $)	-	20.0	65.0	140.9	254.8	415.0	631.3	915.1	1,280.1	1,742.0	2,319.4	-
D) Assuming Price Review Board in 1986 and 8% + 4% = 12%		-	2,260.0	2,531.2	2,834.9	3,175.1	3,556.2	3,982.9	4,460.8	4,996.1	5,595.7	6,267.2	7,019.2
E) Difference for year from 1986	1) Year	-	-	22.6	50.9	85.8	128.7	181.0	244.4	320.8	412.4	521.9	652.5
	2) Cum. Total (Current $)	-	-	22.6	73.5	159.3	288.0	469.0	713.4	1,034.2	1,446.6	1,968.5	2,621.0

TABLE 3

SAVINGS FROM PRICE REVIEW BOARD
(RE DRUGS UNDER 10 YEARS OLD)
(MILLIONS OF CURRENT $)

Sales Value of Drugs
less 10 years old

		1985	1986	1987	1988	1989	1990	1991	1992	1993	1994	1995	1996
A) Assuming no Price Review Board and 8% + 5% = 13%		$600.0	$678.0	$766.1	$865.7	$978.3	$1,105.5	$1,249.2	$1,141.6	$1,595.1	$1,802.4	$2,036.7	$2,301.5
B) Assuming Price Review Board in 1985 and 8% + 4% = 12%		600.0	672.0	752.6	843.0	944.1	1,057.4	1,184.3	1,326.4	1,485.6	1,663.8	1,863.5	2,087.1
C) Difference for Year from 1985	1) Year	-	6.0	13.5	22.7	34.2	48.1	64.9	85.2	109.5	138.6	173.2	-
	2) Cum. Total (Current $)	-	6.0	19.5	42.2	76.4	124.5	189.4	274.6	384.1	522.7	695.9	-
D) Assuming Price Review Board in 1986 and 8% + 4% = 12%		-	678.0	759.4	850.5	952.5	1,066.8	1,194.9	1,338.3	1,498.8	1,678.7	1,880.1	2,105.8
E) Difference for year from 1986	1) Year	-	-	6.7	15.2	25.8	38.7	54.3	73.3	96.3	123.7	156.6	195.7
	2) Cum. Total	-	-	6.7	21.9	47.7	86.4	140.7	214.0	310.3	434.0	590.6	786.3
	(Current $)												