BRIEF REGARDING BILL 102, AN ACT TO AMEND THE DRUG INTERCHANGEABILITY AND DISPENSING FEE ACT AND THE ONTARIO DRUG BENEFIT ACT

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On Behalf of the Medical Reform Group by

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Introduction

The Medical Reform Group (MRG) of Ontario is a democratic organization of about 250 doctors and medical students that was formed in 1979. We are dedicated to the following principles:

1. Health care is a right. The universal access of every person to high quality, appropriate health care must be guaranteed. The health care system must be administered in a manner which precludes any monetary deterrent to equal care.

2. Health is political and social in nature. Health care workers, including physicians, should seek out and recognize the social, economic, occupational, and environmental causes of disease, and be directly involved in their eradication.

3. The institutions of the health system must be changed. The health care system should be structured in a manner in which the equally valuable contribution of all health care workers is recognized. Both the public and health care workers should have a direct say in resource allocation and in determining the setting in which health care is provided.

In this brief we want to focus on two matters:

- the question of changing from the definition for substitution from "same" to "similar," and
- the economic viability of the brand-name pharmaceutical industry.

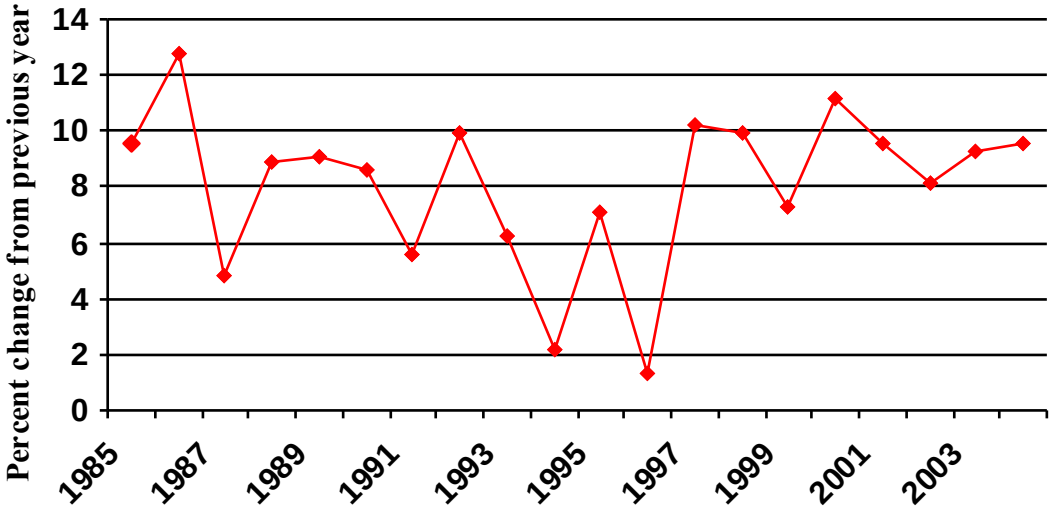
Rising drug expenditures

As a group of physicians we recognize that we have two obligations: one is to preserve the financial viability of the Canadian health care system and the second is to ensure that patients receive the best quality care. With regard to the former, drug expenditures in Canada are the single fastest rising component in health care spending, recently going up nationally at over 8 per cent per year after accounting for inflation. (See Figure 1, below.)

Changing the definition for substitution from "same" to "similar"

One way to help control these costs is through the use of generic substitution. Part of the proposed bill will lower generic prices to 50% of the price of the brand-name product. However, brand-name companies frequently seek to limit the impact of generic substitution by introducing new formulations of their products shortly before the patent expires and then using their promotional budgets to switch physician prescribing to these new formulations. By the time the generic for the original formulation comes out physicians are no longer prescribing this version and as such much of the potential for savings from generics is lost.

Figure 1: Increase in drug spending: retail costs after accounting for inflation



Bill 102 seeks to negate this tactic of the brand-name industry by changing the criteria for substitution from drugs that are the "same" (same active ingredient in the same formulation) to ones that are "similar" (same active ingredient but in a different formulation). The brand-name industry and some patient groups have argued that allowing substitution of similar drugs will potentially compromise patient safety. While this is a theoretical possibility and may happen rarely in individual cases there are no grounds for thinking that this will be a widespread occurrence.

British Columbia has allowed therapeutic substitution for the past decade through its program of reference based pricing (RBP). Under this system, groups of drugs are identified where the general medical consensus, backed up by clinical research, is that all of the drugs in the group are equally safe and effective. The BC government then only reimburses pharmacists for the least costly drug in the class. Should patients want a more expensive product they are responsible for paying the difference unless there is a genuine medical need for the more expensive product in which case the government covers the entire cost. The effects of RBP have been heatedly debated but the rigorous research that has been done into this policy has failed to demonstrate any negative health outcomes for patients. (See: Grootendorst et al. CMAJ 2001;165:1011-9; Schneeweiss et al. Clinical Pharmacology 2006; 79:379-88; Schneeweiss et al. Clinical Pharmacology 2003;74:388-400). RBP allows for a much broader level of substitution than does what is being proposed under Bill 102.

The MRG concludes that the health outcomes from changing the definition of substitution from "same" to "similar" are likely to be negligible. However, there should be allowance for dispensing, with full coverage, of a particular formulation of a product should there be a genuine medical need. Furthermore, the MRG recommends that the definition of "similar" be the same active ingredient + equal clinical outcomes as judged by a panel of medical experts.

Financial viability of the brand-name pharmaceutical industry

The brand-name pharmaceutical industry has been arguing that should Bill 102 be passed into legislation that it could negatively impact on its financial viability and therefore threaten the industry's investment in Ontario. The industry has a long history of making this sort of claims. In the early 1970s when Manitoba was going ahead with mandatory generic substitution the then president of the Pharmaceutical Manufacturers Association of Canada, Dr. William Wigle, said that if the research-oriented companies could not meet the prices they could be forced out of business. The industry also threatened to discontinue all marketing efforts in Manitoba. Five years later, the brand-name industry was lobbying in Ontario in an effort to get the Ontario government to abandon its Drug Benefit Formulary. At that time the industry pointed out that employment was "flat" and any further emphasis on lowest price manufacturing could lead to the transfer of sections of the industry to low labour cost countries.

This week, my colleague Dr. Norman Kalant has published in the most recent issue of ***Healthcare Policy*** the results of research undertaken with a McGill University colleague, and he will describe their results briefly.

Before passage of Bill C-22 in 1987 and Bill C-91 in 1993, the pharmaceutical industry argued that it needed strong patent protection to increase its revenues and thus be able to increase Research and Development (R&D) expenditure; this in turn would increase the production of valuable drugs .

Higher drug prices were to be regarded as an investment in health care. In fact R&D spending did increase substantially (though temporarily) but the number of important new drugs produced after passage of Bill C-91 was not increased over the number produced before. On the other hand, the US industry increased production of new drugs by 60 per cent during the same period though there was no new legislation.

NEW DRUGS MARKETED BEFORE AND AFTER PATENT LAW ENACTED

	CATEGORY 2 / PRIORITY NME*		OTHER	
	1989-1994	1995-2000	1989-1994	1995-2000
CANADA	36	26	477	521
USA	73	80	277	489

* Category 2 for Canada; Priority NME for US indicate "breakthrough" drugs

We compared the Canadian subsidiaries with their parent firms with regard to the output of their R&D, taking into account the size of their R&D expenditures. Patent applications and scientific publications were considered as "units" of new knowledge resulting from R&D. The Canadian subsidiaries produced far fewer units per $1000 of R&D than the parent

firms. This is not due to the small size of the Canadian companies and the small amounts of R&D expenditures, since one exception to the Canadian pattern (Merck Frosst) with R&D expenditure of the same order as that of the other Canadian firms, had many more units per $1000 of R&D; it was very similar to its parent firm.

PUBLICATIONS AND PATENT APPLICATIONS OF PARENT FIRMS AND CANADIAN SUBSIDIARIES (1998-2004)

PARENT	R&D[1]	PUB[2]	PAT[3]	(PAT+ PUB)/(R&D)	SUBSIDIARY	R&D[1]	PUB[2]	PAT[3]	(PAT+ PUB)/ (R&D)
ABBOTT	10284	2996	733	0.36	ABBOTT LABORATORIES	63	0	0	0
ASTRAZENECA	18102	3433	790	0.23	ASTRAZENECA CANADA	506	18	1	0.04
AVENTIS PHARMA	19884	2623	1096	0.19	AVENTIS PHARMA	267	2	0	0.01
BRISTOL-MYERS SQUIBB	14356	2399	610	0.21	BRISTOL-MYERS SQUIBB CANADA	316	2	0	0.01
JOHNSON & JOHNSON	25814	1043	496	0.06	JOHNSON & JOHNSON MERCK	0	0	0	0
MERCK	18554	7282	1500	0.47	MERCK FROSST CANADA	690	194	211	0.59
NOVARTIS PHARMA	25652	5420	760	0.24	NOVARTIS PHARMA CANADA	334	6	0	0.02
PFIZER	36614	4516	835	0.15	PFIZER CANADA	815	24	0	0.03
WYETH	12862	2060	421	0.19	WYETH AYERST CANADA	277	0	0	0

1 Research and Development expenditure ($000's)
2 Publications in scientific and professional journals
3 Number of patents applied for.

The record of Merck Frosst demonstrates the feasibility of developing a successful research enterprise in the context of the Canadian economy.

The report of the Patented Medicines Prices Review Board for 2004 indicates that approximately $150M were provided in support of R&D at universities and hospitals. Taking McGill University as an example, we determined how many and what types of project received such support. We determined the number of scientific publications of which the lead author was affiliated with McGill, generated a random sample of 100 papers, then examined these manually to find a statement of financial support. In this instance we found no publications supported by the Canadian pharma industry.

Since the PMPRB reports that the industry gave $9.2M to Quebec universities in 2004, there is a large discrepancy between the support and the outcomes of research. This begs the question of what the money was used for. It is another example of the lack of clarity in the reporting of information by the industry and by the PMPRB.

SOURCES OF FINANCIAL SUPPORT OF RESEARCH PERFORMED AT McGILL UNIVERSITY - 2004

TOTAL PUBLICATIONS	1207
SAMPLE SIZE	100
SOURCES OF SUPPORT	
CANADIAN INSTITUTE FOR HEALTH RESEARCH	54
NATIONAL SCIENCE AND ENGINEERING RESEARCH	10
COUNCIL	
NATIONAL INSTITUTES OF HEALTH	10
FRSQ	6
MSSQ	6
OTHER	14
CANADIAN PHARMACEUTICAL INDUSTRY	0

The hollowness of these threats can be seen by looking at the current profit picture of the industry. Figures from Statistics Canada show that, as measured by rate of return on shareholders' equity, currently the industry is roughly twice as profitable as the average for all manufacturing industries in Canada. Clearly, despite the regulations imposed by the Patented Medicine Prices Review Board limiting introductory prices and the rate of rise of prices and provincial controls such as Ontario's price freeze, in economic terms the industry is still thriving.

Final thoughts

According to the government, Bill 102 is expected to save over $220 million in its first fiscal year. The Medical Reform Group firmly believes that this money must be reinvested to expand Ontario's social safety net and not to help fund tax cuts.

Finally, we note that the Bill will create a position of Executive Officer. The creation of such a position must not be used to remove political accountability from the Minister of Health for actions that are taken with respect to Ontario's drug programmes.

We'll be very pleased to answer any questions the committee may have.