05-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 STEVEN G. MORGAN

I, **STEVEN G. MORGAN**, of the City of Vancouver, in the Province of British Columbia, **MAKE OATH AND SAY**:

1. I have been researching economic aspects of the pharmaceutical sector for over 10 years. I am Assistant Professor at the Centre for Health Services and Policy Research (CHSPR) at the University of British Columbia, where I am a managing member of CHSPR faculty and Research Lead for the Program in Pharmaceutical Policy. I currently hold two prestigious fellowships for excellence in health care policy research: a Scholar Award from the Michael Smith Foundation for Health Research and a New Investigator Award from the Canadian Institutes of Health Research. I obtained a BA(Hons) in economics at the University of Western Ontario, an MA in economics at Queen's University at Kingston, and a PhD in economics at the University of British Columbia. I then conducted post-doctoral training in health economics and health care policy at CHSPR and at the Centre for Health Economics and Policy Analysis at McMaster University.

2. My research focuses on the determinants of pharmaceutical expenditure, pharmaceutical and health care financing, economic aspects of drug advertising, and strategies to promote evidence-based policy and practice in health care. I have published, or have in press, 47 academic papers, 29 of which are peer-reviewed (the most scholarly form of publication). The journals in which I have published work on prescription drug expenditures, financing, and advertising are among the top health policy and economics journals. I have also published 35 non-refereed papers, including 14 reports to federal and provincial governments. Among the reports to government that I have written are a report on pharmaceutical policy for the National Forum on Health[1], and a report on the determinants of health expenditures for the (Romanow) Commission on the Future of Health Care in Canada)[2]. I recently published 2 first-of-their-kind reports on the trends and determinants of pharmaceutical expenditure in Canada (2005; The Canadian Rx Atlas, and The British Columbia Rx Atlas).

3. I am considered one of Canada's leading authorities in pharmaceutical policy and economics. I believe I have particular expertise with regard to the causes and consequences of pharmaceutical expenditure trends over time and variations across regions. I am routinely called upon to offer expert analysis and advice for government and government agencies (such as the Canadian Institute for Health Information and the Patented Medicine Prices Review Board). I have also been an invited speaker for a US Congressional Staff Briefing on lessons that the US can draw from pharmaceutical policies in Canada, the UK, New Zealand, and Australia.

4. My work has been judged to be of high scientific merit and policy relevance and has consequently been supported by peer-reviewed funding from public granting agencies, including the Canadian Institutes of Health Research and the Michael Smith Foundation for Health Research. I have also been appointed to peer review committees of national and provincial agencies that fund health care research, and was

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[1] Morgan SG. Issues for Pharmaceutical Policy. In: Canada Health Action: Building on the Legacy. Papers Commissioned by the National Forum on Health, Volume 4, Striking a balance, health care systems in Canada and elsewhere. Sainte-Foy, Québec: Éditions MultiMondes; 1998

[2] Morgan SG, Hurley J. Influences on the Health Care Technology Cost Driver. Discussion Paper #14. Saskatoon: Commission on the Future of Health Care in Canada; 2002; February 2002.

recently elected by my peers to serve on the board of directors of the Canadian Association for Health Services and Policy Research. Attached as "**Exhibit 1**" to this affidavit is a copy of my curriculum vitae.

INTRODUCTION

5. The purpose of this affidavit is to provide my opinion, as a health economist trained in health economics and industrial organization, on issues related to the economic effects of direct-to-consumer advertising (DTCA) of prescription drugs in the context of the Canadian health care system and economy.

6. Prescription drugs now play a prominent role in health care. They are used to ameliorate suffering, foster healing, and prevent illness. How drugs are prescribed by doctors and used by patients directly affects safety, effectiveness, and cost. Research indicates that promotional activities of pharmaceutical manufacturers can be one of the most powerful influences on prescribing and patient demand. These activities therefore have a significant impact on public health and the economic sustainability of the health care system.

7. In this affidavit I will describe the economic aspects of pharmaceuticals and the pharmaceutical industry with particular attention to the unique characteristics of pharmaceuticals (prescription drugs in particular) and of the pharmaceutical industry in North America and Canada in particular that render this sector of the economy "imperfect" from the perspective of microeconomic theory.

8. I then provide data on the level, nature and sources of financing of expenditures on prescription drugs as well as data on other components of health care in Canada. The detailed information generated through my research on recent trends in drug spending in Canada is provided, along with information about trends in the US and other OECD countries. I also provide statistical information regarding research and marketing investments by pharmaceutical manufacturers, including current and historical data on investment in direct to consumer advertising of prescription drugs.

9. After reviewing market characteristics and statistics, I summarize findings of a systematic review of the literature on the association of direct to consumer advertising of prescription drugs with changes in numbers of patient visits to physicians; total volume of prescriptions written; market share for advertised drugs; prescription drug prices; prescription drug expenditure; and expenditure on other healthcare services such as diagnostic testing.

10. After summarizing available research evidence, I describe the predicted financial impacts of direct to consumer advertising of prescription drugs that follow from economic theory. Finally, I provide estimates of the impact of direct to consumer advertising of prescription drugs on prescription drug costs in the US where DTCA is permitted. I also provide estimates of the potential financial impact for Canada.

PART I – ECONOMIC ASPECTS OF PHARMACEUTICALS AND THE PHARMACEUTICAL INDUSTRY

11. Economically efficient allocations of resources arise from free market transactions when there is full information, standard financial incentives, and perfect competition. However, the presence of one or more market imperfections (such as imperfect information, non-standard financial incentives, or imperfect competition) will imply that free market transactions will no longer guarantee efficient allocation of resources. The widely accepted economic theory of the "second best"[3] states that, given one or more market imperfections, social welfare can be improved by introducing further market imperfections (e.g., regulations). The pharmaceutical sector is characterized by a number of market imperfections, some of which are natural due to the characteristics of the products created and the technologies used to create them, other market imperfections are created by policy.

[3] Lipsey RG, Lancaster K. The General Theory of Second Best. Review of Economic Studies 1957;24(1):11-32.

A. PHARMACEUTICALS

12. There are several characteristics of pharmaceuticals that distinguish them from ordinary commodities. Foremost among these differences is that drugs are "inputs" used to achieve better health, not end products in and of themselves. Because the use of medicines involves costs, inconvenience, and risk of adverse events, healthy individuals should not choose to consume prescription drugs. Those who would knowingly purchase medicines in the absence of medical need are likely to be suffering from one of several disorders: including, for example, Munchausen's syndrome (a disorder wherein patients pretend to have illnesses in order to obtain medical care), hypochondria (a disorder wherein patients believe that they have symptoms of serious disorders despite medical reassurance and evidence to the contrary), or addiction (a disorder wherein patients have become psychologically or physically dependent on the medicine). As the esteemed health economist Robert Evans puts it "those who would purchase health care when they are not sick, are sick".[4] For the balance of the population, prescription drugs are a component of overall health care to be used with caution and due diligence in an effort to maintain or improve health status.

13. The second important distinction between prescription drugs and ordinary consumer goods is that those in medical need would desire treatment only if the expected improvement in health status from taking the medicine outweighs the associated risks, and if the balance of risks and benefits are superior to the use of alternative treatments, including non-drug treatments. This has direct implications for economic efficiency. For, a necessary though not sufficient requirement for efficient allocation of resources is that they not be wasted in the production of desired outcomes. Paying for health care, including pharmaceuticals, that does not improve health would be wasteful and therefore inefficient. Similarly, paying more for a treatment that produces the same outcome as a lower-cost alternative would also be economically inefficient.

14. It follows, then, that evaluation, according to acceptable scientific standards, of the needs for as well as the benefits, risks, and alternative options to

[4] Evans RG. Strained mercy: the economics of Canadian health care. Toronto: Butterworths; 1984.

prescription drugs is essential to economic efficiency in this sector. Given the population exposure to medicines, this fact cannot be ignored. Roughly two out of three Canadians will fill at least one prescription this year. Many will live longer and/or better as a result. However, no drug is perfectly safe or of value under all circumstances. Adverse drug reactions occur often and have been estimated to be between the fourth or sixth leading cause of death.[5]

15. Evaluating the benefits and risks of medicines, in comparison to alternative drug and non-drug treatments, is a considerably challenging task. It is not something that can be done by trial and error. A person who feels better or worse after drug consumption cannot know with certainty whether nature, placebo, or the drug was responsible for their resulting health improvement or deterioration. Indeed, it is often the case that the patient's physician will be equally uncertain. To know, with reasonable scientific certainty, whether a drug is comparatively safe and effective requires that thousands of patients be randomly assigned to various options, typically under circumstances where both patients and providers are unaware of which treatment is being administered. Moreover, for the majority of drugs now sold in Canada, determining the impact on the health of the patient requires long periods of follow-up. Elsewhere, I have summarized this challenge as follows:

> "In the case of preventative, long-term therapies, years pass before the outcomes are realized from which individual patients are to infer product quality. The task, for an individual, borders on impossible. For example, a drug to prevent heart attacks might lead to 5 in 100 people experiencing a heart attack over a five-year period rather than 7 in 100 without drug treatment. This drug may be wondrously effective by clinical standards; but how many of 100 potential patients could verify an implied advertising message that the product would prevent their heart attack?"[6]

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[5] Lazarou J, Pomeranz BH, Corey PN. Incidence of Adverse Drug Reactions in Hospitalized Patients: A Meta-analysis of Prospective Studies. JAMA 1998;279(15):1200-1205; Tam VC, Knowles SR, Cornish PL, Fine N, Marchesano R, Etchells EE. Frequency, type and clinical importance of medication history errors at admission to hospital: a systematic review. CMAJ 2005;173(5):510-515.

[6] Morgan SG, Mintzes B, Barer M. The economics of direct-to-consumer advertising of prescription-only drugs: prescribed to improve consumer welfare? Journal of Health Services Research and Policy 2003;8(4):237.

16. As reflected in their status as prescription-only drugs, virtually all prescription drugs satisfy one or more of the following: they are indicated for the treatment of medical conditions requiring professional diagnosis and monitoring, they contain the risk of a range of negative outcomes including serious adverse reactions, or they may become addictive or habit forming. Thus, it is important to carefully assess a patient's need for treatment and capacity to benefit as well as assess the available drugs' ability to address the patient's needs. It should be noted, in particular, that those drugs that address simple and easily identified conditions and that do not come with significant risks to patients are typically available without a prescription and are therefore not subject to regulations governing the promotion and sale of prescription-only drugs.

17. It has been argued that, because medicines can have complex effects on biological systems, and because they are licensed for sale based on controlled clinical trials that are relatively short in duration and involve study subjects (e.g., volunteer patients) that are generally younger and healthier than those who receive prescriptions in "real world" clinical settings, the true balance of risks and benefits related to prescription drugs must be determined through a combination of pre-market evaluation and rigorous post-market study as well.[7] Increased attention to adverse drug reporting systems and recent high profile drug withdrawals illustrate the importance of measuring the benefits and risks of medicines and carefully managing their use based on best available evidence of benefits, risks and costs.

18. An important implication of the fact that prescription drugs are of value only for their impact on patients is that "more" is not necessarily "better" when it comes to prescription drugs. Simply increasing consumption of medicines (at an individual or population-level) will not necessarily result in better outcomes. Other things being equal, increased consumption may be necessary for producers to increase sales but it is neither necessary nor sufficient for improving the health of patients or of the population. For both individuals and populations, economically efficient use of pharmaceutical therapy

[7] Laupacis A, Paterson JM, Mamdani M, Rostom A, Anderson GM. Gaps in the evaluation and monitoring of new pharmaceuticals: proposal for a different approach. Canadian Medical Association Journal 2003;169(11):1167-70.

requires that the right drug gets to the right patient at the right time and the right price. Achieving such an allocation requires scientific evidence, expert appraisal, and professional judgement. While patient preferences over the possible effects of medicines are important considerations, guiding drug utilization by preferences over the medicines themselves, or even over unsubstantiated hopes and expectations, would not ensure safe and effective use and therefore not ensure economic efficiency in the pharmaceutical sector. Given pharmaceutical's role within and reliance on the health care system, economic inefficiency in the pharmaceutical sector would likely translate to inefficiency within the health care system.

B. THE PHARMACEUTICAL INDUSTRY

19. There are several features of the pharmaceutical industry that render it distinct from conventional markets. Among the "market imperfections" in the pharmaceutical industry are economies of scale in the discovery and production of drugs, legal monopolies, in the form of patents, granted over new discoveries, and non-standard financial incentives of both patients and prescribers (typically doctors, but sometimes nurses or pharmacists).

20. Economies of scale: The pharmaceutical industry is characterized by economies of scale in basic research, product development, and manufacturing. These activities require significant fixed costs in highly specialized equipment, as well as highly trained personnel. Such fixed costs of specialized capacity create barriers to market entry: would-be competitors are not simply free to enter any given drug market in order to compete and drive prices down, as is required for perfect competition to be realized.

21. Fixed costs render advantages to larger firms. The costs of entering the pharmaceutical industry virtually necessitate global corporations because it would simply not be viable to research, develop, and manufacture a product to serve any one national market. The world's largest 10 pharmaceutical manufacturers in 2005 all had revenues exceeding US$14 billion in 2005; their combined 2005 revenues were over US$230 billion: 38.21% of the world market. Pfizer, the world's largest pharmaceutical company,

had sales of approximately US$44.28 billion in 2005: 7.36% of the world market[8] Concentration of revenues in the industry is slightly higher in Canada. In 2005, the 10 largest Canadian pharmaceutical manufacturers each had Canadian sales of over $570 million; their combined 2005 Canadian revenues were $9.33 billion: 56.32% of the Canadian market (measured at ex-manufacturer sales).[9] Pfizer's Canadian sales for 2005 were $2.248 billion: %13.6 of the Canadian market.

22. Smaller pharmaceutical companies do exist, typically serving therapeutic markets in which they have particular technical expertise. However, because the start-up costs for the pharmaceutical sector are measured in tens or hundreds of millions of dollars (not tens or hundreds of thousands), even "small" pharmaceutical companies are relatively large in comparison to niche competitors in most other economic sectors. Moreover, for most "start-up" pharmaceutical and bio-technological companies, the path to success will eventually involve being acquired by a larger company that will take the start-up's promising technology through the stages of product development, manufacturing and sales.

23. Legally protected monopolies: In the drug research and development process, hundreds of potential drugs are identified and tested, most of which are screened out due to toxicity, lack of efficacy, or both. By the time a drug comes to the market, it represents a heavy investment, not only in its own development, but also in prospects that failed and in the years of clinical trials and research necessary to obtain regulatory approval for sale. Hundreds of millions of dollars are "sunk" in order to develop a successful product. Much, though not all, of this investment is made by companies who seek to obtain a return on their investment. To recoup the massive, fixed costs of research investment, two things must happen: first, the product must sell for more than it cost to

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[8] Pharmaceutical Executive. Pharm Exec 50: The World's Top 50 Pharmaceutical Companies. Pharmaceutical Executive 2006:77-88.

[9] IMS Canada. Prescription drug purchases by Canadian hospitals and pharmacies reach $16.57 billion in 2005. 2006 [cited 2006 March 30]; Available from: http://www.imshealthcanada.com/htmen/4_2_1_66.htm

produce and, second, enough of the drug must be sold to recoup the investment. Unless the first requirement is satisfied, the second will never be reached. If a product is not priced at a premium over production costs, fixed costs cannot be recouped.

24. To make it possible for innovators to charge a premium over manufacturing costs, which is necessary to recoup research investment, countries grant temporary monopolies on the technology through patents. If patents were not granted other firms could simply imitate the innovator's product and begin selling at production costs as these competitive firms have research investment costs to recover. Patents are granted for 20 years and are typically received while a drug is still in pre-market clinical testing. From the time a product is approved for sale until its patent expires, the patent-holding firm has no direct competition. This allows firms approximately 10 to 15 years of monopoly before competitors can bid the price down. During this period, the patent-holder will charge the highest price the market will bear at the targeted sales level. This occurs not only in the country where the drug was discovered, but also in every country where the manufacturer can patent and market it.

25. For the patent system to provide incentives for efficient innovation (incentive to search for valued technologies and to do so in cost-effective ways), the patent holding firm must obtain a reward only in proportion to the value of the end product, not the cost of the research in the first place. This is because patents are "forward looking" instruments: at any given point in time, a patent is granted not to reward past research but to provide incentive for would-be investors in future research. If the incentive for research is proportional to the social value of the end product, then firms will typically invest only in research likely to result in valued technologies. Of course, if an end product is of no value to society, no rewards should be conferred upon the investor, regardless of how costly the research investment: for, research investments sometimes fail. Similarly, if an end product is of dramatic value to society, its reward should be dramatic, even if the cost of developing the technology was minimal: research investments sometimes pay significant returns.

26. Efficiency of innovation stimulated through a patent system therefore requires that the market reward patented products (through price and volume of use) only in proportion to social value. The social value of a prescription drug, as discussed above, will be proportionate to its impact on the health of patients, relative to all available treatment alternatives. As patients are unable to determine the value of the pharmaceutical product (for reasons outlined above) policy or regulatory intervention may be necessary to ensure that the price and volume of drug use is indeed proportionate to relative health benefits. In addition to the challenges establishing the proven value of a product for a particular patient, a unique demand-side market imperfection in the prescription drug sector relates to the financial incentives of purchasers (patients) and their agents (prescribing physicians).

27. Financial incentives of patients and prescribers: Many patients lack a standard financial incentive to carefully consider price when making drug purchases because public or private insurance covers the cost. When people do not pay for something, they tend to consume more of it than would be considered economically efficient, a phenomenon known as "moral hazard" in economics. In health care, the moral hazard caused by insurance will not be to simply induce demand for care (as mentioned above, the only people who would demand health care when they are not sick are, in fact, sick). Moral hazard in health does, however, imply that insured individuals will not be sensitive to differences in the cost of alternative approaches to dealing with their medical conditions. This statement of fact is not meant to imply that patients should bear the costs of drugs prescribed, for there is ample of evidence to show that patients respond to out-of-pocket charges for pharmaceuticals in ways that lead to adverse health consequences and increased total health care costs.[10] It is simply important to note that many consumers in this market will not be price sensitive because they do not face the entire costs of their medicines.

[10] Soumerai SB, Ross-Degnan D, Fortess EE, Abelson J. A critical analysis of studies of state drug reimbursement policies: research in need of discipline. Milbank Quarterly 1993;71(2):217-252; Tamblyn R, Laprise R, Hanley JA, Abrahamowicz M, Scott S, Mayo 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.

28. Similarly, virtually no prescribing physicians (in Canada) have financial incentive to carefully consider price when making prescribing decisions because physicians bear none of the cost of the drugs they prescribe. Indeed, research surveys have consistently shown that relatively few prescribers have adequate knowledge of the relative cost of commonly prescribed drugs.[11]

29. The lack of price sensitivity among prescribers and patients can result in inefficient product selection decisions. For, if neither the patient nor prescriber is affected by the relative cost of alternatives, neither would have incentive to choose the lower cost option among two drug alternatives that produce equivalent health outcomes. It has long been acknowledged that in the Canadian pharmaceutical industry this lack of price sensitivity has generated the unusual market behaviour wherein brand-name manufacturers often compete not on price but on marketing activities.[12] Research on the determinants of drug expenditures over the past decade reflect this reality, by illustrating that drug expenditure trends are driven not only by increased use of medicines but by increased use of newer, more expensive alternatives in the place of older less costly ones offering similar health related benefits.

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[11] Reichert S, Simon T, Halm EA. Physicians' attitudes about prescribing and knowledge of the costs of common medications. Arch Intern Med 2000;160(18):2799-803; Barclay LP, Hatton RC, Doering PL, Shands JW. Physicians' perceptions and knowledge of drug costs: results of a survey. Formulary 1995;30(5):268-269; Miller LG, Blum A. Physician awareness of prescription drug costs: a missing element of drug advertising and promotion. Journal of Family Practice 1993;36(1):33-36; Ryan M, Yule B, Bond C, Taylor RJ. Do physicians' perceptions of drug costs influence their prescribing? Pharmacoeconomics 1996;9(4):321-31.

[12] Canada. Report concerning the manufacture, distribution and sale of drugs. Ottawa: Department of Justice; 1963; Canada. Provision, distribution and cost of drugs in Canada: Royal Commission on Health Services. Ottawa: Queen's Printer; 1965; Canada. Report of the Commission of Inquiry on the Pharmaceutical Industry. Ottawa: Supply and Services Canada; 1985; Canada. Directions for a Pharmaceutical Policy in Canada. In: Canada Health Action: Building on the Legacy, Synthesis Reports and Issues Papers Volume II. Ottawa: National Forum on Health; 1998.

PART II – PRESCRIPTION DRUG EXPENDITURES

A. EXPENDITURE ON HEALTH CARE AND PRESCRIPTION DRUGS

30. Canadians spent $142 billion on health care in 2005.[13] The largest single component of this expenditure is for hospitals at $42.4 billion for 2005. Second only to hospital care, and growing more rapidly than any other component of health spending including hospital care, is expenditure on pharmaceuticals, at $24.8 billion. Prescription drugs account for $20.6 billion (or 83%) of this total expenditure on pharmaceuticals.[14] The third largest category of health expenditures in Canada is payments to physicians, which accounted for $18.2 billion in 2005. All other components of health care (including dentistry, optometry, and other non-medical health services; long term care; public health; capital investment; administration and management; and more) combined to cost Canadians a total of $60.8 billion.

31. Globally, manufacturers in the pharmaceutical sector sold approximately US$602 billion worth of pharmaceuticals in 2005. Canadian sales by manufactures in 2005 were $16.56 billion,[15] which translate to $20.6 billion when wholesale and retail mark-ups (including pharmacists' fees) are added.[16]

B. MAJOR CATEGORIES OF PRESCRIPTION DRUG EXPENDITURE

32. Eighty-one percent of prescriptions written in Canada are written by general- and family-practitioners.[17] A vast majority of the total number of prescriptions and total expenditure on prescription drugs in Canada are for drugs to treat common,

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[13] CIHI. National Health Expenditure Trends, 1975-2005. Ottawa: Canadian Institute for Health Information; 2006.
[14] CIHI. Drug Expenditures in Canada 1985-2005. Ottawa: Canadian Institute for Health Information; 2006 May.
[15] IMS Canada. Prescription drug purchases by Canadian hospitals and pharmacies reach $16.57 billion in 2005. 2006 [cited 2006 March 30]; Available from: http://www.imshealthcanada.com/htmen/4_2_1_66.htm
[16] CIHI. Drug Expenditures in Canada 1985-2005. Ottawa: Canadian Institute for Health Information; 2006 May.
[17] IMS Canada. Prescription drug purchases by Canadian hospitals and pharmacies reach $16.57 billion in 2005. 2006 [cited 2006 March 30]; Available from: http://www.imshealthcanada.com/htmen/4_2_1_66.htm

well-known conditions. The five leading therapeutic categories in terms of expenditures are cardiovascular drugs (primarily used to treat high blood pressure); psychotherapeutic agents (primarily used to treat depression and anxiety); cholesterol agents (primarily used to treat high cholesterol); antispasmodic drugs (primarily used to treat ulcers and heartburn); and antiarthritic agents (primarily used to treat joint pain).[18] In 2004, these five drug classes account for over half of all prescription drug expenditure in Canada.[19] The top 10 drug categories, which include systemic antiinfectives (e.g., antibiotics), analgesics (pain killers), neurologicals (for psychosis and dementia), hormones (e.g., hormone replacement therapy), and diabetes therapies, accounted for approximately three-quarters of drug spending in 2004.

C. TRENDS IN PRESCRIPTION DRUG EXPENDITURE

33. Between 1996 and 2005, prescription drugs were the fastest growing component of health spending in Canada, increasing in cost from $7.6 billion to $20.6 billion (or growing at an average annual rate of 11.7% per year). Expenditure on other major components of health care grew as follows: hospitals from $25.2 billion to $42.4 billion (5.9% per year); physician payments from $10.8 billion to $18.2 billion (6.0% per years); all other health care from $31.1 billion to $60.8 billion (7.7 percent per year).

34. After adjusting for inflation and population growth, real per-capita expenditure on prescription drugs in Canada more than doubled from $307 in 1996 to $637 in 2005 (both figures expressed in terms of 2005 dollars). Real per-capita expenditure on prescription drugs in Canada had previously doubled from $151 in 1983 to $307 in 1996 (both figures expressed in terms of 2005 dollars). Historical data on real per-capita drug expenditure in Canada are presented in **Figure 1**.

35. Pharmaceutical expenditure growth over the past decade has been more rapid in North America than in the rest of the world. According to IMS Health data, pharmaceutical sales in North America outpaced global pharmaceutical sales in each year

[18] IMS Canada. Top Therapeutic Classes, Drug Store Purchases. 2006 [cited 2006 May 26]; Available from: http://www.imshealthcanada.com/htmen/3_2_17.htm

from 1999 to 2004 (earlier data were not available); North American sales grew slower than global sales in 2005.[20] IMS Health estimates of year-over-year growth rates for sales regions are provided in **Table 1**.

36. Though North America has been an outlier in terms of the pace of drug cost growth over recent years, detailed data collected by the Organisation for Economic Co-operation and Development (OECD) illustrate a significant difference between the US and Canada that has emerged over the past decade. Between 1975 and 1995, per capita expenditure on prescription drugs in the US was no more than US$21 higher than per capita expenditure on prescription drugs in Canada (using purchasing power parity for currency conversion so as to avoid spurious variations due to exchange rate volatility). Since 1995, the difference in per capita expenditure on prescription drugs between the two countries has grown dramatically. In 2003, per capita expenditure on prescription drugs in the US was US$203 higher than per capita expenditure on prescription drugs in Canada. These data are illustrated in **Figure 2**.

37. In my opinion there are two important facts that may be drawn from the data on total expenditure on prescription drugs. The first is that prescription drug expenditures in both Canada and the US have been growing rapidly in over the past decade and that such spending in North America has outpaced spending in other developed countries around the world. Drug spending has been driven by a number of drug utilization and pricing dynamics that will be reviewed in the next section of this affidavit. The second important fact to be drawn from the data on total expenditure on prescription drugs is that, although per capita spending in Canada has grown rapidly, per capita spending in the US has grown even more quickly. (Further below in this affidavit I will review the fact that the difference between US and Canadian expenditures on prescription drugs per capita has grown markedly since 1995, yet was relatively stable for 20 years prior to 1995.)

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[19] Morgan S, McMahon M, Lam J, Mooney D, Raymond C. The Canadian Rx Atlas. Vancouver: Centre for Health Services and Policy Research; 2005 December.

[20] IMS. Global Pharmaceutical Sales by Region, 2005. 2006 [cited 2006 May 26]; Available from: http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_77478579_77479643,00.html

D. CAUSES OF PRESCRIPTION DRUG EXPENDITURE TRENDS

38. Trends in prescription drug expenditure in Canada have been studied closely. Canadians, including myself, have pioneered methods for determining the factors that cause growth in spending. This research illustrates the extent to which expenditures have been driven by population aging, increased use of medicines, substitutions toward more costly alternatives, or increases in prices for available drugs. Further work answers the question, are breakthrough drugs (defined as the first drug to effectively treat a particular illness or a drug that provides a substantial improvement over existing products) driving recent trends in utilization and expenditure?

39. Data from British Columbia are arguably the best data on drug utilization and expenditure in the world. By law, every prescription dispensed in the province must be recorded into a system to monitor for dangerous drug combinations and administer pharmacy benefits. After appropriate anonymization, these data are used to study the impacts of pharmaceutical products and policies. With peer-reviewed funding from the Canadian Institutes of Health Research (the most objective and academically prestigious type of support for health services research in Canada), I have conducted several studies on drug expenditure trends using these data from British Columbia. These studies compute determinants of drug expenditures over time, including the portion of drug expenditures (and trends) accounted for by drugs of different levels of therapeutic novelty. They have been published in the British Medical Journal (one of the world's most respected medical journals), in Medical Care and Health Services Research (both among the top 5 journals in the field of health services and policy research), and elsewhere.[21]

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[21] Morgan S, Bassett KL, Wright JM, Yan L. First-Line First? Trends in Thiazide Prescribing for Hypertensive Seniors. PLoS Medicine 2005;2(4):e80; Morgan SG. Statistics and drug utilization: Are prescribing rates really that high? Canadian Medical Association Journal 2001;165(11):1507-1508; Morgan SG. Quantifying Components of Drug Expenditure Inflation: The British Columbia Seniors' Drug Benefit Plan. Health Services Research 2002;37(5):1243-1266; Morgan SG. Booming prescription drug expenditure: a population-based analysis of age dynamics. Medical Care 2005;43(10):996-1008; Morgan SG. Prescription Drug Expenditures and Population Demographics. Health Services Research 2006;41(2):411-428; Morgan SG, Agnew JD, Barer ML. Seniors' prescription drug cost inflation and cost containment: evidence from British Columbia. Health Policy 2004;68(3):299-307; Morgan SG, Bassett KL, Wright JM, Evans

40. From 1996 to 2003, per capita expenditure on prescription drugs in British Columbia increased 123% (from $141 to $316). Such growth can be mathematically attributed to four factors: population aging, price changes, volume of drugs used, and therapeutic choices. Population aging can alter expenditure on medicines given that older individuals have higher needs and higher average drug expenditure per capita. This determinant of drug expenditures turns out to play only a minor role in drug expenditure growth (less than one-tenth of the total change in expenditures in BC from 1996 to 2003). Similarly, price changes play only a minor role in drug expenditure growth. Prices charged for specific brands of medicine tend to remain constant over time. Moreover, when averaged over the price of brand-name and generic purchases, the average amount paid for off-patent drugs has fallen.

41. Price changes, particularly stemming from switching to generic alternatives, should not be confused with the cost-impact of therapeutic choices. Therapeutic choices are the decision regarding which drug, from all available options, will be used for a given patient and given course of therapy. Therapeutic choices can have significant financial implications. For, while there is often price competition among generic drugs, there is seldom price competition among brand-name drugs within chemical classes. Due to the non-standard financial incentives of patients and prescribers, new entrants into established drug categories seldom price their products significantly below competitors (a few do, but the numbers of such examples are rare, as reflected in the data on drug price trends); moreover, newer generations of chemical classes are typically priced higher than older generations of drugs used to treat the same condition.

42. The clearest examples of non-competitive pricing dynamics in the pharmaceutical market come from the various classes of drugs used to treat high blood pressure. Low dose thiazide diuretics, which have been available for decades and have been shown to offer as good or better outcomes for the majority of patients with high blood pressure, cost as little as one-hundredth the price of newer, patented angiotensin-

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RG, Barer ML, Caetano PA, et al. "Breakthrough" drugs and growth in expenditure on prescription drugs in Canada. British Medical Journal 2005;331(7520):815-816.

converting enzyme (ACE) inhibitors or angiotensin-II receptor blockers (ARBs).[22] And, while generic versions of the older ACE-inhibitors are now available, new ACE-inhibitors and ARBs (a closely related drug class) are priced at a substantial premium.[23]

43. As a result of the vast range in prices for different drugs to treat the same conditions, and the tendency for physicians and patients to select brand-name products despite price differences, between 40 to 50 percent of drug expenditure inflation observed in BC is due to trends toward the use of more expensive treatment options over time.[24] (Approximately 50 percent of recent expenditure inflation owes to the volume of therapy received by individuals of all ages, and 10 percent owes to the aging of the population.) Similar patterns of increases in use and costs of treatment options are found at a national level in Canada, though not adjusted for age of the population.[25]

44. To determine whether the substitutions toward more costly medicines over time reflect the use of breakthrough medicines that offer significantly better therapy, my colleagues and I linked prescription drug expenditure data from British Columbia to classifications of therapeutic novelty done by the Patented Medicine Prices Review Board (PMPRB). The PMPRB appraises the therapeutic novelty of every patented medicine in Canada to distinguish breakthrough drugs from other medicines for the purpose of monitoring drug prices. Of the 1,147 patented drugs brought to market from 1990 to 2003, 68 (5.9%) met the regulatory criteria of being a breakthrough: "…the first drug to treat effectively a particular illness or which provides a substantial improvement over existing drug products".[26] A French agency has determined that a similarly low

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[22] Morgan S, Bassett KL, Wright JM, Yan L. First-Line First? Trends in Thiazide Prescribing for Hypertensive Seniors. PLoS Medicine 2005;2(4):e80.

[23] Morgan SG, Kozyrskyj A, Metge C, Roos N. Pharmaceuticals: Therapeutic Interchange and Pricing Policies. Winnipeg: Manitoba Centre for Health Policy; 2003 October.

[24] Morgan SG. Booming prescription drug expenditure: a population-based analysis of age dynamics. Medical Care 2005;43(10):996-1008; Morgan SG. Prescription Drug Expenditures and Population Demographics. Health Services Research 2006;41(2):411-428.

[25] Morgan SG. Drug spending in Canada: recent trends and causes. Medical Care 2004;42(7):635-42.

[26] PMPRB. Patented Medicine Prices Review Board: Annual Report 2002. Ottawa: Patented Medicine Prices Review Board; 2003.

percentage of products on the European market are considered substantial improvements over existing alternatives.[27]

45. A majority of new, patented drugs brought to market are new dosage forms of existing medicines or what are called "me-too" drugs. Me-too drugs are chemically similar to the pioneering drugs in a therapeutic class, typically offering undifferentiated clinical benefits, but are distinct enough to be granted their own patents. These me-too drugs are not the same as generic medicines, which are government certified to be chemically equivalent to the original brand-name product and cannot legally be sold until all relevant patents on the original product have expired.

46. Any new drug that came to market from 1990 to 2003 that was chemically related to a medicine deemed by the PMPRB to be breakthrough was labelled a "new breakthrough" medicine for our study. This ensured that our methods would bias toward over-estimating the amount of spending breakthroughs. New drugs that, according to the PMPRB, did not provide "a substantial improvement over existing drug products" and were in no way related to such a breakthrough were called "new me-too" drugs. Older drugs, those on the market prior to 1990, were called "vintage brand" or "vintage generic" depending on whether they were a brand or generic drug.

47. Our study found that new breakthrough drugs accounted for 6% of expenditures and 1% of utilisation in 1996, and 10% of expenditures and 2% of utilisation in 2003. "Vintage" brands and generics combined accounted for 75% of total utilization in 1996 and 54% in 2003. Owing to their relatively low cost, these products accounted for only 53% and 27% of respective total annual expenditures. In contrast, new me-too drugs accounted for 44% of utilisation and 63% of expenditures by 2003. Their average cost per day of therapy was twice that of vintage brands and four times that of vintage generics. Thus, in British Columbia, most (80%) of the increase in drug expenditure between 1996 and 2003 was explained by the use of new, patented drug products that did not offer substantial improvements over less expensive alternatives available prior to 1990.

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[27] Anonymous. Drugs in 2001: a number of ruses unveiled. Prescrire International

48. Owing to the unique nature of the pharmaceutical industry and of pharmaceutical goods, drug pricing and utilization has been influenced more by competition in marketing activities, to professionals in Canada and to both professionals and consumers in the United States, than by competition in prices per unit of value in terms of proven health outcomes. And, owing to the fact that only newer, patented drugs will be promoted by for-profit companies (this is explained in detail below), it is my opinion that this form of promotional competition has resulted in rewards that are not proportionate to relative clinical value. For, in a market reflecting perfect competition and full information, newer "me-too" products would be priced competitively with comparable off-patent generics and used only when evidence suggests they offer clinically relevant advantages over the off-patent products.

E. SOURCES OF FINANCING FOR PRESCRIPTION DRUGS IN CANADA

49. Unlike medical and hospital care, which are primarily paid for by government, the private and public payment for prescription drugs is almost equal. The major public source of payment is through provincial drug plans, which finance approximately 40 percent of national prescription drug expenditure. Federal drug plans and social insurance plans (such as workers compensation) each fund 3 percent of national expenditure. Private insurance plans, which are predominantly employment-based extended health benefit plans, finance 34 percent of national expenditure on prescription drugs. The remaining 20 percent of expenditure is financed by payments made out-of-pocket by patients.

PART III – PRESCRIPTION DRUG MARKETING AND RESEARCH INVESTMENTS

50. Data concerning the research and marketing activities of prescription drug manufacturers in Canada are kept confidential. To my knowledge, there are no current data on the scale of both of these activities that are publicly available. However, commissions of inquiry into the pharmaceutical industry during the 1960s and 1980s

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2002;11(58):58-60.

uncovered data for Canadian firms through investigations. The Restrictive Trade Practices Commission (RTPC) "Report Concerning the Manufacture, Distribution and Sale of Drugs" found that the proportion of net sales by pharmaceutical companies in Canada that was dedicated to research in 1959 varied from zero to a maximum of 8 percent (see page 73 and table XXIV of Appendix Q from the RTPC report.)[28] The RTPC found that the proportion of net sales dedicated to marketing activities in 1959 ranged from 10.2 percent to a maximum of 51.55 percent, and estimated the average investment in promotional activity to be 24.92 percent of sales.[29] The 1985 Commission of Inquiry on the Pharmaceutical Industry reported that the average proportion of sales going to promotional activities was approximately 21 percent, whereas the ratio of research and development to sales was 4.5 percent.[30] Thus, for periods when data has been made public through government inquiries, pharmaceutical manufacturers have spent significantly more on marketing activities than they have on research and development.

51. Though recent Canadian data are not available, recent estimates of pharmaceutical manufacturers' relative investment in research and marketing activities can be obtained by audit of the forms that US corporations are required to file with the Securities and Exchange Commission. This US information will be indicative of the pharmaceutical industry's ratio of marketing to sales in a country that permits brand-name DTCA of prescription drugs (thus, it would portend the level of marketing that might occur if Canada adopted similar laws with regard to DTCA). The US information will also be indicative of research investment in the country that his home to many of the largest pharmaceutical manufacturers (thus, it would generally overstate the amount of marketing that could reasonably be expected in Canada).

52. An American consumer organization, Families USA, recently compiled data from Securities and Exchange Commission filings for the seven largest US drug

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[28] Canada. Report concerning the manufacture, distribution and sale of drugs. Ottawa: Department of Justice; 1963.
[29] Ibid.
[30] Canada. Report of the Commission of Inquiry on the Pharmaceutical Industry. Ottawa: Supply and Services Canada; 1985.

manufacturers.[31] Their data (provided in **Table 2**) show that, averaged across the seven largest US drug manufacturers, spending on "Marketing, Advertising, and Administration" account for 32% of revenues and spending on "Research and Development" accounts for approximately 14% of revenues. According to IMS Health data for the same year, total industry sales in the US were US$235.4 billion and the estimated direct cost of promotions was US$27.73 billion or 11.8% of total sales.

53. The share of total revenues spent directly on marketing activities by pharmaceutical manufacturers is likely somewhere between these two estimates (32% based on the Families USA data and 11.8% based on IMS data). However, important forms of indirect drug marketing are also often hidden within research and development accounts. The most notable of these activities are what are referred to as "seeding studies":

> "Features that distinguish such trials from scientifically rigorous studies include the use of a design that does not support the stated research goals, the recruitment of investigators not because they are experts or leading researchers but because they are frequent prescribers of competing products in the same therapeutic class, disproportionately high payments given to "investigators" for their work (although the only work may be to write prescriptions for the drug), sponsorship of the studies by the company's sales and marketing division rather than its research department, minimal requirements for data, and the collection of data that are of little or no value to the company."[32]

54. Based on data collected through enforcement activities, the Health Care Inspectorate of the Netherlands estimated that post-market studies aimed at promoting products and building relationships with prescribers could account for as much as 20% of the "true" investment in marketing and promotions by pharmaceutical manufacturers.[33]

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[31] Families USA. The Choice: Health Care for People or Drug Industry Profits. Washington, DC: Families USA; 2005. Report No.: Families USA Publication No. 05-104.

[32] Kessler DA, Rose JL, Temple RJ, Schapiro R, Griffin JP. Therapeutic-Class Wars -- Drug Promotion in a Competitive Marketplace. N Engl J Med 1994;331(20):1350-1353.

[33] Van Egmond-Vettenburg J, ter Steege H. Marketing plans for medicinal products available on prescription only: The current situation (second revised edition). Amsterdam: The Hague: Health Care Inspectorate; 2001 July.

Firms would report much of this marketing promotions spending as research and development expense.

55. Total promotional expenditure on pharmaceuticals in the US has grown considerably since 1996. In 1996, total US expenditure on promotional activities (including drug samples) was US$9.16 billion; in 2004, that total was US$27.73 billion (just over three times the expenditure in 1996).

56. The findings from the preceding sources, including Canadian investigations of the 1960s and 1980s and more recent US data, all indicate that pharmaceutical manufacturers invest more heavily in marketing and promotional activities than in research and development. This would be consistent with the investment strategies expected of firms in this industry in which, due to the variety of market imperfections described above, drug pricing and utilization is influenced more by competition in marketing activities, to professionals in Canada and to both professionals and consumers in the United States, than by competition in prices per unit of value in terms of proven health outcomes.

DIRECT TO CONSUMER ADVERTISING

57. The first brand-name DTCA campaign to include drug information began in 1983.[34] Though the ads would technically be permitted under US law, the US Food and Drug Administration (FDA) asked the pharmaceutical industry to abide by a voluntary moratorium on DTCA from September 1983 to September 1985. After the moratorium was lifted, firms spent an estimated US$35 million on DTCA in 1987.[35] Because print and broadcast advertising was permitted provided that a lengthy review of product information was provided within the ads, DTCA spending in the US grew to US$380 million by 1995; and more than double to US$790 million in 1996. In November 1997, the FDA issued new guidelines on television and radio broadcast DTCA. These guidelines lifted the requirement that broadcast ads contain a summary of product

[34] 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; 1991 August 1990; Snowbird, Utah, USA: American Council on Consumer Interests; 1991. p. 159-168.

information provided that the ads informed audiences that such information could be found via a toll free phone line or website. Spending on DTCA continued to increase at a rapid pace, with increasing emphasis on broadcast advertising. In 2005, firms spent an estimated US$4.24 billion on DTCA. The growth in DTCA spending in the United States is illustrated in **Figure 3**.

58. Some analysts might consider DTCA a relatively minor share of advertising expenditure by manufacturers. For, in the USA, DTCA rose from approximately 9% of total expenditure on promotional activities (including drug samples) in 1996 to approximately 15% in 2004 (at the time of preparing this report, data on all forms of marketing, including drug samples, were only available for 1996 to 2004). Other components of total expenditure for 2004 were as follows: value of drug samples provided (57% of promotional spend); sales representative contacts with professionals (26% of promotional spend); and professional journal advertising (2% of promotional spend).

59. The apparently modest rise in DTCA as a share of promotional spending must be interpreted with the understanding that DTCA is not a substitute for other promotional activities. In particular, to gain maximum return on investment in DTCA, a firm must increase spending on other promotional channels (see, e.g., the articles footnoted below).[36] Most notably, to maximize the return on investment in DTCA a firm must invest in sales representative contacts with prescribing physicians and in drug samples available for consumers to ensure that when a consumer visits a doctor to talk about the advertised product, the doctor is prepared and has samples of that product so that competing firms do not gain a significant share of the induced demand for the therapeutic class. It is therefore not surprising that, while DTCA expenditure in the US increased by 408% (or 5-fold) from 1996 to 2004, spending on sales representative contacts and drug samples increased 144% and 224% respectively.

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[35] Ibid.

[36] Gascoigne D. DTC at the Crossroads: A “Direct” Hit...or Miss? IMS HEALTH; 2004; Gascoigne D. The ‘Science’ of Promotional Planning: Evidence-based Analyses Optimize Promotional Returns: IMS HEALTH; 2006 May; Mertens G. Direct to Consumer Advertising:

60. Based on the trends in DTCA and other forms of drug promotion in the US, it is my opinion that the rapid increase in DTCA did not supplant other forms of product promotion. Rather, DTCA has lead to increased spending on complementary promotional channels. Thus, the total investment in promotional activities that is related to DTCA in the US is much higher than the US$4.24 billion that firms spent directly on DTCA during 2005.

PART IV – EFFECTS OF DTCA OF PRESCRIPTION DRUGS

61. The following contains two approaches to explaining the impact of DTCA. The first approach is to provide a summary of a systematic review of literature on the impact of DTCA. This is followed by a review of what economic theory would predict is the effect of DTCA.

A. A SYSTEMATIC REVIEW OF RESEARCH EVIDENCE

62. To inform policy and practice, the systematic review of an entire body of evidence offers several advantages over the evaluation of any single study[37] . Systematic review reduces the likelihood of being misled by the potential anomalies or biases in any single study. Confidence in findings increases when similar results are found in multiple, distinct studies (e.g., multiple teams investigating the impact of advertising) and when they are robust to changes in study context (e.g., studying the impact of advertising on more than one drug category, in more than one context, or both). Moreover, by following established methods for systematic review involving comprehensive searches to identify relevant studies and appraisal to ensure that all studies meet acceptable scientific standards fosters transparency and objectivity.

63. A systematic review of research evidence concerning the impact of DTCA was recently conducted by Gilbody, Wilson and Watt, and published in a peer-reviewed

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Global Drug Promotion. London: FT Healthcare, A division of Financial Times Professional Ltd.; 1998.

[37] Lavis J, Davies H, Oxman A, Denis J-L, Golden-Biddle K, Ferlie E. Towards systematic reviews that inform health care management and policy-making. Journal of Health Services Research and Policy 2005;10(Sup 1).

academic journal.[38] These authors reviewed all published studies found through a comprehensive of multiple research citation databases from database inception through to 2004. Their focus was on the impact of DTCA on health seeking behaviours of patients at the point of access to care; requests for prescription only medicines; patient-doctor communication and satisfaction with care; prescribing patterns; and direct and indirect costs (including drug costs, healthcare and social costs).

64. From a body of 2853 potentially relevant research publications, Gilbody and colleagues identified only four studies that met the strict standards of epidemiologic inquiry that are necessary to detect a causal association between DTCA and outcomes. The findings of Gilbody, et al. in their article entitled "Benefits and harms of direct to consumer advertising: a systematic review" is attached to this affidavit as "**Exhibit 2**." From these studies, Gilbody and colleagues determined that evidence was sufficient to conclude the following:

> "Direct to consumer advertising is associated with increased prescription of advertised products and there is substantial impact on patients' request for specific drugs and physicians' confidence in prescribing. No additional benefits in terms of health outcomes were demonstrated."[39]

65. The identified impact on "physicians' confidence in prescribing" was negative. A controlled comparison study of patients in Sacramento (who would be exposed to DTCA in their local media) and Vancouver (who would only be exposed to DTCA from US-based media sources) found that residents in Sacramento were more than twice as likely to make requests for drugs promoted with DTCA than residents in Vancouver, that patients who make such requests are over 16 times more likely to be prescribed a drug than patients who do not request advertised drugs, and that doctors report that in 50 percent of the cases where they prescribed a requested drug the particular brand of drug would not necessarily be the chosen prescription if a clinically

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[38]Gilbody S, Wilson P, Watt I. Benefits and harms of direct to consumer advertising: a systematic review. Qual Saf Health Care 2005;14(4):246-50;
[39] Ibid.

similar patient had presented with without requesting the product.[40] That is, physician compliance with patient requests is sub-optimal approximately half of the time. The article by Barbara Mintzes, et al, (2003) which supports these points is attached to this affidavit as **"Exhibit 3"**

66. The fact that physicians will comply with patient requests even if not clinically optimal can be explained by the nature of the economic incentives of both doctors and patients in this market. Patients, in both Canada and the US, are free to choose physicians. Thus, if advertising induces sufficient brand-loyalty in the patient and a physician does not grant requests for the brand, the patient may choose to seek the prescription from another doctor. On the professional side, a vast majority of physicians in Canada and the US are paid on fee-for-service or capitation remuneration models that provide incentive to constrain the time that they have to consult and counsel patients. Spending extra time counselling patients on the reasons that a drug promoted by DTCA may not be the best choice comes at an opportunity cost: time spent treating other patients. In the face of a patient that appears brand loyal, it would therefore be economically rational (though not necessarily clinically appropriate or cost effective) for physicians to select a drug that offers no likely benefit or one that, in contrast to available options, elevates the risk of adverse events, reduces the potential to benefit from treatment, or increases the cost of treatment in contrast to alternative treatment options. Any of these compromises in decisions about prescribing would result in an allocation of resources that would be socially inefficient: resources would unnecessarily be wasted or patients put at unnecessary risks. Such compromises made by prescribers are, however, understandable because still further resources would be wasted if the alternative is for the brand-loyal patient to seek a prescription from another physician.

B. UPDATING AND EXPENDING THE SYSTEMATIC REVIEW

67. I have updated and expanded the systematic review by Gilbody and colleagues. Using established standards for search, identification, and retrieval, the Information Specialist and Research Coordinator of the Program in Pharmaceutical

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[40] Ibid., and Mintzes B, Barer ML, Kravitz RL, Bassett K, Marion SA. How does direct-to-consumer advertising (DTCA) affect prescribing? A survey in primary care environments with

Policy at the UBC Centre for Health Services and Policy Research searched 12 research citation databases in the subject areas of health and economics (ABI-Inform, CINAHL, EMBASE, NLM HSR Project, Medline, PsycInfo, Web of Science, database of abstracts of reviews of effectiveness, Cochrane central register of controlled trials, Business Source Premier, EconLit, and International Pharmaceutical Abstracts) as well as the Internet via search tools (Google Scholar, Scirus, and Vivisimo meta search) for scientific studies of the impact of DTCA on financial aspects of the pharmaceutical sector (drug price, drug utilization, drug expenditure, and/or health care utilization and expenditure). The review was restricted to English language studies published from 1987 to May 2006.

68. The strategy used was broad enough to identify the largest number of studies of possible interest. A total of 1774 unique titles were found and searched manually to identify potentially relevant studies for this review. Thirty-five potentially relevant studies were identified and retrieved for my review. (The search strategy used here resulted in fewer total citations than Gilbody and colleagues because our search terms were restricted to those related to the outcomes of interest outlined above while Gilbody and colleagues searched similar medical subject headings (MeSH) but also searched MeSH's relating to consumer attitudes, education and health information.

69. I supervised the literature search; personally read all potentially relevant studies; personally identified those meeting the methodological criteria (that study design allowed for the estimation of the statistical significance of associations between DTCA and identified outcomes); personally extracted data regarding study subject, data, methods, and research findings; and personally summarized research findings in tabular format.

70. I sought information about the impact of DTCA on health services and pharmaceutical use and costs. Specific outcomes of interest were as follows: patient visits to physicians; total volume of prescriptions written; market share for advertised drugs; prescription drug prices; prescription drug expenditure; and expenditure on other healthcare services.

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and without legal DTCA. CMAJ: Canadian Medical Association Journal 2003;169(5):405.

71. As had been found by Gilbody and colleagues, I found very few epidemiologic studies with sufficient scientific control to determine a causal association. The lack of well controlled epidemiologic studies in part because marketing phenomenon are not easily subject to the kinds of trials required to determine causality (like the controlled clinical trials used to study drugs themselves); it is seldom possible to assign otherwise-comparable populations to be "exposed" or "not exposed" to advertising. There are, however, several econometric analyses of trends in drug spending that could be missed by a systematic review that sought only epidemiologic studies with sufficient scientific control.

72. I therefore expanded the inclusion criteria for reviewing studies, allowing for both epidemiologic and econometric analyses. Applying the criteria that eligible studies had to have evaluated the impact of direct to consumer advertising using statistical methods that were sufficient to establish the statistical significance of any association between DTCA and the outcome identified above resulted in the identification of 19 unique studies. Those studies that were published in multiple venues were included in this review only once. Published reports of the 19 eligible studies are listed in Appendix. This includes the studies reviewed by Gilbody and colleagues.

73. While the scientific merit of the 19 studies identified varies, the findings are remarkably consistent. No study found that DTCA resulted in a decrease of the outcomes of interest: patient visits to physicians, total volume of prescriptions written, market share for advertised drugs, prescription drug prices, prescription drug expenditure, or expenditure on other healthcare services. Because of the similarities of findings across studies, the literature can reasonably be summarized in table format, as reported in **Table 3**. In **Table 3**, and in the following paragraphs that summarize **Table 3**, a "positive association" between DTCA and an outcome means that an increase in DTCA is associated with an increase in the outcome, and "no association" means that the statistical analysis conducted in the relevant study (or studies) did not result in a statistically significant association (positive or negative) between DTCA and the specific outcome being assessed.

74. There is one eligible study reporting no association between DTCA and change in prescription drug prices, one study reporting no association between DTCA and the volume of prescription use, and one eligible study reporting no association between DTCA and prescription market share. However, the majority of studies found that DTCA is associated with increased use of drugs and medical services. Of the 19 studies deemed eligible for data extraction 5 reported a positive association between DTCA and number of physician visits, 11 eligible studies reported a positive association between DTCA and the volume of prescriptions used, 5 eligible studies reported a positive association between DTCA and market share for advertised products, 1 eligible study reported a positive association between DTCA and prescription expenditures, and 3 eligible studies reported a positive association between DTCA and the use of other health care services (e.g., diagnostic tests).

75. Though there are relatively few studies that meet the highest of scientific standards, a now significant body of research evidence indicates that DTCA is positively associated with increases in patient visits to physicians, total volume of prescriptions written, market share for advertised drugs, prescription drug expenditure, and expenditure on other healthcare services.

76. Current evidence does not support an association between DTCA and changes in the prices charged for advertised products. However, the most important pricing decision for pharmaceuticals is the initial price of a new product, relative to therapeutic alternatives. As mentioned above, because of a variety of market imperfections in the pharmaceutical sector, new patented pharmaceuticals typically charge a premium over established therapeutic alternatives, vying for market share through competition in marketing rather than competition in prices. The association between the initial price level set for a product and the manufacturers' ability to engage in DTCA has yet to be evaluated. Theory would indicate that this association would be positive: because brand recognition and brand loyalty create a form of market power, and given market imperfections in the pharmaceutical sector such as the non-standard financial incentives of both patients and prescribers, the ability to engage in DTCA would increase the optimal launch price for a new patented products.

C. PREDICTION BASED ON ECONOMIC THEORY

77. Despite all of the features of the products, consumers and marketplace that make pharmaceuticals and the pharmaceutical industry distinct, the manufacturers of prescription drugs are motivated by the same incentives as for-profit corporations in any sector of the economy: for-profit manufacturers strive to maximize profits. For-profit drug companies are not charitable organizations, limited partnerships, or owner-operated companies for which objectives involve a complex mix of return on investment and other personal or social objectives. Investor-owned, for-profit corporations, in any sector of the economy, strive to maximize return on shareholder investment. This is not a value judgement. It is simply a factual statement that return on investment is the primary (if not sole) objective of for-profit firms.

78. Increased sales of advertised brands: A corollary to the fact that prescription drug manufacturers aim to maximize profits is that pharmaceutical marketing campaigns must increase the advertising firm's sales, by increasing the quantity sold, the price per unit, or both. If sales do not increase by an amount at least equal to the cost of advertising, plus the cost of producing any additional units of the product sold, plus a return on the investment in marketing activities, profit-maximizing firms would not be motivated to invest in such activity. There will be examples of marketing campaigns that fail to generate required sales; but they will be short lived. Only "successful" campaigns will survive.

79. Evidence from the pharmaceutical industry confirms that DTCA generates significant return on investment (ROI). IMS Management Consulting recently conducted an analysis of return on investment from DTCA for 49 brands that used DTCA between 1998 and 2003. David Gascoigne, the Practice Leader of Promotion Management at IMS Management Consulting summarizes the findings of this study as follows:

> "… 90 percent of the brands in the study demonstrating positive ROIs. Seventy percent of the brands analyzed have an ROI in excess of $1.50 for each dollar invested; 35 percent were in excess of $2.50.The best performing brand in the study yielded an ROI of $6.50 per dollar invested. To put these results in perspective, consider that when compared with advertising in almost any other

> industry, the ROI from branded pharmaceutical DTC is nearly unprecedented in terms of the positive sales response generated."[41]

80. The return on investment from DTCA is currently highest among brands with the largest sales and lowest among brands with smallest sales.[42] This point is supported by David Gascoigne, in his article entitled "DTC at the Crossroads: A 'Direct' Hit…or Miss", attached to this affidavit as **"Exhibit 4"**. For example, the ten advertised brands with sales exceeding $1 billion experienced a return on investment of $3.66 for every dollar spent on DTCA.

81. Advertising only for newer, more expensive medicines: The second corollary that follows from the profit maximization of manufacturers is that firms will only have incentive to advertise when they can capture enough of the sales generated from the advertising campaigns. Manufacturers are not in business to promote their competitors products, even if their competitors might offer equal or superior health-related benefits and even if their competitors do so at lower cost to patients, insurers or government drug plans.

82. If a firm invests in advertising about a drug that was also manufactured by competing firms, those competitors could steal much of the return to advertising investment. Advertising might build brand loyalties for particular drugs; however, as mentioned above, the social value of pharmaceuticals, and therefore the economic efficiency of the pharmaceutical sector, is fundamentally based on established scientific evidence of comparative health benefits because guiding drug utilization by preferences over, or loyalties to, particular brands themselves would not ensure safe and effective use.

83. The fact that products must have sufficient market power both to capture adverting-induced sales and to charge prices over the cost of production in order to pay for marketing activity is important in the pharmaceutical sector. It implies that the incentive for engaging in DTCA will fall disproportionately (if not exclusively) on firms selling product protected by patents. For, the business generated by advertising for a brand that is off-patent will tend to be captured by generic competitors. Because of the

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[41] Gascoigne D. DTC at the Crossroads: A "Direct" Hit…or Miss? IMS HEALTH; 2004.

lack of market power in off-patent segments of the market, drugs for which the patent has expired will not generally be advertised by suppliers, even if they are scientifically proven to be as good or better than newer medicines.

84. The fact that firms selling older, off-patent drugs will have only a fraction of the patent holding firm's incentive to engage in DTCA implies that direct-to-consumer advertising will induce trends toward using newer, patented products to the exclusion of older, less expensive, off-patent drugs. Evidence of this is found in the advertising expenditure data. Every prescription drug among the top 10 in terms of DTCA spending from 1998 to 2005 (years for which data were available at the time of preparing this report) was, at the time of DTCA spending, a patented brand-name drug.

85. The US DTCA spending patterns for Prilosec (omeprazole), sold by AstraZeneca, and Claritin (loratadine), sold by Schering Corporation, illustrate the importance of patent protection for DTCA spending. (Note that loratadine was a prescription-only drug in the US, whereas it had non-prescription status in Canada.) The patents on omeprazole and loratadine were due to expire in 2001 and 2002, respectively. Though AstraZeneca and Schering were also engaged in legal attempts to extend the patents on their products, each company patented modifications of their original drugs: AstraZeneca patented esomeprazole magnesium (sold under the brand Nexium) and the Schering Corporation patented desloratadine (sold under the brand Clarinex). These patented modifications of the original products were launched with major marketing campaigns during the final years of the patents on their initial products. Each of these products was judged by the Patented Medicine Prices Review Board to a Category 3 medicine: "a new drug or new dosage form of an existing medicine that provides moderate, little or no improvement over existing medicines".[43]

86. Prilosec had been among the top 10 prescription drugs in terms of DTCA from 1998 to 2000. In 2001, Prilosec fell off the DTCA charts, while its patented sibling,

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[42]Ibid.

[43] PMPRB. Patented Medicine Prices Review Board: Annual Report 2001. Ottawa: Patented Medicine Prices Review Board; 2002; PMPRB. Report on New Patented Drugs - Aerius. Ottawa; 2004 July.

Nexium, entered the market as the #3 ranked brand-name drug in terms of DTCA for 2001. Nexium has been the #1 ranked brand in terms of DTCA from 2003 to 2005. In 2005, AstraZeneca spent $224 million on DTCA for Nexium.

87. Claritin had been the #1 ranked brand in terms of DTCA in 1998 and 1999, and was #3 in 2000, #8 in 2001, and #2 in 2002. It then fell off the DTCA charts in 2003, when its patented sibling, Clarinex, entered as the #5 ranked brand in terms of DTCA spending for 2003. Clarinex has since fallen off the list of top 10 brands in terms of DTCA spending.

88. By advertising their new, patented modifications of drugs that were coming off-patent, the manufacturers could switch consumers to the market segment over which they retained market power (through the new patent) and avoid the loss of revenues to generic competition in the off-patent segment. It is worth noting that in markets satisfying the conditions of full information, standard financial incentives and perfect competition, switching to the patented modifications of the original drugs when they offer no significant improvement in outcomes over their off-patent sibling and when they are considerably more expensive than the generic versions of the original product would not occur.

89. Summary of economic theory: Elsewhere, in my opinion, I have summarized the predictions about the effects of DTCA on welfare and economic efficiency as follows:

> "Economic theory can be used to make a number of predictions regarding the supply of consumer-directed prescription drug advertising and its impact on consumer welfare. The theory of the firm predicts that when for-profit pharmaceutical manufacturers invest in advertising, it must induce a transfer of wealth from consumers (or their purchasing agents) to producers. Given the unique characteristics of pharmaceuticals it is reasonable to assume that the transfer of wealth induced by advertising will be accompanied by improvements in public welfare when advertising is strictly informative. Economic theory then suggests that to rule out non-informational claims about drug products, it must be assumed that consumers have fixed preferences over the potential characteristics of products being advertised, and that none of those

> characteristics are related to advertising *per se*. While this assumption appears reasonable for consumers of pharmaceutical products, a number of subsequent criteria necessary for economic theory to predict the profitability of only informative advertising seem less reasonable. Unlike ordinary goods, the value of pharmaceutical products is unlikely to be "known" in the same way that consumers experience ordinary goods. Drugs affect consumers indirectly through their often-complex and always-uncertain impact on health status. Moreover, an individual's demand for pharmaceuticals would not increase upon the observation of a satisfactory outcome, making the market susceptible to the lemons problem in advertising. All of these factors suggest that firms may find it profitable to use persuasion and exaggeration in consumer-oriented marketing activities. Consequently, economic theory would suggest that consumer-directed advertising for prescription drugs would not be strictly informative. Because lay individuals cannot readily verify claims about the therapeutic quality and safety of prescription-only drugs, firms likely can (and will) profit from consumer-directed advertising that is exaggerated and/or biased. Pharmaceutical products for which consumers might be equipped to judge quality and, therefore, to reward only truthful advertisers are generally the ones scheduled as non-prescription drugs. Finally, regardless of how informative advertising might be, manufactures of newer, patented products will have a disproportionate opportunity to extract the rewards necessary to finance direct to consumer advertising in the first place, leading the market supply of information to concentrate on newer products to the exclusion of older ones."[44]

PART V – ESTIMATED IMPACT OF DTCA ON DRUG COSTS

90. Combining theory and prior research evidence with statistical trends in expenditure on prescription drugs and on DTCA can yield estimates of the financial impact of DTCA advertising in the US and predictions for Canada.

91. One of the ways to estimate the direct financial impact of DTCA on prescription drug expenditures is to consider the level of sales needed to justify the

[44] Morgan SG, Mintzes B, Barer M. The economics of direct-to-consumer advertising of prescription-only drugs: prescribed to improve consumer welfare? Journal of Health Services Research and Policy 2003;8(4):237.

DTCA investment made by the manufacturers. Dr. Meredith Rosenthal and colleagues report that "Industry officials suggest to us that their target changes in sales are in the range of four to five times the change in DTCA spending at the brand level (increased sales are also associated with increased production costs, sales commissions, licensing fees, and general administrative costs)"[45]. This would then imply that the US$4.24 billion dollars spent on DTCA in 2005 was intended to induce roughly US$16 billion to US$20 billion in sales for the advertised brands. Given that firms must cover the cost of increased expenditure on the other forms of promotion that accompany DTCA ads (sales representative visits to prescribers and drug samples), even a US$20 billion estimate for induced sales from DTCA is likely lower than sales required to cover the increase in total promotional mix associated with DTCA campaigns. Moreover, the cost to consumers would include additional amounts for the wholesale and retail mark-ups (approximately 20 to 25% over manufacturer revenues[46]; thus, the total increase in payments (including mark-ups) induced by DTCA in the US for 2005 would be in the neighbourhood of US$25 billion.

92. Estimating the total impact of DTCA using directly induced sales for firms who advertise fails to consider the possibility that such sales are achieved at the expense of competing firms or that advertising creates spill-over sales for competing brands. The research evidence on the effects of DTCA reviewed above indicates that DTCA campaigns expand markets and shift market shares.

93. It stands to reason that market-stealing activity does not significantly harm the patent holding firms that have financial incentive to advertise. If DTCA was a "zero sum game" wherein the harm from DTCA-induced market-stealing among brands made the brands no better off than they would be if DTCA was prohibited, then economic

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[45] Rosenthal MB, Berndt ER, Donohue JM, Epstein AM, Frank RG. Demand Effects of Recent Changes in Prescription Drug Promotion; Demand Effects of Recent Changes in Prescription Drug Promotion. Frontiers in health policy research.Volume 6 2003:1 at pages 17-18.

[46] NIHCM. Prescription Drug Expenditures in 2001: Another Year of Escalating Costs. Washington: National Institute for Health Care Management Foundation; 2002 2002; U.S. House of Representatives. Prescription Drug Pricing in the United States: Drug Companies Profit at the Expense of Older Americans. In: Minority Staff SID, Committee on Government Reform, editor.; 1999.

theory would predict that manufacturers and their industry associations would not support DTCA. Brand-name pharmaceutical manufacturers are, however, supporters of DTCA in the US and supportive of expanding it elsewhere.

94. It should be noted that the support of the brand-name pharmaceutical industry for DTCA does not preclude the possibility that DTCA by patent holding firms substantially reduces market share for off-patent brands; for such brands expect to lose market share to generic manufacturers when their patent expires.[47] Indeed, patent holding manufacturers may wish to use DTCA to switch patients off of medicines for which patent expiry is near or past back onto a patented medicine. The cases of Nexium and Clarinex are illustrative of such a DTCA strategy.

A. THE NET IMPACT OF DTCA ON PRESCRIPTION DRUG SPENDING

95. An estimate of the overall impact of DTCA in the US can be obtained by considering the trends in drug expenditure in the US and Canada before and after the increase in American DTCA. Others have noted that the increase in DTCA in the US began prior to the 1997 change in regulations.[48] The true beginning of major expansion in the use of DTCA in the US was 1996, when DTCA spending more than doubled over 1995 levels (from US$380 million to US$790 million).

96. As mentioned above, between 1975 and 1995, the difference between per capita expenditure on prescription drugs in the US and Canada was never more than US$21. From 1995 to 2003, this difference grew from US$21 to US$203.

97. Over the entire period of 1975 to 2003, the prescription pharmaceutical sectors in Canada and the US have been otherwise very similar. Unlike our systems for

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[47] Berndt ER, Ling D, Kyle MK. The Long Shadow of Patent Expiration: Do Rx to OTC Switches Provide an Afterlife? In: Feenstra RC, Shapiro DM, editors. Scanner Data and Price Indexes: Proceedings from the NBER Conference on Research in Income and Wealth. Chicago: University of Chicago Press; 2002.

[48] Rosenthal MB, Berndt ER, Donohue JM, Epstein AM, Frank RG. Demand Effects of Recent Changes in Prescription Drug Promotion; Demand Effects of Recent Changes in Prescription Drug Promotion. Frontiers in health policy research.Volume 6 2003:1; Rosenthal MB, Berndt ER, Donohue JM, Frank RG, Epstein AM. Promotion of prescription drugs to consumers. New England Journal of Medicine 2002;346(7):498-505.

insuring medical and hospital care, pharmaceuticals are financed and managed in similar ways in Canada and the US. While governments in Canada finance a higher percentage of total pharmaceutical costs than governments in the US—38% versus 21% in 2003 (most recent data available)—both countries rely on a mix of private and public insurance to cover prescription drugs[49]; thus, neither country has had a single payer that would control prices and utilization. And, although Canada has a quasi-judicial body to provide oversight on patented drug prices, prices of medicines in the two countries would be relatively comparable after adjustments for manufacturers' rebates to public and private drug plans in the US are factored in.[50] The similarity in per capita expenditure on prescription drugs between 1975 and 1995 is consistent with the fact that the two countries had, for a long time, faced similar pressures with similar tools for expenditure management.

98. From 1995 to 2003, the difference in per capita expenditure on prescription drugs in the US and Canada grew over ten-fold (967%). Over the same period, DTCA in the US grew nearly 10-fold (874%). That, following 20 years of stasis, the difference in prescription drug expenditure per capita between Canada and the US would steadily rise in apparent lock-step with the new phenomenon of DTCA spending in the US would be a rather remarkable coincidence. Other than the change in US DTCA spending, there have been no other major changes in the pharmaceutical sectors in Canada or the US that could explain the direction and magnitude of recent divergence in prescription drug expenditure levels between the two countries. Shares of public financing for prescription drugs in both countries rose slightly in both countries, but were not significantly changed (the medicare drug benefit, which may be considered the largest change in the history of drug coverage in the US, began in 2006).[51] The patterns of population aging were comparable.[52] No other significant pharmaceutical regulations

[49] OECD. OECD Health Data 2005. In: CD-ROM: OECD; 2005.
[50] U.S. House of Representatives. Prescription Drug Pricing in the United States: Drug Companies Profit at the Expense of Older Americans. In: Minority Staff SID, Committee on Government Reform, editor.; 1999; von Oehsen WH. Pharmaceutical Discounts Under Federal Law: State Program Opportunities. Washington, DC: Public Health Institute; 2001 May.
[51] OECD. OECD Health Data 2005. In: CD-ROM: OECD; 2005.
[52] George MV, Statistics Canada. Demography Division. Population projections for Canada, provinces and territories, 2000-2026 = Projections démographiques pour le Canada, les provinces

took effect in either country. And, no major reforms were made to the health care systems in which pharmaceuticals are consumed.

99. Thus, the total value of the change, between 1995 and 2003, in the difference in per capita expenditure on prescription drugs in the US and Canada provides a rough estimate of the impact of DTCA on prescription drug expenditure in the US. This amounts to approximately US$53 billion per year by 2003. (If Canadian drug expenditures over the period are converted to US dollars using exchange rates, rather than purchasing power parity indexes, the estimate of DTCA induced expenditure in the US rises to US$59 billion.)

100. An alternative method for measuring the aggregate impact of DTCA on prescription drug expenditure in the US would be to simulate spending trends using findings from studies of particular drug classes. Specifically, for the 25 largest therapeutic categories of medicine in the US, accounting for 70 percent of the total spending on prescription drugs, Rosenthal and colleagues estimated that DTCA caused 22 percent of drug expenditure growth between 1999 and 2000.[53] If DTCA was responsible for 22 percent of total prescription drug spending growth from 1995 through to 2003, then the total impact of DTCA on prescription drug expenditure in the US would be just over $40 billion per year by 2003.

101. To compare the 2003 estimates of the net impact of DTCA to the more current estimate of retail sales needed to justify manufacturers spending on DTCA during 2005 requires that the 2003 estimates be forecast through to 2005 because OECD data for 2004 and 2005 are not yet available. To be conservative in the estimated impact of DTCA on total prescription drug expenditure in the US, I simply use the 2003 figures (US$53 billion and US$40 billion) as 2005 estimates level of DTCA induced prescription drug

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et les territoires, 2000-2026. Ottawa: Statistics Canada = Statistique Canada; 2001; US Census Bureau. U.S. Interim Projections by Age, Sex, Race, and Hispanic Origin. 2004 [cited 2005 Jan 19]; Available from: http://www.census.gov/ipc/www/usinterimproj/

[53] Rosenthal MB, Berndt ER, Donohue JM, Epstein AM, Frank RG. Demand Effects of Recent Changes in Prescription Drug Promotion; Demand Effects of Recent Changes in Prescription Drug Promotion. Frontiers in health policy research.Volume 6 2003:1.

expenditure in the US. (Forecasting the estimates based on post-2000 growth rates would have raised the 2005 aggregate estimates to US$77 and US$62 billion.)

102. The methods just described provide a ballpark for the likely impact of DTCA on annual expenditures in the US as of 2005: between US$25 billion and US$53 billion. Due to brand spill-over from the market expansion effects of DTCA, and the fact that DTCA campaigns require additional spending on other promotional channels (e.g., sales representative visits with doctors and drug samples), it is likely that the actual impact of DTCA on US prescription drug expenditures in 2005 was closer to the range of US$40 billion to US$53 billion than to the US$25 billion required to cover advertisers' costs.

B. POTENTIAL IMPACTS FOR CANADA

103. The preceding estimates for the US provide a basis for gauging how much DTCA would cost the Canadian system by the time DTCA investment reached the levels that exist in the US. US DTCA expenditure is still growing, so the current (2005) estimates will underestimate the potential long-run annual cost-impact of DTCA in Canada.

104. As is still the case in the US, it will take several years of growth in DTCA before equilibrium levels of Canadian DTCA spending would occur. One can expect the growth in Canadian DTCA would be more rapid than in the US, for manufacturers have learned many lessons from their now 10 year experience targeting advertisements at consumers in the US. It took US DTCA 5 years to reach an early plateau in 2000 and then 3 more years (from 2002 to 2005) to reach 2005 levels. Given learning from the US experience, I expect that Canadian DTCA spending would reach levels that are comparable on a per capita basis to the 2005 levels in the US after only 5 years.

105. Scaling the year 2005 US estimates for Canadian population size and converting to Canadian dollars (using an estimated exchange rate of 0.90) would yield an estimated range for the likely impact of DTCA in Canada on annual expenditures:

between $3.0 billion and $6.4 billion per year relative to a base of $20.6 billion of annual spending on prescription drugs in Canada.

106. There is no reason to believe that the estimated $3.0 billion to $6.4 billion increase in Canadian prescription drug expenditures would be borne disproportionately by any particular payers in Canada. Thus, based on estimates generated relative to 2005 expenditure levels, DTCA induced costs to provincial governments would fall in the range of $1.18 billion to $2.5 billion; costs to the federal government would fall in the range of $90 million to $190 million; costs to social insurance plans (e.g., workers compensation boards) would fall in the range of $100 million to $210 million; costs to private insurance sponsors (primarily employment related benefits packages) would fall in the range of $1.04 billion to $2.21 billion; and finally costs to patients paying out-of-pocket would fall in the range of $590 million to $1.25 billion.

PART VI – EFFECTS ON CANADA'S ECONOMY

107. The rise in cost of prescription drugs impacts patients, government and the private sector. Set against inevitable resource constraints, increasing expenditure on prescription drugs implies that difficult decisions have to be made.[54] For, investment in one medicine diverts resources away from another, and increased investment in medicines more generally draws resources away from investment in other forms of health care or non-medical services consistently shown to be important determinants of population health such as childcare, education, and community services.[55]

108. For the public sector, the rising cost of prescription drugs will come at the expense of spending on other health services, education or other government priorities. The estimated $1.18 billion to $2.5 billion increase in annual expenditure on prescription drugs from provincial drug plans might otherwise finance hiring approximately 4,500 to

[54] Ham C, Coulter A. Explicit and implicit rationing: taking responsibility and avoiding blame for health care choices. Journal of Health Services Research and Policy 2001;6(3):163-9; Maynard A. Rationing health care: an exploration. Health Policy 1999;49(1-2):5-11.

[55] Evans RG, Stoddart GL. Producing health, consuming health care. Soc Sci Med 1990;31(12):1347-63.

9,600 new physicians in Canada, or approximately 11,000 to 25,000 new nurses, and continue to pay their salary every year. Alternatively, the increase in financial pressure caused by DTCA may force provinces to erode public drug coverage, placing a greater share of national pharmaceutical expenditures on the sponsors of private insurance and onto patients themselves.

109. For private companies, prescription drug expenditures financed through employer-sponsored shares of extended health benefits have long been the largest and fastest growing component of health related employee benefits for many companies in Canada.[56] Increasing private sector drug costs by $1.04 billion to $2.21 billion per year will place greater pressure on employers and reduce the competitive labour-market advantage that Canada has over the United States. Owing to Canada's relatively efficient universal health care system, in which government works to control health spending and the proliferation of high-cost health care technologies, Canada is one of the lowest cost developed countries to do business in.[57] Even after accounting for tax-financed health care, companies operating in the US pay twice what Canadian firms pay for health related expenses in contributions to employees' health insurance plans. Given that pharmaceuticals are the second largest component of total health care costs, and by far the largest component of private health care costs in Canada, an acceleration of Canadian expenditure on prescription drugs due to DTCA would reduce the current advantage of locating North American operations in Canada vis-à-vis the US.

110. The impact of DTCA on increased prescription drug expenditure must be considered within the context of health care. The efficient allocation of health care services would be that which delivers the maximum proven health benefits at given levels of expenditure. Increased spending on pharmaceuticals might be consistent with increased health benefits. However, this is not always the case. Increased use of higher

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[56] Alvi S. Health Care and Private Sector Competitiveness. Ottawa:The Conference Board of Canada; 1995 June. Report No.:139-95

[57] Canada. Canada tops G7 again as most cost-competitive country in which to do business. In: Canada IT, editor.; 2006. p. 1; Green JP, MacBride-King JL. Corporate health care costs in Canada and the U.S. Does Canada's Medicare System Make a Difference? Ottawa: The Conference Board of Canada; 1999 March.

cost medicines that substitute for lower cost alternatives may simply generate more expenditure without commensurate health benefits. Neither theory nor evidence concerning the impact of DTCA support claims of an increase in appropriateness or quality of care, when compared to the status quo in Canada, which is to allow for unbranded 'disease awareness' advertising. In contrast, both theory and evidence indicate that DTCA will be cost-expanding and that it will disproportionately increase utilization of and expenditure on newer, patented products. It is my opinion that DTCA will therefore exacerbate the fact that, due to the market imperfections in this sector, pharmaceutical manufacturers compete in marketing activities rather than competing in price. The result would be an even less economically efficient allocation of resources and a significant threat to public and private drug plans in Canada.

PART VII – CONCLUSION

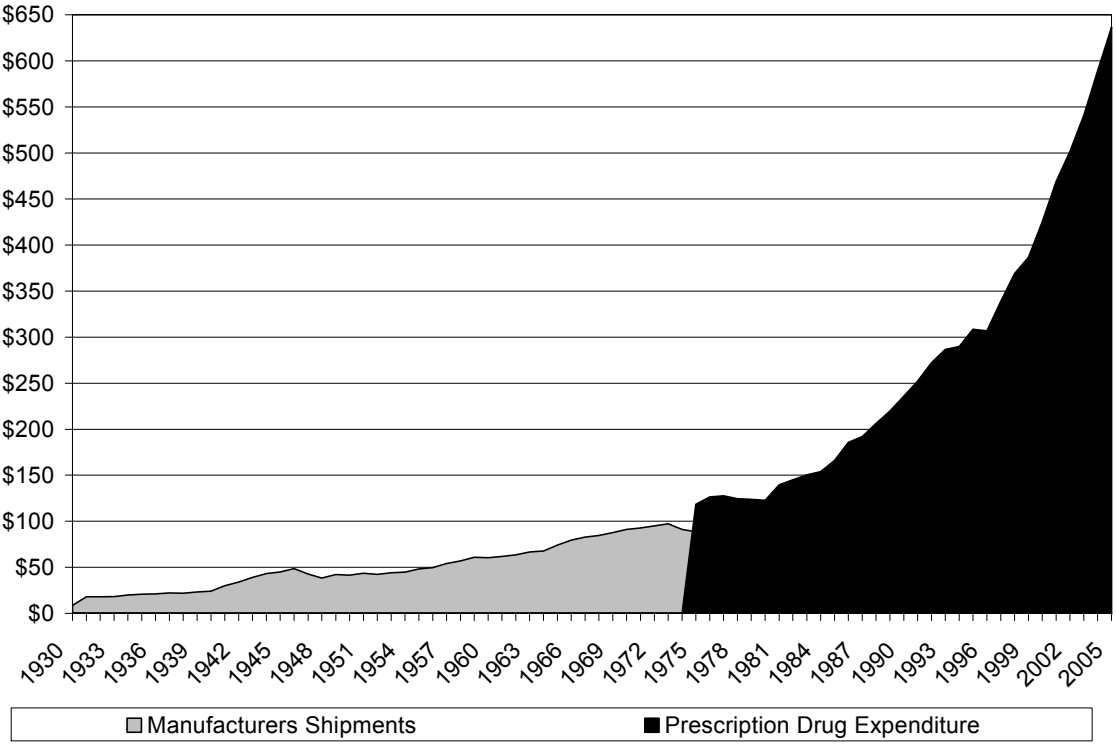
111. Experience in the US indicates that brand-name DTCA has a significant effect on the demand for and expenditure on advertised medicines. The resource implications are in addition to already rapid drug cost growth (e.g., that observed in Canada vis-à-vis the USA).

112. Allowing brand-name DTCA in Canada would induce billions of dollars of additional expenditure in Canada's pharmaceutical sector. This will add considerable pressures on government, employers, and Canadian citizens. Given the structure of the pharmaceutical industry, the role of pharmaceuticals within the health care system, and imperfections in the market for pharmaceuticals, changes in drug utilization induced by brand-name DTCA would not necessarily be an improvement in the allocation of resources in this sector.

113. The notable difference between the brand-name DTCA (not permitted in Canada) and disease awareness DTCA (permitted in Canada) is that the former will focus on particular brands in efforts to build market power based on brand recognition and loyalty. Such advertising is designed to build brand recognition and loyalty among patients who are generally not adequately trained or equipped to evaluate the complex

scientific information about the nature of the disease states that a particular drug would be indicated for and about the relative risks and benefits of all available treatment alternatives (including patented drugs, non-patented drugs, and non-drug treatments). Prescription drug use that is guided by brand recognition and loyalty instead of careful scientific consideration of the capacity to benefit from treatment and the relative costs and benefits of treatment alternatives could not reasonably be considered of societal value.

Figure 1: Inflation-adjusted (to 2005 dollars) per capita sales of medicinal and pharmaceutical products and retail expenditure on prescription drugs, 1930 to 2005



Source: Wholesale data extracted from Statistics Canada, Historical statistics of Canada, Quantity and value of shipments of selected manufactured commodities, R770, Medicinal and pharmaceutical preparations. Retail data extracted from Canadian Institute for Health Information, National Health Expenditures Database, and Drug Expenditures in Canada (various issues). Population estimates and consumer price index (all items, general inflation index) from Statistics Canada.

Table 1: Growth in Global Pharmaceutical Sales by Region

Year-over-year Growth at Constant Currency

	North America	Europe (EU 2002-2002)	Rest of Europe	Japan	Asia (excluding Japan), Africa and Australia	Latin America	Total
1999	14.0%	7.0%		6.0%		-7.0%	9.0%
2000	14.0%	8.0%		3.0%	10.0%	9.0%	10.0%
2001	17.0%	10.0%		4.0%	9.0%	0.1%	12.0%
2002	12.0%	8.0%	9.0%	1.0%	11.0%	10.0%	8.0%
2003	11.0%	8.0%	14.0%	3.0%	12.0%	6.0%	9.0%
2004	7.8%	5.7%	12.4%	1.5%	13.0%	13.4%	7.1%
2005	5.2%	7.1%		6.8%	11.0%	18.5%	6.9%

Share of World Market

	North America	Europe (EU 2002-2002)	Rest of Europe	Japan	Asia (excluding Japan), Africa and Australia	Latin America	Total
1999							
2000	48.2%	23.7%		16.2%	5.9%	6.0%	100.0%
2001	50.0%	24.0%		13.0%	8.0%	5.0%	100.0%
2002	51.0%	22.0%	3.0%	12.0%	8.0%	4.0%	100.0%
2003	49.0%	25.0%	3.0%	11.0%	8.0%	4.0%	100.0%
2004	47.8%	27.8%	1.8%	11.1%	7.7%	3.8%	100.0%
2005	47.0%	30.0%		10.7%	8.2%	4.2%	100.0%

Growth Rates Based on IMS Data

Source: Global Pharmaceutical Sales by Region, 2005. IMS Health, Inc., Fairfield, CT

Figure 2: Difference between per capita expenditure on prescription drugs in the USA and per capita expenditure on prescription drugs in Canada, measured in US dollars per capita using purchasing power parity for currency conversion.

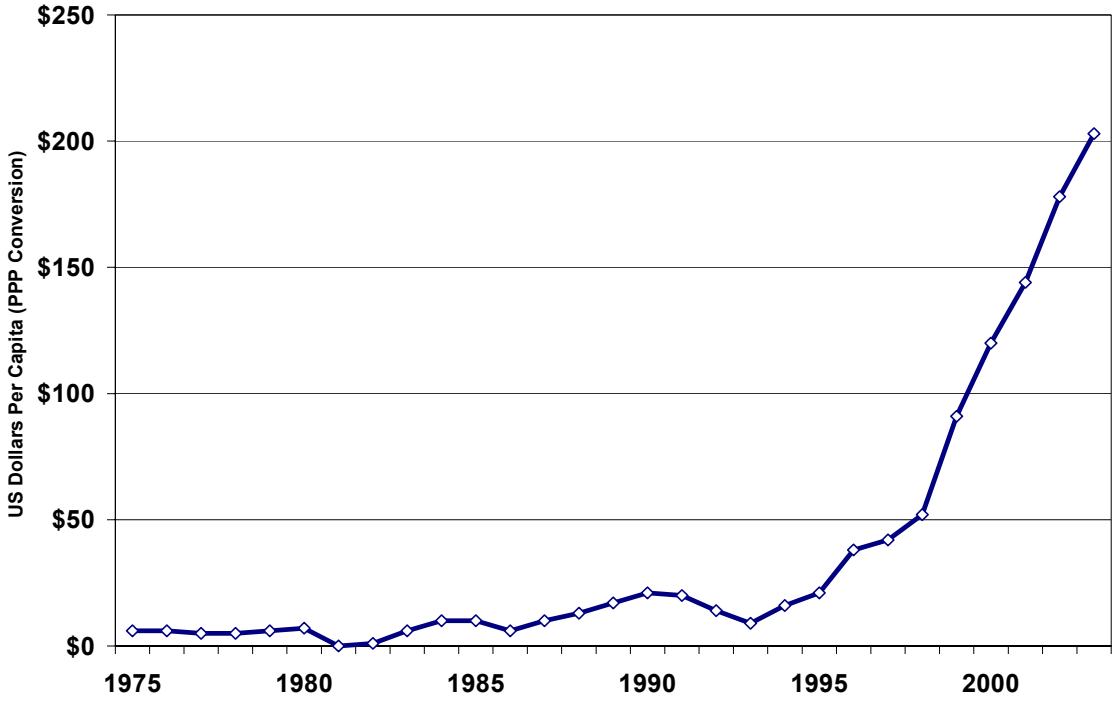


Table 2: 2004 Financials for U.S. Pharmaceutical Companies within the Top 200 U.S. Corporations

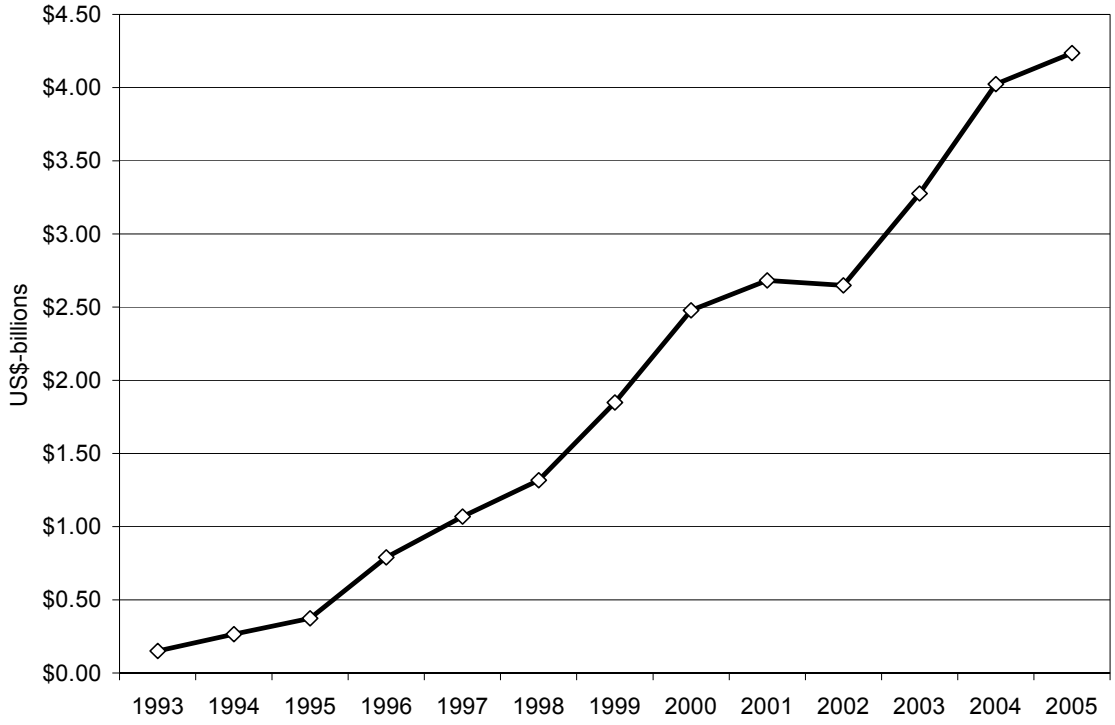
Company	Revenue (Net Sales)*	Amount and Percent of Revenue Allocated to:					
		Marketing, Advertising, and Administration*		R&D*		Profit (Net Income)*	
		$	%	$	%	$	%
Pfizer Inc.	$52,516	$16,903	32%	$7,684	15%	$11,361	22%
Johnson & Johnson	$47,348	$15,860	33%	$5,203	11%	$8,509	18%
Merck & Co., Inc.	$22,939	$7,346	32%	$4,010	17%	$5,813	25%
Abbott Laboratories	$19,680	$4,922	25%	$1,697	9%	$3,236	16%
Bristol-Myers Squibb Company[1]	$19,380	$6,427	33%	$2,500	13%	$2,388	12%
Wyeth	$17,358	$5,800	33%	$2,461	14%	$1,234	7%
Eli Lilly and Company	$13,858	$4,284	31%	$2,691	19%	$1,810	13%
Total	**$193,079**	**$61,542**	**32%**	**$26,246**	**14%**	**$34,351**	**18%**

* Millions of US Dollars

[1] Marketing, advertising, and administration for Bristol-Myers is the sum of two line items: "Marketing, Selling, and Administrative" and "Advertising and Product Promotion"; the other companies report marketing and advertising spending together.

Source: Computations from 2004 SEC form 10-K for each company conducted by Families USA and reported in Families USA (2005) "The Choice: Health Care for People or Drug Industry Profits" Families USA Publication No. 05-104 Washington, DC www.familiesusa.org

Figure 3: US DTCA Expenditure (US$ billions), 1993 to 2005



Source: IMS Health, Total U.S. Promotional Spend by Type (various years), collected over period from 2000 through 2006

PART VIII – TABLE 3: SUMMARY OF STUDIES ASSESSING ASSOCIATION BETWEEN DTCA AND IDENTIFIED OUTCOMES

	Number of studies reporting findings of:		
	Decrease	**No change**	**Increase**
Physician visits	0	0	5
Volume of prescription use	0	1	11
Prescription market share	0	1	5
Prescription prices	0	1	0
Prescription expenditure	0	0	1
Other health care use or costs	0	0	3

PART IX – APPENDIX 1: STUDIES FOUND THAT ASSESS ASSOCIATION BETWEEN DTCA AND IDENTIFIED OUTCOMES

Anantharaman, R., A. Parthan, et al. (2005). "Examination of the relationship between direct-to-consumer advertising expenditure and price." Drug information journal 39(1): 13.

Calfee, J. E., C. Winston, et al. (2002). "Direct-to-consumer advertising and the demand for cholesterol-reducing drugs." Journal of Law and Economics 45(2): 673.

Basara, L. R. (1996). "The impact of a direct-to-consumer prescription medication advertising campaign on new prescription volume." Drug information journal 30(3): 715.

Burak, L. J. and A. Damico (1999). "Effects of direct-to-consumer advertising of pharmaceutical products on college students." Health marketing quarterly 17(2): 19.

Datti, B. and M. Carter (2004). "The effect of direct-to-consumer advertising on prescription drug use by older adults." Gerontologist 44: 430.

Donohue, J. M., E. R. Berndt, et al. (2004). "Effects of pharmaceutical promotion on adherence to the treatment guidelines for depression." Medical care 42(12): 1176.

Hansen, R. A., J. C. Schommer, et al. (2005). "The association of consumer cost-sharing and direct-to-consumer advertising with prescription drug use[star, open]." Research in Social and Administrative Pharmacy 1(2): 139

Hansen, R. A., S. J. Shaheen, et al. (2005). "Factors influencing the shift of patients from one proton pump inhibitor to another: The effect of direct-to-consumer advertising." Clinical therapeutics 27(9): 1478.

Hollon, M. F., E. B. Larson, et al. (2003). "Direct-to-consumer marketing of osteoporosis drugs and bone densitometry; Direct-to-consumer marketing of osteoporosis drugs and bone densitometry." Annals of Pharmacotherapy 37(7/8): 976.

Huh, J. and L. B. Becker (2005). "Direct-to-consumer prescription drug advertising: understanding its consequences." International Journal of Advertising 24(4): 441.

Iizuka, T. and G. Z. Jin (2005). "The Effect of Prescription Drug Advertising on Doctor Visits." Journal of Economics and Management Strategy 14(3): 701.

Kravitz, R. L., R. M. Epstein, et al. (2005). "Influence of Patients' Requests for Direct-to-Consumer Advertised Antidepressants: A Randomized Controlled Trial." JAMA: Journal of the American Medical Association 293(16): 1995.

Ling, D. C., E. R. Berndt, et al. (2002). "Deregulating Direct-to-Consumer Marketing of Prescription Drugs: Effects on Prescription and Over-the-Counter Product Sales." Journal of Law and Economics 45(2): 691.

Mehta, A. and S. C. Purvis (2003). "Consumer response to print prescription drug advertising." Journal of Advertising Research 43(2): 194.

Mintzes, B., M. L. Barer, et al. (2003). "How does direct-to-consumer advertising (DTCA) affect prescribing? A survey in primary care environments with and without legal DTCA." CMAJ: Canadian Medical Association Journal 169(5): 405.

Rosenthal, M. B., E. R. Berndt, et al. (2003). "Demand Effects of Recent Changes in Prescription Drug Promotion; Demand Effects of Recent Changes in Prescription Drug Promotion." Frontiers in health policy research.Volume 6: 1.

Spence, M. M., S. S. Teleki, et al. (2005). "Direct-to-consumer advertising of COX-2 inhibitors: Effect on appropriateness of prescribing." Medical Care Research and Review 62(5): 544.

t Jong, G. W., B. H. Stricker, et al. (2004). "Marketing in the lay media and prescriptions of terbinafine in primary care: Dutch cohort study." BMJ.British Medical Journal 328(7445): 931.

Zachry Iii, W. M., M. D. Shepherd, et al. (2002). "Relationship between direct-to-consumer advertising and physician diagnosing and prescribing." American Journal of Health-System Pharmacy 59(1): 42.

Sworn before me at the City of

in the Province of

on the day of , 2006.

A Commissioner for Taking Affidavits within British Columbia	**Steven G. Morgan**

FORM 4C – BACKSHEET – Rules of Civil Procedure, Rule 4.02(3)

05-CV-303001PD2

CANWEST MEDIAWORKS INC.	AND	ATTORNEY GENERAL OF CANADA
Applicant		Respondent

ONTARIO
SUPERIOR COURT OF JUSTICE

Proceeding Commenced at Toronto

AFFIDAVIT OF STEVEN MORGAN
(Sworn , 2006)

Department of Justice
Ontario Regional Office
The Exchange Tower
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Our File: 2-563638
Law Society No.: 17838A

Solicitors for the Respondent