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 DR. DON FULGOSI

I, Dr. Don Fulgosi, of the City of Toronto, in the Province of Ontario, make oath and say as follows:

1. I am a practicing psychiatrist. Since 1971, I have been licensed to practice medicine in the Province of Ontario, and have been prescribing drugs to patients throughout this time. I obtained my Certification and Fellowship in Psychiatry, and in 1974 became a Fellow of the Royal College of Physicians and Surgeons of Canada (FRCPC). Since then, I have specialized in psychopharmacology, which is the branch of pharmacology that deals with the effects of psychoactive drugs on patients with psychiatric disorders. In particular, for many years I have practiced, lectured, and taught on depressive and anxiety disorders and their co-morbidities and treatment. My *curriculum vitae* is attached as Exhibit "A" to this affidavit.

The Arguments Against DTCA

6. The arguments made by these affidavits for prohibiting DTCA of prescription drugs fall into three major categories:

- DTCA results in increased and inappropriate prescribing of newly introduced drugs, thereby increasing the risk of adverse drug reactions (ADRs);[2]
- DTCA leads to "medicalization of normal life" and "disease mongering", thereby increasing the prescribing of unnecessary remedies;[3] and
- DTCA thus causes increased costs to individuals and society, without demonstrable improvements in health outcomes. [4]

7. In my opinion, these arguments are not supported by empirical evidence, and they are certainly not borne out in my own experience.

8. These arguments are also artificial and abstract in the Canadian context because they do not acknowledge the extent to which Canadians are already exposed to DTCA through U.S. media. From my own experience, I am aware that DTC advertisements of prescription drugs appear regularly on U.S. television channels available in Canada by cable or satellite, in U.S. magazines sold in Canada, and on internet sites based in the U.S. and elsewhere that are accessible in Canada. My patients frequently report to me that they have seen a drug advertised on one or more of these media. Thus, the question is not really whether DTCA is good or bad, but rather whether Canada's DTCA prohibition is defensible given that Canadians are regularly exposed to DTCA through U.S. media in any event.

---

[2] Affidavit of Joel Lexchin, sworn June 30, 2006 ("Lexchin Affidavit"), at paras.10, 62, 63, 72.
[3] Affidavit of Michael Wilkes, sworn July 12, 2006 ("Wilkes Affidavit"), Exhibit 2, p. 16; Affidavit of Maurice Nelson Graham Dukes, sworn July 13, 2006, ("Dukes Affidavit"), Exhibit 2, pp. 10-11.
[4] Lexchin Affidavit paras 57-63;Wilkes Affidavit, Exhibit 2, pp. 16-19; 26-27; Dukes Affidavit, Exhibit 2, pp. 26-29.

9. Another essential part of the context is that pharmaceutical manufacturers can and do advertise directly to physicians in Canada. This kind of advertising, known as "detailing", accounts for the vast majority of drug advertising in both the U.S. and Canada. Although spending on DTCA has increased dramatically in the U.S. since the FDA changed its policy in 1997, it remains at only 15% of moneys spent on drug promotion – 84% is spent on direct promotion to the doctors.[5] DTCA complements detailing, but does not supplant it. Thus, the issue is not whether drugs should be advertised at all, but whether patients as well as doctors should have access to information from pharmaceutical companies on their products.

10. In addition, DTCA is highly concentrated on a sub-group of products (usually for older consumers with chronic conditions) with a low incidence of side-effects. This sub-group includes anti-allergy drugs, anti-inflammatory drugs, cholesterol-lowering drugs, anti-anxiety drugs, and antidepressant drugs.[6] Any discussion of the benefits and risks of DTCA must be undertaken with this context in mind.

1. Whether DTCA Increases Risk of ADRs

(a) No Empirical Basis to Conclude that DTCA Increases ADR Risk

11. Several of the responding affidavits put forward the argument that DTCA, by focusing on newly-patented drugs that have not been the subject of lengthy clinical experience, expose patients to increased risks of ADRs.

---

[5] M.B. Rosenthal et al., "Promotion of Prescription Drugs to Consumers" (2002) *New England Journal of Medicine* ("NEJM") vol. 346, no. 7, pp. 498-505.

[6] M.B. Rosenthal et al., "Promotion of Prescription Drugs to Consumers" (2002) NEJM vol. 346, no. 7, pp. 498-505.

12. This argument seems to be contradicted by these witnesses' own evidence. As Lexchin points out in his affidavit, Gilbody et al[7], in a thorough analysis of the literature on the DTCA of prescription drugs up to 2004, including 2853 citations, concluded that only 4 studies/6 reports had scientific validity. The central finding of the Gilbody Study was the "void of evidence of wider impact of DTCA" (beyond increases in prescribing), and the fact that "no studies examined the impact of DTCA on health outcomes, costs, or social consequences".[8] It is therefore difficult to see how the data support a conclusion of increased risks of ADRs.

13. It must be recalled that prescription drugs are not only lawful, they are beneficial. Under the highly-regulated drug approval regime in Canada (as in the U.S.), in order for a new drug to be approved for therapeutic use in Canada, there must be "substantial evidence of both the safety and efficacy of the drug under its recommended conditions of use, as well as the quality of the drug."[9] In his affidavit, Lexchin notes that Canada's Patented Medicine Prices Review Board ("PMPRB") classifies new drugs for pricing purposes, and he cites figures of slightly over 10% being classified as Category 2 "breakthrough" or "substantial improvement" drugs, while most of the remainder are classified as Category 3 drugs providing "moderate, little or no improvement" over existing drugs.[10] Lexchin draws from this the generalization that most newly-approved

---

[7] S. Gilbody et al., "Benefits and Harms of Direct to Consumer Advertising: a systematic review" (2005) *Quality and Safety in Health Care,* vol. 14, no. 4, pp. 246-250.
[8] S. Gilbody et al., "Benefits and Harms of Direct to Consumer Advertising: a systematic review" (2005) *Quality and Safety in Health Care,* vol. 14, no. 4, pp. 246-250 ("Gilbody Study").
[9] Affidavit of Ann Sztuke-Fournier, page 38 at para. 106.
[10] Lexchin Affidavit, page 15, para. 31.

drugs are simply "me-too" drugs that offer no therapeutic advantages over existing treatments.[11]

14. In his affidavit, Lexchin acknowledges that the PMPRB categories are criticized by pharmaceutical manufacturers.[12] However, leaving aside the criticisms he reports of this classification, it is clear that prescription drugs must be found to offer therapeutic benefit and meet safety and quality standards to be approved for use, and that in many if not a majority of cases new drugs offer benefits over existing alternatives.

15. Prescribing drugs requires doctors to weigh benefits against risks. For a new drug to get through Health Canada's approval process, the benefits must outweigh the risks for the recommended conditions of use. (If that is not the case, then there has been a failure in the approval process.) Lexchin argues in his affidavit that risks might not be fully understood at the approval stage, and so, to the extent that DTCA expands the use of newly approved drugs, it increases exposure to risk of ADRs.[13] However, in the absence of empirical evidence, it is highly speculative to assume that any increase in risks outweighs the increase in benefits offered by a new drug. To the contrary, if we have any confidence in the drug approval process the logical assumption would be that typically the increase in benefits is greater.

16. It is also a gross oversimplification to characterize the majority of new drugs as "me-too" drugs, suggesting that they have nothing new to offer to patients. While many

---

[11] Lexchin Affidavit, p. 16, para. 35.
[12] Lexchin Affidavit, p. 15, para. 32.
[13] Lexchin Affidavit, pp. 17-19.

drugs may be similar in their basic chemistry and therapeutic effects, the differences may be very significant at the level of the individual patient. An example from my own field of psychopharmacology is this: beginning in the late 1980s and early 1990s, some pharmaceutical companies introduced a number of different selective serotonin reuptake inhibitors ("SSRIs"), and related agents, for treatment of depression and other mental disorders. These include fluoxetine (Prozac), fluvoxamine (Luvox), paroxetine (Paxil), sertraline (Zoloft), venlafaxin (Effexor), mirtazapine (Remeron), citalopram Celexa), es-citalopram (Cipralex), bupropion (Welbutrin),and moclobemide (Manerix). These drugs are all thought to function in much the same way: by boosting levels of serotonin and/or other neurotransmitters in the brain. However, in my practice treating patients, I have found that individuals exhibit markedly different reactions to different SSRIs or related medications.

17. There is also reason to question the ethics of the position Lexchin takes in his affidavit that, owing to uncertainties in the reliability of the approval process, DTCA should be prohibited because of its tendency to cause a larger population to use new drugs. A prohibition on DTCA also causes many patients to miss out on the potential benefits of the new drugs. Even if it is assumed (without empirical evidence, and contrary to the regulator's conclusions during the approval process) that the larger population is better off being "protected" from the new drugs because of the possibility of increased risks of ADRs, this amounts to saying that the smaller population that is prescribed these drugs without DTCA must be unwitting "guinea pigs" for the rest.

18. There are strict ethical constraints around the use of patients for clinical trials, including the need for patient consent and disclosure of the fact that the drug is experimental. In his affidavit Lexchin suggests that the early post-approval period should be treated a kind of extension of clinical trials, with a deliberate public policy of restricting the number of patients exposed to the new drug because of safety concerns. If this is so, shouldn't the group that is exposed be chosen by some means other than the fact that they or their doctors happened to hear about the drug, and shouldn't they be required to provide their informed consent to the alleged risks?

19. I do not mean to suggest that it is impossible for there to be a failure in the regulatory approval process for new drugs. Clearly, such failures have occurred in past. Vioxx, which is relied upon by Lexchin and other opponents of DTCA as an example of DTCA's dangers, may (or may not) represent such a failure, judging by reports of serious ADRs leading to its voluntary withdrawal from the market. (Even in this case, the evidence is mixed on the role of DTCA, with some evidence suggesting that DTCA led to more targeted prescribing of that drug – i.e., towards those whose risk profile suggested the drug was indicated, and away from those for whom it was contra-indicated.[14]) However, new drugs also provide benefits, and there can be costs in foregone benefits if newly-approved drugs are not taken up quickly. The costs of foregone benefits may not grab the headlines like ADRs do, but they are nevertheless real.

---

[14] Bradford, W.D., Kleit, A. et al. "The Effect of Direct to Consumer Television Advertising on the Timing of Treatment", Paper presented at the Public Meetings on Direct to Consumer Promotion of Medical Products of the U.S. Food and Drug Administration's Centre for Drug Evaluation and Research: November 1, 2005; http://www.fda.gov/cder/ddmac/dtc2005/transcript1.pdf, ("Transcript of FDA Pulbic Meeting on DTCA, November 1, 2005"), p. 76-77; Bradford, W.D. & Kleit, A., "Evaluating the Welfare Effects of Drug Advertising" *Regulation* (Spring, 2006), p. 58-62.

20. It must also be recognized that drawing conclusions from reports of ADRs is at best, an inexact science. For example, patients who take placebos as part of a drug trial regularly report ADRs, which are a physical impossibility because they contain no active ingredient. Consider the following data involving patients reporting side-effects in the clinical trials of Celebrex (a drug which is similar to Vioxx but was not withdrawn from the market), and compare the reporting of side-effects among those who took a placebo against those who in fact took Celebrex:[15]

Reported Side-Effect	Celebrex	Placebo
Abdominal pain	4.1%	2.8%
Diarrhea	5.6%	3.8%
Dyspepsia	8.8%	6.2%
Nausea	3.5%	4.2%
Back pain	2.8%	3.6%
Injury-accident	2.9%	2.3%
Headache	15.8%	20.2%
Insomnia	2.3%	2.3%
Sinusitis	5.0%	4.3%
URI	8.1%	6.7%

Also, it is always open to question whether a reported ADR is truly caused by the drug, or is attributable in whole or in part to other factors. Thus, Lexchin's comments on the numbers of ADRs reported should not be taken out of context.

[15] Source: *Compendium of Pharmaceuticals and Specialties* (CPS), 2006.

21. Taken as a whole, new prescription drugs that have been through the regulatory approval process represent enormous advances in the treatment of medical conditions and the welfare of patients. One need only think of the state of medicine a century ago, before the widespread use of pharmaceuticals, to be reminded of this basic fact.

22. In any event, even if there were some increased risk of ADRs arising from the quicker uptake of newly-approved drugs because of DTCA, that outweighed the increased benefit to patients (although I do not believe the evidence supports this), other mechanisms could be used to address this risk. Rather than prohibiting DTCA, regulators could require special warnings for newly-improved drugs, or impose a time-limited moratorium on DTCA (for example, for the first year or two after approval). This could be done either across the board or on a selective basis, for drugs that are identified as meriting more careful treatment.[16] I understand that there have been proposals discussed in Congress to give the FDA this power in the U.S.

(b) Evidence of Benefits from DTCA

23. In my own field, psychiatry, pharmaceuticals have revolutionized the treatment of psychiatric disorders in recent decades, and have led to much more effective treatments of serious conditions such as schizophrenia, bipolar disorder, major depression, and many other illnesses. Psychopharmacology is now recognized as an important sub-

[16] Of these two alternatives, it may be better policy to limit advertising selectively, because so much depends on the particular disease and drug. An example raised before the FDA in its 2005 Public Hearing on DTCA was drugs to treat cancer, where it was pointed out by Dr. Abell, a fellow in hematology and oncology at the Dana Farber Cancer Institute, that "two years is longer than the natural history of many different types of cancer... and may in fact be too long for patients to gain the possible benefits of direct to consumer advertising in terms of education.": Public Hearings on Direct to Consumer Promotion of Medical Products of the U.S. Food and Drug Administration's Centre for Drug Evaluation and Research: November 2, 2005, Transcript, p.285.

specialty within the field of psychiatry. This is an area of rapid change, and new drugs are constantly being developed as we gain knowledge and experience with the intricacies of the human brain.

24. In my own experience and on the published evidence, DTCA can play a positive role in the treatment of psychiatric disorders. One significant challenge in this area is that there are large numbers of people suffering from these disorders, who are undiagnosed, untreated, and unaware that effective treatments are available. Left untreated, their relationships, work life, and general health are adversely affected, and they may even be at risk for suicide. Simply getting these patients into doctors' offices to be diagnosed and treated represents a very substantial benefit. There is evidence that DTCA is effective in letting these patients know that there are effective treatments available for their conditions, and in bringing them into doctors' offices to be diagnosed and treated.

25. Another notorious challenge for patients with psychiatric disorders is encouraging them to comply with prescribed treatments. Frequently, patients are prescribed a psychotropic drug to address debilitating depression, anxiety or other conditions. After a while, the drug starts to take effect and they start to feel better, so they stop taking the drug, perhaps to avoid unpleasant side effects. If this occurs without medical advice and supervision, the patient may soon revert to their former state, or even worse. Again, there is evidence that exposure to DTCA encourages compliance, by reinforcing the message that the prescribed drug is effective in treating the patient's underlying condition.

26. Another characteristic of psychotropic drugs, in my experience, is that they are highly idiosyncratic in their effects on individual patients.[17] Brain chemistry is very subtle, and the effects of prescription drugs on neurotransmitters are still very far from being fully understood. What works for one patient may be ineffective for another, or may cause intolerable side effects in a third. In many cases, drugs are initially quite effective, but over time, patients do not respond to them as well as they did at first. In this context, it is quite common for treating physicians to try a number of different drugs and dosages with patients, in an attempt to find the optimum medication regimen.[18]

27. In his affidavit, Lexchin argues that DTCA is inappropriate because it assumes that all patients respond in the same way to the same treatment. I disagree. In my experience, DTCA plays a role in informing patients of their options. A patient who has seen a drug advertised on TV or in a magazine may bring it up during an appointment. In my experience, when this occurs, particularly in the context of both prescription and non-prescription anti-depressants and anxiolytics, it can lead to a useful discussion of the possible treatment options for the patient. An advertised drug may not be appropriate for the patient, but the discussion may lead to a prescription that is. From the literature, it appears that my experience is typical – there is evidence that DTCA leads to increased demand for the class of drugs advertised, but does not have much effect on market share within the class, which may indicate that patients request specific

---

[17] K.J. Ressler and C.B. Nemeroff, "Depression" in R.N. Rosenberg, S.B. Prusiner, S. DiMauro , R.L. Barchi and E.J. Nestler, eds., *The Molecular and Genetic Basis of Neurologic and Psychiatric Disease,* 3rd ed. (Philadelphia/Boston: Butterworth/ Heinemann, 2003) 725-740.

[18] F.E. Bloom and D.J. Kupfer, *Psychopharmacology: The Fourth Generation of Progress* (New York: Raven Press, 1995).

drugs but are prescribed other drugs within the same class after discussion with their treating physician.[19]

28. On many occasions, I have had the experience of patients asking me about a drug that they have seen advertised in U.S. media, before it is even available in Canada, leading me into a discussion of what alternatives might be appropriate for them now, when the drug might be approved for use in Canada, and whether it might be appropriate for them to try if or when such approval is received. I have no objection to this kind of discussion – I regard it as fundamentally healthy for patients to be involved in decisions about their own care. After all, it is their health which I am trying to treat. Particularly in the case of patients with psychiatric disorders, patient involvement and education is an extremely important and beneficial aspect of effective treatment.

29. As noted by Ms. Sztuke-Fournier in her affidavit, there are approximately 7,000 prescription drugs licensed for use in Canada. Out of these, some 3,000 are listed in the *Compendium of Pharmaceuticals and Specialties*, the most common reference tool used by doctors in their day-to-day treatment of patients. Each one of these drugs has its own characteristics, including therapeutic qualities and risks of ADRs. This represents an enormous body of knowledge.

---

[19] M.B. Rosenthal et al., "Promotion of Prescription Drugs to Consumers" (2002) NEJM vol. 346, no. 7, pp. 498-505; J.M. Donohue and E.R. Berndt "Effects of Direct-to-Consumer Advertising on Medication Choice: The Case of Antidepressants" (2004) *Journal of Public Policy and Marketing*, Vol. 23, no. 2, pp. 115-127; J.M. Donohue, et al., "Effects of Pharmaceutical Promotion on Adherence to the Treatment Guidelines for Depression" (2004) *Medical Care*, Vol. 42, no. 12, pp. 1176-1185.

30. As a specialist in psychopharmacology, I believe that I am likely familiar with all or most of the drugs that are or may be useful to my patients. In the case of my own patients, the fact that they may learn of treatment options through DTCA is beneficial because it can lead to useful physician/patient discussions. I may have overlooked a possible treatment, or I may find that having to explain why a particular drug is not appropriate leads me to discover more about my patient's symptoms or side-effect profile, or I may find that the discussion leads me to other possibilities that I have not yet tried. At a minimum, this kind of discussion is helpful in that it educates and engages my patients in their own treatment and care.

31. For physicians who are not specialists in psychopharmacology, such as family physicians, it is my opinion that discussions generated by DTCA can play an even more positive role. Most patients with psychiatric disorders such as major depressive or anxiety disorders initially seek treatment with their family physician. It is almost impossible for a non-specialist to keep up with all of the innovations in treatment in this area. A family physician, whose patients present with a wide range of medical issues, cannot reasonably be expected to carry around the details of hundreds or thousands of different prescription drugs in his or her head. Patients exposed to possible treatment options through DTCA may well bring up drugs that their family physicians are not intimately familiar with. This may generate a referral to a specialist, or cause the family physician to investigate possibilities that s/he would not otherwise have considered. Again, it is hard to see how giving patients an additional source of information can be a bad thing.

32. The responding affidavits appear to me to take an unduly paternalistic approach which ignores the reality that patients these days are extremely interested in their options for medical treatment, and will search out information on these options. In many cases, my patients have searched out information on the internet prior to discussing treatment options with me. While I am the "gatekeeper" on treatment options, because I provide prescriptions, I am typically only one source of information for my patients. They are exposed to information through advertising in U.S. media available in Canada, the internet, patient support groups, and other sources. Frankly, I would rather that they obtain their information through the highly-regulated and highly-visible channel of DTCA, in which I understand advertisers are required to present a "fair balance" between claims of effectiveness and possible side effects, than through exclusive reliance upon unregulated or unpoliced internet websites.

(c) Prescription vs. Over-the-Counter Drugs

33. The irrationality of prohibiting DTCA of prescription drugs is even more apparent when one considers that direct-to-consumer advertising of non-prescription, or "over-the-counter" drugs ("OTC drugs") is legal and very widespread. It is true that generally speaking, OTC drugs do not have as significant side-effects, or carry as great a risk of ADRs, as many prescription drugs. This is why they are not restricted by Health Canada in the form of being available only by prescription. However, there are many OTC drugs with potentially serious side-effects, especially when taken in larger quantities, and access to these drugs is essentially unrestricted. Unlike the case with a prescription drug, where a patient's need for the drug must be evaluated by the prescribing physician as "learned intermediary" who can ensure that its risks and

either major depression or adjustment disorder.) Lexchin also refers to, but dismisses, a 2003 study by Weissman et al. that reported benefits of DTCA. Lexchin relies in particular on the Kravitz Study to support his conclusion[23].

36. Lexchin's stated conclusion based upon the various studies is much stronger than the data in the studies themselves. With respect to Toop et al., Lexchin cites survey responses where 44% of New Zealand physicians who responded reportedly either strongly or slightly agreed that as a result of a patient request they had switched to/started medication with an advertised drug "which they felt offered little benefit over treatment they would ordinarily use"; and 84% believed that DTCA "did not improve their prescribing"[24]. These statements do not support a conclusion of medically inappropriate prescribing - at most, they are neutral.

37. Furthermore, the responses in the Toop survey were solicited by avowed opponents of DTCA, as is evident from the survey cover letter:

> ***IMPORTANT ISSUE PLEASE READ***
>
> Enclosed is a short survey seeking your impressions, attitudes and experiences of direct to consumer advertising (DTCA) of prescription medicines.
>
> A number of concerned academic General Practitioners are urging the government to reconsider a ban on such advertising. Only two countries allow advertising of prescription medicines to the public – America and New Zealand. It is allowed here by default rather than by design simply because there has never been any legislation prohibiting it. As recently ago as last month, the European Parliament threw out (by a massive 12 to 1 majority)

[23] Lexchin Affidavit, pp. 35-36, paras. 71-73, citing the Kravitz Study, which is appended as Exhibit 5 to the Lexchin Affidavit.
[24] Lexchin Affidavit, p. 33, para. 65.

> legislation aimed at allowing DTCA in Europe. Australia, South Africa and a number of other countries have reviewed and reaffirmed their bans...
>
> In order to support the case for a ban it is important to gather current evidence of the effects DTCA has had in New Zealand. You will see that the questions are predominantly about the effects DTCA has had on you as a prescriber and on your patients. Most of the questions are adapted from similar overseas questionnaires.[25]

38. With respect to the study by Mintzes et al., doctors in Vancouver and Sacramento were asked about patients who requested DTCA drugs. (Notably, a high proportion of patients in both cities reported being exposed to DTCA in the past year, despite the prohibition in Canada – 98% in Sacramento vs. 87% in Vancouver.)[26] In response to the question "if you were treating another similar patient with the same condition, would you prescribe this drug?", the study reports that 50% of the time their answer was "possibly" or "unlikely". The authors, of whom Lexchin is one, interpret this statistic as reflecting ambivalence about treatment choice.

39. However, in addition to the factors cited by Lexchin for regarding this study as only "exploratory", these results are difficult to base any conclusions on because no breakdown is given between the two categories, and no explanation is given by the doctors themselves as to what they meant by their responses. I note also the criticisms made of the methodology of the Mintzes study by Stephen Walter in his affidavit sworn

---

[25] Covering letter, part of Appendix 3: New Zealand GP Survey, Toop et al., "Direct to Consumer Advertising of Prescription Drugs in New Zealand: For Health or For Profit?", Lexchin Affidavit, Exhibit 7.

[26] B. Mintzes, M. Barer, R. Kravitz, et al, (2003) "How does direct-to-consumer advertising (DTCA) affect prescribing? A survey of primary care environments with and without legal DTCA" *Canadian Medical Association Journal*, vol. 169, pp. 405-412 at page 407 and Table 2. See also, B. Mintzes' presentation to the U.S. Food and Drug Administration's Public Meeting on Direct to Consumer Promotion, September 22, 2003, Washington, D.C., available at: http://www.fda.gov/cder/ddmac/DTCmeeting2003_presentations.html, ("Transcript of FDA Public Meeting on DTCA, September 22, 2003"), p. 190.

44. As for the Kravitz Study's comments about prescribing antidepressants to SP's presenting with symptoms of adjustment disorder, in my professional opinion such prescriptions are not necessarily inappropriate. Adjustment disorder can be a serious condition that can lead to major depression. Furthermore, there is solid evidence to suggest that treating so-called "minor depressions" can lead to improvement of the condition, of the patient's psychosocial and occupational functioning, and the patient's long-term course and prognosis.[31]

45. In other studies, DTCA has been found to influence getting a prescription for antidepressants, but has virtually no demonstrated influence on the choice of the specific antidepressant (class effect, not the choice of a specific drug); by contrast, drug detailing to doctors influenced which antidepressant was prescribed.[32]

46. Also, the length of time since the FDA approval of the drug, the number of indications for the drug, and the drug's low incidence of side-effects, correlated directly and significantly with prescribing the drug,[33] contradicting the claim that new, unproven, and risky drugs are being prematurely introduced.

47. And, last but not least, the analysis of how increases in advertising expenditures – detailing vs DTCA – influenced the chances of a specific drug being prescribed,

---

[31] L.L. Judd, et al., "Psychosocial disability during the long-term course of unipolar major depressive disorder" (2000) *Archives of General Psychiatry*, vol 57, no. 4, pp. 375-80; H.S. Akiskal, et al., "Subthreshold depressions: clinical and polysomnographic validation of dysthymic, residual, and masked forms" (1997) *Journal of Affective Disorders*, vol. 45, no. 1, pp. 53-63.

[32] J.M. Donohue, et al., "Effects of pharmaceutical promotion on adherence to the treatment guidelines for depression" (2004) *Med Care*, vol. 42, no. 12, pp. 1176-85; T. Iizuka, G.Z. Jin, *Working paper*, 2003, Vanderbilt University; M. Wosinka, *Doctoral Dissertation*, 2002, University of California, Berkeley.

[33] Donohue, *supra*.

demonstrated that detailing was 30 times more likely than DTCA to increase prescribing of a specific drug.[34]

48. Lexchin's opinions in his affidavit on the effect of DTCA on prescribing practices must also be put into context. Even if the studies he cites did support his conclusion, the negative effects would be quite small.

49. There is information available from surveys of both doctors and patients on the impacts of DTCA. According to a study by Weissman et al.,[35] a survey of doctors on encounters with patients exposed to DTCA for prescription drugs reveals a variety of impressions. Improved communication and education of patients is cited, but some doctors also report patients seeking unnecessary prescriptions, leading to increased pressure to prescribe and increased time spent with patients.

50. Weissman et al. report that where a DTCA drug was prescribed, 46 % of the doctors surveyed indicated that the advertised drug was the best choice, while 48% indicated that others were equally effective. Of the doctors polled, 40% thought DTCA had a positive effect, 30% thought it had a negative effect,[36] and 30% thought it had no

---

[34] J.M. Donohue, E.R. Berndt, "Effects of Direct-to-Consumer Advertising on Medication Choice: the Case of Antidepressants" (2004) *Journal of Public Policy & Marketing*, vol. 23, no. 2, pp. 115-127.
[35] J.S. Weissman et al., "Physicians Report on Patient Encounters Involving Direct-To-Consumer Advertising", (2004) *Health Affairs*, Vol. 23, (April 28, 2004), pp. 219-33 ("Weissman Study").
[36] Lexchin reports a much higher figure of 71% at paragraph 98 of his affidavit, based upon a 1997 survey by M.S. Lipsky and C.A. Taylor, "The Opinions and Experiences of Family Physicians Regarding Direct-to-Consumer Advertising", *Journal of Family Practice* 45:495-499. One explanation for this higher number might be that this was a much earlier survey, when doctors were much less used to (and potentially felt more threatened by) DTCA. Weissman et al. also report that earlier surveys may have been affected by bias due to use of non-randomized samples: Weissman Study, p. 233.

U.S. (in studies conducted for *Prevention Magazine*) since 1997, when U.S. restrictions on DTCA were loosened. According to *Prevention Magazine*'s annual surveys, patients do not rely exclusively upon DTCA, but rather use it along with other sources, including (increasingly) the internet.[42] Also, some patterns have remained quite stable despite increased expenditures on DTCA in the U.S. since 1997.

58. This polling of consumers has found that awareness of DTCA is extensive (92% in 2004, down from 99% in 2001, report having seen or heard a DTC ad).[43] The vast majority of ads were for erectile dysfunction drugs, anti-allergy and anti-ulcer drugs, and cholesterol-lowering drugs.

59. Most consumers recall seeing both risk and benefit information: 79% remember risk information, 71% benefit information; 49% paid a lot of attention to risk information, only 29% paid a lot of attention to benefit information (data for 2004). About 1/2 of consumers exposed to DTCA sought further (printed) information on risks. [44]

60. Those who spoke to their doctors, paid more attention to risk information, and used secondary sources of information more. In other words, the more attention consumers paid to the risk information and the more information on risks they sought, the more likely they were to ask doctors for a specific drug prescription. This finding

---

[42] Princeton Survey Research Associates, *Prevention Magazine's 8th Annual Survey on Consumer Reaction to DTC Advertising of Prescription Medicines*, June 2005 ("*Prevention Magazine's 8th Annual Survey*"), p. 4-5. See also Transcript of FDA Public Meeting on DTCA, September 22, 2003, p. 120-121. Similar data appear in survey research conducted by the FDA: see Aikin et al., "Patient and Physician Attitudes and Behaviours Associated With DTC Promotion of Prescription Drugs – Summary of FDA Survey Results" (2004), p.2: http://www.fda.gov/cder/ddmac/Final%20Report/FRfinal111904.pdf.

[43] *Prevention Magazine's 8th Annual Survey*, p.6-7.

[44] *Prevention Magazine's 8th Annual Survey*, p.11.

- They are based upon the logical fallacy that money spent on a DTC-advertised drug would otherwise be spent on malaria research, or some other cause deemed sufficiently worthy by proponents of the DTCA ban; and
- They are based upon the paternalistic assumption that patients cannot determine for themselves, in consultation with their prescribing physician, what is in their best interests.

68. Medicalization refers to the categorization of "life's normal vagaries and vicissitudes" as medical problems, requiring medical care. As a term of opprobrium, it is frequently applied to the "drug-pushing doctors" and the "Big Pharma", who, out of their own "venal" interests, are said to foster exaggerated anxiety about "non-pathological" conditions, and encourage "healthy" people to seek "unnecessary medical products and services".

69. However, there is considerable evidence that public health is threatened far more significantly by under-diagnosis and under-treatment of diseases. It is well-recognized that there is substantial under-diagnosis of many of the major diseases and known risk factors for which effective treatments exist (hypertension, hyperlipidemia, diabetes, osteoporosis, depression and chronic anxiety). Even when diagnosed, these diseases are alarmingly under-treated.

70. It is this failure to treat that, coupled with non-compliance with established treatment, has been shown to lead to a considerable socioeconomic burden of unnecessary and avoidable morbidity and mortality.[50] By contrast, there has been no

[50] In the area of mood disorders, see, e.g.: R. Hirschfeld, M. Keller, et al., "The National Depressive and Manic-Depressive Association consensus statement on the under-treatment of depression" (1997) JAMA, vol. 277, no. 4, pp. 333-340; F. Angst, et al., "Mortality of patients with mood disorders: Follow-up over

empirical demonstration that DTCA-related treatment of "nonpathological" conditions, as characterized by those who support its prohibition, has led to any morbidity or mortality.

71. Many of the major diseases listed above are treatable by drugs that are among the most advertised in the U.S. This is to be expected. It is in the interests of pharmaceutical companies to get patients who have conditions that are treatable by prescription drugs, but who are not currently seeking treatment, into doctors' offices to be diagnosed and treated. Doctors don't seek out patients; rather, patients must generally initiate contact. In many cases, it makes sense for advertisers to focus their efforts on prescription drugs that are known to be effective, and in areas where the need for treatment by prescription drugs is greatest.

72. Even for drugs characterized as "lifestyle" drugs, the doctors' visits generated by DTCA can have substantial public health benefits. A middle-aged male patient (historically, among the most reluctant to seek medical advice and treatment, and therefore often chronically under-treated) who suffers from erectile dysfunction might see a doctor to obtain a prescription for Viagra or Cialis. When he gets to the doctor's office, he might well be diagnosed as suffering from an underlying condition such as

---

34-38 years" (2002), vol. 68, no. 2, pp. 167-181; L.L. Judd, M.B. Keller, et al., "A prospective 12-year study of subsyndromal and syndromal depressive symptoms in unipolar major depressive disorders" (1998) *Archives of General Psychiatry* vol. 55, pp. 694-700; L.L. Judd, et al., "Major depressive disorder: a prospective study of residual subthreshold depressive symptoms as predictor of rapid relapse" (1998) *Journal of Affective Disorders* vol. 50, pp. 97-108; J.M. Murphy, et al. "A 40-year perspective on the prevalence of depression: The Stirling County Study" (2000) *Archives of General Psychiatry* vol. 57, pp. 209-215; R. Kessler, et al., "Lifetime and 12-month prevalence of DSM-III-R psychiatric disorders in the US: Results from the National Comorbidity Survey" (1994) *Archives of General Psychiatry* vol. 51, pp. 8-19; R.C. Kessler, et al., "Prevalence, correlates, and course of depression in the National Comorbidity Survey" (1997) *Journal of Affective Disorders*, vol. 45, pp. 19-30; R. Kessler, et al., "The epidemiology of major depressive disorder: results from the National Comorbidity Survey Replication (NCS-R)" (2003) JAMA, vol. 289, pp.3095-3105.

diabetes, heart disease or hypertension, be put on medication to control this life-threatening condition, and encouraged to make lifestyle conditions that will improve his overall health.[51]

73. Another area where DTCA is attacked for "creating new and nonexistent pathologies" and "profoundly influencing physicians' prescribing practices" is the area of depressive and anxiety disorders. This happens to be my own area of expertise, so I can directly address some of the issues raised, from the perspective of my clinical and academic experience over the last 35 years. (I note that there is a conspicuous dearth of clinicians among the deponents of the responding affidavits, which may explain some of their dismissive attitudes on this subject.)

74. In my opinion, calling minor depressions (be they relatively brief or chronic) and adjustment disorders with depressive features "normal reactions to the vagaries of life", betrays not only a deep unfamiliarity with the natural course of these disorders over a lifetime, but also a degree of callousness towards suffering that can often be alleviated.

75. Examining the extant literature on "minor" depressive disorders, it becomes clear after just a cursory examination that "minor" depressions tend to grow into "major" depressions, which, by the time they are diagnosed and treated, may have become treatment-refractory (with all the tragic consequences for the individuals and hugely

[51] Transcript of FDA Public Meeting on DTCA, September 23, 2007, pp. 63, 150.

increasing financial costs to society).[52] In other words, early treatment of depressive disorders can yield significant public health benefits.

76. It is also important to pay attention to the enormously important clinical, as well as humanitarian, issue of quality of life in considering this issue. Labeling social anxiety disorder (SAD) as a medical non-entity (just "shyness") dismisses the impact that treatment, or failure to treat, can have on the patient's quality of life. The cost of this disorder, especially if severe, can be a profoundly diminished quality of life, with severe impairments in personal, social, and vocational functioning.[53]

77. Moreover, on balance, the literature (reviewed above) on the nature and the characteristics of DTCA of antidepressant drugs does not support the claim that DTCA leads to a harmful medicalization of normal life.

78. Another example cited of "medicalization" is treatment for symptoms of menopause, a "normal and natural event in life". While no-one would dispute that menopause is a natural event, for some women its symptoms can carry serious health implications. Let me examine, briefly, what the condition can entail.

79. Menopausal (perimenopausal) symptoms include hot flushes with sometimes profuse perspiration (affecting over 75% of women, half of them for over 5 years), psychological symptoms (depression, anxiety, irritability, memory loss), and profound

---

[52] H.S. Akiskal, et al., "Subthreshold depressions: clinical and polysomnographic validation of dysthymic, residual, and masked forms" (1997) *Journal of Affective Disorders*, vol. 45, no. 1, pp. 53-63.
[53] M. Shields, "Social Anxiety Disorder: Beyond Shyness" (2004) *Health Reports* (Statistics Canada), vol. 15 (Suppl.), pp. 45-61.

changes in the lower genital tract (degenerative changes in the skin and mucosa, atrophic vaginitis with dyspareunia and urinary frequency/urgency, and loss of pelvic muscle tone with urinary incontinence, cystitis, and vaginitis).

80. Major health hazards related to menopause include cardiovascular disorders and cerebrovascular disorders (dramatic rise in the incidence of heart attacks and strokes) and osteoporosis (affecting health outcomes, e.g., fractures, functional capacity, and quality of life, in a most profound way).

81. Yet, according to the proponents of the prohibition on DTCA for remedies that address these issues, menopause is a prominent example of a "new and nonexistent pathology", of "medicalization of normal life and disease-mongering", and of "promoting drug sales for trivial problems of normal life and over-treatment of nonpathological conditions".

82. This leads to the logical fallacy in the argument that DTCA should not be permitted because it encourages pharmaceutical companies to concentrate on "lifestyle" drugs rather than, for example, research into finding a cure for malaria. There is no logic or evidence to suggest that prohibiting DTCA makes a cure for malaria any more likely. The number of assumptions that would need to be made to reach such a conclusion illustrates how far-fetched this suggestion is. First, it would have to be assumed that society is only prepared to spend a fixed amount on health care; second, that "lifestyle drugs" are competing with malaria research for that fixed amount; third, that pharmaceutical companies are best equipped to conduct malaria research; and

finally, that prohibiting pharmaceutical companies from advertising will make them any more likely to conduct malaria research than permitting advertising.

83. I would suggest that it is at least as likely that so-called "lifestyle drugs" are competing with other consumer products rather than malaria research. Furthermore, despite the pejorative label, there is nothing inherently wrong with patients enhancing the quality of their lives with prescription drugs for conditions that are not life-threatening. To return to the example of prescribing Viagra or Cialis for erectile dysfunction, and leaving aside for the moment the indirect benefits of detecting other undiagnosed conditions, why shouldn't a patient have the choice of spending a portion of his disposable income on these drugs (quite possibly improving the quality of his relationship with his partner) rather than on a myriad of other consumer products?

84. The criticism that "lifestyle drugs" are prescribed as part of the "medicalization of normal life" is highly paternalistic. It seems that those who use these terms are totally comfortable appropriating for themselves the role of the final (and uncontested) arbiters of what constitutes "normal life's problems" vs "medical conditions", and what does or does not warrant attention and treatment.

85. It must be emphasized that the question of who pays for the drugs is a separate question from whether advertising of drugs should be prohibited. In fact, drugs characterized as "lifestyle drugs" may not be covered by provincial drug formularies; if the concern is that <u>public</u> funds are being allocated towards treatment of conditions that should not be a social priority, then there is no reason why these drugs need to be listed

or that their costs need to be fully reimbursed. That, however, is different from saying they cannot be advertised.

86. Proponents of the DTCA prohibition also argue that information coming from "Big Pharma" is inevitably biased in ways in which information from doctors (for once, we are now the "good guys") and public agencies is not. What is forgotten, however, is that all the stakeholders in the health system have their own motives and agendas. Pharmaceutical companies want to increase sales and market share (a legitimate business goal); doctors want to guard their professional "territory" and be free from "interference" in dispensing their medical expertise; and governments have an interest in minimizing the cost of health care in ways that do not lose votes. The criticism that information coming to patients from pharmaceutical companies is "biased" ignores the reality that no other actor or entity has the incentive to ensure that patients receive this information.

87. In any event, if there is reason to be concerned with bias in advertising, the solution is for the regulator to require unbiased advertising. Health Canada has already published detailed guidelines on how to advertise non-prescription drugs in an unbiased manner,[54] and the FDA requires fair balance in U.S. DTCA of prescription drugs.

---

[54] Health Canada, "Consumer Advertising Guidelines for Marketed Health Products (for Nonprescription Drugs including Natural Health Products)", August 2006, http://www.hc-sc.gc.ca/dhp-mps/advert-publicit/pol/guide-ldir_consom_consum_e.html.

3. Whether DTCA Leads to Increased Costs to Individuals and Society Without Demonstrable Improvements in Health Outcomes

88. I am not an economist, and I do not purport to be able to give an opinion on whether DTCA leads to increased economic costs to society. On the basis of my own expertise and experience, however, from a medical point of view I have seen no evidence of harm arising from DTCA. In my experience, where a patient requests a drug that s/he has seen advertised, and is actually prescribed that drug, s/he obtains medical benefit from the drug. At the individual patient level, DTCA provides patients with valuable information that the patient might not otherwise obtain. By the time the prescription is written, DTCA is never the sole source of information, because the doctor must have formed the medical opinion that the prescription is clinically appropriate.

89. As well, patients have frequently gone to other sources such as websites or literature to obtain more information before speaking to their doctor. Doctors themselves receive information from drug companies in the form of detailing, which is a far more significant part of drug advertising. I do not see how allowing patients access to an additional source of information is a bad thing, from my perspective as a practicing psychiatrist.

90. In my opinion, the current prohibition on DTCA in Canada is not justified.

SWORN before me at the City of Toronto in the Province of Ontario, this 8th day of June, 2007

A Commissioner, etc.

ANDREW LOKAN

Don Fulgosi

660795_1

This is **Exhibit A** referred to in the Affidavit of **Don Fulgosi** sworn before me this 8th day of June, 2007.

A Commissioner, etc.

DON Z. FULGOSI, M.D., F.R.C.P.(C), PSYCHIATRY

SENIOR CONSULTANT FOR PSYCHIATRY AND NEUROSCIENCES

123 EDWARD STREET, SUITE 502
TORONTO, ONTARIO M5G 1E2
TEL. (416) 595-2714 FAX: (416) 595-2710
E-MAIL: dfulgosi@sympatico.ca

PROFESSIONAL APPOINTMENTS

Current:	Private Practice and Consultancy in Psychiatry and Neurosciences Consultant to "Entec Corporation" for Measuring Employee Engagement and Emotional Wellness
2004 – 2005	Partner, GFK&Associates Senior Clinical Advisor, Psychiatry and Neurosciences
2000 – 2004	Vice-president, Concilience Health Resolution Services, Inc. Senior Clinical Advisor, Psychiatry and Neurosciences
1997 – 2000	Director, Psychiatry and Behavioural Health Sciences King's Health Centre
1999 – 2000	Consultant, Interdisciplinary Health Division King's Health Centre
1996 – 1997	Private Practice and Psychiatric Consultancy First Canadian Medical Centre
1993 – 1996	Private Practice and Psychiatric Consultancy Scotia Plaza Medical Centre
1974 – 1993	Solo Private Practice and Psychiatric Consultancy

POST-GRADUATE EDUCATION

1985	Family Mediation, Level I and II, Intensive Training Program, School of Continuing Studies, Faculty of Social Work, University of Toronto
1974	Certification and Fellowship from the Royal College of Physicians and Surgeons of Canada, in the Specialty of Psychiatry
1970 – 1974	Post-graduate training in Psychiatry, Toronto, Canada: Sunnybrook Hospital, Clarke Institute of Psychiatry, Mount Sinai Hospital

WORK EMPHASIS

1. **Clinical:**

   - Psychopharmacological and psychotherapeutic treatment of depression and anxiety disorders
   - Relationship of depression to major medical comorbidities, especially heart disease and diabetes type-2
   - Structured stress management and life-style counseling

2. **Educational:**

   - CME lectures and workshops for:
     Psychiatrists, gynecologists, cardiologists and general practitioners
   - Educational talks for:
     Paramedical and lay audiences
   - Publications on:
     Treatment and management of depression
     Depression as an underlying cause of physical ailments
     Relationship of depression and coronary heart disease
     ("The Aching Heart")

PRESENTATIONS:

Vanquishing the Malignant Sorrow:
From Treatment of Depression to Neuroprotection

Blue Genes, Black Bile and Second Hits:
New Horizons in Psychopharmacology of Depression

The Day that Music Died:
Varied Clinical Presentations of Depression

Can Stress Kill?
Neurobiology of Chronic Stress and Allostatic Load

The Aching Heart:
Relationship between Heart Disease and Depression

Twitchy Brain: Troubled Mind, Aching Heart:
Relationship between Brain "Wiring", Depression, and Heart Disease

Gloomy, Fat, and Heading for a Heart Attack:
How to Avoid the No. 1 Risk to Our Health and Longevity in the 21st Century

Baby Boomers Turned 60: Apocalypse Redux:
The Looming Reversal of Health and Longevity Trends in the 21st Century

Black Moon Rising:
Adult-onset Diabetes in Kindergarten

Cheating Time:
Toward Greater Longevity and Healthier Ageing

"Off Course, It's All in Your Head!"
Neurobiology of Chronic Pain

The "Crab" and the "Soul":
Psychobiology of Cancer Management

Doing Well by Doing Good:
Stone Age Prescription for Information Age Stress

Are You Crazy?
Neuroeconomics, Evolutionary Psychology, and Human Behavior in Real Life: Ready for the Business Prime Time?

Beyond 2001:
The Gaping Disconnect between Evolved Human Nature, and Life and Work in the 21st Century

Blue Moon Rising:
Work-stress, Depression, and the Bottom Line

The Monkey Shaved:
Updating Our Stone Age Brain for Coping with the Information Age Challenges

Work and Health in the Next Society:
Human Nature, Work Structure, and the Ageing Population

AUDIENCES

- Medical Conferences and Workshops across Canada
- RBC Dominion Securities
- Conference Board of Canada
- Employers Reinsurance Corporation
- Canadian Association of Disability Underwriters (CADU)
- International Home Office Underwriters Association (IHOU)
- Canadian Psychiatric Awareness Committee
- Television interviews and panel talks with: ROB TV, CITY-TV, CHEX TV

SPECIAL INTERESTS

- Evolutionary adaptations, human nature, and psychological health
- The role of physical activity in illness prevention and wellness promotion
- Sports and fitness