Court File No. 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 RICHARD G. FRANK

I, Richard G. Frank, of the Town of Lexington, in the State of Massachusetts, make oath and say as follows:

I. Qualifications

1. I am the Margaret T. Morris Professor of Health Economics at Harvard University Medical School. I teach in Harvard's university-wide doctoral program in health policy. I also teach undergraduates health policy and health economics. I am a Research Associate at the National Bureau of Economic Research. Since 1981, I have conducted research and taught in the area of health economics. I have lectured and published papers on the economics and regulation of the pharmaceutical industry as well as other facets of the health sector. I serve as a Co-Editor of the *Journal of Health Economics*. I also serve on the editorial boards of *Health Affairs* and the *Journal of Mental Health Policy and Economics*. A copy of my curriculum vitae is attached as Exhibit A.

2. My research activities address the economics of the pharmaceutical industry. I have analyzed pricing practices in the pharmaceutical industry in a

study sponsored by the U.S. Congress' Office of Technology Assessment. A paper based on that research won the Georgescu-Roegen Award from the Southern Economic Association for the Best Article in the *Southern Economic Journal* 1992-1993. I have conducted statistical studies of price competition in the brand name and generic prescription drug markets, the impact of drug formularies and direct to consumer advertising ("DTCA") on prescription drug spending and I have examined the impact of new drugs on non-drug health care spending.

3. I was elected to the Institute of Medicine of the National Academy of Sciences in 1997. I recently served as Vice Chair of the congressionally appointed Citizen's Health Care Working Group. I have been a consultant to the Province of Ontario, U.S. state governments and federal agencies of the U.S. government. I have testified as an economic expert on matters related to the economics of the pharmaceutical industry before state and federal courts. During the last 5-7 years I have served as an expert on behalf of defendant wholesale druggists in the *Brand Name Prescription Drug* litigation. In that matter I analyzed the role of wholesale druggists in determining price differences for branded drugs across types of buyers. I served as an expert in the *Merck-Medco Managed Care LLC v. Rite Aid Corp et al.* litigation where I analyzed the economics of pharmacy networks. I served as an expert for the U.S. Federal Trade Commission in its investigation of the competitive impacts agreements between and brand name manufacturer and a potential generic drug supplier concerning the drug Cardizem. I served as an expert for the plaintiffs in a class action matter where I considered whether a class wide analysis was the appropriate approach for assessing liability and damages (*St. Charles Hospital and Rehabilitation Center v. Mylan Laboratories*). Finally, I have served as an expert to the plaintiffs in the *Terazosin Hydrochloride* antitrust litigation. In that matter I examined liability and impact related to an agreement by Abbott Laboratories and generic manufacturers.

II. Background and Context

I have been retained by counsel for CanWest MediaWorks Inc. ("CanWest") to provide an overview and assessment of research on the impact of direct to consumer advertising of prescription drugs on the access to, quality and cost of health care. I have also been asked to comment on some of the evidence presented by the Attorney General in the matter of *CanWest Mediaworks Inc v. Attorney General of Canada*. I will comment in particular on the affidavit of Professor Morgan sworn June 30, 2006 and the affidavit of Dr. Wilkes sworn July 12, 2006.

A. Consumerism in Health Care

4. Health care delivery in western countries has undergone enormous technological and philosophical changes. The patient role was once one of passivity and dependence, where the sick person accepted directives based on the judgments of medical professionals regarding what was in their best interest. Modern views of health care delivery take a different tack. The U.S. Institute of Medicine's highly regarded report entitled *Crossing the Quality Chasm* ("IOM Report") recognizes a different role for the patient. That report recommends redesign of the health care processes in accordance to the following rules (among others):

- Customization (of care) based on patient needs and values.
- The patient as the source of control, emphasizing that patients should be given necessary information and the opportunity to exercise the degree of control they choose over health care decisions.

- Shared knowledge and the free flow of information. Patients should have unfettered access to their own medical information and clinical knowledge.[1]

5. The patient in modern health care systems is increasingly placed in the role of consumer that encompasses both the implied sense of autonomy and the commercial implications. The health care system in Canada differs from U.S. health care in important ways but increased patient autonomy and growth in consumerism is not limited to American health care. The expanded role of patients is highlighted by efforts across western nations to measure and publicly report the quality of care delivered by providers.[2] The modern view of clinical care has the patient as an active participant in a variety of health care decisions. As the IOM Report notes, information is central to patient decision-making. It is important to consider pharmaceutical promotion in the context of these developments.

B. Key Economic Features of Markets for Prescription Drugs

6. Prescriptions drugs carry a set of unique economic attributes that are important for understanding incentives to promote products. The most critical economic feature of prescription drugs is the fact that it is a low marginal cost-high fixed cost industry. That is, the long run supply of new prescription drug products depends critically on research and development (R&D) activity that is costly, risky and time consuming. In the short run R&D costs are fixed and the costs of manufacturing another unit of output is literally "pennies a pill". For brand-name drugs that are protected by patents, prices are multiples of short run manufacturing costs, thereby making conventionally measured accounting profit

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[1] Institute of Medicine (2001), *Crossing the Quality Chasm: A New Health System for the 21st Century* Washington: NAS Press p.8. The bullet points paraphrase and take language from the report.

[2] Hussey PS et al (2004); "How Does the Quality of Compare in Five Countries?" *Health Affaires* 23(3): 89-100.

margins very high.[3] One implication of these features of the industry is that expanding sales will generally make positive contributions to short run profits. This creates an incentive for pharmaceutical manufacturers to promote their products. This incentive is blunted in Canada compared to the U.S. where price-cost mark-ups are lower.

7. A second set of economic characteristics relates to the informational attributes of prescriptions drugs. Economists have long made a distinction between *experience* and *search* goods.[4] Search goods do not require an individual to consume the product in order to learn about its salient features. Reports on the product's specifications are sufficient for a consumer to understand the product. Experience goods, in contrast, have performances that can be heterogeneous across individuals and are hard to predict based on product specifications. Thus experience goods require that an individual consumer use the product in order to obtain information about the product. Prescription drugs are thought to fall under the heading of experience goods because effectiveness, side effects, and potential interactions with other drugs vary across individuals and their clinical circumstances. It is worth noting that it is this heterogeneity in response along with competitive impacts than can make so-called "me too" drugs valuable products.[5]

8. It has been hypothesized that levels of promotion would be higher for experience goods relative to search goods because of the economic importance of getting people to try a particular product.[6] Taken together, the cost structure of the pharmaceutical industry along with the fact that drugs can be viewed as

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[3] Congressional Budget Office (2006), *Research and Development in the Pharmaceutical Industry* Washington D.C.: CBO, October

[4] Nelson, P (1974), "Advertising as Information" *Journal of Political Economy* 82(4) 729-754

[5] An example of the benefits of "me too" drugs can be found in a discussion of psychotropic medications by Huskamp. See Huskamp HA (2003), "Managing Psychotropic Drug Costs: Will Formularies Work?" *Health Affairs* 22(5): 84-96. See especially pages 89-90. Also see Congressional Budget Office (1998), *How Increased Competition from Generic Drug Has Affected Prices and Returns in the Pharmaceutical* Industry Washington: CBO, July. This is a point that is largely overlooked in the reports of Drs. Morgan and Wilkes.

[6] Nelson (1974) op. cit.

having important features in common with experience goods, suggest that there would be strong incentives for manufacturers of prescription drugs to promote their products.

9. A third critical feature is the role of the physician in decisions regarding the purchase of prescription drugs. Physicians are viewed as "learned intermediaries" who serve to advise and constrain the decisions of their patients. Physicians typically (but not always) have a greater understanding than their patients of the risks and benefits associated with the use of particular prescription drugs for a specific set of clinical circumstances. Thus, consumers may only purchase prescription drugs with the consent of a physician. Consumers are therefore not left entirely to follow their own impulses in response to promotion, testimonials from friends and family, or other sources of counsel about prescription drugs.

10. Dr. Wilkes points to an article that he co-authored with Kravitz and others ("Kravitz Study"), which highlights two sets of limits on the role of the learned intermediary.[7] In that study, by using actors to play the role of standardized patients with symptoms of either major depression or adjustment disorder, these actors were randomized to either make no suggestions about treatment, a general suggestion about psychotropic medication, or a specific recommendation about the drug Paxil. The results show that for patients portraying symptoms of major depression that made no suggestion about drug treatment, only 31% were prescribed appropriate antidepressant medications. For patients portraying symptoms of major depression that made a general suggestion about medications, 76% received an antidepressant prescription. Among those making a request for Paxil, 53% received a prescription.

11. For the actors portraying patients with adjustment disorder (where the

[7] Kravitz R et al (2005), "Influence of Patients' Requests for Direct to Consumer Advertised Antidepressants"*JAMA* 293:1995-2002

authors report that there is no clinical consensus that antidepressants are indicated), those actors making a specific request were most likely to receive a prescription for an antidepressant (55%), compared to 39% for those making a general request, or 10% for those making no request. In combination these results show that educated consumers have the potential to improve clinical decision-making by reducing under treatment. Under treatment is quite common.[8] They also indicate the possibility that misinformed consumers can affect clinical decision-making, resulting in over use.

12. A fourth feature of pharmaceutical markets is the presence of health insurance. Health insurance offers the benefits of risk spreading and protection against the financial consequences of illness. It also drives a wedge between an individual and the financial consequences of their consumption choices. This means that individuals will be less sensitive to the relative prices of competing products than if they had no insurance. (In the U.S. this is offset somewhat by price sensitive purchasers such as HMOs and Pharmacy Benefit Managers (PBMs). In Canada different provinces have adopted schemes such as reference pricing for making consumers price sensitive.) The implication of lower price sensitivity is there will be some tendency towards moral hazard in consumption of medical care.

13. These economic characteristics create the public policy challenge raised by direct to consumer advertising of prescription drugs. That is, there exist side-by-side potential gains in economic welfare from permitting some forms of product specific advertising ("Product Claim DTCA"[9]), and potential threats to economic efficiency stemming from incentives to mislead consumers and

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[8] For example Hussey et al (2004) op cit. show that for different condition patients in Canada, the U.S. and other western nations receive less than the recommended level of care.

[9] Other forms of DTCA are "condition advertising", which mention the medical condition for which a drug is prescribed together with a message to "speak to your doctor about available treatments" but do not name the drug, and "reminder advertising", which mentions the name of the drug but not the condition it is used to treat. "Reminder advertising" has been criticized in the U.S.: see e.g. remarks of Dr. Temple summarizing Public Meeting of Food and Drugs Administration ("FDA") on DTCA, September 23, 2003, p.227.

physicians, leading to inappropriate use of prescription drugs. As a result, the U.S. and other nations are engaged in on going policy debates about how to design regulations that allow consumers to obtain the potential gains from DTCA, while limiting any untoward effects of DTCA. Achieving such a balance appears to require a great deal of oversight of the accuracy of DTCA claims and of the mode in which information is presented.

III. Assessing the Impact of Direct to Consumer Advertising of Drugs

14. Economic theory offers a useful framework for considering incentives related to promotion of prescription drugs. However, it offers little guidance for determining whether direct to consumer advertising or other forms of promotion enhance or reduce economic welfare. Economic theory has long debated whether advertising was primarily informational or persuasive. The former view sees advertising as providing information to consumers, thereby enhancing their ability to make efficient choices. Relevant information includes the existence of a product, its price and its attributes.[10] The latter view argues that advertising is meant to persuade and even to mislead consumers. It creates differences that are not real. In this way consumers are manipulated and real competition between products reduced.[11] While both views have some merit, one cannot make a judgment about the relative importance of each without a careful, comprehensive and balanced examination of the data on the behavior of providers and consumers and the relevant health care institutions.

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[10] Schmalensee R. (1972), *The Economics of Advertising* Amsterdam: North Holland Press

[11] Galbraith JK (1967), *The New Industrial State*, Boston: Houghton-Mifflin. The Reports of Morgan and Wilkes appear to subscribe to the simple persuasiveness view of advertising.

A. Evidence on the Impact of DTCA on Demand for Drugs

15. The literature is nearly unanimous regarding evidence that advertising increases demand. That is hardly surprising. Advertising increases demand in most markets and common sense suggests that prescription drug manufacturers would not persist in making the sizable outlays if no benefits were being realized. Yet this set of observations alone does not advance the assessment of whether or not DTC advertising improves economic welfare. To make such judgments one must begin by assessing the social costs and benefits associated with such activities. In addition one may also want to consider any distributional effects of DTC advertising. Merely establishing that DTCA is associated with increased demand tells us little on its own. For example, if the evidence suggests that the increased demand is appropriate then that would tend to suggest improved welfare; if it were not then that would imply a tendency to create overuse. While I will not attempt to review the literature here especially given the multiple efforts aimed at that task among the reports in this case and elsewhere (including a recent report by the U.S. Congress General Accounting Office),[12] I will comment on what I see as the weight of the evidence.[13]

16. I have reviewed the affidavit sworn by Julie Donohue on May 22, 2007 in this matter. I agree with her analysis and conclusions.

17. The basic message of the US GAO Report and of Donohue's Affidavit is that the effects of DTC advertising are complicated and mixed. That is, spending on prescription drugs grows in response to such promotion, and some of this spending has positive effects on quality of and access to care while in other cases the effects suggest over use of services and wasteful expenditures. On balance the net effects on social welfare are highly uncertain and they likely vary

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[12] For a set of observations on the impact of DTC advertising in the U.S. see US GAO (2006), *Prescription Drugs: Improvements Needed in FDA's Oversight of Direct to Consumer Advertising* Report # GAO-07-54.

[13] The Affidavits of Julie Donohue, Steven G. Morgan and Michael S. Wilkes all cover the literature albeit with very different approaches to offering balanced assessments and with different emphasis.

considerably according to clinical and social contexts. In fact, the study by Kravitz and colleagues discussed above offers some of the strongest evidence highlighting such a view.[14]

18. In sharp contrast to these views are the assertions advanced by Professor Steven Morgan.[15] Professor Morgan asserts that much if not all the difference in growth of pharmaceutical spending between the U.S. and Canada between 1995 and 2003 is due to DTCA. The analysis and estimates of the cost impact of DTC advertising is a center piece of his view that allowing DTC advertising in Canada would result in "an even less economically efficient allocation of resources and a significant threat to public and private drug plans in Canada" (Morgan Affidavit p. 43).

19. Dr. Morgan describes his methodology for estimating the drug spending impact on DTC advertising in the following fashion:

> "An estimate of the overall impact of DTCA in the U.S. can be obtained by considering the trends in drug expenditure in the U.S. and Canada before and after the increase in American DTCA. Others have noted that the increase in DTCA in the U.S. began prior to the 1997 change in regulations...."(p. 37)

20. This general approach is frequently used in economics. When it is used appropriately great pains are taken to show that a) pre-policy change trends in the "treated" versus "untreated" groups were the same; and b) other key factors determining drug spending (in this case) were not changing at the same time that the policy was being introduced. Morgan appears to be aware of these methodological demands, as he states: "Other than the change in U.S. DTCA spending, there were no other major changes in the pharmaceutical sectors in Canada or the U.S. that could explain the direction and magnitude of recent divergence in prescription drug expenditure levels between the two countries" (p. 38). In general one would expect a balanced analysis from an economist who

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[14] Kravitz et al (2005) op. cit.
[15] Affidavit of Steven G. Morgan in CanWest Media Works Inc. v. Attorney General of Canada

identifies himself as one of Canada's leading authorities on pharmaceutical economics, to involve an exhaustive search for possible confounding factors that might explain changes in drug spending trends in the two countries prior to making such strong assertions.

21. Table 1 provides a time series from U.S. National Health Accounts on the percent of drug expenditures that were paid out of pocket by Americans, an indicator of the extent of insurance coverage for prescription drugs. It is instructive to note that there has been a substantial decline in the out of pocket share paid by consumers of prescription drugs in the U.S. It has declined from 59.1% in 1990 to 29.7% in 2003, a nearly 50% decline in the consumers' out of pocket share. Since 1995 there has been a 13-percentage point drop in the consumer out of pocket share for prescription drug expenditures. Economic theory and empirical evidence suggests that when consumers face lower out of pocket costs they tend to spend more.[16] Thus if Canadian insurance arrangements were not expanding during this time period, as Morgan claims on page 38 of his Affadavit, then the change in U.S. insurance coverage relative to Canada may be quite important in explaining growth in spending on prescription drugs in the U.S. It appears that Morgan may be attributing these insurance effects to DTC advertising. This important change in the U.S. prescription drug financing appears to have been overlooked by Professor Morgan and this omission represents a potentially fatal flaw in his work.

22. The Morgan Affidavit is filled with other instances where research methods were casually applied and literature selectively discussed in connection with strong conclusions about the impact of DTC advertising. I will offer only some examples of this practice. The first relates to the review of the study by Mintzes

[16] See for example Newhouse JP (1993), *Free for All?* Cambridge: Harvard University Press. This book summarizes the RAND Health Insurance Experiment showing that lower cost sharing increases demand for medical care including prescription drugs.

et al.[17] Here physicians from Sacremento and Vancouver were recruited to participate in a study of DTC advertising. A main finding of the study was that patients who recalled seeing a DTC ad were more likely to request a prescription from their doctor. Since this study compares people and places that differ in numerous ways other than the level of exposure to DTC advertising (like culture, insurance arrangements), attributing all differences in levels and patterns of prescribing to DTC advertising may be quite misleading.

23. The second example involves Professor Morgan's analysis of how drug-spending differences between the U.S. and Canada have grown over time. He shows data on real per capita drug expenditure differences between the U.S. and Canada in Figure 2 of the Affidavit. This is a prelude to the analysis discussed earlier. This takes drug expenditures and analyzes them as if they are unrelated to health spending. The impression created is that there has been an explosion in U.S. drug spending over Canada's beginning in the mid-1990s. These data in the narrow sense are correct. But it is instructive to look at drug spending not only by itself but in relation to overall health care spending in the two nations. Note that in 1960 the nominal dollar difference in overall health care spending was $22 per capita, or 17.6% more in the U.S. By 2004 the nominal difference in per capita health spending is $2937, or 92.7% higher in the U.S. Turning to the drug spending shares of the health dollar, one can see that since 1980 it is Canada that has devoted an increasingly larger share of its health dollar to drugs. So one might well infer that the U.S. just spends more on all health care than Canada, and that health spending differences have been growing rapidly over time. Moreover, the U.S. has actually seen slower growth than Canada in the share of its health dollar devoted to drugs over the last 25 years. These are complicated phenomena; my aim is not to offer a complete explanation but rather to illustrate how Morgan's analysis and presentation of data is imbalanced and potentially misleading.

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[17] Mintzes et al (2003), "How Does Direct to Consumer Advertising Affect Prescribing? A Survey of Primary Care Environments With and Without Legal DTCA" CMAJ

24. A third example is notable because it involves his use of my work. On page 36 of his affidavit, Professor Morgan quotes from my paper with Rosenthal and others.[18] He does so to obtain a parameter for the impact of spending on DTCA on prescription drug spending. However, rather than quoting the results of our empirical analysis of the issue, he quotes from a discussion of an interview we conducted with pharmaceutical industry marketing executives. It is a curious choice to rely on second-hand reports of conversations with executives instead of statistical evidence on exactly the parameter of interest that is reported on the same page of the manuscript that he cites. The statistical estimates imply a smaller impact than the claims made by the executives. Later in his affidavit Morgan uses our estimates to estimate the aggregate impact of DTCA on prescription drug spending. On page 39 of his affidavit Professor Morgan states that "Rosenthal and colleagues estimated that DTCA caused 22 percent of drug expenditure growth between 1999 and 2000". While this statement is not false, it is misleading. On page 23 of our paper we state the following. "The two different aggregation approaches yielded estimates of DTCA attributable spending growth of 22 percent and 13 percent, respectively, of total prescription drug spending growth." Thus, Professor Morgan's use of convenient second-hand quotes and selective reporting of results creates an unbalanced reflection of the actual scientific evidence that is available on the impact of DTCA. This is frequently referred to as "cherry picking" results - not a practice of the evenhanded scholar.

25. Finally, it is also surprising that Professor Morgan chose not to mention one of the most important findings from our study. That is, that DTCA increased demand for all drugs in a therapeutic class and that we did not find strong evidence suggesting that DTCA conferred large brand specific advantage in demand growth.[19] We were, however, reluctant to conclude strongly that DTCA

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[18] Rosenthal MB, et al (2003), "Demand Effects of Recent Changes in Prescription Drug Promotion" in D Cutler and A Garber (eds) *Frontiers in Health Policy Research*, Cambridge: MIT Press

[19] Rosenthal et al (2003) p.21

has only class level effects because the individual drug estimates we obtained were not very stable. My point is not to suggest that no brand specific evidence exists, but rather to highlight a tendency in Morgan's report to play down or ignore findings that are inconvenient to his argument. So his statements in paragraph 113 of his affidavit presume that there is evidence to support brand specific effects of DTCA. This has yet to be established and Professor Morgan's failure to fairly represent what is known on this issue makes matters seem more settled than they really are.

B. Performance of Prescription Drug Markets and DTCA

26. The pharmaceutical industry has produced great value to people around the world over the past 30 years.[20] It has also made increasing claims on the resources of advanced and developing countries. The pharmaceutical industry has also frequently not allocated resources in the manner in which many believe would be most worthwhile from the perspective of advancing the health of the public.[21]These ills are not primarily due to the presence of DTCA. In fact, debate about aligning incentives for drug companies to develop drugs with the greatest public health significance dramatically pre-dates any direct to consumer marketing.[22]

27. There are also reasons for concern about the details about how direct to consumer advertising and physician-focused promotion is regulated in the United States. Recent reviews by the General Accountability Office have suggested that not enough scrutiny has been devoted to the content of DTCA promotions.[23] There are also suggestions that have been made to the Food and Drug Administration regarding how the timing and content of DTC promotions might be

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[20] For a discussion of some prominent example of the benefits of pharmaceutical advances see Culter DM (2004), *Your Money of Your Life* Oxford UK: Oxford University Press
[21] Affidavit of Michael S. Wilkes p. 6
[22] See for example Task Force on Prescription Drugs (1968), "The Drug Makers and the Drug Distributors" *Background Papers*, Washington DC: USGPO
[23] See US GAO (2006) op cit

altered to create more even-handed information on the benefits and risks of specific drug products and greater consumer protection.[24]

28. Dr. Wilkes reviews some evidence on the impact of DTCA on the quality of care and the nature of the physician-patient interaction. Dr. Wilkes draws conclusions on these issues on pages 15 and 16 of his affidavit. He notes "DTC advertising motivates some patients to talk to their health care providers about these ads and even make explicit requests based upon them."[25] Wilkes goes on to note that the skill of the physician is important in handling such requests. He also states that "even when physicians respond to an ad motivated request without defensiveness, the clinical quality of care could suffer if the physician becomes distracted by focusing on the drug requested rather than the nature of the clinical concerns." Logically, such problems should also arise from allowing consumers to search the Internet for information on treatment for their illnesses or when patients that join illness support groups. The concerns raised by Wilkes seem fundamentally related to patients actively coming into a physician's office armed with information or views about their therapies. The changes in the role of patients in the health care system, including their rights to participate in clinical decisions and opportunities to learn about their illnesses and available treatments, are a basic feature of modern health care. Physicians are being obliged to learn how to interact with patients that are intent on being active participants in their own care.

29. Dr Wilkes' strictly negative assessments of the impact of DTCA overlook some of the benefits of DTC induced patient requests. As discussed earlier in this affidavit (paragraphs 9 and 10), Dr. Wilkes' own research shows important positive impacts of patient contacts that might mirror DTCA induced visits for people with major depression. While the Kravitz Study clearly documents both positive and negative potential impacts of DTCA, Dr. Wilkes appears to have only

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[24] Institute of Medicine (2006), *The Future of Drug Safety: Promoting and Protecting the Health of the Public* (Washington DC: NAS Press)
[25] Wilkes affidavit p.15

been impressed with the indications of over use generated in his study and largely overlooks the reduction of unmet need for a major mental disorder that is associated with significant morbidity and mortality.[26] The U.S. Government Accountability Office (GAO) comes to a more mixed conclusion about the impacts of DTCA on consumers.[27] In the GAO Report it is stated that "(S)tudies about DTC advertising and the increased utilization of prescription drugs it can prompt suggest that its effect on consumers can be both positive and negative".[28] The report goes on to review a number of possible positive and negative impacts on consumers of DTCA. Among the potential positive impacts are improved communication between doctors and patients; increased rates of diagnosis and treatment of high cholesterol; and improved identification and treatment of depression. The report also identifies potential negative impacts such as distortion in prescribing towards less appropriate medications for pain management and over treatment of adjustment disorder with inappropriate drugs (the result suggested by the Kravitz study).[29]

C. A Comment on the Counterfactual

30. Professor Morgan offers some analyses that examine a world with DTCA levels similar to those of the United States in the years 1997-2004 and compare it to a world where there is virtually no DTCA. This comparison underlies a number of his conclusions about the spending impact associated with DTCA. For example, Professor Morgan uses the estimates made by Rosenthal et al or reports from industry sources to construct estimates of the increased spending that would occur in Canada if current regulations about DTCA were changed. Using a "no DTCA world" as the counterfactual in assessing the effect of permitting DTCA in Canada is incorrect and will almost certainly lead to an upward bias in the impact of DTCA on Canadians.

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[26] See for example *Mental Health: A Report of the Surgeon* Genera, Washington DC: USGPO, 1999
[27] U.S. GAO (2006) p. 16
[28] U.S. GAO (2006) p. 16
[29] U.S. GAO p16-17

31. This view is based on facts reported in Professor Morgan's affidavit. On page 407 of the paper by Mintzes and colleagues (included as Tab 3 to the Morgan affidavit) it is noted that 87.4% of Vancouver patients report having seen 1 DTC ad and 30% more than 10 in the last year. This means that Canada does not represent a situation that mirrors the counterfactual used by Morgan in conducting his analyses. In fact, given the significant penetration of U.S. media into the Canadian market as described in the affidavit of Kathy Gardner sworn June 4, 2007, it is likely that a substantial segment of the Canadian population is currently exposed to pharmaceutical DTCA. Hence, the impact of changes in DTCA regulations would likely cause an increase in DTCA exposure over and above what already exists, but this is not the same as assuming that no such exposure currently exists. It also means that some of the spending impacts that are included in the Rosenthal et al study and other analyses have already taken place in Canada.

D. An Observation on the Application of the Opportunity Cost Concept

32. In considering policy that affects the use of health care resources it may be appropriate to consider the alternate uses of resources in improving health and managing chronic diseases. Both Professor Morgan and Dr. Wilkes undertake such exercises.[30] However, both make arguments that are misleading in that they are based on implied assumptions about health resource allocations or the manner in which health care funds are actually spent.

33. Professor Morgan states the following:

> "...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

[30] See for example Morgan's discussion in paragraphs 107 and 110 of his affidavit. Wilkes makes a similar set of observations at the bottom of page 17 of his report.

> determinants of population health such as childcare, education and community services".

This statement appears to assume that Dr. Morgan has strong evidence that scarce dollars not devoted to pharmaceutical products would be clearly directed to more socially valuable health and non-health care activities. In a world of considerable decentralized decision making over health care and non-health care services it is important to carefully offer evidence in support of such an assertion. Some recent surveys on the quality of care across nations raises questions regarding the effectiveness of health care spending in Canadian (and U.S.) primary care practices. For example, when Canadian primary care physicians were asked how well prepared their practices were to deliver care to patients with multiple chronic conditions, 55% reported they were well prepared compared to 93% in Germany and 68% in the U.S.[31]Similarly, 40% of Canadian primary care physicians reported being well prepared to treat mental disorders like depression compared to 70% in Germany and 37% in the U.S. Canadian primary care physicians also report relatively low rates of adoption of quality improvement techniques.[32]The point here is that one is far from guaranteed that reallocation of funds away from prescribing will result in valuable health and non-health care services that will lead to net improvements in the health of Canadians. One cannot simply assume that dollars shifted from prescribing will be efficiently and effectively spent on the most socially valuable activities.

34. Dr. Wilkes makes some similar assertions and additionally seems to assume that there is some fixed budget for health care, implying that growth in prescription drug spending necessarily means a reduction in services like child health services or immunizations. Wilkes makes the following statement:

> "In the same vein, budget cuts in health care, and the public health consequences to which they surely lead, are also inextricably linked

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[31] See Schoen C., et al (2006), "On the front line of care: primary care doctor's office systems, experience, and Views in Seven Countries" *Health Affairs (web exclusive)* November: W555-W571

[32] See Schoen et al Exhibit 6.

> to the skyrocketing cost of prescription medications, which is in turn due in part to DTCA".[33]

35. Wilkes offers no evidence to support this assertion. The very fact that health care services have been rising rapidly in Canada and causing consternation underscores the point that there is no fixed budget for health care. Rather the concern is that rapid growth in health care causes health services to claim an increasingly large part of national income, something that is viewed by many as troubling. If this is the case, there is no direct one-to-one connection between prescription drug spending and other types of health care spending. Moreover, the data that exist seem to make Wilkes' basic claim about the havoc in resource allocation caused by DTCA implausible. Consider the case of the U.S. during a recent period where prescription drug spending was growing very rapidly (20% per year). My results with Rosenthal and others estimated an upper bound impact of DTCA on demand growth of about 22%. This means that the largest impact on drug spending that might be attributed to DTCA is about 4.4% (0.20x0.22). Now recall that in the U.S. drug spending has accounted for between 10% and 12% of national health spending. This means that DTCA might at the very most affect one half of one percent of health spending, hardly an impact large enough to disrupt public health programs (especially if the funding streams are separate).

IV. Conclusions

36. Direct to consumer advertising is in part a product of the rise of consumerism in health care. It is accompanied by a variety of legal and technological changes (the internet) that aid consumers to play an active role in making decisions about their health and health care.[34] The evidence on the impact of DTCA on spending and quality of care is decidedly mixed. It alters the

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[33] Wilkes affidavit p. 17.

[34] See Fox, S., Internet Health Resources. Washington DC: Pew Internet and American Life Project. October 29, 2006. Available on-line at http://www.pewinternet.org/pdfs/PIP_Online_Health_2006.pdf.

doctor-patient relationship, it probably expands diagnosis and treatment for some important untreated conditions and it has probably led to inappropriate use of some drugs. These varied impacts are complex and it is difficult to arrive at clear conclusions about the net benefits to the policy.

37. After multiple reviews under two different administrations in the U.S., the consistent policy conclusion is that some Product Claim DTCA should continue to be permitted. There have, however, been a variety of suggestions made about how to improve the regulation of content in ads, and the timing of the use of advertisements. I believe that the existing evidence supports such an approach. Thus there are legitimate concerns about how DTCA is implemented and there are a number of reasonable ideas to modification of existing U.S. arrangements that would likely decrease troublesome impacts of DTCA on quality of care.

38. The affidavits by Professor Morgan and Dr. Wilkes are strikingly unbalanced in their reviews of the existing evidence. Professor Morgan makes fatal errors of methodology and interpretation of data that discredit his basic conclusions. Dr. Wilkes overlooks data and research that are inconvenient to his arguments. He arrives at conclusions that are contradicted in part by his own research. He also makes strong claims that are on their face implausible. It appears that Dr. Wilkes would like to return to the days that doctors gave all the orders and did not have to deal with pesky patients that came to their appointments armed with information, questions or ideas about their own treatment.

39. DTCA must be assessed on the basis of its actual impacts and not on the sins of a changing world that makes the physician's job more complex and taxing. In my view the evidence suggests a complex array of positive and negative effects on health care delivery and health. The balance of the evidence is not in my view consistent with a complete ban on direct to consumer advertising of prescription drugs.

SWORN before me at the City of
Boston in the
State of
Massachusetts this
19 day of June, 2007

Wilma R. Stahura
A Commissioner, etc.

Richard G. Frank

Table 1
US Out of Pocket Spending on Prescription Drugs 1990-2003

Year	% Out of Pcoket
1990	59.1
1995	42.7
200	31.5
2001	30.2
2002	29.5
2003	29.7

Source: Center for Medicare and Medicaid Services, Office of the Actuary, National Health Statistics Group. Available at: www.cms.hhs.gov/statitics/nhe

Table 2
Per Capita Health spending and the Drug Share of Health Spending US and Canada

Year	US		Canada	
	$ per capita	*Rx% of Health $*	*$ per capita*	*Rx% of Health $*
1960	147	16.2	125	12.9
1970	352	12.2	299	11.3
1980	1072	9.0	783	8.5
1990	2752	9.1	1737	11.5
2000	4588	11.7	2503	15.9
2004	612	12.3	3165	17.7

Source; OECD 2006