Court File No. OS-CV-303001PD2

ONTARIO
SUPERIOR COURT OF JUSTICE

B E T W E E N :

CANWEST MEDIAWORKS INC.

Applicant

- and -

ATTORNEY GENERAL OF CANADA

Respondent

AFFIDAVIT OF JEAN BELLEVILLE

I, JEAN BELLEVILLE, of the Town of Brossard, in the Province of Quebec, AFFIRM THAT:

1. I am an actuarial consultant with SAI Inc., a Montreal-based organization founded in 1991. SAI works with both public and private corporations, insurance companies and trade unions on the negotiation and creation of benefit plans. I therefore have knowledge of the matters deposed to below.

2. My particular area of expertise is working with trade unions. For the past 22 years, I have worked exclusively with unions, assisting them at the bargaining table in the negotiation of benefit packages with employers. I am therefore intimately familiar with the dynamics of collective bargaining and have personally observed the effect that the rising cost of health care, and in particular the rising cost of prescription drugs, has had on labour relations.

3. The purpose of this affidavit is to consider the role of employment-based health plans in the provision of drugs to working Canadian men and women, the impact of increasing

prescription drug costs on these plans, the likely impact of further increases in the cost of prescription drugs and in the number of drug claims that would result if direct-to-consumer advertising ("DTCA") were permitted in Canada. As set out in greater detail below, it is my considered view that increasing drug costs in Canada has had and will continue to have a deleterious impact on collective bargaining and on the lives of working men and women in this country, a problem which will only be exacerbated if DTCA is permitted.

MY BACKGROUND

4. I obtained a bachelor's degree in mathematics from the University of Montreal in 1971. I have been a fellow with the Canadian Institute of Actuaries (FICA) and the Society of Actuaries (FSA) since 1983.

5. Over the past 35 years I have worked in the area of group insurance and retirement plans. From 1972 to 1985 I was employed with two insurance companies, Quebec Mutual Assurance Company and La Laurentienne, during which time I became familiar with all aspects of group benefit plans. It was this experience which enabled me to pursue my career as an actuarial consultant. From 1985 to 1990 I worked in this capacity with a consulting firm, Blondeau & Company, following which I joined other actuaries to found SAI Inc., as set out above.

6. Since joining SAI, I have worked exclusively with trade unions in the creation and negotiation of group insurance and retiree benefit plans. I have counselled unions in their discussions with insurance providers as well as in their yearly re-negotiation of insurance premiums. I have also advised unions in their negotiations with employers, particularly with respect to their benefits improvements and the determination of the formula for the sharing of the cost of benefit plans.

7. I am therefore familiar with the trend which has seen the cost of benefit plans increase dramatically over the past ten years and will see those costs continue to rise in the future.

THE ROLE OF COLLECTIVE BARGAINING

8. Canada's Medicare system is commonly regarded as its most important social program and is based on providing universal health care on the basis of need, not on the ability to pay. However, prescription drugs, which are an essential component of health care, are not covered by the national Medicare system. While the provinces have various plans to provide public funding for prescription drugs, particularly for seniors and for those on social assistance, many Canadians must purchase insurance or pay for prescription drugs out of their own pockets. Most private insurance for prescription drugs is provided through workplace health benefit plans.

9. Prescription drug insurance is one component of extended health benefits plans, which also include various medical supplies, paramedical specialists such as chiropractors and physiotherapists, the cost of a private or semi-private room in the case of hospitalization, vision care and travel insurance. Extended health plans are in turn part of a more comprehensive group insurance program which provides employees with dental care insurance, life insurance and coverage for short and long term disability. Group insurance programs are funded by the plan sponsors, that is employers and employees, who pay the insurance premiums.

10. Many of the employees covered by work-based drug plans are unionized. As such, their benefits and the cost sharing formulas between the employer and the employees are negotiated in collective agreements as part of their remuneration package. In Canada, 58% of all employees, a total of 7.6 million people, have coverage at some level for drug costs through a private insurance plan for extended health benefits at their place of work. These work-based plans also cover an additional 4 million adults and 4.4 million children, the designated spouses and dependents of the employees in question. In total,

16 million people, that is over half of all Canadians, have coverage for their drug costs at some level through work-based drug insurance plans.[1]

11. Through these insurance plans, sponsors pay just over one third of the total expenditures on prescription drugs in Canada, 34.4% in 2005. This amounted to $7.1 billion in 2005, out of a total expenditure on prescription drugs of $20.6 billion. The remaining expenditures were covered by public funds (46%) and payments that are made by individuals out of their own pockets (19.6%).[2]

12. The amount of $7.1 billion paid by sponsors is for expenditures directly on drugs, but it is not the total cost to sponsors of drug insurance plans. These plans are typically administered by insurance companies that charge for their services. As estimated by one expert: "The actual cost of prescriptions (i.e. the medication and the professional fee), make up 75% of prescription drug plan costs for an employer. The remaining 25% of the costs is generated by the insurance administrator's costs (including adjudicating transaction costs), plan reserves, taxes and commissions or fees for the benefits consultant or broker." [3] By this estimate, plan sponsors paid $7.1 billion in 2005 for drugs and another $2.4 billion for insurance costs, for a total of $9.5 billion.

13. Where these plans offer only partial coverage (for example, where less than 100 percent of prescription charges are covered or where there are deductibles), the difference is paid for by the employees themselves and therefore falls under the category of out-of-pocket expenditures mentioned above.

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[1] Applied Management with Fraser Group Tristat Resources, *Canadians' Access to Insurance for Prescription Medicines,* Volume 2, submitted to Health Canada, March 2000, pp. 28-29.

[2] Canadian Institute for Health Information. *Drug Expenditures in Canada 1985 to 2005*, Ottawa, 2006, p. 56, Table A.1.

[3] Hutty, S. *Third Party Issues: Understanding Drug Benefits for Better Patient Care*, Regina: Canadian Council on Continuing Education in Pharmacy, June 2002, p.2.

14. I have spent a significant part of my career negotiating such benefit plans for unions. I am therefore acutely aware of the pressure that rising costs, and in particular the rising cost of prescription drugs, are exerting on work-based health benefit plans and on labour relations, which conditions are discussed in greater detail below.

THE PRESSURE OF INCREASING DRUG COSTS ON WORK-BASED HEALTH BENEFIT PLANS

15. The rapid rise in drug expenditures over the last decade has placed enormous pressure on work-based extended health plans. The contribution of sponsors to drug expenditures was $7.1 billion in 2005, compared to $2.4 billion in 1995, [4] an increase of nearly 200%.

16. The logical consequence of these dramatic increases in expenditures on prescription drugs, has been an equally dramatic rise in the cost the insurance premiums that cover drug expenditures, which have been increasing by at least 10-12% per year. In my opinion, this is a good estimate of the rising cost of premiums over the last ten years.

17. The cost of insurance premiums is commonly expressed as a percentage of annual earnings of the covered employees, relating the cost of benefits to the cost of the employees' earnings. This provides a convenient way to assess the value of the benefits at the bargaining table. For example, in 2006, the cost of a typical drugs plan is in the range of 3% to 4% of annual earnings while, in 1996, the corresponding range was only about 1.3% to 1.7% of annual earnings, again indicating the very substantial increases in costs that have occurred over the last ten years.

18. The preceding percentages are averages for a group of employees, including individual and family coverage, and also different levels of earnings. Actually, the overall cost of 3% to 4% for a group may represent 1.5% to 2% of annual earnings for an employee with

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[4] Canadian Institute for Health Information. *Drug Expenditures in Canada 1985 to 2005*, Ottawa, 2006, p. 56, Table A.1.

individual coverage but 3.7 % to 4.8 % for an employee with family coverage. In addition, since the premiums are flat amounts and consequently independent of the level of salary earned by an employee, the corresponding percentages are significantly higher for lower-paid employees and lower for higher-paid employees (a good estimate would be 20 % lower or higher). As a corollary, the lowest-paid employees and employees opting for family coverage are much more affected by any increase in the premiums (or in the cost of drugs).

19. However calculated, there is no doubt that insurance costs for drug coverage have increased very dramatically over the last ten years. Moreover, since the drug component of extended health plans constitutes between 70% to 80% of the total cost of the plans, the impact of increasing drug costs is very significant. Employers have responded to these increases in benefit premiums by seeking to contain and reduce their own costs. In labour negotiations, employer proposals to reduce benefit costs are now the norm. Any reduction in the extent of health coverage or in the share of the health cost supported by the employer is immediately transferred to the employees in the form of additional premiums or medical expenses.

20. It is important to note that while drug cost increases are driving the rising cost of work place health plans, employer proposals are not limited to drug plans specifically, but involve the whole extended health care plan and, in many cases, other negotiated benefits as well.

21. Over the course of the past ten years I have encountered the following four main employer proposals aimed at reducing their costs for benefit plans.

1. Increasing employees' contributions to the cost of premiums

22. Employees may be required to pay a higher dollar amount towards their premium costs, or their percentage share of the premium costs may be increased, such as a 25-75% split

instead of 0-100%. An even less appealing option from the employees' point of view is that the employer pays only a fixed amount, while the employees are responsible for all additional costs, including any increases. This means that the employees will carry the full burden of the rapidly increasing cost of insurance premiums.

2. Reducing the level of benefits

23. Higher employee deductibles mean that employees pay a larger initial set dollar amount for the year, before benefit coverage begins. The higher the deductible, the lower the cost of the benefit package to the employer.

24. Prescription charges, paid by the employees for each prescription, reduce the cost of the drug plan, but penalize those dependent upon or in greater need of prescription drugs. The higher the per prescription payment, the more those in ill-health must pay compared to their more healthy fellow employees.

25. Maximum amounts mean that employees are insured only to an overall maximum dollar amount per year, beyond which the employee must pay all further costs. This poses an obvious problem to employees who exceed the maximum and must then pay themselves for further prescription drugs and other extended health care costs. The effect is that those most in need of health coverage are uninsured beyond a certain point.

3. Flexible benefits

26. Flexible benefits, also commonly referred to as "cafeteria plans", constitute the most extreme and the most perilous employer response to increasing costs. Under flexible benefits, employees find themselves forced either to pay for the rapidly increasing costs of insurance, or to reduce their benefits package and leave themselves unprotected.

27. Flexible benefits do not offer employees a standard package of benefits, but require each employee to choose a level of benefit coverage from a range of options and pay more for the better options. Flex plans inevitably mean that some employees do not make the appropriate choice and are not covered for benefits that they need. Such employees cannot move to an improved level as needed since there is a waiting period to move between different "levels" of benefits of one to three years.

28. Flexible plans commonly include not just drug coverage, but other extended health benefits, plus dental care. A major concern is that life insurance and long-term disability are sometimes part of the flexible plan. These are benefits that cover serious life events and the results of poor coverage can be devastating for employees and their families. Flexible plans are the most disturbing example of increasing drug costs leading to serious deterioration in the broader benefit coverage of employees.

29. From the employers' point of view, flexible plans mean that employer costs are more predictable and contained. As premium costs rise, employees either contribute a higher share of the cost or take a lower level of benefits. With the increasing cost of benefit plans, benefit consultants are promoting flexible benefits as an important means of controlling costs and employers are increasingly taking that advice and proposing flexible plans at the bargaining table.

4. Reducing or eliminating benefits for retirees

30. Drug and other benefit coverage for retirees are particularly vulnerable in this situation, because they are more expensive and because they represent a potentially substantial long term liability for employers. Consequently, employers are especially concerned to reduce, if not eliminate, benefits or insurance contributions for future retirees.

31. In 2006, Hewitt Associates conducted a survey of 218 Canadian companies and found that 57% planned to reduce the level of post-retirement benefits over the next 3 years, while a further 4% said they intended to eliminate them entirely.[5]

32. In March 2007, Bell Canada announced the elimination of benefits for future retirees. For Bell employees retiring as of January 2012, most benefits will be cut, and all benefits will be eliminated for those retiring after 2017. Both Nortel and Sears Canada have announced the end of post-retirement benefits as of 2008.[6]

THE CONSEQUENCES OF INCREASING DRUG COSTS

33. The consequences of increasing drug costs over the last 10 years on work-based benefit plans are very clear.

34. Many of the 16 million Canadians covered for drug insurance and other extended health benefits in work-based plans have less benefit coverage than in the past. Current and future retirees also have less coverage.

35. All Canadian employees are paying substantially more for the drugs and other extended health care that they need, whether through increased payments for insurance premiums, or various increased costs such as deductibles, payments per prescriptions or maximum amounts.

36. The reduction in benefits and the increased costs do not only affect access to drugs, but also other extended health care benefits and, in some cases, dental care, life insurance, and coverage for disability.

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[5] Hewitt Associates, "Hewitt Survey: Changes in Retiree Health Care Coverage Imminent", Press Release, 6 March 2006.

[6] Janet McFarland, "Bell takes the axe to future post-retirement benefits", Globe and Mail, Report on Business, 28 March 2007.

37. It is well documented that when individuals are forced to pay more for drugs, they do not always take the necessary treatments. As a result, visits to doctors and emergency rooms rise, increasing the total costs to the health care system.[7]

38. There is increased tension over benefit packages between unions and employers, resulting in more acrimonious negotiations and more strikes. There have been a number of strikes in which the sole issue has been the benefits package and others where it has been one of the primary issues. I have read the affidavit of Brian Payne sworn on August 2, 2006, in which he cites a number of examples of strikes that occurred over benefit packages. Attached as Exhibit "A" to this affidavit is a copy of Mr. Payne's aforementioned affidavit.

THE CONSEQUENCES OF INTRODUCING DTCA IN CANADA

39. I am not an expert on DTCA, as it applies to the pharmaceutical industry or otherwise. However, I have read the Affidavit of Steven G. Morgan relied upon by the Respondent in this case and gather from it that if DTCA is introduced in Canada, the effect will be a heavier and more dramatic increase in the cost of prescription drugs over the coming years than anticipated under present conditions.

40. It is clear that the drug cost increases of the last ten years have already undermined the provision of drugs and other extended health benefits to many Canadian employees, their spouses and dependents and retirees.

41. The continuation of this present trend in drug cost increases means that health benefit plans and drug coverage as they currently exist are not easily sustainable. I have projected that if the same trend (i.e. 10% per year) continued over the next ten years,

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[7] Tamblyn R., Laprise R., Hanley J.A., Abrahamovwicz M., Scott S., Mayor N., et al. "Adverse events associated with prescription drug cost-sharing among poor and elderly persons", Journal of the American Medical Association, 2001; 285(4), 421-429.

approximately a further 3% to 4% of annual earnings would be required, paid either by employers or employees, just to maintain benefits coverage where it is now, without any negotiated improvements. I am advising union negotiators that to date they have only seen the tip of the iceberg in terms of demands by employers for concessions and flexible benefits and only the beginning of reduced benefits for many Canadians.

42. In a paper recently published by Stephen Morgan, a copy of which is attached as Exhibit "B" to this affidavit, he estimates that if DTCA had been introduced to Canada as it was in the United States, plan sponsors (i.e. employers and employees) would have paid additional drug expenditures of between $1.04 and $2.21 billion in 2005, over and above the $7.1 billion that they actually paid. This would have added between 15% to 30% to the cost of current and future premiums (and also to out-of-pocket expenditures). There is no doubt in my mind that in such a scenario, insurance for drugs and other health benefits for Canadians would have deteriorated at a more rapid pace.

43. Turning to the future, introducing DTCA to Canada, which will mean yet more rapidly rising drug costs, will put further pressure on the negotiation of health benefit plans and related benefits. Insurance coverage for the half of all Canadians covered in work-based plans will deteriorate, leading to increased costs for individuals, more ill health as employees find themselves unable to meet those costs, and more total health care costs as other parts of the health system deal with the results. As unions struggle to mitigate these consequences, negotiations will become more antagonistic and there will be an increased number of strikes over work-based benefit plans.

44. I swear this affidavit in support of the Canadian Health Coalition, the Canadian Federation of Nurses Unions, Women and Health Protection, the Communications, Energy and Paperworkers Union of Canada, the Canadian Union of Public Employees, Terence Young, the Society for Diabetic Rights and the Medical Reform Group who

oppose the relief sought by the Applicant in this matter and for no other or improper purpose.

AFFIRMED BEFORE ME at the City of Montreal, in the Province of Quebec on May 3rd, 2007.

Commissioner for Taking Affidavits

PIERRE DESJARDINS
166 905

JEAN BELLEVILLE

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This is Exhibit "A" referred to in the
affidavit of Jean Belleville
sworn before me, this 3rd
day of May 20 07

A COMMISSIONER, ETC

Commissaire à l'assermentation
PIERRE DESJARDINS
166 905
Tous les districts judiciaires du Québec

Court File No. OS-CV-303001PD2

ONTARIO
SUPERIOR COURT OF JUSTICE

B E T W E E N:

CANWEST MEDIAWORKS INC.

Applicant

- and -

ATTORNEY GENERAL OF CANADA

Respondent

AFFIDAVIT OF BRIAN PAYNE
(sworn ~~July~~ August 2, 2006)

I, **BRIAN PAYNE,** of the City of Ottawa, in the Province of Ontario, **AFFIRM THAT**:

1. I am the National President of the Communications, Energy & Paperworkers Union of Canada (hereafter referred to as "CEP") and as such, I have personal knowledge of the facts to which I hereinafter depose.

2. CEP is one of Canada's largest unions, and represents more than 150,000 workers, including those employed at pulp and paper mills, telephone companies, and in the oil, gas, chemical and mining industries. Our membership also includes printers, journalists, radio and TV broadcasters, graphic artists, hotel workers, computer programmers, truck drivers and nurses.

CEP's Commitment to Medicare

3. In addition to working to improve the terms and conditions of employment of our members through collective bargaining, CEP also advocates for progressive legal and policy reforms that will benefit all in society, such as strengthening Canada's publicly funded health care system.

4. Because of the critical importance of ensuring that all Canadians have access to health care, CEP has undertaken one of the largest initiatives in its 10-year history to bring to the attention of our members, and employers, the crucial issues facing Canada's healthcare system. During this period, CEP has devoted about $400,000 toward educating our members and the wider public about the need to not only protect, but expand, our publicly funded health care system.

5. CEP believes, based on our own research and that of others, that privatized healthcare would neither be in the interests of our members nor of their employers. The U.S. experience which we have studied suggests that private care would be of lower quality and more expensive, ultimately leading to increased costs for employers and reduced competitiveness for the Canadian economy generally.

The Problem of Ensuring Adequate Drug Benefit Insurance Coverage

6. A key element of any collective agreement we negotiate is the provision to our members of the benefits of private health insurance for services not covered by medicare, such as dental care and prescription drugs.

7. Unfortunately, over recent years the cost of such benefits has risen sharply. In 2003, for example, private insurance premiums rose by 16.6%, and the cost is expected to double every 5 years.

8. A key reason for these increases has to do with the cost of insurance for prescription drugs, which typically represents over two-thirds of the cost of the benefit plan. These costs are rising because both drug use and drug costs are rising. Both cost pressures are related to the promotional activities of the pharmaceutical industry, including direct to consumer advertising.

9. To ease these cost pressures, many employers are now proposing that workers either pay more for existing benefits, or settle for fewer benefits. Because these private insurance

plans represent such an important benefit for our members, these pressures have become key stumbling blocks during collective bargaining.

10. In fact, this problem has become so intractable that it has been an important cause of several recent strikes, including the following:

- Local 333.15 – 120 workers at Wood Wyant (Cascades), Pickering, Ontario were on strike for 2 months in spring 2003, refusing a system of co-payments and caps for health benefits.
- Local 789 – 300 workers at Domtar, Vancouver, were on strike for 2 1/2 months early 2004, the major issue being the rejection of cost-sharing concessions on health benefits.
- Locals 401, 410, 506 – Aliant, Atlantic provinces, 3,200 Aliant workers on strike for 4 months to August 2004, one issue being drug benefits, and obtained a cap on annual costs for workers of $400.
- Local 1129 – 100 workers continue their strike against Norampac in B.C., begun in April 2004, in part a struggle against employer demands to increase worker contributions to health benefits. (See separate sheet)

11. I know from our own research, and from discussions with fellow officers in other unions, that the problems CEP is encountering in trying to secure adequate health benefits for our members are endemic to collective bargaining right across the public and private sectors.

12. In order to deal with this problem in a systemic way, our Union and others have worked with the Canadian Health Coalition to propose an expansion of the public health care system to include universal coverage for necessary prescription drugs. Much of the research and analytical work that informed this initiative was undertaken by the CEP research department. I understand that a copy of our collective proposal: *More for Less, A National Pharmacare Strategy*, is attached to the affidavit of Mike McBane, the National Coordinator of the Canadian Health Coalition, which Affidavit has been sworn and will be filed in this matter. Attached this affidavit as Exhibit "A" is my letter and a fact sheet concerning this initiative which was sent to all CEP locals.

13. A key component of our proposal calls for a tightening and better enforcement of current controls on the promotional activities of the drug companies including direct to consumer advertising. Conversely, any relaxation of existing controls will only increase costs and further exacerbate current problems of negotiating adequate health care insurance coverage for our members.

14. For these reasons, CEP has a genuine and substantial interest in the outcome of this case and seeks to intervene in order to assist the Court with respect to issues concerning the impact of increasing drug use and costs on labour management relations.

15. I make this affidavit in support of an application to intervene in this case and for no other or improper purpose.

AFFIRMED BEFORE ME at the City of Ottawa, in the Province of Ontario on August 2, 2006.

Commissioner for Taking Affidavits

BRIAN PAYNE

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This is Exhibit "B" referred to in the
affidavit of Jean Belleville
sworn before me, this 3rd
day of May 2007

A COMMISSIONER, ETC.

Direct-to-consumer advertising and expenditures on prescription drugs: a comparison of experiences in the United States and Canada

STEVEN G. MORGAN

Steven G. Morgan, PhD, is Assistant Professor, Health Care and Epidemiology, and Research Lead, Program in Pharmaceutical Policy, Centre for Health Services and Policy Research, University of British Columbia, Vancouver, BC

Competing interests: None declared.

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OVER THE PAST QUARTER-CENTURY, PRESCRIPTION drug manufacturers in the United States have increasingly invested in direct-to-consumer advertising (DTCA) designed to build brand recognition and to foster patients' belief in the quality of their products. Policy-makers in Canada, where limited DTCA is permitted, and in countries that do not permit DTCA are under increasing pressure to allow such marketing activities. In this article I will review recent trends in DTCA and expenditures on prescription drugs in the United States to illustrate the significant impact that brand-oriented, consumer-targeted marketing activities could have on the Canadian health care system.

There are essentially 3 types of DTCA. The first type consists of disease-awareness advertisements, which provide information about a medical condition and encourage people to talk to their physician about available treatments. Such advertisements are permitted in both Canada and the United States. The second type of DTCA consists of reminder advertisements, which may state the name of a product and may provide information about strength, dosage, form and price but may not mention the product's indication or make claims about effectiveness. With relatively few exceptions, reminder advertisements are also permitted in both countries. Product-claim advertisements are the third type of DTCA. These advertisements combine the brand name with claims about indication and effectiveness. This form of DTCA is permitted in the United States but not in Canada.

For-profit pharmaceutical manufacturers invest in DTCA to generate profits.[1] Product-claim advertising is important to manufacturers because it allows them to associate claims with their particular brands. Disease-awareness advertising, in contrast, may prompt consumers to talk to their physicians about treatment but may not result in an expression of brand preferences. The distinction between these 2 types of DTCA is important because, as with other types of products, the ability to build brand loyalty is a potentially valuable means by which drug manufacturers can increase market share.[2] Competing firms may capture some of the demand induced by brand-specific advertisements, but the intent of investing in the advertisements is unquestionably to generate a financial return.[3]

The first US product-claim DTCA was a series of print campaigns that began in 1982 and 1983.[4,5] Among the first products advertised (in outlets such as Readers Digest and the Washington Post) were Oraflex (benoxaprofen), Pneumovax (pneumococcal vaccine) and Zovirax (acyclovir). These DTCA advertisements were permitted under US law provided that product labelling information was presented with the advertisement. (This is similar to the requirement for medical journals to publish the product monograph for prescription drugs advertised in their pages.) Shortly after the first product-claim advertisements were launched, the US Food and Drug Administration (FDA) asked the pharmaceutical industry for a voluntary moratorium while consultations on DTCA took place. Limited DTCA occurred during the moratorium, which was lifted in September 1985.[5] It is estimated that, by 1987, firms were spending US$35 million annually on DTCA in the United States.[4]

US law permitted broadcast product-claim advertisements that contained information about major side effects and contraindications (the "major statement") and a brief summary of product labelling information, or that contained the major statement and made "adequate provision" to give consumers detailed labelling information in

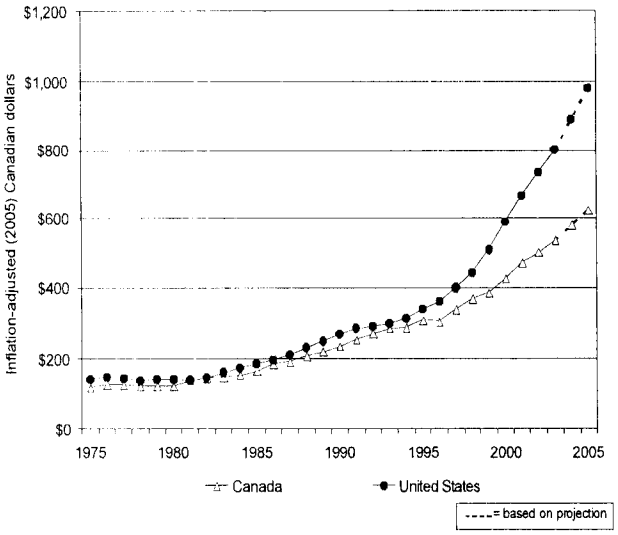

Fig. 1: Per capita expenditure on prescription drugs in the United States and Canada, 1975-2005. The source of the prescription drug expenditure data is *OECD Health Data 2005* www.oecd.org/health/healthdata. Data for 2004 and 2005 are projections of the trend from 2000 to 2003. Currencies were converted using GDP purchasing-power parity values from *OECD Health Data 2005* www.oecd.org/health/healthdata. Inflation adjustment was conducted using the Statistics Canada Consumer Price Index, All Items, http://cansim2.statcan.ca/

connection with the broadcast advertisement.[6] Use of broadcast product-claim advertising was limited in the early days of DTCA. However, DTCA spending accelerated in the mid-1990s as manufacturers began to use television reminder advertisements to reinforce product-claim advertisements placed in other media.[5] Spending on DTCA reached US$380 million in 1995 and more than doubled to US$790 million in 1996.

Then, in August 1997, the FDA introduced new guidelines about what constituted adequate provision for labelling information with broadcast DTCA.[6] In addition to the requirement to include a major statement about risk, the advertisement would have to refer consumers to 4 sources for further information: a toll-free telephone service, concurrently running print advertisements or brochures, the consumer's health care provider and a Web site.[6] Spending on DTCA grew at a rapid pace after the publication of these guidelines, with increasing emphasis on broadcast advertising. In 2005, firms spent an estimated US$4.24 billion on DTCA — 11 times the amount spent in 1995.

From 1996 to 2004, DTCA grew from 9% to 16% of total expenditures on pharmaceutical promotion, including the retail value of professional samples.[7–9] Excluding professional samples, DTCA grew from 19% of expenditures on pharmaceutical promotion in 1996 to 37% in 2005.[8] If promotional spending by target continues to grow at the rates seen from 1996 to 2005, consumer-targeted promotional expenditures will exceed professional-targeted expenditures in 2011.

It is important to note, however, that DTCA is not a substitute for promotions that target health professionals. For a DTCA campaign to be successful, the advertiser must also invest in complementary marketing activities targeted at professionals.[5,10,11] Professional detailing ensures that prescribers are prepared for DTCA-induced patient visits (so that the prescriber–manufacturer relationship is not strained by such visits), and increased distribution of samples ensures that prescribers have the advertised product at hand (so that competing firms do not benefit excessively from DTCA-induced demand). It is therefore not surprising that while DTCA expenditures in the United States increased by 408% from 1996 to 2004, spending on sales representative contacts and drug samples increased 144% and 224% respectively in the same period.

As mentioned earlier, DTCA and other promotions are intended to increase sales of advertised brands. On the basis of an analysis of 49 brands that were the subject of DTCA between 1998 and 2003, IMS Management Consulting concluded that the return on investment from DTCA is "nearly unprecedented in terms of the positive sales response generated."[10] DTCA can also affect sales of competing products positively or negatively. An estimate of the overall impact of DTCA on prescription drug expenditures in North America can be obtained by considering US and Canadian expenditure levels before and after the increase in US DTCA. If DTCA has had a significant impact on total prescription drug expenditures in the United States, then it is expected that the difference between expenditure levels in the United States and Canada will have changed.

Figure 1 illustrates inflation-adjusted per capita expenditures on prescription drugs in the United States and Canada from 1975 to 2005. This figure, which takes general inflation and population growth into consideration, shows that the past decade was one of particularly rapid growth in prescription drug expenditures in both countries. Inflation-adjusted prescription drug expenditures per capita doubled in Canada from 1995 to 2005 and increased even more rapidly in the United States.

The difference in per capita expenditures on prescription drugs in the United States and Canada began to increase at almost exactly the same time that DTCA began to flourish in the United States (Fig. 2). From 1975 to 1994, the difference in inflation-adjusted expenditures on prescription drugs between the United States and Canada was never more than $36 per capita (measured in year 2005 Canadian dollars). Over the same period,

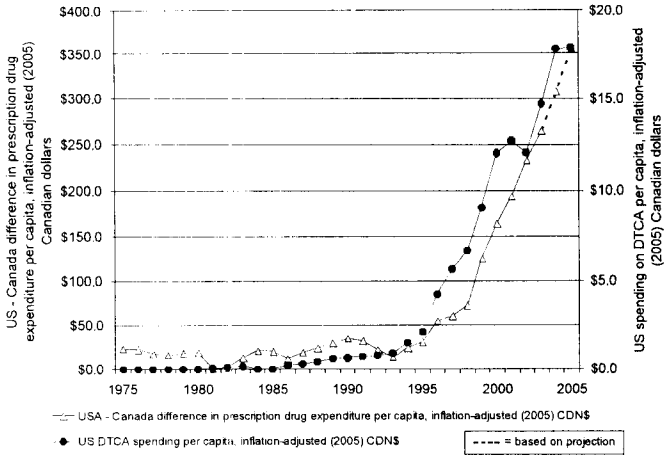

Fig. 2: US spending on direct-to-consumer advertising (DTCA) and the United States-Canada difference in per capita expenditures on prescription drugs, 1975-2005. DTCA data for 1996 2005 are from IMS Health, Total US Promotional Spend by Type (various years), collected from 2000 through 2006, http://www.imshealth.com/. DTCA data for 1993-1999 are from IMS Health as quoted in: Findlay S. Direct-to-consumer promotion of prescription drugs: economic implications for patients, payers and providers. *Pharmacoeconomics* 2001;19(2):109-19. DTCA data for 1987-1989 are from: Masson A. Direct-to-consumer advertising: a continuing controversy. In: Meyer RN, editor. *Enhancing Consumer Choice: Proceedings of the Second International Conference on Research in the Consumer Interest*; 1990 Aug 9-11; Snowbird (UT). Ames (IA): American Council on Consumer Interests; 1991. p. 159-68. DTCA data for 1990-1992 are based on an interpolation of growth between 1989 and 1993. DTCA data for 1981-1986 are based on an interpolation of growth between 1980 and 1987, with expenditures for 1994 set to zero (moratorium year). The prescription drug expenditure data are from *OECD Health Data 2005* www.oecd.org/health/healthdata. Data for 2004 and 2005 are projections of the trend from 2000 to 2003. Currencies were converted using GDP purchasing power parity values from *OECD Health Data 2005*. Inflation adjustment was conducted using the Statistics Canada Consumer Price Index, All Items http://cansim2.statcan.ca/.

spending on DTCA in the United States was never more than $2 per capita (year 2005 Canadian dollars). Inflation-adjusted per capita spending on DTCA in the United States grew from just over $2 in 1995 to just under $18 in 2005 (year 2005 Canadian dollars). Over the same period, the difference in inflation-adjusted per capita expenditures on prescription drugs between the 2 countries grew from approximately $31 to approximately $356 (year 2005 Canadian dollars).

Some have suggested that the recent growth in pharmaceutical expenditures in the United States has been driven in part by the fact that the proportion of pharmaceutical purchases paid for out of pocket is falling.[12] However, out-of-pocket spending has represented a steadily declining share of US expenditures on prescription drugs since 1960, with the most rapid decline occurring between 1989 and 1996, before the major changes illustrated in Figure 2 (data provided in the appendices).

That the difference in prescription drug expenditures per capita between Canada and the United States would start to rise in the mid-1990s in apparent lockstep with the new phenomenon of spending on DTCA in the United States, after 20 years of relative stasis, would be a rather remarkable coincidence. There have been no other policy, demographic or economic changes that could explain the direction, magnitude and timing of the recent divergence between the 2 countries' per capita expenditures on prescription drugs.

The recent divergence in per capita expenditures between Canada and the United States gives an indication of the potential impact of increased DTCA in Canada and possibly of the introduction of DTCA in countries where it is currently not permitted. If, over the last decade, Canada had followed a path of DTCA similar to that taken by the United States and if per capita expenditures on prescription drugs had risen as much in Canada as they have in the United States, Canadian expenditures on prescription drugs would be approximately $10 billion higher per year than they currently are. This amount would be sufficient to pay annual salaries of $250,000 to 40,000 physicians.

The DTCA-associated increased spending on prescription drugs may be of value if it is on treatments that are appropriate and cost-effective. However, after reviewing studies published to 2004, Gilbody and colleagues concluded that, while DTCA is associated with increased requests for and use of advertised products, no health benefits have been established.[13] A more recent study involving standardized patients randomly assigned to make no request, brand-specific requests or general requests for treatment of adjustment disorder or major depression found that general and brand-specific requests resulted in better quality of care (defined as receiving some form of treatment for their condition).[14] Not surprisingly, patients who request a specific brand are more likely to receive that specific brand rather than available alternatives.[14]

It is certainly desirable to make better use of prescription drugs in Canada, although doing so may result in increased pharmaceutical expenditures. However, to promote safe, effective and efficient medicine use, policymakers would be well advised to maintain and enhance restrictions on product-claim (brand-specific) DTCA, because such advertisements are designed to instil product preferences in people who often do not have the information, training or incentive to compare the risks, benefits and costs of the available treatment options.

If, owing to a lack of economic incentive for non-branded advertising, manufacturers fail to promote awareness of conditions that are critical to the health of

the population, the appropriate public policy response would be to invest in publicly sponsored campaigns to promote better use of prescription drugs, not to relax restrictions on product-claim DTCA and thereby give manufacturers the opportunity to instil brand preferences in patients. The potential impact of product-claim DTCA on the Canadian health system is simply too large to accept such advertising before other ways to promote better use of prescription drugs have been thoroughly explored.

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Appendices: see following pages

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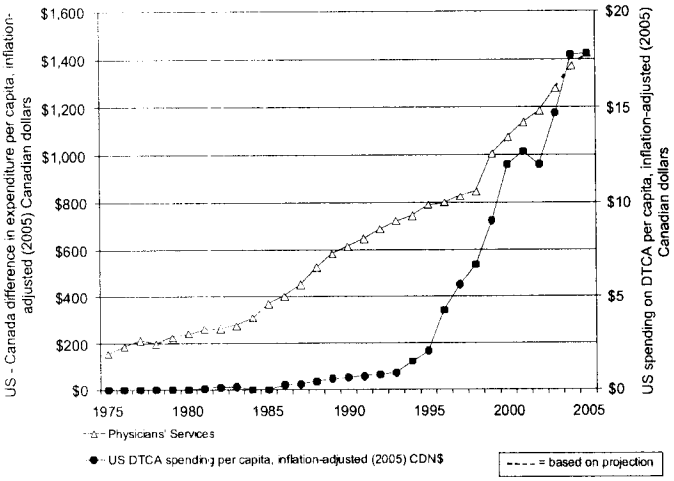
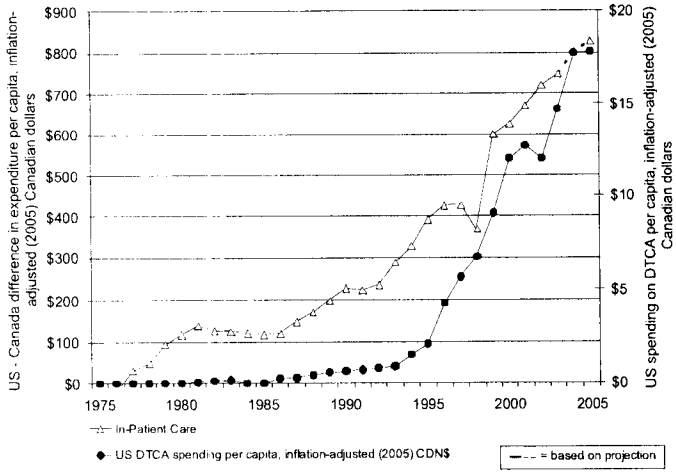
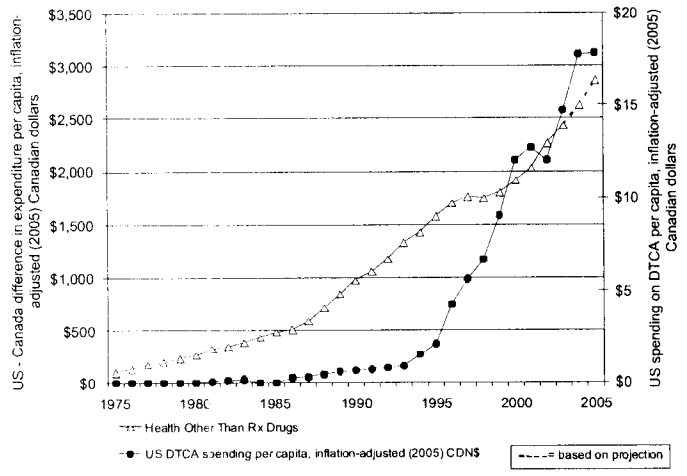
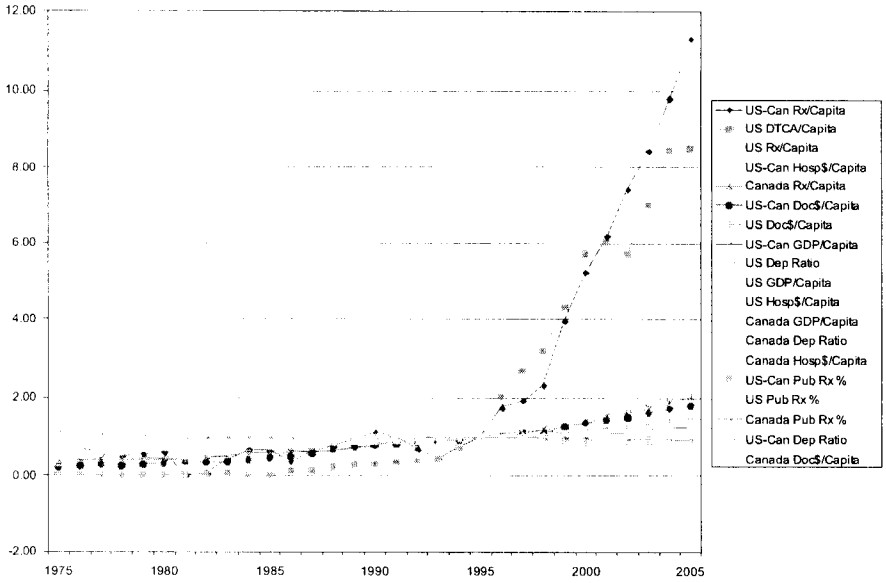
Appendices







Appendix 1: United States-Canada differences in inflation-adjusted per capita expenditures on in-patient care, physicians' services and all non-pharmaceutical spending.



Appendix 2: **Indexes of various economic variables in Canada and the United States.**
1995 value = 1.00
Rx/Capita = per capita expenditures on prescription drugs, year 2005 Canadian dollars.
Doc$/Capita = per capita expenditures on physician services, year 2005 Canadian dollars.
Hosp/Capita = per capita expenditures on in-patient care, year 2005 Canadian dollars.
GDP/Capita = per capita gross domestic product, year 2005 Canadian dollars.
Dep Ratio = economic dependency ratio (share of total population that is either under 20 or over 65 years of age).
Pub Rx % = percentage of total prescription drug expenditures paid for by public drug plans.
The source of the prescription drug expenditure data is *OECD Health Data 2005* www.oecd.org/health/healthdata.
Inflation adjustment was conducted using the Statistics Canada Consumer Price Index, All Items, http://cansim2.statcan.ca/

Estimates of autoregressive parameters

Lag	Coefficient	Standard error	t Value
1	-0.559711	0.159481	-3.51

Algorithm converged.

Maximum likelihood estimates

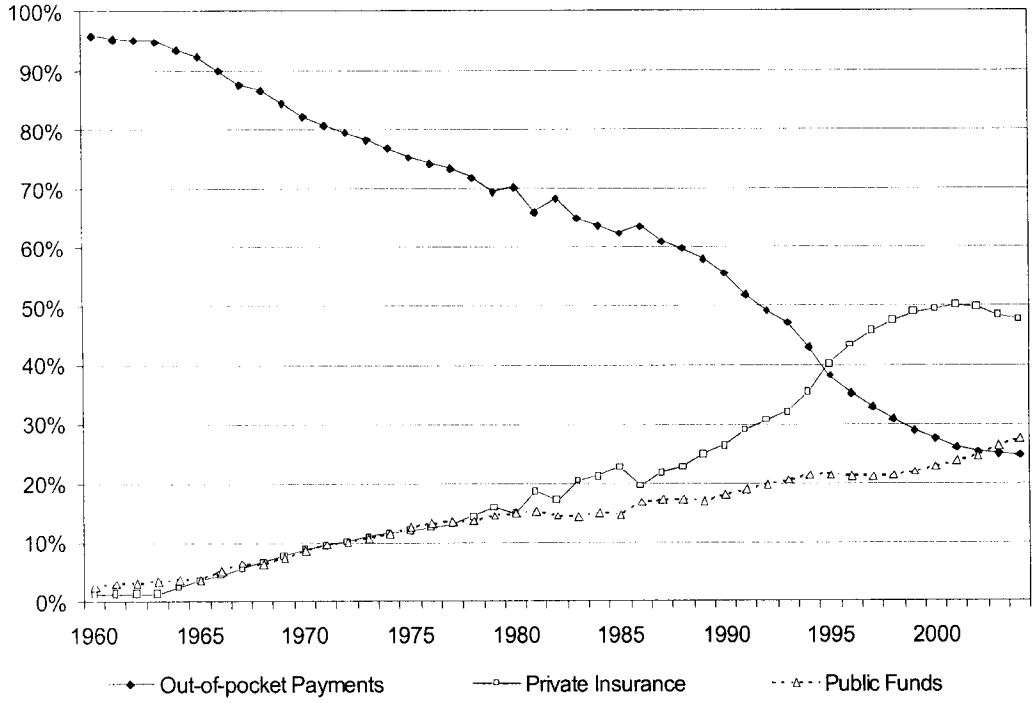
SSE	6207.5923	DFE	27
MSE	229.91083	Root MSE	15.16281
SBC	267.929421	AIC	262.193472
Regress R-Square	0.6764	Total R-Square	0.9782
Durbin-Watson	1.2474		

Variable	DF	Estimate	Standard error	t Value	Approx Pr > |t|	Variable Label
Intercept	1	-4.5633	47.1262	-0.10	0.9236	
Time	1	3.2844	3.3346	0.98	0.3334	Time
DTCA	1	12.4715	2.7250	4.58	<.0001	DTCA
AR1	1	-0.9249	0.1217	-7.60	<.0001	

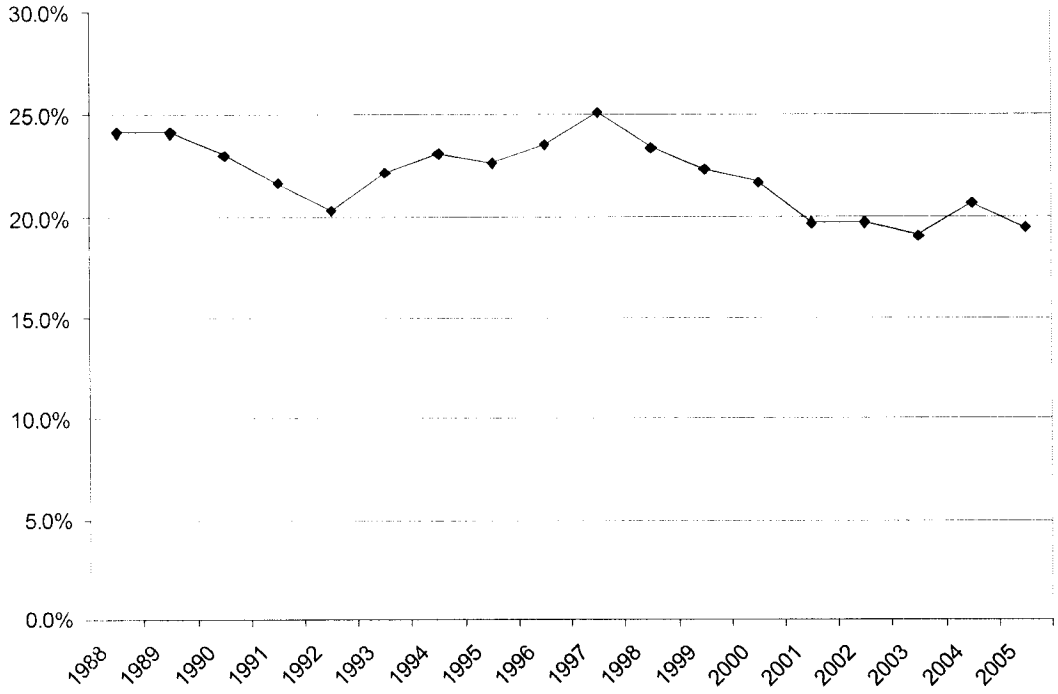
Autoregressive parameters assumed given.

Variable	DF	Estimate	Standard error	t Value	Approx Pr > |t|	Variable Label
Intercept	1	-4.5633	40.1711	-0.11	0.9104	
Time	1	3.2844	2.3775	1.38	0.1785	Time
DTCA	1	12.4715	2.7160	4.59	<.0001	DTCA

Appendix 3: Linear regression model results.



Appendix 4: **Shares of US pharmaceutical expenditures by source of funds.**
Data source: US Department of Health and Human Services. *National health expenditures by type of service and source of funds, CY 1960-2004.* Available: www.cms.hhs.gov/NationalHealthExpendData/02_NationalHealthAccountsHistorical.asp#TopOfPage (accessed 2006 Oct 30).



Appendix 5: **Out-of-pocket payments as a percentage of Canadian prescription drug expenditures.**
Data source: Canadian Institute for Health Information. Drug expenditures in Canada.
Available: www.cihi.ca/cihiweb/dispPage.jsp?cw_page=AR_80_E (accessed 2006 Oct 30).