BRIEF OF THE CANADIAN HEALTH COALITION

AND THE MEDICAL REFORM GROUP

TO THE

HOUSE OF COMMONS COMMITTEE ON BILL C-91

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EXECUTIVE SUMMARY

The federal government has introduced Bill C-91 which will abolish compulsory licensing for drugs, with the consequence that the company introducing a new drug onto the Canadian market will be in a monopoly position until the patent on the drug expires—about 13 years. The government claims that this bill will lead to increased investment in Canada by the multinational drug companies and at the same time consumers will be protected against undue price increases. Similar claims were made when Bill C-22 was passed in 1987. In this brief, the Canadian Health Coalition and the Medical Reform Group will first analyze the effects of Bill C-22 inorder to see how well reality matches the initial set of predictions around the bill. We will then focus our attention on the question of whether or not the new legislation is really necessary for the economic viability of the multinational sector of the pharmaceutical industry. Finally, we will conclude with an analysis of the likely impact on consumer prices should Bill C-91 be enacted.

To date the large generic drug companies have not suffered financially due to Bill C-22, but the full impact on them has yet to be felt. When Bill C-22 was introduced the government and the industry promised that it would lead to the creation of 2,000 new R & D jobs between 1988 and 1995 in the pharmaceutical industry. To date, R & D jobs have only been increasing at 215 per year, well short of the 250 necessary. Although prices on patented drugs have been rising at less than the Consumer Price Index since 1988, prices on all drugs, patented and unpatented, have been going up faster

than the CPI. More importantly, the delay in the appearance of generic competitors means that significant cost savings are foregone. If there is a single generic competitor, the difference between the generic drug and the brand name one is 24%; when there are four generic competitors the difference is 65%. If there was generic competition for the cholesterol lowering drug Mevacor, the Ontario Drug Benefit Plan could be saving more than $1.4 million annually. Spending on R & D in Canada has increased significantly, but most of the money is being used to fund clinical trials, not to do basic research. In a survey of leading medical researchers 90% foresaw a likely conflict of interest in accepting money from the drug industry; 80% deemed pharmaceutical clinical research "me too" research; and 40% were worried about a potential delay in the publication of unfavourable results.

The pharmaceutical industry in Canada has consistently shown high profit levels. Over the decade ending in 1987 the pretax rate of return on equity for drug manufacturers averaged 34.5% compared to an average for all manufacturing industries of 15.2%. Despite these enviable figures the industry argues that it needs increased patent protection inorder to realize an essential return on its investment in the drug discovery and development process in Canada. The drug companies claim that it takes a global investment of US$231 million to bring a new drug from discovery to marketplace and only one in three drugs recover their R&D costs. However, the studies that the industry uses to back up these claims deal with only a very narrow universe of new drugs and drug companies and it is not clear that their results can be generalized in the way that PMAC

does. Moreover, recent research has challenged their conclusions. A survey of 39 American, Japanese and European companies found that the large majority said that it took less than US$200 to research and develop a new drug.

New drugs are launched in Canada at a substantial premium compared to older, and in many cases, just as effective drugs. Between 1982 and 1989 antihypertensives, antiarthritics and ulcer medications introduced onto the Ontario market were priced 35-60% higher, on a daily treatment cost basis, than existing drugs. With compulsory licensing newly introduced patented medications are subject to price competition from generic products within seven to ten years. Without compulsory licensing there is no price competition until the patent expires. At this point that is an estimated 13 years, but if approval times for new drugs drop, as both the government and the industry hope they will, then instead of 13 years it could be 14 or 15 years.

The Medical Reform Group and the Canadian Health Coalition believe that the benefits from Bill C-22 have not been clearcut and that the costs may only be beginning to be recognized. Therefore, we cannot accept the government's pronouncements about the effects of Bill C-91. Furthermore, we can find no evidence that the new bill is necessary for the economic health of the industry. On-the-contrary, there is good reason to believe that the elimination of compulsory licensing will only serve to drive up the cost of prescription drugs. Therefore, we recommend that the government abandon its plans to proceed with Bill C-91.

INTRODUCTION

When the federal government announced the introduction of Bill C-91 Michael Wilson, Minister for International Trade, claimed in a press release that the measures in the bill "will result in increased research and development . . . the creation of high-paying, skilled jobs and new training opportunities for our medical and scientific communities." (1) According to his cabinet colleague, Pierre Blais, Minister of Consumer and Corporate Affairs, new powers to the Patented Medicine Prices Review Board would "ensure that Canadians continue to have access to reasonably priced drugs." (1) A sheet of facts and figures that accompanied the press release said that "forecasts indicate that the generic industry will continue to grow at rates at or above the average growth rate of the Canadian pharmaceutical industry as a whole." Similar promises were made five and six years ago with respect to the effects of Bill C-22 which gave companies protection from compulsory licensing for 7 to 10 years.

A letter to Kathleen Connors of the National Federation of Nurses Unions over the signatures of both Mr. Wilson and Mr. Blais argued that the changes to Canada's patent legislation were necessary to offer innovators a suitably attractive business environment. (2) The implication in this statement and also in a graph entitled "Canada lags behind its competitors in effective patent protection" was that the financial health of the Canadian innovative pharmaceutical industry was suffering as a result of Canada's current

patent policy. Once again, these statements echo ones made for the rationale behind Bill C-22.

In this brief, the Canadian Health Coalition and the Medical Reform Group will first analyze the effects of Bill C-22 in four areas: impact on generic firms, impact on job creation, impact on prices and provincial drug costs and impact on R&D spending inorder to see how well reality matches the initial set of predictions around Bill C-22. We will then focus our attention on the question of whether or not the new legislation is really necessary for the economic viability of the multinational sector of the pharmaceutical industry. Finally, we will conclude with an analysis of the likely impact on consumer prices should Bill C-91 be enacted.

THE EFFECTS OF BILL C-22

1. Impact on Generic Firms

Predictably, the opinions about the effects of Bill C-22 on the generic companies operating in Canada were widely divergent. When Michel Cote, then Minister of Consumer and Corporate Affairs, introduced the first version of Bill C-22 he said that the bill would "not put them out of business" and spoke of a "flourishing generic industry" (3, p.8-9). On-the-other-hand, the brief from the CDMA to the House of Commons Legislative Committee on Bill C-22 warned that the effect of the bill would be to "substantially cut the cash flow of the Canadian owned industry" and severely damage these companies (4, p.23).

The 1969 legislation allowing for compulsory licence to import marked the start of many of the Canadian-owned generic drug

companies and in the ensuing years this sector of the pharmaceutical industry experienced rapid growth. Employment went from 800 in 1975 (5) to 2,100 in 1986 (4). Overall sales by generic firms increased by 20% from 1980 to 1983 (5) while the three largest companies were experiencing a growth in sales of 30% per annum in the mid1980s (4). Between 1979 and 1983 generic exports enjoyed an average annual growth rate of 47% a year (4).

The generic companies are privately owned and therefore it is difficult to gather information about their economic health. However, there are some measures that can be used to judge how this group of companies is doing. Sales by generic firms were about 8% of the total Canadian pharmaceutical market in the early to mid 1980s (6,7) and have remained at this level to 1990 (8). Growth in the generic market from 1985 to 1990 has been double that of pharmaceutical market as a whole (8) and this is reflected in the growth of the two largest Canadian-owned generic companies. Apotex rose from the 36th largest company based on dollar sales in 1986 to the 3rd largest by 1990 and Novopharm went from number 18 to number 5 over the same time period (unpublished figures). However, as an unpublished paper from the Department of Consumer and Corporate Affairs notes, the major impact of Bill C-22 will not be felt until 1993 to 1994 (9). It is quite possible that there will be negative effects even for the large generic producers. In 1983 about one-third of all sales by generic companies represented sales of compulsory licensed products, but by 1990, this figure had risen to 43% (9). With a delay in the introduction of new products obtained under compulsory license sales and profits in the generic industry may decline.

So far, the large generic companies have been prospering despite Bill C-22. Whether this conclusion holds for the smaller companies is unknown.

2. Impact on Job Creation

The question of how many jobs Bill C-22 would create and what kind of jobs they would be underwent subtle alterations as the debate over the bill progressed. In his initial speech in June 1986 Cote promised that "over 3,000 new scientific and research-related jobs will be created" (3, p.6). By the time that the new Minister of Consumer and Corporate Affairs, Harvie Andre, testified before the House of Commons Legislative Committee on Bill C-22 in December 1986 the promise was for the creation of "up to 3,000 jobs by 1995--above and beyond those that would otherwise exist in the industry" (7, p.13). Note that these jobs were now not necessarily scientific and research related and also the implication that 3,000 was not a firm figure. The suggestion that not all of the jobs would be for scientists and researchers had already appeared in a document prepared in the spring of 1985 by the Department of Consumer and Corporate Affairs. This report estimated that only 1,700 of the 3,000 jobs would be created in the professional category and filled mainly by PhD-level applicants. Another 650 jobs were classed as "technical" meaning they would go to laboratory technicians and require services of someone with community college training or an undergraduate degree in science. . The remaining 620 jobs would be

filled by "others" e.g. managers, cleaners, animal keepers, statisticians and clerks (10).

When John L. Zabriskie, past chairman of the board of PMAC and president Merck-Frosst Canada Inc., was confronted with the conclusions of the Consumer and Corporate Affairs report during his testimony before House of Commons Legislative Committee on Bill C-22 he contradicted its predictions and claimed that 85% of the jobs to be created would be degree jobs and the remaining 15% would be for support staff. However, he also threw in a new wrinkle which was that only two thirds of the 3,000 jobs would be created in the pharmaceutical industry and the rest would come from increased industry R & D spending in hospitals, medical schools, etc. (11, p.56).

If the industry is to create even 2,000 new R & D jobs between 1988 and 1995 as promised, that would mean 250 new jobs a year. Figures from Statistics Canada show an increase of 415 R & D jobs between 1987 and 1989, with most of the increase coming in degree-level jobs (12). The Statistics Canada survey that produced these figures is based on replies from pharmaceutical companies both inside and outside PMAC, so it is quite likely that some of the increased R & D employment came from non-PMAC members. However, even assuming that PMAC companies generated all the increase there is still a shortfall of about 45 jobs per year in meeting the target for new job creation. According to an internal PMAC survey of 48 of its members (13), the industry had created 447 R & D jobs between 1987 and 1990, suggesting that only about 150 such jobs were being added annually.

The same PMAC survey found that another 939 new jobs had been created, about 700 of which were in marketing and sales (13). The CDMA has documented a loss of 700+ manufacturing jobs in the multinational segment of the industry since the passage of Bill C-22 (14) and since the CDMA released its figures there was the announcement of another 240 jobs to be lost with the closure of a Cyanamid Canada plant (15).

The number of jobs created outside of the pharmaceutical industry is unknown. While there has been an increase in the number of R & D jobs, if the present rate continues the industry will fall short of its target of 2,000 new jobs. Finally, the 939 new non-R & D jobs created is almost lost exactly equivalent to the 940 jobs lost.

3. Impact on Prices and Provincial Drug Costs

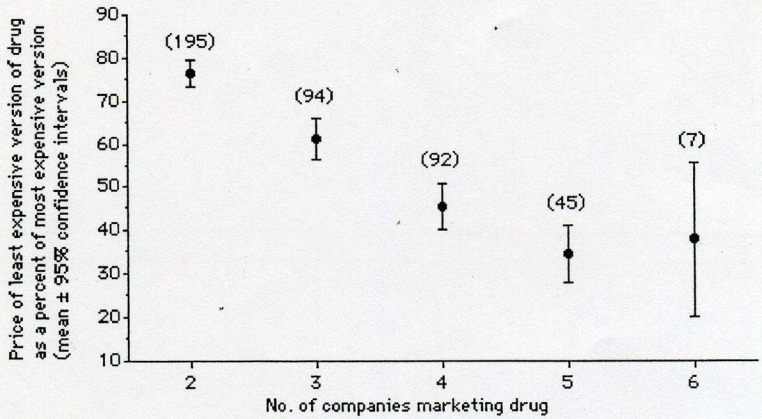
To allay fears that the companies would use their increased period of protection against generic competition to unduly raise prices, Bill C-22 also created the Patented Medicine Prices Review Board (PMPRB). According to Harvie Andre the Board would look at "the continuing market price of **all** drugs, not just those subject to compulsory licensing" (emphasis added) and help to ensure continued savings for Canadians (7, p. 6). The Board was authorized to monitor and report on the introductory price of new drugs and also the rate of rise in drug prices. If a company introduced a new drug at an "excessive" price or if the rate of rise of prices of its drugs exceeded the rate of rise of the Consumer Price Index (CPI), the Board has the authority to impose penalties. Drugs with excessive

prices can lose their protection from compulsory licensing and the Board can also remove this protection from a second drug manufactured by the same company.

From about 1979 on, drug prices had consistently risen faster than the CPI (16,17). The fourth report of the PMPRB appeared to show a reversal of that trend. From 1987 to the end of 1991, prices of drug products increased at the rate of 2.9% annually versus an annual CPI increase of 4.4% (18). However, the PMPRB is only authorized to monitor the prices of **patented** drugs, a very important distinction which Mr. Andre appears to have blurred. Patented medicines account for less than half of the estimated total sales of pharmaceutical products in Canada. When we consider all pharmaceuticals sold in the country, the annual rate of rise in prices is 4.7%, which is higher than the CPI figure (18).

More important than the rate of rise in drug prices is the absence of generic competition. Generic drugs provide price competition and actually result in lower prices. An analysis of drug prices in Ontario shows that if the same drug is sold by two companies there is almost a 24 percent difference in price; if the drug is marketed by five companies there is a 65 percent difference in price. (Figure 1).

FIGURE 1: RELATIONSHIP BETWEEN NUMBER OF COMPANIES MARKETING A DRUG AND PRICE SPREAD BETWEEN LEAST EXPENSIVE AND MOST EXPENSIVE VERSIONS OF A DRUG (NUMBER OF DRUG PREPARATIONS IN BRACKETS)



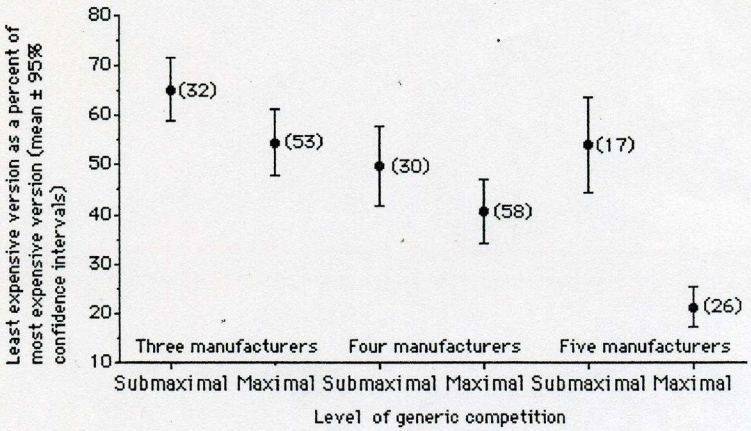
Analysis of Variance Table

Source:	DF:	Sum Squares:	Mean Square:	F-test:
Between groups	4	104554	26139	50
Within groups	429	225176	525	p = .0001
Total	433	329730		

All points are statistically different from each other at the $p<0.05$ level except for four companies versus six and five companies versus six.

Figure 2 carries the analysis of generic competition a step further and shows the price spread between the least and most expensive versions at two levels of generic competition (submaximal and maximal) and at three different levels of overall competition (three, four or five manufacturers). ("Maximal generic competition" was defined as the largest number of generic companies that could be in competition with a brand name company within any overall level of competition; for instance, if a total of four companies sold a drug preparation maximal generic competition would be three generic companies and one brand name company. "Submaximal generic competition" would be less than three generic companies and more than one brand company.) A two factor analysis of variance shows that the price spread is influenced not only by the level of overall competition, but also by the degree of generic competition at each level of overall competition. In-other-words, the more generic companies marketing a copy of a drug, the larger the price spread.

FIGURE 2: EFFECT OF LEVEL OF GENERIC COMPETITION AND NUMBER OF COMPANIES SELLING A DRUG ON THE PRICE SPREAD BETWEEN THE LEAST AND MOST EXPENSIVE VERSIONS OF A DRUG (NUMBER OF DRUG PREPARATIONS IN BRACKETS)



Two Factor Analysis of Variance Table

Source:	df	Sum of Squares:	Mean Square:	F-test:	P value:
Level of generic competition (A)	1	14097	14097	30	.0001
No. of companies (B)	2	15740	7870	17	.0001
AB	2	4221	2111	5	.0117
Error	210	97592			

Closely related to the question of changes in drug prices, is the effect of Bill C-22 on the cost of provincial drug plans. These plans

represent one of the most rapidly increasing areas in provincial health care spending. The average annual rate of growth of the Nova Scotia Pharmacare Program during the 1980s was over 18% compared to 7.15% in the rate of inflation (19), while the Ontario Drug Benefit Plan (DBP) went from 2.6% of the provincial spending on health care in 1978/79 to 5% by 1988/89 (20).

The Department of Consumer and Corporate Affairs estimated that Bill C-22 might cost the provinces $100 million between 1987 and 1991 due to the fact that some generic drugs would not be coming onto the market as anticipated by provincial health ministries. Accordingly, the federal government set aside this sum of money to be transferred to the provinces (7, p.12). Whether or not that amount has proved to be adequate has not yet been analyzed. The Ontario assistant deputy health minister in charge of the DBP projected the minimum impact of Bill C-22 on the Ontario market alone at $340 million over 10 years, without including the cost of new drug entries. When these were included in the calculations the effect on Ontario rose to about $1 billion over 10 years based on extrapolation of data contained in Eastman Report (21, p. 2).

The amount paid by Ontario's DBP in prescriptions for the cholesterol lowering drug lovastatin (Mevacor) provides one example of the extra costs to the provinces. In the first ten months of 1990 doctors wrote prescriptions for this drug worth $5.93 million (DBP, unpublished figures). Had a generic equivalent to Mevacor been available, the cost to the province would have dropped by $1.41 million to $4.52 million; with more than one generic competitor, the savings would be even larger.

Therefore, while the rate of rise in the price of drugs still under patent has been slowed, the same is not necessarily true of prices for other drugs. Furthermore, the lack of generic competition has removed the effect of price competition and may be adversely affecting provincial drug plans.

4. Impact on R & D Spending

Before the passage of Bill C-22, R & D spending in Canada, as a percentage of sales, had been below 5% (22). The multinational companies publicly committed themselves to increase that level to 10% by 1996. Michel Cote contended that Canada would become a "leader in pharmaceutical development" (3, p.9).

PMAC member companies appear to be well on the way to achieving their goal. By 1991, they had reached a R & D to sales ratio of 9.6% (18). According to a PMAC ad in the *Globe and Mail* that kind of spending makes "sure that Canada remains a key player in the global search for new cures" (23). However, even the 10% figure will still leave Canada far behind the current level of spending in other industrialized countries. Figures from the CDMA show that in 1989 Sweden was spending 21.8% of sales on R & D, the United Kingdom 20.9%, West Germany 17.9% and the United States 14.2% (24).

Even the 9.6% figure may not be quite what it appears. Only companies that have medications under patent are required to report their R & D expenditures to the PMPRB. Forty-four of the 66 PMAC

members fit that description and therefore the 9.6% figure is the average R % D spending for these companies (18). How much research are the other 22 companies doing? We don't know. PMAC does not point out this distinction in their publicity about how quickly they are approaching their 10% goal.

While R & D spending has increased since Bill C-22, so has Canada's negative trade balance in R & D payments. In 1987, before the Patent Act was changed, pharmaceutical companies in Canada were making foreign payments of $63 million for R & D and other technology and receiving $15 million, for a balance of -$48 million. By 1989, the respective figures were $101 million, $12 million and -$89 million (12). Not all of these changes can necessarily be attributed to PMAC companies since the Statistics Canada survey includes other pharmaceutical firms. A more accurate idea of the changes in foreign R&D payments made and received by PMAC companies comes from another set of Statistics Canada figures. In 1987, Canadian companies were paying $7 million to foreign affiliates and receiving $13 million, for a positive balance of $6 million. By 1989, payments were up to $30 million and receipts down to $10 million, for a negative balance of $20 million (12). It is not clear if these foreign payments are included in the increase R & D spending that PMAC companies are claiming.

So far, most of the money is going into clinical research. Total spending in 1991 on R & D was $355.2 million of which $203.4 million went to applied or clinical research (18). Although the money seems to be going into legitimate research, the increase in spending is seen as a mixed blessing by key medical figures engaged

in pharmaceutical research in Canada. They were happy about the availability of funding, but they also expressed a number of misgivings about drug industry funding: 90% foresaw a likely conflict of interest; 80% deemed pharmaceutical clinical research "me too" research; while 75% saw it as "might as well" research; and 40% were worried about a potential delay in the publication of unfavourable results (25).

Harvie Andre claimed that Bill C-22 would give Canada the potential to undertake pharmaceutical research and development on a world scale (7, p.3). Here, he was contradicting the conclusions of both a study for the Organization for Economic Cooperation and Development (OECD) and the Eastman Report. The authors of the OECD study noted that whenever governments have deliberately tried to encourage pharmaceutical innovation, in countries where it only exists on a low level, "the results have been disappointing" (26, p.232). Commenting directly on the Canadian situation they said that "an additional factor which must be considered in assessing the relatively low proportion of funds directed to pharmaceutical R & D in Canada is that technology and the results of innovation from parent corporations have been so readily available and so economically attractive in the short term, that the growth of national innovative technological capacity has been severely inhibited" (26, p.173). The Eastman Report concluded that "Canada does not now possess either the scientific manpower or the physical infrastructure that would make it a major world centre for basic pharmaceutical research. Nor, in the opinion of the Commission, would it be wise for governments to seek to create such an environment in competition

with heavily supported long-established centres in other countries" (6, p.423).

By 1991, R & D spending in Canada on basic research, where drug discoveries are made, was 26.5% of total R & D (18). That figure is certainly an improvement on the 19% being spent in 1988 (27), but it falls far short of the U.S. mark of 47.5% (28). Moreover, in interviews with senior executives of eight Canadian pharmaceutical companies it was the general consensus that it would be difficult for all but a few companies to either finance or staff a company-owned basic research facility in Canada (28). Finally, visits to five Canadian medical schools and interviews there with senior administrators as well as established scientists engaged in pharmaceutical-industry-sponsored research found that Bill C-22 has had a minimal impact on basic research in this environment (29).

While, there is no doubt that Bill C-22 has resulted in increased R & D spending the consequences of the increase are not so clear cut. Most of the money is going into clinical research and the people receiving this money have reservations about its benefits. The prospects for Canada to become a major centre for basic pharmaceutical research are still limited.

IS BILL C-91 NECESSARY FOR THE FINANCIAL HEALTH OF THE MULTINATIONAL PHARMACEUTICAL INDUSTRY?

The pharmaceutical industry in Canada has consistently shown high profit levels. Over the decade ending in 1987 the pretax rate of

return on equity for drug manufacturers averaged 34.5% compared to an average for all manufacturing industries of 15.2%. (Table 1) Despite these enviable figures the industry argues that it needs increased patent protection inorder to realize an essential return on its investment in the drug discovery and development process in Canada (30). This argument rests on a couple of "facts" that the industry recites almost like a mantra: it takes a global investment of US$231 million (Can$268 million) to bring a new drug from discovery to marketplace; (30) and only one in three drugs recover their R&D costs (31).

TABLE 1: RATE OF RETURN ON EQUITY, BEFORE TAXES, 1978-1987

Year	Pharmaceutical industry (%)	All manufacturing (%)	Ranking of pharmaceutical industry out of 87 manufacturing industries
1978	22.7	17.4	20
1979	28.3	21.9	17
1980	30.1	20.1	10
1981	31.0	17.4	6
1982	30.0	5.4	7
1983	33.9	9.9	3
1984	40.3	15.7	2
1985	41.1	12.7	3
1986	45.5	14.9	1
1987	42.2	16.2	1

Statistics Canada. *Corporation financial statistics--detailed income and retained earning statistics for 182 industries.* Ottawa, various years.

When the multinational companies cite their high research costs and their one in three rate in recovering R&D costs they are using the results of two studies (32,33). However, both of these analyses rest on a shared set of major limitations that are never articulated by PMAC and its member companies. Only New Chemical Entities (NCEs) researched and developed entirely by the company marketing the drug are considered. The sample therefore leaves out: new drugs that were developed conjointly with, or entirely by, government, nonprofit institutions and universities; drugs licensed from other companies; and newly marketed drugs that are not NCEs such as long acting versions of a drug, combination products or other new formulations of existing products. In fact, according to the DiMasi paper, R&D outlays for licensed or acquired NCEs were only one-quarter of those for self-originated NCEs. Only about 40% of all the NCEs introduced by American owned companies are self-originated (33).

The study by DiMasi and coworkers (33), and probably the one by Grabowski and Vernon (32) although it is hard to be sure from the description of their methodology, only looked at costs to U.S.-owned companies, excluding foreign owned firms that may have different cost structures.

Both of these studies deal with only a very narrow universe of new drugs and drug companies and it is not clear that their results can be generalized in the way that PMAC does.

Finally, both studies incorporated "opportunity costs" into their calculations. In the case of pharmaceutical manufacturing,

opportunity costs are the value of the productive opportunities foregone by the decision to use the available resources to make drugs rather investing those resources in some other endeavour. Over half of the R&D costs computed by DiMasi (33) are opportunity costs. As Jones (31) points out opportunity costs are theoretical economic costs, not a measure of what a company actually spends. They do not appear in the balance sheet or in the statement of profits and losses. "They are not used in calculating earnings per share, shareholder's equity or return on investment. They are certainly not considered when companies try to attract investors, creating the extraordinary situation in which executives whisper of great profits to financial analysts, while economists proclaim that the returns are not really so high . . . If opportunity costs are to be used to defend drug prices they should be used fairly. The value of lost opportunities should also be calculated from things like excessive promotional budgets and the cost of new products that offer no additional benefit, marketed at prices higher than the older products. If the price we pay out were added to the value of the opportunities lost through such wasteful expenditures, the cost of medicines to society would be seen to be dramatically higher than is now believed."

The DiMasi study has recently been questioned by the United States Office of Technology Assessment (OTA) in a preliminary report. That report described the US$231 million figure as "an arbitrary number with no intrinsic meaning." The OTA found no evidence of dramatic rises in clinical research time that would explain claims of steeply rising research costs (34). A new survey of

49 leading pharmaceutical companies in Europe, Japan and the United States confirms the OTA's skepticism. Of the 39 companies which responded to questions on the cost of researching and developing an NCE, 13 firms gave estimates of less than US$100 million; 19 companies quoted US$100-200 million and the remaining seven said more than US$200 million. Five Japanese companies suggested that the R&D cost for an NCE was about US$73 million (35).

EFFECT OF BILL C-91 ON CONSUMER PRICES FOR DRUGS

According to figures supplied by the Association of the British Pharmaceutical Industry, five years after their launch new products account for almost 21% of total pharmaceutical sales in Canada, ranking Canada fourth in this regard out of eleven western industrialized nations (36). These new products are introduced at a premium compared to already existing drugs. Between 1982 and 1989 antihypertensives, antiarthritics and ulcer medications introduced onto the Ontario market were priced 35-60% higher, on a daily treatment cost basis, than existing drugs. In most cases these newer drugs had no therapeutic advantage over the older products (37). The effect of newly introduced drugs on the cost of prescriptions to consumers is revealed in a report from Green Shield (38), a not-for-profit Ontario company offering prepaid extended health services plans including pharmaceuticals. Between 1988 and 1991 the drug cost per prescription of new patented medications went from $25.74 to $42.35, an annual rise of 13.3%, compared to a

change from $13.98 to $16.04, or an annual rise of under 4%, for all medications.

Of course, this pattern of price rises would exist with or without compulsory licensing. The difference is that with compulsory licensing newly introduced patented medications are subject to price competition from generic products within seven to ten years and as we showed earlier even a single generic competitor results in a price difference of almost 24%. Without compulsory licensing there is no price competition until the patent expires. At this point that is an estimated 13 years, but if approval times for new drugs drop, as both the government and the industry hope they will, then instead of 13 years it could be 14 or 15 years. The Green Shield Report gives some insight into the effect of generic competition on the rate of rise of prescription costs. Whereas the annual average rise in the cost per prescription of new patented drugs rose 13.3% between 1988 and 1991, the average cost for existing patented drugs, which were only went up 8.0% per year over the same time period (38). New patented drugs introduced after 1987 were covered by Bill C-22 and immune from compulsory licensing for seven to ten years, whereas existing patented drugs were still subject to compulsory licensing. Therefore, generic competition probably accounted for much of the 5% difference in the rate of rise of prescription costs between the two groups of drugs.

The PMPRB even with its expanded powers under Bill C-91 will not be able to do control the rate at which doctors substitute new drugs for older ones and therefore the PMPRB will not be able to control rising prescription costs.

CONCLUSION

The Medical Reform Group and the Canadian Health Coalition believe that the benefits from Bill C-22 have not been clearcut and that the costs may only be beginning to be recognized. Therefore, we cannot accept the government's pronouncements about the effects of Bill C-91. Furthermore, we can find no evidence that the new bill is necessary for the economic health of the industry. On-the-contrary, there is good reason to believe that the elimination of compulsory licensing will only serve to drive up the cost of prescription drugs. If this happens it will have serious negative effects on the ability of the provinces to continue with their drug programs in their present form and the eventual losers will be Canada's elderly and poor. Therefore, we recommend that the government abandon its plans to proceed with Bill C-91.

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