Court File No. 05-CV-303001PD2

ONTARIO
SUPERIOR COURT OF JUSTICE

BETWEEN:

CANWEST MEDIAWORKS INC.

Applicant

and

ATTORNEY GENERAL OF CANADA

Respondent

AFFIDAVIT OF DR. RICHARD DOLINAR

I, Dr. Richard Dolinar, of the City of Phoenix in the State of Arizona, make oath and say as follows:

1. I am a clinical endocrinologist, licensed to practice in the State of Arizona. I have been a medical doctor since 1972, and in that capacity I have treated many thousands of patients. I completed my fellowship in endocrinology in 1983 at Duke University. I am a Member of the Board of Directors of the American Association of Clinical Endocrinologists, and I have previously served on the Board of Directors of the Arizona Affiliate of the American Diabetes Association, and as President of the Arizona Chapter of the Juvenile Diabetes Research Foundation. I have published many articles on the treatment and awareness of diabetes, and have lectured internationally on health care topics. My curriculum vitae is attached as Exhibit "A".

2. I have been interested in the topic of direct-to-consumer advertising ("DTCA") of prescription drugs for the last several years. I testified on the subject before the Senate Subcommittee on Consumer Affairs in 2001. I have also lectured on the topic on many occasions. I have given Congressional briefings, and presentations to State legislatures, patient advocacy groups, medical societies, and others. I have also written articles on the topic for newspapers and have been interviewed on national television by CBS.

3. I have been asked by CanWest Mediaworks Inc. ("CanWest") to give opinion evidence on the effects of DTCA upon patient care and prescription practices, from my perspective as a practicing endocrinologist in a jurisdiction (the United States of America) where DTCA is permitted, though heavily regulated. I have also been asked to comment upon evidence filed by the Respondent and the Intervenors.

4. I am a doctor in private practice, in partnership with six other endocrinologists. I estimate that our practice serves over 10,000 patients. This experience – 35 years of clinical practice, primarily treating patients for conditions such as diabetes – provides the basis for my opinions as expressed in this affidavit. From time to time in the past, I have done some work on contract with the Pharmaceutical Research and Manufacturers Association ("PhRMA"), the industry association for pharmaceutical companies in the United States. However, the views that I hold on DTCA were arrived at prior to and completely

independently of any connection with PhRMA. In fact, my work with PhRMA arose only after I had testified publicly about the benefits of DTCA.

5. In this affidavit, I will respond to certain arguments against DTCA made by affiants for the Respondent and Intervenors. I have reviewed the affidavits of Doctors Wilkes, Lexchin, Graham Dukes, and Abramson. I will respond in particular to Dr. Wilkes and Dr. Abramson.

6. Dr. Wilkes addresses the impact of DTCA in the U.S. from his perspective as a Professor of Medicine at the School of Medicine, University of California, Davis. Professor Wilkes expresses the opinion that "DTCA has negative effects (and no positive effects) on public health".[1] For the reasons given below, I disagree strongly with Professor Wilkes. Also, as discussed below, while DTCA has attracted controversy in the U.S., it is well established and is accepted by the majority of consumers and practicing physicians. Professor Wilkes' opinion does not represent the majority view in the U.S.

7. Dr. Abramson primarily addresses what he perceives as flaws in the drug approval process, and only incidentally deals with DTCA. I disagree strongly with Dr. Abramson, who in my opinion gives a strikingly unbalanced and unrealistic critique of the regulatory regime for prescription drugs. Again, I would not consider his views to be in the mainstream in the U.S. I will make some

[1] Report of Dr. Wilkes, Exhibit 2 to Affidavit of Dr. Wilkes sworn July 12, 2006 ("Wilkes Report"), p.1.

comments on his critique, but the main point is that it is peripheral to the discussion of DTCA. What he suggests are problems with DTCA are entirely dependent upon his thesis that the drug approval process is fundamentally flawed, and systematically results in the wrong drugs being approved for the wrong reasons. If his thesis is valid (and I do not believe it is) then the solution is to fix the drug approval process, not to prohibit DTCA. If his thesis is not valid, then he has little or no independent critique of DTCA.

The Regulation of DTCA in the United States

8. DTCA has been permitted in the United States for many years, though in heavily regulated form. DTCA first emerged in the 1980's. From 1983 to 1985, the Food and Drug Authority ("FDA"), the federal agency which regulates prescription drug approvals and which primarily regulates promotion activity for prescription drugs, requested a voluntary moratorium on DTCA while it sponsored a series of public meetings and conducted research. In 1985, the FDA withdrew the moratorium on the basis that existing regulations provided "sufficient safeguards to protect consumers" when applied to DTCA.

9. In 1993, the FDA requested drug manufacturers to voluntarily submit proposed DTC promotional material prior to use, allowing the FDA to comment upon proposed materials before they reached consumers. Following further

public hearings in 1995 and 1996,[2] the FDA clarified that preclearance of DTCA prior to use was not required, and in 1997 the FDA issued draft guidance on the manner in which broadcast DTCA could meet regulatory requirements. The FDA's final guidance document on broadcast DTCA was published in August, 1999.[3] A copy of the 1999 final guidance document for broadcast advertisements is attached as Exhibit "B".

10. Since 1999, the FDA has held further public hearings on DTCA. On September 22-23, 2003, public hearings were held at which the FDA and other persons and organizations presented the results of their research into DTCA, with emphasis on the impact of DTCA on public health.[4] On November 1-2, 2005, the FDA held further public hearings focusing on whether DTCA presented the benefits and risks of using medical products in an accurate, non-misleading, balanced, and understandable way.[5] The 2003 and 2005 FDA Public Hearings provided a forum for an extensive examination into many aspects of DTCA, from a range of disciplines and perspectives.

11. The FDA published draft guidance documents in February, 2004, addressing *inter alia* the topic of disclosing risk information in consumer-directed

---

[2] Transcript of the FDA's Direct-to-Consumer Promotion Public Hearing, October 18-19, 1995, Silver Spring, MD, can be found at http://www.fda.gov/cder/ddmac/meetings.htm. Transcript of the FDA's Public Meeting on FDA and the Internet: Advertising and Promotion of Medical Products, October 16-17, 1996, Silver Spring, MD, is found at http://www.fda.gov/opacom/morechoices/transcript1096/fdainet.html.

[3] http://www.fda.gov/cder/guidance/1804fnl.pdf

[4] http://www.fda.gov/cder/ddmac/DTCmeeting2003.html ("2003 FDA Public Hearings").

[5] http://www.fda.gov/cder/ddmac/dtc2005/default.htm ("2005 FDA Public Hearings").

print advertisements.[6] Also in 2004, the FDA published a report entitled "Patient and Physician Attitudes and Behaviors Associated with DTC Promotion of Prescription Drugs – Summary of FDA Survey Research Results".[7] This historical development is set out in the Notice of Hearing in the Federal Register for the 2005 FDA Public Hearings,[8] attached as Exhibit "C".

12. The FDA thus has over 20 years of experience in regulating DTCA, in broadcast and print media, and the internet. The FDA's various public hearings on DTCA and related issues have provided opportunities for the FDA itself and various experts, organizations and individuals to present and exchange research information on topics related to DTCA, including its impacts upon public health and the patient-doctor relationship, and its value as communication.

13. The FDA administers provisions set out in the *Federal Food, Drug, and Cosmetic Act*, s.502(n), which require a "true statement" of the drug's name and ingredients, and "such other information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations".[9] The regulations under the Act flesh out these requirements, and impose obligations not to make false or misleading statements, and to present a "fair balance" between information relating to side effects and contraindications and information

---

[6] "Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements", February, 2004; http://www.fda.gov/cder/guidance/5669dft.pdf.
[7] http://www.fda.gov/cder/ddmac/researchka.htm (November 19, 2004).
[8] 70 Fed.Reg. 54054, September 13, 2005.
[9] 21 U.S.C. 352(n).

relating to effectiveness of the drug (the "Fair Balance Requirement").[10] A copy of these provisions is attached as Exhibit "D".

14. The Federal Trade Commission ("FTC") also has a role to play with respect to DTCA. The FTC enforces s.5 of the *Federal Trade Commission Act*, which broadly prohibits "deceptive or unfair acts or practices in or affecting commerce", and s.12, which more specifically prohibits the dissemination of false advertisements for foods, drugs, devices, services, or cosmetics. While the FTC and FDA share jurisdiction, the FDA exercises primary responsibility for DTCA pursuant to a memorandum of understanding between the two agencies.[11] In December, 2003 the FTC issued Staff Comments in relation to the 2003 FDA Public Hearings, setting out the views of FTC staff on the economic effects of DTCA. The FTC Staff concluded that DTCA "can play an important role in providing information about prescription drugs that may spur consumers to seek help for a previously untreated condition, encourage them to talk to a doctor about a new drug, or otherwise take a more proactive role in minding their health",[12] but made certain recommendations to ensure truthfulness and comprehensibility in DTCA. A copy of the 2003 FTC Staff Comments is attached as Exhibit "E".

---

[10] 21 CFR 202.1.
[11] *In the Matter of Request for Comments on Consumer-Directed Promotion: Comments of the Staff of the Bureau of Consumer Protection, the Bureau of Economics, and the Office of Policy Planning of the Federal Trade Commission*, December 1, 2003 ("2003 FTC Staff Comments").
[12] *Ibid.* at p.37.

15. The detailed examination of issues relating to DTCA by the FDA and FTC, two expert government agencies with jurisdiction over DTCA, has not caused these agencies to call into question the basic premise behind allowing DTCA – that providing truthful and balanced information to patients about effective treatments for their medical conditions should be encouraged, not prohibited.[13] Rather, these agencies have focused upon ways to maximize the benefits of DTCA while minimizing the potential costs, through regulating the content of advertisements. As the FDA has gained experience and expertise it has "fine tuned" its approach, and no doubt there is always room for improvement. But in my experience and opinion, as detailed below, the U.S. model of permitting DTCA in a form regulated by an expert agency, to ensure truthfulness and fair balance, is a workable system.[14]

The Evolution of DTCA in the United States

16. As the regulatory regime has changed and both the FDA and pharmaceutical companies have gained experience, DTCA has evolved in the U.S. Prior to 1997, broadcast advertisements were permitted in two forms that I understand from counsel are currently permitted by regulatory authorities in

[13] Reportedly, an FDA official characterized the debate about DTCA in 2003 as having moved from "Is it a good thing?" to "This is a good thing, and how can we make it better?": Hoek, Gendall and Calfee, "Direct-to-consumer advertising of prescription medicines in the United States and New Zealand: An analysis of regulatory approaches and consumer responses" (2004) *Int. J. Advertising* 23: 197-227, at 201-2.

[14] The U.S. requirements of adequate provision of information and fair balance between benefits and risks have been said to result in advertising with greater product detail and better risk disclosure, tending to be less emotional, than advertising which has been permitted in New Zealand: Hoek, Gendall and Calfee, *supra* at 206-7, 209.

Canada: "help-seeking" advertisements that urge patients to see a physician for specific treatments, and "reminder" advertisements that mention specific drug brands without specifying an illness or condition to be treated.[15] These forms of advertising have been criticized for leaving patients guessing as to the purpose of the advertisement.[16] "Help-seeking" advertisements are said to be less effective at motivating patients to take concrete steps because they do not provide tangible solutions,[17] while "reminder" advertisements have been criticized as being incomprehensible to many viewers.[18]

17. As described above, in 1997 the FDA put forward its new guidelines permitting DTCA to make claims that a specific product could treat a specific condition ("product claim" ads), subject to truthfulness and fair balance requirements. Over the next several years, there was a decrease in the number of FDA warning letters, which some attributed to the fact that pharmaceutical companies gained a better understanding of what was permitted after an initial period of uncertainty.[19] Increasingly, the FDA's attention (and public reaction) has turned to the content of DTC ads, and how best to ensure that the ads present benefits and risks of using medical products in an accurate, non-misleading, balanced, and understandable way. As noted above, this was the

---

[15] Hoek, Gendall & Calfee, *supra* at 202.
[16] Hoek, Gendall & Calfee, *ibid.*
[17] 2005 FDA Public Hearings, *Transcript*, Nov. 1, 2005, pp. 94-95.
[18] See Dr. Temple's summary of the 2003 FDA Public Hearings, *Transcript*, September 23, 2003, p.227.
[19] T. Hartgraves, "DTC Prescription Drug Advertising: The History and Impact of FDA Regulation", April 30, 2002, http:/www.leda.law.harvard.edu/leda/data/506/hartgraves.pdf, at p. 15-16. This is a controversial topic - others attributed the decline to less effective enforcement due to budgetary constraints.

specific focus of the FDA's 2005 Public Hearings. Late in 2005, PhRMA adopted some voluntary guiding principles on DTCA ("PhRMA Guiding Principles"), which its members agreed to adhere to. The PhRMA Guiding Principles are attached as Exhibit "F".

18. The PhRMA Guiding Principles provide in part as follows:

- That DTCA should be accurate and not misleading, should make claims only when supported by substantial evidence, should reflect balance between risks and benefits, and should be consistent with FDA approved labeling;
- That pharmaceutical companies should spend an appropriate amount of time to educate health professionals about a new medicine before commencing the first DTC advertising campaign for a medicine;
- That working with the FDA, companies should continue to responsibly alter or discontinue a DTC advertising campaign should new and reliable information indicate a serious previously unknown safety risk;
- That companies should submit all new DTC television advertisements to the FDA before releasing them for broadcast;
- That DTCA should include information about availability of other options such as diet and lifestyle changes where appropriate; and
- That television advertising that identifies a product by name should clearly state the conditions for which the medicine is approved and the major

risks associated with the medicine being advertised (i.e., that "reminder" advertisements should not be used).

19. One area in which surveys report that patients have expressed concern with the content of DTCA is the manner in which risks are disclosed. Recently, Pfizer Inc. ran advertisements for Celebrex, a Cox-2 inhibitor in the same family as Vioxx, which commence with warnings of side effects, and run for two and a half minutes, apparently to allow the drug's risks and benefits to be fairly balanced. (Unlike Vioxx, Celebrex was never withdrawn from the market, but the FDA requires that prescribing information for Celebrex carry the FDA's strictest warning.) Reportedly, Pfizer spent more than a year discussing the content of the advertisements with the FDA prior to running them. Attached as Exhibit "G" is a copy of an article dated April 2, 2007 from Bloomberg.com discussing these advertisements.

20. The Celebrex example shows that it is difficult to generalize about the content of DTC ads. To some extent, it appears that pharmaceutical companies may be adjusting their advertising to respond to concerns and to meet the demands of consumers, as well as the FDA's requirements. Individual ads can always be criticized, but this is an issue for the regulator. It is certainly not beyond the power of the regulator to require that advertisers meet the Fair Balance Requirement in whatever manner the regulator believes to be appropriate to the circumstances.

DTCA and the Need for Prescription Drugs

21. The Respondent's affiants argue that "the primary mechanism of marketing is to create a "want" for a product on the part of the consumer that is strong enough to be felt as a need." In essence they argue that advertising is attempting to induce people to buy goods for which they have no real need; to create desires where absolutely none would otherwise exist. However, when this claim is examined more closely, it is not substantiated.

22. Generally, the main purpose of advertising is to inform and to persuade. When companies come to the market place with new consumer products they need to inform consumers of them. Otherwise how would the consumers know that these new products even existed; or where to buy them? We no longer live in small villages where all communication is only by word of mouth. After making consumers aware of the product, advertising then attempts to persuade consumers to buy it. Advertising doesn't create the need. The need is already there but unfulfilled. Advertising makes people aware of the alternatives available to them to meet their needs.

23. Pharmaceutical advertising fits this description. In the case of prescription drugs, pharmaceutical companies use advertisements to inform the public of drugs that could potentially be of benefit to them. This is similar to consumer products as set out above. But pharmaceutical advertisements, rather than

encouraging patients to go to the pharmacy and purchase the drug, attempt to persuade them to see their doctor in order to determine if the drug is the right one for them (i.e.; is "needed" for them).

24. In my opinion, there is no evidence that DTC advertising creates needs, or even "wants", for drugs where none would otherwise exist. If one is watching a commercial for an arthritis drug, a "want" for that drug is not created if one does not have arthritis or symptoms of it. If the pharmaceutical advertisement doesn't pertain to us, then, just as we do with other advertisements, we tend to simply ignore it. Research conducted by the FDA backs this up – according to a 2002 survey of 500 physicians on DTCA ("2002 FDA Survey"), the vast majority of patients who ask about a drug have the condition that the drug is used to treat.[20]

25. On the other hand if a patient has the disease or symptoms of it, the advertisement encourages him or her to "see his or her doctor" in order to make a determination as to whether it is needed for his or her care. Sometimes the drug is right for the patient. Other times it is not. Prescription drugs are not sold over the counter and can not be purchased without a prescription. Only after the physician determines that there is a "need" is the drug then prescribed. If the physician's judgment is that the patient would be better served by a different drug, or an alternative therapy, then the patient is not prescribed the advertised

[20] 2002 FDA Survey of 500 physicians, including 250 specialists: "[w]hen a patient asked about a drug, 88% of the time they had the condition that the drug treated": U.S. Food and Drug Administration, *FDA Talk Paper*, Jan. 13, 2003, http://www.fda.gov/bbs/topics/ANSWERS/2003/ANS01189.html. There is no evidence that I am aware of that this is a lower percentage than in an environment without DTCA.

drug. The 2002 FDA Survey reported many reasons why physicians did not prescribe an advertised drug, including that the advertised drug was not right for the patient or that other drugs were more appropriate, that other alternatives were less expensive, that the patient did not require a prescription drug, or that the patient could engage in behavioral and diet changes.[21]

26. Advertising can help patients meet their inherent needs in ever more improved ways. With new and improved drugs and therapies, patients are able to decrease their suffering, increase the quality of their lives, and often prolong their lives. Generally, patients responding to advertising are doing so because of unmet needs, not because of needs that previously didn't exist. Without a pre-existing underlying "need" there is no "want."

The Educational Value of DTCA

27. The Respondent's affiants argue that DTCA is not educational, because it is intended to sell a product. However, in my experience and opinion, DTCA fulfills an important educational function that is not generally met by any other means. In its heavily regulated form as permitted in the U.S., DTCA does provide important information to patients about prescription drugs and the potential need they may have for them. Again, this is borne out by survey evidence from both physicians and patients. According to the 2002 FDA Survey

[21] Aikin et al, "Patient and Physician Attitudes and Behaviours Associated with DTC Promotion of Prescription Drugs – Summary of FDA Survey Research Results", Nov.19, 2004, http://www.fda.gov/cder/ddmac/Final%20Report/FRFinalExSu1119042.pdf, p. 7.

of physicians and a subsequent 2004 survey of patients by the FDA, 77% of patients surveyed reported that DTCA increased their awareness of new drugs, and 72% of physicians reported that DTCA increased patient awareness of possible treatments.[22] The executive summary of the FDA's 2004 Report on these surveys is attached as Exhibit "H".

28. Similar findings are reported from the annual patient surveys conducted for *Prevention Magazine* – according to the 2007 *Prevention Magazine 10th Annual Survey on Consumer Reaction to DTC Advertising of Prescription Medicines*[23] (attached as Exhibit "I"), 30% of consumers strongly agree, and 47% somewhat agree, that DTC ads tell people about new treatments.

29. DTCA provides important information pertinent not only to the particular drug that is being advertised but also to the disease that is being treated. It often includes symptoms of the disease that the drug treats and pertinent facts about it.[24] To take an example from my own specialty, diabetes, advertisements often point out how common the disease is (one out of five people over age 60 have it[25]) and the symptoms associated with it such as fatigue and frequent urination. I

---

[22] *FDA Survey Final Report (Executive Summary)*, p. 4, 8. While both patients and physicians had criticisms of the content of DTC ads, they appear to be in agreement on the basic point that ads inform patients of possible treatments..

[23] *Prevention Magazine 10th Annual Survey on Consumer Reaction to DTC Advertising of Prescription Medicines* ("*10th Annual Prevention Magazine Survey*), (March, 2007), p. 17.

[24] The *10th Annual Prevention Magazine Survey* reports that 28% of consumers strongly agree, and 50% somewhat agree, that DTC ads alert people to symptoms related to a medical condition: p.17.

[25] American Diabetes Association , "Total Prevalence of Diabetes & Pre-diabetes", accessed 7/13/07
http:www.diabetes.org/utils/printthispage.jsp?PageID=STATISTICS_233187. Data for Canada

have had patients come to my office and tell me that they made the appointment because they saw an advertisement on TV describing the symptoms for diabetes. They are concerned that they might have it and want to be evaluated. Many such patients after I tested them did have it.

30. As another example, advertising has, over the past decade, educated the American public regarding the dangers of high cholesterol, and the need to adequately treat it in order to decrease the incidence of heart attack, stroke and death. Because of the heightened awareness regarding this problem, which was brought about by DTCA, many Americans have gone to their doctor and received proper treatment for it. I would expect that this has helped to save lives.

31. The argument that DTCA is not educational because pharmaceutical companies are seeking to make a profit misses the point. How else would patients learn about some of these drugs (which can be life-saving) if they were not educated by DTCA? Not everyone with a chronic disease sees their doctor on a regular basis. Some quit going after "all" of the drugs have been tried and nothing worked. Then a new drug becomes available. How could they learn about it if not for DTCA?

---

are similar – according to a recently published study, 1 in 10 Ontarians (of all ages) have diabetes, and this already high rate is increasing with the aging of the population and increased obesity rates: Lipscombe LL, Hux JE, "Trends in diabetes prevalence, incidence, and mortality in Ontario, Canada 1995-2005: a population-based study" *The Lancet* 2007; 369:750-56

32. Public health authorities occasionally run public health campaigns to address preventable diseases, but they have neither the resources nor the incentive to advise patients of specific treatments available for specific conditions on a sustained and systematic basis. This point was made eloquently by Dr. Temple of the FDA during the 2005 FDA Public Hearings. Speaking of advertisements by the National Institute of Health, he noted that "[t]he ads show up as far as I can tell very late at night. They are never part of the Super Bowl, and it's obviously a matter of money..." He questioned rhetorically whether public authorities "are going to come up with several billion" to run public information campaigns.[26] Doctors, for their part, are certainly not in any position to initiate contact with their patients to advise them of possible new treatments – I cannot possibly be expected to go through the charts of 10,000+ patients at my clinic, determine which patients might benefit from a new drug, and then contact them to arrange an appointment. Even if doctors could do this, word of such treatments would not reach many people who are not in regular contact with a doctor. Our system is demand-driven, and depends upon patients to identify the need for contact with medical professionals.

33. Advertisements also educate patients regarding the need to keep their illnesses, such as diabetes, under control. By maintaining good control of the blood sugars the risk of developing complications from diabetes is significantly reduced. For those patients who are under-treated DTCA educates them as to why control is important and encourages them to see their doctor.

[26] 2005 FDA Public Hearings, *Transcript*, Nov. 2, 2005, p. 90.

34. If a patient is not educated as to the existence of a drug and what it can do, s/he will not know to pursue it. Years ago when the drug Glucophage first came out I had the following experience occur. This was a pill which made it possible for some patients with Type 2 diabetes to maintain control of their blood sugars without taking their insulin shots. This offered real advantages - no more shots for some diabetic patients. But in at least one HMO health clinic in California, the physician incentives were structured in such a way that any physician ordering "off formulary" drugs would be financially penalized. This drug was off formulary. One can only wonder, as to how many physicians in that clinic told their patients of this new drug, which could potentially replace their insulin injections with a pill.

35. The benefits of a new treatment are not confined to its medical advantages. Being made aware of such treatments and pursuing them could potentially save a patient's job if he is an interstate truck driver. Commercial driving licenses, in the U.S., are rescinded when a patient begins insulin injections. However, the license can be maintained if the diabetes is in control with pills. Thus, giving a patient that little bit of information that such a drug exists, could help save his job.

36. DTCA advertisements can not be expected to, nor can they even attempt to, provide in-depth medical education regarding the pathophysiology and

sequelae of a disease. Nor is it possible for them to explain in great detail what biochemically is the mechanism of action of therapy. In my opinion, the patient can more appropriately explore these topics as necessary with his or her physician and discuss with him or her in greater detail how they apply to his own unique situation.

37. The main purpose of DTCA is not to teach anatomy, histology, physiology, biochemistry etc. The main purpose is first to educate the general public as to the availability of a product that could potentially decrease their suffering or in some cases even save their lives. DTCA's second purpose is to then encourage those who might benefit from the drug to see their physician to determine if it is appropriate. How many patients today suffer needlessly because they are not aware of drugs that could treat them? DTCA attempts to reach out to such patients and help correct the problem. Merely making it known that such a drug exists and encouraging patients to see their doctor can make all of the difference in the world.

38. In this context, I disagree with the concerns that the Respondent's affiants express regarding the patient's ability to understand and interpret DTCA. In my experience, DTCA messages are specifically constructed and designed to communicate effectively with the consumer. However, like other things in life, some advertisements are more effective than others. Some are better than others at presenting balanced information. But the overall message is a

consistent one: "We have a drug that might help you. See your doctor to determine if it is appropriate for you." Patients then use that message and combine it with other sources of information – most importantly, information from their doctor.[27]

39. I have treated patients for more than 35 years. It is my experience and opinion that for the most part patients get the intended message. Furthermore, when the DTCA message is brought up in the office visit by my patients, it has on more than one occasion, opened the door to discussions that might otherwise have never occurred. I recall two of my patients, who after seeing a drug advertisement, came to my office and confided in me that they were having erectile dysfunction. Ultimately they were found to have prostate cancer. Those conversations occurred because of DTCA. Those men might still be walking around today (if they were fortunate enough to still be alive) with undiagnosed prostate cancer if it were not for DTCA.

40. This underlines the fact that as much as experts might debate the systemic impacts of DTCA on prescribing practices, at the level of the individual patient there is no denying that DTC advertisements contain information that many patients find valuable.[28]

---

[27] The 2007 *10th Annual Prevention Magazine Survey* reports that more than half of those who talked with their doctor about an advertised medicine looked for additional information from their doctor about it, with a majority also looking for information online: p.23.

[28] According to a recent (2006) survey by the Kaiser Family Foundation, a majority (53%) of doctors and almost two thirds (64%) of patients say that DTC ads provide useful information most of the time or sometimes: Kaiser Family Foundation, "Prescription Drugs: Advertising, Out-of-Pocket Costs, and Patient Safety from the Perspective of Doctors and Pharmacists",

41. Nor do I agree with the criticism that DTCA is inevitably one-sided, incomplete, and circumvents the physician process by which drugs are usually prescribed.

42. Given the constraints of time on TV and radio and the constraints of space in the print media I believe that reasonable people will differ in opinion as to what to include and what to exclude in DTCA advertisements. But given those constraints my observation has been that DTCA usually does provide the viewer or reader with the potential advantages of taking the drug.[29] Under the Fair Balance Requirement of the FDA, information is also provided as to the potential adverse effects of the drug. Whether the appropriate balance has been struck with any given individual advertisement is a question that can be dealt with by the regulator. I am aware that there have been criticisms of individual advertisements, and of the manner in which the FDA deals with complaints,[30] but overall, in my experience and opinion, the FDA's oversight and the Fair Balance Requirement provide a workable system.

43. To put this in context, what other advertisers provide such adverse information regarding their products? One can only imagine the results if other

---

http://www.kff.org/kaiserpolls/upload/7583.pdf.

[29] Typically, benefit claims are made in qualitative form, and it has been suggested that information quantifying the benefits would be more helpful to patients: see Woloshin et al, "The Value of Benefit Data in Direct-to-Consumer Drug Ads", (2004) *Health Affairs* W4-234 – 245.

[30] See e.g. US GAO (2006), *Prescription Drugs: Improvements Needed in FDA's Oversight of Direct to Consumer Advertising* Report # GAO-07-54.

advertisers were held to the same standard. I could see the automobile advertisements now. After showing the shiny new vehicle and why a motorist should buy one, at the end of the advertisement would be a statement that proclaimed "50,000 people die in the U.S. each year in automobile accidents. If you are pregnant, don't drive!" Or, how about the fast food chain advertisements? After encouraging consumption of their new huge beef burger there would be a statement that said, "Fast foods can contribute to obesity, heart attacks, stroke and death!" Nobody has proposed banning advertising for these products, yet they can carry serious risks to public health.

44. Arguably, to be totally fair and balanced, DTCA of prescription drugs would have to provide information as to the potential sequelae if one does not treat the condition for which the drug is prescribed, after the potential side effects of the drug are enumerated. For example, assume that a particular diabetes drug is used to keep blood sugars under control. But its potential side effects include nausea, vomiting and diarrhea and this is made apparent in the advertisement. Arguably, this same advertisement should also educate the patient as to what might happen if they fail to keep their blood sugars under control, which is the purpose of this drug. Loss of control of blood sugars can result in an increased risk of heart attack, stroke and death. By doing this the patient would arguably be in a much better position to decide in consultation with his or her physician whether to take the drug. This is not how the FDA interprets the Fair Balance Requirement, but the example illustrates that there can be

disadvantages to requiring too much emphasis on potential side effects of a drug, which can be taken out of context by patients.[31]

45. My experience has been that DTCA has been helpful when I initiate therapy. If the patient has seen it advertised s/he will often say so. Patients thus have at least some basic information about the drug. And starting with that we are able to discuss it further. This tends to save some time and stimulate more specific questions.

46. DTCA can be particularly helpful in educating underserved populations about critical health issues and potential treatments. The National Medical Association, America's oldest and largest association of African-American physicians, has concluded based upon surveys of its members that "DTC advertising... has a positive impact on both African-American physicians and patients and, notably, underserved populations"; and that "that net benefit has increased since 2001, indicating a positive trend". DTC "continues to drive patients to visit their doctors", which is "very important within the African-American population given that both the 2003 and 2004 National Health Disparities Reports noted that blacks tend to have a lower use of routine care

---

[31] This point was made at the 2003 FDA Public Hearings, *Transcript*, September 22, 2003, p. 253-54:

> "Dr. Day: Well, we saw some in the slides today, I believe, from Dr. Hausman, you know, that people are scared and don't want to take drugs because there are side effects. [They think] "I already have one health condition, why do I want ten more?"
>
> Doctors fear it more than, I think, patients exhibit it. They often bring that up. That they don't want to have all those side effects out there. It's going to keep patients away from effective therapies."

and higher rates of avoidable admissions to both emergency departments and hospitals."[32] Attached as Exhibit "J" is a copy of the 2006 Survey of Physicians of the National Medical Association. Similarly, a study presented to the 2003 FDA Public Hearings found that Hispanics in South Texas were somewhat more likely than a comparator group to use DTCA to find out about drugs.[33]

47. Also, DTCA does not occur in a vacuum. Patients get some information from DTC ads, and continue learning about the drugs advertised in an ongoing process. Ten years ago, when DTCA restrictions were loosened, relatively few patients sought further information on the internet, but now going online for such information has become mainstream – the *10th Annual Prevention Magazine Survey* reports that 81% of consumers now access the internet for health information. Of those who go online, 74% look for information on a specific medical condition or illness, and 41% look for information on prescription medicines (of whom 44% have visited the website of an advertised brand).[34] The reality is that in today's world, patients come to doctors' offices armed with information from a variety of sources, including DTCA, and expect to be able to discuss the pros and cons of specific therapies with their doctors.

48. The issue is not whether DTCA is perfect. No single source of information can meet this standard. There is such a vast quantity of medical information in

---

[32] Morris et al., ""For the Good of the Patient," Survey of the Physicians of the National Medical Association Regarding Perceptions of DTC Advertising, Part II, 2006" (2007) 99 Journal of the NMA 287-93, at 292-93.
[33] 2003 FDA Public Hearings, *Transcript*, Sept. 22, 2003, p. 234.
[34] *10th Annual Prevention Magazine Survey*, p. 6, 27.

today's world, including information on thousands of prescription drugs,[35] that it simply does not make sense to restrict the range of sources from which patients are able to receive information. Instead of prohibiting patients from receiving information on pharmaceuticals from the companies that make them, it makes much more sense to permit these companies to provide information on their products, subject to appropriate regulatory controls to ensure accuracy and fair balance. In today's world, it is vital that patients have access to a range of sources of information about available treatments, so they can have informed conversations with their treating physicians.

49. In my opinion, the issue is not whether DTCA may have imperfections, but rather whether there is any compelling reason why DTCA should not be permitted as a source of information, available to patients in conjunction with information from other sources, on prescription drugs which may be beneficial for them. I see no reason why it should not be permitted in appropriately regulated form. In my experience and my professional opinion, DTCA helps in the process of educating patients.

The Criticism that DTCA is "Disease Mongering" is Unfounded

50. I disagree that "DTCA is characterized by the use of marginally ethical techniques, particularly disease mongering." Regarding "healthy individuals",

[35] Davenport, T & Glaser, J. "Just-in-Time Delivery Comes to Knowledge Management" (2002) Harv. Bus. Rev. 107.

sometimes "they are suffering from a pathological state requiring medicinal treatment"[36] and are not aware of it. And in such cases they do need to be informed. Take for example high cholesterol levels. Seemingly "healthy individuals" were walking around with high levels and feeling fine. Prior to the advertisements placed by the pharmaceutical industry they were not aware that elevated levels over time could result in heart attacks, stroke and death. The pharmaceutical industry's campaign to notify such individuals of the dangers involved and the potential treatments available was highly successful. Once informed, many people then went to their doctor and received treatment for it.

51. The Respondent's affiants argue that DTCA focuses on newly-approved drugs. This is not surprising. One of the main purposes of advertising is to inform the public of a new drug or treatment that might be of benefit to them. DTCA of new drugs brings the public new information. The Respondent's affiants also make the sweeping claim that most newly-approved drugs are simply "me too" drugs that offer no significant benefit over existing treatments.[37] This ignores the fact that drugs do not need to be "breakthrough" drugs to offer incremental advances in treatment methods. It also ignores the well-documented fact that individual patients react differently to different drugs, even those that are chemically similar. Receiving the best treatment possible for their individual needs is always in the patient's best interest. Therefore to limit the choice of drugs available to that patient is counterproductive. Further, even where drugs

[36] Report of Dr. Graham Dukes, p. 10.
[37] Wilkes Report, p. 7, 17.

are similar in their profiles and characteristics, there can be benefits to having a number of different drugs available. For example, when Rezulin was withdrawn from the market there were two other TZD drugs to replace it – Actos and Avandia.[38]

52. Each year new drugs are brought to the marketplace. Some might represent a small step forward rather then a quantum leap in drug development. But that is how science progresses, incrementally. This is much like a child in school progressing from one grade to the next. One doesn't go from 1st grade to the 8th grade in one step but rather by many little steps as he progresses incrementally through the grades in between. Likewise in the automotive industry, each year incremental improvements are made. Some years the improvements are greater then in other years. But when one looks back over many years the changes have been substantial. Compare a 1950 car to a 2007 car. Both will get you from point A to point B. Both can do it safely as long as you don't collide with another object before reaching point B. But if you do collide the 2007 car has airbags and seatbelts to help protect you. The 1950 car did not. To limit a consumer's choice to 1950 cars would be unthinkable.

---

[38] The availability of these drugs was key to the withdrawal of Rezulin. While Rezulin was known to carry risks of serious liver complications, these risks were judged to be less than the risks of leaving diabetics untreated. This was the basis for the FDA's initial decision to approve Rezulin. It was only after Actos and Avandia were shown to provide similar benefits with less risk that the FDA asked the manufacturer to withdraw Rezulin: HHS *News*, March 21, 2000: www.fda.gov/bbs/topics/NEWS/NEW00721.html.

53. The U.S. Veterans Health Administration may provide an example of what happens when the choice of new drugs is limited. In 1997 for the first time it implemented a VA National Formulary. This formulary contains:

- only 22% of the 77 priority-reviewed drugs approved by the FDA since 1997;
- only 38% of the drugs approved by the FDA in the 1990's;
- only 19% of the drugs approved by the FDA since 2000.

The VA's own data shows that: "The life expectancy of veterans increased substantially before the National Formulary was introduced...but did not increase...after it was introduced." Furthermore, "the estimates implied that the use of older drugs in the VA system reduced the mean age at death... 2.04 months."[39] Similar data on the relationship between vintage of drugs used to treat a patient and the patient's 3-year probability of survival, taken from a study of over 500,000 people in Puerto Rico, showed significantly lower mortality rates for patients treated with newer drugs.[40]

54. As noted above, one must consider patient heterogeneity. A drug that is safe and efficacious and works on one patient might not work on another. Therefore the physician must be able to choose from a variety of drugs in order to pick the best one for the individual patient. All patients don't respond in the same way to the same drugs. For example take an older medication such as penicillin. For one patient it could save their life if they have pneumonia. For

---

[39] Frank R. Lichtenberg, Medical Progress Report, No. 2, Oct 2005, www.manhattaninstitute.org.
[40] Frank R. Lichtenberg, "The Effect of Drug Vintage on Survival: Micro Evidence from Puerto Rico's Medicaid Program", National Bureau of Economic Research (2004) http://www.nber.org/papers/w10884.

another patient it could take their life if they have an anaphylactic reaction to it - same drug, different patients, different results. For those patients who cannot take penicillin other newer antibiotics are now available. Thus, to evaluate and compare drugs to one another with out taking into consideration the heterogeneity of the patients being treated is unduly simplistic.

55. To take another example, "statins" are a class of drug used to treat high cholesterol levels. Patients with elevated levels of cholesterol are at increased risk of developing strokes and heart attack. Several different statins have been the subject of DTCA campaigns (Crestor, Lipitor etc.). To Professor Wilkes, they might be classified as "me too" drugs, but at the level of the individual patient, they can have different side effects.[41] In my own experience, I have found it necessary to switch patients from one to another because of the way they responded to the drug that I first tried them on. DTCA can play a positive role in informing patients of the different options that might be available to them.

56. With respect to the "disease mongering" criticism made by the Respondent's affiants, the conditions treated by statins are far from trivial – they put patients at great risk of health complications or even death. It is not "disease

[41] See, e.g., with respect to treatment by statins: Brown AS, Bakker-Arkema RG, et al. "Treating Patients with Documented Atherosclerosis to National Cholesterol Education Program Recommended Low-density-lipoprotein Cholesterol Goals with Atorvastatin, Fluvastatin, Lovastatin and Simvastatin." *J Am Coll Cardiol* 1998; 32:665; Jones PH, Davidson MH, et al. "Comparison of the Efficacy and Safety of Rosuvastatin versus Atorvastatin, Simvastatin and Pravastatin Across Doses" *Am J Cardiol* 2003 Jul 15; 92 (2):152-60; Mulder AB, van Lijf HJ, et al. "Association of Polymorphism in the Cytochrome CYP2D6 and the Efficacy and Tolerability of Simvastatin", *Clin Pharmacol Ther* 2001 Dec; 70 (6): 546-51; Chasman DI, Posada D, et al. "Pharmacogenetic Study of Statin Therapy and Cholesterol Reduction". *JAMA* 2004 Jun 16; 291 (23): 2821-7.

mongering" to encourage patients who might have these conditions to see their doctor. Even for drugs characterized as "lifestyle" drugs – by which I assume the critics are referring to drugs like Viagra and Cialis – there are benefits to bringing patients into doctors' offices, as I have described above. Middle-aged men, who are likely to seek attention for erectile dysfunction, are at risk for Type-2 diabetes, and are notoriously difficult to persuade to see a doctor. In some cases, a man seeking advice on erectile dysfunction, and possibly a prescription to Viagra or Cialis, will be diagnosed with an underlying condition such as diabetes, and given appropriate treatment for that condition.[42]

57. Moreover, even if the Respondent's affiants regard some conditions as trivial (and who, exactly, are they to make that judgment?), that is no reason why patients shouldn't be able to learn about effective treatments for them. Among all of the criticisms made of drugs advertised by DTCA, none of the Respondent's affiants have questioned the effectiveness of the drugs. If they work, why shouldn't patients be told about them?

58. Professor Wilkes expresses his opinion that "DTCA will inevitably lead to the loss of critical services", but he does not provide any evidence for this

[42] Curkendall SM, Jones JK, Glassier D, Goehring E. "Incidence of medically detected erectile dysfunction and related diseases before and after Viagra (sildenafil citrate)" [Abstract 324]. *Eur Urol* 2000; 37 (Suppl 2): 81. The authors report that since Viagra was introduced into the U.S. market in April 1998, there has been a substantial increase in the number of new ED claims, and of the 980 men first coming into the system with ED between April and August 1998, many had new claims for one of the study diseases within a month of their new ED claims (18% with hypertension, 16% with diabetes, 15% with benign prostatic hyperplasia, 4% with prostate cancer, 5% with ischemic heart disease, 0.8% with depression). In the authors' view, these data suggest that seeking medical attention for ED may contribute to early detection of serious, often asymptomatic, concomitant conditions.

opinion. With respect, this does not follow at all. It must be kept in mind that the question of who pays for drugs, and how, is separate from whether patients can be told about them. A publicly-funded drug plan can make its own decisions as to which drugs to subsidize, and to what extent, based upon public health priorities. (In my experience these decisions are not always rational, because drug plans can have their own agendas influenced by factors other then the health and well-being of patients, but I leave this aside.) Some drugs are in demand from patients, but are rarely covered by drug plans. Restricting access to information about effective drugs from patients who can benefit from such information is not the way to deal with difficult issues about allocation of public resources.

59. Wilkes also assumes that higher expenditures on prescription drugs always result in higher overall health care costs. Again, this is not supported by empirical evidence. Appropriate medication use can lower overall health care costs – for example, a study of diabetes patients in Asheville, North Carolina, in which pharmacists provided community-based pharmaceutical care services (PCS), showed that while the cost of prescriptions rose significantly for patients who received ongoing PCS, their overall cost of treatment was lower because they needed fewer inpatient and outpatient physician services.[43]

[43] Craner CW, Bunting BA et al, "The Asheville Project: long term clinical and economic outcomes of a community pharmacy diabetes care program" *J Am Pharm Assoc* 43(2): 173-184, 2003.

60. The "disease mongering" criticism made by Professor Wilkes, at its core, is highly paternalistic. It assumes that someone other than patients themselves should be deciding what treatments, for what conditions, patients should be told about. This may have been the model of medical treatment fifty or a hundred years ago, but it no longer makes sense (if it ever did) in an age of vastly increased information and patient empowerment.

No Empirical Evidence that DTCA's Risks Outweigh its Benefits

61. Professor Wilkes appears to stop short of claiming that DTCA leads to patients receiving clinically inappropriate prescriptions with adverse health consequences, but this claim is made by Professor Lexchin. Lexchin's claim appears to be that because DTCA tends to focus on newer drugs, and the risks of adverse drug reactions ("ADRs") for newer drugs may be less well known, DTCA is inherently risky. I disagree with this analysis.

62. I accept that it is possible that "the true efficacy and safety of a drug is not known at the time of its introduction to the market." If a side effect is very rare and will only manifest itself in one out of 500,000 patients it is quite likely that its existence will not be known until after the drug is in the marketplace and hundreds of thousands of patients have taken it.

63. However, prior to their release into the marketplace, prescription drugs are put through a very rigorous process. Only those drugs which have successfully completed this process are released. No one man or one agency is omniscient. Therefore after being released drug adverse events are monitored to detect any previously unknown side effects. And, if and when they occur, if they are sufficiently serious then the drug is removed from the marketplace.

64. The other side of the coin is often forgotten in such discussions. What about the patient, the patient whose life could depend on this new drug or the patient who is suffering? Delay in release of a new drug can result in needless suffering for some patients and even death for others. In our imperfect world our knowledge of many things is not always complete so we proceed with the best available information possible and use it to make the best judgments possible. Treatment of patients always involves a clinical judgment involving risk versus benefit.

65. What is missing in Lexchin's analysis is any empirical evidence that the risks of ADRs from newly-approved drugs outweigh their benefits. For this to be generally the case, then we would have to assume that the approval process is fundamentally unsound, and more often wrong than right. DTCA is not really the issue.

66. The relevance of DTCA is that it can encourage a more rapid change in prescribing patterns. That is one of the purposes of DTCA, to inform. We live in an electronic age in which much of our information is brought to us via the media. And if such information encourages us to visit our physician to seek care regarding a particular illness then DTCA has been successful. Because the information is transmitted electronically it can be disseminated very quickly and a faster change in prescribing patterns can occur.

67. One example would be the use of the flu vaccine. When flu epidemics occur patients are advised via DTCA to see their physicians in order to receive the flu vaccine. It helps get these patients to the office. Overnight physicians are administering more flu vaccinations. Their prescribing patterns change, in a way that clearly contributes to public health.

68. The Respondent's and Intervenors' affiants refer repeatedly to Vioxx as an example of the downside of DTCA, but this is a simplistic approach to a complex issue. Vioxx was voluntarily removed from the market, possibly prematurely. It was a drug which offered significant benefits for many patients who had severe arthritis. For some it was the only drug which offered relief. Thus during recent months, orthopedic surgeons in the US have called for its return to the market.[44] On the other hand, it carried risks of side effects, and was not appropriate for all patients. It may or may not have represented a failure in the approval process - I

[44] Kazman S, Conway K, "A national survey of orthopedic surgeons regarding the Food and Drug Administration and the availability of new therapies" (January 30, 2007) http://www.cei.org/pdf/5732.pdf, accessed July 14, 2007, at p. 7.

express no opinion on this. DTCA may have led to a more rapid uptake of the drug, and thereby led to more patients both receiving its benefits and being exposed to its risks. A fairer and more sophisticated assessment would advert to and attempt to quantify both sides of this issue,[45] and put it into context by noting the many new drugs that appear to have brought benefits without undue risks.

69. Of course, widespread promotion of a drug that actually provides benefit to patients will result in its increased use. And of course the more people who are taking a drug the greater the actual number who might get an adverse reaction. But there is no evidence that I am aware of that DTCA changes the percentage of the patients having an adverse reaction.

Dr. Abramson's Critique of the Drug Approval Process

70. The drug approval process is a complex subject. I do not intend to address it at length. However, I note that despite Dr. Abramson's lengthy critique he does not attempt to make the case that newly-approved drugs carry more risks than benefits, across the board. That would be contrary to the conclusions reached by the FDA for all of these drugs that they are safe and effective, and

[45] There is some mixed literature on Vioxx, and the issues as to whether it was (or would still be) a reasonable treatment option on the basis of what was (or is) known about the drug's effects are complex: see e.g. the review of studies (from Merck's point of view) in Scolnick, EM, "Vioxx: A Scientific Review" www.merck.com/newsroom/Vioxx/pdf/VIOXX_scientific_review.pdf, accessed July 15, 2007. For an analysis of the Vioxx issue with specific reference to the impact of DTCA, see Bradford, W.D. & Kleit, A., "Evaluating the Welfare Effects of Drug Advertising" *Regulation* (Spring, 2006), p. 58-62.

contrary to the overwhelming evidence that on the whole, over time, advances in pharmacology have brought enormous health benefits to patients.

71. Unless Dr. Abramson can show that the drug approval process systematically results in erroneous decisions, that newly approved drugs bring more harm than good on an aggregate basis, then it is hard to see how his criticisms to the effect that the approval process is not always perfect can justify a ban on DTCA. Even if it is the case that a few drugs are approved that turn out to do more harm than good, they are a small minority in the overall system. Curtailing the spread of information about beneficial new drugs results in lost opportunity for patients to obtain the best possible care.

72. With that in mind, I have the following comments to make about Dr. Abramson's critique. First, virtually every example he raises to illustrate the supposed inadequacies of the drug approval and safety monitoring system would be contested by other experts, and many of these examples raise complexities that are completely ignored in his commentary. For instance, he notes that he co-authored a commentary in *The Lancet* about "the lack of evidence supporting the recommendations for treatment of women and people over the age of 70 with statins for the primary prevention of heart disease".[46] Apparently, in his view, the existence of strong data that statins are beneficial in other populations does not justify doctors in extrapolating from these data and prescribing them for women and the elderly. Yet the most recently reported data indicate that just as one

[46] Affidavit of Dr. John Abramson sworn May 7, 2007 ("Abramson Affidavit"), para. 3.

would expect, elderly patients obtain just as much benefit from statin therapy as younger patients, though they are significantly less likely to be prescribed statins.[47] How many patients were exposed to increased risk of heart attacks due to the views of Dr. Abramson and others that the "evidence" did not support statin therapy for this population? This example shows that there are dangers arising from undue conservatism in drug therapy, just as there can be dangers arising from being too quick to prescribe drugs.

73. Second, he is critical of the fact that pharmaceutical companies fund clinical trials, and that such trials are no longer primarily carried out in academic medical centers. I would respond that it is just as well that pharmaceutical companies have stepped in to fund research, as public funding has dried up. Further, the change in location of trials has partly been driven by the regulator's desire that trials take place in the actual setting in which clinicians would be using the drugs – out in the community. This does not mean that the results of the trials are necessarily less reliable.

74. Third, he makes a lengthy attack on the "commercial interests" of pharmaceutical companies, based on the assumption that these cannot be the same as patients' interests. I have no doubt that pharmaceutical companies seek to maximize shareholder value, but in the long run, they do so by coming to the marketplace with drugs that optimize the patient's health most effectively and

[47] "Aggressive Statin Therapy Beneficial for Elderly Patients", *Internal Medicine News*, Vol. 40, No. 10, May 15, 2007.

efficiently. Pharmaceutical companies, and researchers who work on clinical trials, must also consider their reputations with clinicians and with the public. To this extent, the goals of pharmaceutical companies and patients are largely aligned. For all the criticisms made by Dr. Abramson and others of private pharmaceutical companies and their role in drug development (this is a very old debate), over the long run the U.S. pharmaceutical sector has proven to be very innovative and has contributed greatly to patient welfare.

75. Fourth, he assumes that sources of information which are not associated with pharmaceutical companies are always pristine. Unfortunately, this is not the case. Politics and other agendas can intervene and play a part in the way in which even prestigious medical journals publish studies – as is alleged to have occurred when the *New England Journal of Medicine* "rushed onto its Web site a limited and flawed analysis of safety concerns around the diabetes drug Avandia" in order to influence debate in Congress.[48]

76. Fifth, and more generally, he bases his views on drug approval on "evidence-based medicine", an approach to data interpretation that not all physicians (especially clinicians) would agree with.[49] As a rhetorical label, "evidence-based medicine" implies that its adherents are more careful than

---

[48] S. Gottlieb, "Journalistic Malpractice", *Wall Street Journal*, May 29, 2007, p. A15.

[49] Cohen AM, Stavri PZ, et al "A Categorization and Analysis of the Criticisms of Evidence-Based Medicine", *Int. J. Med Inf* 2004; 73 (1): 35-43; Cohen AM, Hersh WR, "Criticisms of Evidence-Based Medicine", *Evidence-Based Cardiovascular Medicine* (2004) 8, 197-98; Holmes D, Murray SJ, et al, "Deconstructing the evidence-based Discourse in Health Sciences: Truth, Power and Fascism", *International Journal of Evidence-Based Healthcare* 4 (3), 180-186.

others, requiring a higher level of proof before making or approving of particular treatment decisions. However, medical data are fluid, complex, and constantly changing and being updated and/or reinterpreted. Physicians do not deal with "evidence" in the sense that judges and lawyers would understand it in a court of law. A clinician must apply his or her best judgment, on the basis of this evolving body of information and opinion, when deciding how to treat patients and (where applicable) which medications to prescribe. Drugs that are approved by the FDA as safe and effective for particular uses may not all have gone through the kind of studies that Dr. Abramson would endorse (though the FDA approval process is long and arduous), but they generally represent reasonable treatment options on the state of knowledge at the time. As with the example of statins and the elderly, referred to above, waiting too long for more conclusive data before making treatment decisions such as prescribing a particular drug for a particular type of patient can result in sub-optimal care. To my knowledge, no study has ever demonstrated that the so-called "evidence-based medicine" approach leads to better health outcomes.[50]

77. With respect to Dr. Abramson's specific comments on DTCA and its impact upon women, I agree that women's physiology and health issues differ from those of men. I also agree that women tend to use health services more

[50] Cohen AM, Stavri PZ, et al "A Categorization and Analysis of the Criticisms of Evidence-Based Medicine", *supra*: "There is little defense for a movement that does not hold to its own principles. EBM expends medical resources without any of the proof it requires of other interventions or changes in clinical practice. EBM must evolve to include a broader definition of high quality evidence that will allow for studies that can demonstrate the efficacy or effectiveness of EBM, or lack thereof. Until then, EBM will continue to be an interesting, but unproven theoretical approach to the practice of medicine."

often than men, both because of their own needs and because they often have a caregiving role for other family members. Women also live longer than men, on average – and the increased lifespans of both men and women are due in no small part to the tremendous advances in pharmaceuticals in the last century. Where I disagree fundamentally with Dr. Abramson is that I do not believe that women are any less capable than men of evaluating information presented to them in DTC ads, combining it with information from other sources, and reaching an informed decision with their doctor as to the best treatment for them. His views are, in a word, patronizing.

78. Dr. Abramson raises specific examples of statins, SSRI-antidepressants, Diane-35 and hormone replacement therapy ("HRT"). Each of these examples has its own complexities, and there are differing medical opinions on the issues he raises. I have commented above on recent data on the usefulness of statins for the elderly. In my professional opinion, statins can be appropriately prescribed for women at risk of heart disease.[51] They are approved for this purpose by the FDA, and recommended under American Heart Association guidelines. Just as elderly patients may have missed out on the benefits of statin therapy because of undue conservatism in prescribing practices, Dr. Abramson's

[51] There is substantial medical literature to support this view: see e.g.; Downs JR, Clearfield M, et al, "Primary Prevention of Acute Coronary Events with Lovastatin in Men and Women with Average Cholesterol Levels: results of AFCAPS/TexCAPS. Air Force/Texas Coronary Atherosclerosis Prevention Study" *JAMA* 1998 May 27; 279(20): 1615-22; Baigent C, Keech A, et al "Cholesterol Treatment Trialists' (CTT) Collaborators. Efficacy and Safety of Cholesterol-lowering treatment: prospective meta-analysis of data from 90,056 participants in 14 randomised trials of statins." *Lancet* 2005;366:1267-78; "Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on detection, evaluation,, and treatment of high blood cholesterol in adults (Adult Treatment Panel III)". *Circulation* 2002; 106:3143.

approach would apparently deny women these benefits because it has not been proved to his satisfaction in studies he approves of that women are the same as other populations in their response to these drugs. Dr. Abramson's views on this subject, as published in *The Lancet*, have themselves been criticized by Dr. Baigent of Oxford University (who conducted a major study on this) on the grounds that "the evidence of benefit of statins is so immense that I would be very surprised if we find a group that clearly *doesn't* benefit".[52] But more fundamentally, Dr. Abramson would prevent women from even hearing about the drugs. In my opinion, if there are issues about the effectiveness of approved drugs for women, it is far more appropriate to allow them to be advertised, but require the ads to contain whatever qualifying statements seem to the regulator to be needed as part of the Fair Balance Requirement. That way women can decide for themselves, in consultation with their doctors, whether the therapy is appropriate for them.

79. Similarly, there are many specialists who would disagree with Dr. Abramson's view that anti-depressants are over-prescribed. I have reviewed the affidavit of Dr. Fulgosi, and note his opinion and references to literature that suggest undertreatment of depression is a more serious problem than over-prescribing.

---

[52] Wood S, "Lancet Comment Questions Benefit of Statins in Primary Prevention", *Heartwire* 2007 accessed July 15, 07 at http://www.medscape.com/viewarticle/551324_print.

80. With respect to Diane-35, Dr. Abramson refers to "reminder" ads that have run in Canada, which in his view encourage or suggest non-approved uses. My only comment is that I do not support DTCA of drugs for non-approved uses, and in my opinion, product claim DTCA is much more informative and less open to misinterpretation than "reminder" ads. As noted above, reminder ads have been much criticized in the U.S.

81. Dr. Abramson's comments on HRT illustrate the point that clinicians must deal with evolving data, and use their best medical judgment based upon the information available to them. HRT was an approved treatment in widespread use in the U.S. prior to 2002. In 2002, a report of the Women's Health Initiative Estrogen Plus Progestin Trial ("2002 WHI Trial") called HRT into question by linking it with increased risk of heart attack or stroke.[53] After this report, prescriptions declined, as doctors were more cautious in their prescribing in light of the new data. However, most recently, two studies published in April and June 2007 have provided greater insight into the 2002 WHI Trial. They revealed that the 2002 WHI Trial results were unfairly generalized.[54] New research supports the concept that hormone-replacement therapy has different effects on blood vessels in younger menopausal women (50 to 59 years old) than in women long after menopause.[55] Thus estrogen appears to have a cardioprotective effect if

---

[53] Writing Group for the Women's Health Initiative Investigators, "Risks and Benefits of Estrogen Plus Progestiin in Healthy Postmenopausal Women", *JAMA*, 2002; 228:321-333.

[54] Rossouw JE, Prentice RL, et al, "Postmenopausal Hormone Therapy and Risk of Cardiovascular Disease by Age and Years Since Menopause", *JAMA* 2007; 297: 1465-1477; Manson JE, Allison MA, et al, "Estrogen Therapy and Coronary-Artery Calcification", *N Engl J Med* 2007; 356:2591-602

[55] Mendelsohn ME, Karas RH, "HRT and the Young at Heart", *N Engl J Med 2007*; 356: 2639-

initiated between the ages of 50 and 59 or within 10 years after menopause rather than if initiated more than 10 years after menopause.[56] The implications of these refined observations and shifting interpretations were aptly summarized by the authors of a June 2007 comment on the continued WHI Trial as follows: "As Schopenhauer observed: 'Opinion is like a pendulum and obeys the same law. If it goes past the centre of gravity on one side, it must go a like distance on the other; and it is only after a certain time that it finds the true point at which it can remain at rest.'"[57]

82. The important point is that doctors, patients, the FDA and pharmaceutical companies can only go by the best information that is available to them at the time. Doctors have a saying that "the retro-spectroscope is always right" – in other words, that hindsight is always 20/20. A criticism that in some cases, pharmaceutical companies have informed patients through DTCA of prescription drugs that were later found to have risks of adverse effects, is not a criticism of DTCA itself. Rather, it simply reflects the fact that medical information and interpretation of data evolve, as the HRT example illustrates. Sometimes the evolution is towards a greater understanding of benefits, or towards a conclusion that previously-feared risks were overstated. Dr. Abramson's critique does not

---

2641.

[56] Manson JE, Allison MA, et al, "Estrogen Therapy and Coronary-Artery Calcification", *N Engl J Med* 2007; 356:2591-602. Dr. Abramson also argues that HRT was inappropriately prescribed because it led to increased risks of breast cancer, but this is also a controversial topic: see Chen WY, "Postmenopausal Hormone Therapy and the Risk of Breast Cancer", *UptoDate* (version 15.2, accessed July 19, 2007): "In a report on breast cancer rates in the United States, there was a 7 percent decrease in breast cancer incidence between 2002 and 2003...Some experts attribute this decline in breast cancer to the decrease in use of hormone therapy after the initial WHI publication in 2002, although this interpretation is controversial."

[57] Mendelsohn ME, Karas RH, "HRT and the Young at Heart", *supra.*

change my opinion that patients should have the benefit of access to information about available treatments through DTCA.

The Impact of DTCA Upon the Patient-Doctor Relationship

83. I disagree with the suggestion by Professors Wilkes and Lexchin that DTCA harms the patient-doctor relationship. In my experience, DTCA does encourage a clinical dialogue between patients and physicians. This occurs in my office all of the time and often involves questions about diabetes, high cholesterols, and other medical issues. It is helpful and not irritating.

84. In my experience, the most intense and irritating pressure that physicians feel to prescribe certain drugs, usually stems from the third party payer and not the patient. Frequently pressure is applied to the physician by third party payers to use drugs which are other than his or her first clinical choice. The hassles and financial pressures that we face in such situations are often enormous. Any pressure that a patient would exert compared to this pales in comparison.

85. I disagree with the contention that "a physician must spend a great deal of time re-educating a patient with respect to the DTCA that they have viewed." If I have to spend time "re-educating" a patient about what they have heard or seen since the last visit the source of such misconceptions is more often the Internet rather then DTCA. The Internet is unregulated or unpoliced. Information

obtained there can span the range from very good to totally useless and in some cases actually dangerous. DTCA information comes from the company that manufactures the drug. Who else would know more about it? The advertisements are highly visible, and regulated by the FDA. Thus the information provided is often of much higher quality.

86. The Respondent's affiants argue that DTCA creates a situation where doctors will write prescriptions that they do not believe are necessary or appropriate for their patients, just to satisfy them. This is an insult. To think that physicians give inappropriate prescriptions to patients because they are "...giving patients what they want so as not to alienate them"[58] is absurd. As a professional who has taken the Hippocratic Oath, I am governed by the principle that it is our duty to always do what is best for the patient. Every doctor that I know follows this principle.

87. Most physicians in the U.S. (and I assume many in Canada) have long waiting periods to be seen. To think that physicians must therefore provide unneeded drugs to patients in order to not alienate them and keep them in the practice is ludicrous.

88. Surveys in the U.S. consistently show that DTCA is popular with patients. They may not regard DTCA as the best or only source of information – they rely primarily on their own physicians for medical information, even when exposed to

[58] Lexchin Affidavit, para. 15.

DTCA – but it gives them a place to start. Doctors are more guarded in their reactions to DTCA, but in my opinion this can be partly because they feel threatened by no longer having a virtual monopoly on information about drugs. Even so, the American Medical Association has given qualified support to DTCA.[59] Similarly, the American Society of Health System Pharmacists has expressed support for DTCA subject to certain conditions being met.[60] A 2006 survey by the Kaiser Family Foundation found that twice as many doctors say DTCA-generated inquiries have a positive effect as those who say such inquiries have a negative effect on their interactions with patients.[61]

DTCA and the Cost of Drugs

89. Professor Wilkes seems to suggest that DTCA increases the cost of drugs, but he does not cite any supporting evidence. The cost of drugs can be affected by many factors, including incentive structures which may encourage physicians to prescribe or not to prescribe specific drugs. In my opinion, that is another reason why DTCA is so very important for some patients.

90. It is true that many patients lack a standard financial incentive to carefully consider price when making drug purchases because private or public insurers

---

[59] 2005 FDA Public Hearings, *Transcript*, Nov. 2, 2005, p. 205-6.
[60] 2005 FDA Public Hearings, *Transcript*, Nov. 1, 2005, p. 222.
[61] Kaiser Family Foundation, "Prescription Drugs: Advertising, Out-of-Pocket Costs, and Patient Safety from the Perspective of Doctors and Pharmacists", (2006) http://www.kff.org/kaiserpolls/upload/7583.pdf.

cover all or part of the cost of prescription drugs. But it is equally true that third party payers can structure financial incentives to discourage doctors from prescribing certain drugs. From the patient's point of view, it is best if s/he has information on all available options.

91. Would drugs be more expensive or less expensive without DTCA? There is no obvious answer to this. Consider the economies of scale if a drug is being produced for 100,000 patients versus production for only 100 patients. What would those 100 patients have to pay in order to keep the production line going for their drug? The fixed costs of drug development and production can be huge. Now consider how much cheaper that drug would be if the fixed costs for its production were being shared among 100,000 patients rather then only 100. Thus, greater demand for a drug can lead to lower prices. In fact, testimony presented at the 2003 FDA Public Hearings suggested that there was no obvious correlation between DTCA and drug prices.[62]

92. There is some indirect evidence to show that DTCA could lower costs, in the example of prescription eyeglasses. At one time in the U.S. it was against the law to advertise prescription eye glasses in some but not all States. A study was done comparing the prices in those states that banned it and those States that allowed it. Glasses were cheaper in those States that allowed advertising.[63]

---

[62] Evidence of Dr. Masia, 2003 FDA Public Hearings, *Transcript*, September 23, 2003, p. 43, 47-50.

[63] Benham L, "The Effect of Advertising on the Price of Eyeglasses", *Journal of Law and Economics* Oct 1972, vol 15, No. 2, 337-352.

Certainly, there is no evidence that I am aware of that DTCA inevitably raises drug prices.

Conclusion

93. DTCA has now been an established feature in the U.S. for many years. While it has its critics, including Professor Wilkes and Dr. Abramson, it continues to be permitted by the FDA (in highly regulated form), it has proved popular with patients, and it is accepted by the majority of doctors. I have seen first-hand the benefits that it can bring to my own patients. The criticisms made by opponents, on closer examination, are not compelling and are not supported by empirical evidence. The U.S. experience of regulated DTCA provides a model of a workable system in which product claim DTCA is permitted. In my opinion, the evidence does not support a prohibition on DTCA.

SWORN before me in the City of Phoenix, in the State of Arizona this 23rd day of July, 2007.

Cindy Trowbridge
A Commissioner, etc. / NOTARY PUBLIC

Richard Dolinar MD
Dr. Richard Dolinar

664586_1.DOC

CINDY TROWBRIDGE
Notary Public - Arizona
MARICOPA COUNTY
My Commission Expires
OCTOBER 5, 2007