Brief to the House of Commons Standing Committee on Health
Study on Prescription Drugs

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1. Introduction and Disclosure

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The level of government intervention in health care is greater in Canada than in any other OECD country (Esmail and Walker 2002). Indeed, Canada is the only OECD country to effectively prohibit competition against government health insurance for medically necessary services and the financing of hospitals. The mission of the Health and Pharmaceutical Policy Research Department of the Institute is to measure the consequences of this extraordinarily high degree of government involvement.

Governments in Canada have not historically considered prescription drugs to be medically necessary. Therefore they do not fall under the Canada Health Act and Canadians have greater choice in this area of health care than others.

Nevertheless, there is a large degree of government involvement in prescription drugs in Canada, and it is always appropriate to examine the effectiveness of this involvement.

2. Key Points

The House of Commons Standing Committee on Health can serve the public interest by taking the following measures with respect to prescription drugs:

- Recommending the repeal or significant amendment of the Canada Health Act to allow patients more freedom to spend their money directly on all health services or contract with private health insurers to do so, thereby allowing Canadians to determine the appropriate mix of spending on prescription drugs and other health services.

- Recommending the abolition of the Patented Medicine Prices Review Board.

- Investigating the barriers to entry into Canada's generic pharmaceutical market and making recommendations for lowering them.

- Demanding that the Health Minister report immediately to the House of Commons every time Health Canada takes longer than a fixed period to approve a medicine after the US Food and Drug Administration or European Agency for the Evaluation of Medicinal Products has done so.

- Proposing amendments to the Food and Drug Act to de-regulate direct-to-consumer pharmaceutical advertising in order to improve diagnosis and prescribing.

- Encouraging the Canadian government to use every legal means to stop the illegal trade in prescription drugs from Canada to the United States, and to educate provincial governments, especially Manitoba's, that it is harmful to Canadians' health.

3. Rising Costs

In 2002, prescription drug spending accounted for a forecast 13 percent of health spending in Canada. However, government spending on prescription drugs was only 8 percent of total government health spending. This is because private spending accounts for a larger share of prescription spending than it does in other health services, especially hospitalization and physicians' consultations. In 1985, the same figures were 6 percent and 4 percent (CIHI 2003: 66-67). So, costs of prescription drugs are undoubtedly increasing as a share of health spending. However, this in itself is not significant.

By definition, all components of health costs must add up to 100 percent of total costs. A hundred years ago, electricity was increasing its share of lighting costs from gas, kerosene, and candles. This was not a cause of worry, but a sign of progress. Similarly, rising pharmaceutical spending is more likely part of the solution to managing health costs, not the problem. Two American economists estimated that a 60 year old Canadian woman in 1993 would have increased her life expectancy by over two days for an increase in pharmaceutical spending of a little more than one dollar eight years earlier (Frech and Miller 1999: 47-49, author's calculations). More recent research from the United States shows that one dollar spent on prescription drugs saved over seven dollars of non-pharmaceutical health spending for the years 1996 through 1998 (Lichtenberg 2002). Research at The Fraser Institute has not been able to replicate these results with the robustness of the American research, but our analyses have indicated that increasing prescription spending is a good place to direct health care dollars (Esmail 2003; Zelder 2000).

Provincial drug benefit plans have managed rising costs with a variety of mechanisms. I classify them into two categories: "rationing by need" or "rationing by disease". In the first, the government allocates the drug benefit plan's resources according to the ability of a patient to pay from his own income, that is, a means test. In the second the government tries to decide what drugs provide better value than others, and biases its subsidies in the direction of the medicines that it supposes do so.

The history of provincial drug benefit plans indicates that the former approach is superior to the latter. For example, in the 1990's British Columbia and Manitoba both reformed their drug benefit plans in the face of rising costs. Manitoba implemented a means test, whereby the government levied a deductible at 2 percent or 3 percent of a patient's income. British Columbia, on the other hand, imposed "reference pricing" for a number of therapeutic classes. Pharmacare fully subsidized less expensive drugs in the classes and made patients pay the full difference in price for more expensive drugs, unless their doctor applied for special authority to prescribe a more expensive drug with full subsidy.

Manitoba's policy appears to have been a relative success. In the ten years before the introduction of the means test, Manitoba's real per capita prescription drug costs paid by both Pharmacare and privately increased by 78 percent, with both private and Pharmacare

spending increasing at the same rate. For BC, per capita costs increased by 62 percent, with private costs increasing faster than Pharmacare's costs.

However, from 1996 through 2001, Manitoba's estimated total spending on prescription drugs grew 35 percent, of which Pharmacare grew 54 percent and private spending 25 percent. For BC, total spending growth is estimated to have been 60 percent, of which Pharmacare expenditure grew 71 percent and private spending 49 percent. It appears that the means test allowed Manitoba to break the previous trend whereby its spending was increasing faster than BC's, and resulted in both public and private spending growing less than BC's. As well, total health costs in Manitoba increased slightly less than they did in BC over the last six years: 17 percent instead of 21 percent (Graham 2002a).

These two approaches reflect very different points of view. BC Pharmacare believed that a government-appointed committee had the competency to pick the right drugs for patients. As well as performing poorly on spending, there are indications that the "reference pricing" led to some negative health outcomes (Graham 2002b, and references).

The currently evolving Common Drug Review, managed by the Canadian Coordinating Office for Health Technology Assessment, which receives funding from Health Canada, has strong potential to replicate the mistakes of BC Pharmacare because it operates under the fallacy that a centralized, government-funded body can make better therapeutic decisions than the multitude of physicians and patients who are actually involved in using medicines.

One barrier to the effective use of prescription drugs in Canada is that governments do not have the incentive to determine what the effect of increased prescription drug spending is on other health spending or health outcomes. Nor do they have the ability to optimize the mix of prescription drugs as either complements or substitutes to other health services. This is due to the same fallacy of centralization that inspires the Common Drug Review.

When BC Pharmacare implemented reference pricing, many patients responded by spending their own money on the more expensive medicines that they and their doctors thought that they needed (Graham 2002b: 20-23). Of course, this is not generally possible for health services provided by physicians or hospitals.

The Standing Committee would serve the public interest by recommending the repeal or significant amendment of the Canada Health Act to allow patients more freedom to spend their money directly on other health services or contract with private health insurers to do so. Patients and private insurers will make superior decisions on the mix of health services than governments can.

4. Mechanisms for Reviewing and Controlling Prices of all Prescription Drugs

Controlling prices for patented prescription drugs is not an important issue in Canada. Prices of existing patented prescription drugs have not increased faster than the Consumer Price Index for many years and decreased last year (PMPRB 2003: 8).

The federal body that regulates patented drug prices is the Patented Medicine Prices Review Board (PMPRB). However, it does not contribute to keeping patented drug prices down, and probably causes them to be higher than they would be otherwise. Evidence shows that the drop in the Canadian dollar explains virtually the entire drop in Canadian patented drug prices relative to other countries. Furthermore, because prices of newly launched patented drugs are set with reference to similar drugs that are already sold in Canada, the PMPRB inhibits brand-name drug makers from lowering prices of older medicines (Graham 2000: 12-13; 2002c).

Non-patented, single source prescription drugs are branded drugs which were never patented, or whose patents have expired, and where generic substitutes have not entered the market to compete against them. Their prices are not regulated by the PMPRB. In 1997, US prices for these drugs were 96 percent higher than Canadian prices (Conference of Federal/Provincial/Territorial Deputy Ministers of Health 1999: 6). In contrast, the US price premium for patented drugs in 1998 was 60 percent: the Canadian discount for branded drugs *not regulated* by the PMPRB was far greater than those that *were regulated*. A Fraser Institute survey of price differences for prescription drugs in Canada and the US using 1999 prices confirmed this difference (Graham and Robson 2000: 13). The Standing Committee would serve the public interest by recommending the abolition of the PMPRB.

Generic drugs are relatively expensive in Canada, often higher than even in the United States (Graham and Robson 2000: 11-13; Palmer D'Angelo Consulting Inc. 2002). However, price controls for generic drugs are not the solution to this problem, because there is no way for a government agency to decide what the fair difference between a generic price and a branded price for any given medicine should be. The problem appears to derive from a lack of competition. Two generic drug makers account for over half generic drug sales in Canada (Palmer D'Angelo Consulting Inc. 2002: 8). Therefore, the Standing Committee would serve the public interest by investigating the barriers to entry into Canada's generic pharmaceutical market and making recommendations for lowering them.

5. Mechanisms for Approving New Drugs and Introducing Them on the Market

From 1999 through 2001, the Canadian government took a median 39 weeks longer than the US Food and Drug Administration (FDA) did to approve prescription drugs for sale (Rawson 2003). However, the US FDA has usually taken even longer than its European counterparts to approve new medicines. American analyses of the "drug lag" between the US and Europe in the 1980s and early 1990s indicated that it killed between 16,000 and 110,000 Americans annually (Jones 2002, and references).

The consequences of a similar lag for Canada have not yet been calculated. However, it is undoubtedly an undesirable condition that can be remedied by a range of policies, including one which would allow Canadians to buy properly labeled medicines once they are approved by regulators in the US or Europe (Jones 2002). Patients' and doctors' willingness to use these medicines would indicate how much they valued Health Canada's approval process. The results might be used to justify more fundamental reforms of the approval process, possibly including a complete end to the Canadian system of approval.

Certainly the Canadian Health Minister must be held accountable for this delay. The Standing Committee would serve the public interest by demanding that the Health Minister report immediately to the House of Commons every time Health Canada takes longer than a fixed period, say twenty business days, to approve a medicine after the US FDA or European Agency for the Evaluation of Medicinal Products (EMEA) has done so.

6. Direct-to-Consumer Advertising

Evidence indicates that direct-to-consumer advertising in the US has improved diagnosis and prescribing. The US FDA recently completed a random survey of 500 American physicians on the fifth anniversary of the liberalization of DTC-advertising in the US (Aikin 2003). 92 percent of the physicians recalled patients asking them about medicines that they had seen advertised, and 88 percent of those patients did suffer the relevant condition. Importantly, in 91 percent of cases, patients did *not* try to influence the treatment in a way that would have been harmful.

Indeed, it is likely that direct-to-consumer advertising has positive effects that are above and beyond increased use of appropriate drugs. Other research in the United States demonstrates that patients exposed to direct-to-consumer advertising and who visited their doctors as a result enjoyed positive spillovers in the form of lifestyle advice and recommendations to take non-advertised drugs. Also, advertising speeds up the dissemination of new therapeutic knowledge from which patients and physicians benefit (Calfee 2003, and references).

Even Canadian research, which attempts to show the negative effects of advertising, reports data that demonstrate that advertising is likely positive in its consequences (Mintzes, *et al* 2003). The increased prescribing associated with direct-to-consumer pharmaceutical advertising likely results in far more positive health outcomes than negative (Graham 2003a).

It is immoral for the government to limit direct-to-consumer advertising. In Canada, governments pay almost half of all prescription costs (CIHI 2003: 13). Although most of this is borne by provincial governments, the federal government is increasing its role through the Common Drug Review and a potential contribution to covering catastrophic drug expenses. This means that there is a conflict of interest in those governments' regulating direct-to-consumer advertising of prescription drugs. If the goal of the current regulations preventing advertising is to keep patients ignorant of alternatives, patients won't know if government drug benefit plans are giving them good coverage and will suffer for their ignorance.

Canadians have a right to choose the sources of medical information that they use, and the current level of direct-to-consumer pseudo-advertising conducted by research-based drug makers in Canada indicates that they are striving to satisfy this demand. The Standing Committee would serve the public interest by proposing amendments to the Food and Drug Act to de-regulate direct-to-consumer pharmaceutical advertising in order to improve diagnosis and prescribing.

7. International Comparisons

Canada's prescription drug prices have been dropping versus prices in the United States since the late 1980s (Graham 2000: 6-11; 2002c). This price difference is increasingly obvious to US residents.

Because the US has failed to satisfy the health insurance needs of a small number of its residents, they are now buying lower priced Canadian drugs in increasing quantities. Although this is currently illegal in the US, irresponsible US politicians are encouraging it by proposing laws to promote this "re-importing", instead of developing domestic solutions to their problem. Canadian Internet-based and mail-order pharmacies are satisfying this American demand in the face of drug makers' obvious unwillingness to sell Canadian-priced drugs to US consumers.

The US comprises 37 percent of the world's pharmaceutical market, and a larger share of its profits. Canada comprises less than two percent of the world's market, and contributes negligibly to profits. This means that it makes no sense for drug makers to continue to supply Canada when their medicines are diverted into the US to destroy their margins there.
We have already seen some large, research-based drug makers take steps to reduce supply in Canada. Although drug makers are trying to ensure that they only cut off the grey marketers, the federal government and the government of Manitoba are making it difficult for them to do so. This will push drug makers to err on the side of drastically reducing supplies to all Canadian distributors.

If the drug makers are forced to cut off supplies to Canada, the Canadian government would be tempted to gut its intellectual property laws, thus allowing companies other than the inventors to supply Canadian pills. This would put Canada at risk of violating international rules protecting intellectual property, and jeopardize Canadians' participation in the global trade in innovative products.

Even at its current level, the grey market violates the intellectual property laws that give investors the incentive to finance the research-based pharmaceutical industry. It also challenges the spirit, and perhaps the letter, of the North American Free Trade Agreement. Companies that are headquartered in the US invent most medicines sold in Canada. When Canada entered into the free trade agreement with the US, Canada created an environment that increased research-based drug makers' willingness to risk capital in Canada. If Canada cannot stop this grey market, those investments will become millstones around the companies' necks and because government action is causing the assets to devalue, Canada may be inviting a trade dispute under NAFTA's clauses that prohibit discrimination against foreign investors.

The Food and Drug Act, the Import Permits Act, other laws, and contracts between suppliers and distributors govern the Canadian supply of prescription drugs from abroad. Individuals who undertake the re-export of foreign drugs in spite of private contracts that

prohibit this activity are now breaking these laws and contracts. This practice threatens the existence of the global system for international trade and production of new prescription drugs (Graham 2003b).

The Standing Committee would serve the public interest by encouraging the Canadian government to use every legal means to stop this illegal trade, and to educate provincial governments, especially Manitoba's, that it is harmful to Canadians' health.

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