Court File No. OS-CV-303001PD2

ONTARIO
SUPERIOR COURT OF JUSTICE

B E T W E E N :

CANWEST MEDIAWORKS INC.

Applicant

- and -

ATTORNEY GENERAL OF CANADA

Respondent

AFFIDAVIT OF TERENCE HART YOUNG
(sworn August 31st, 2006)

I, TERENCE HART YOUNG, of the Town of Oakville, in the Province of Ontario, AFFIRM THAT:

1. I have been the founding Chair and then President of Drug Safety Canada (hereafter DSC) since it was founded in 2002 and, as such, have knowledge of the facts herein deposed to.

2. DSC has two arms currently in the process of being incorporated in Canada. Drug Safety Canada Research is a charitable research organization, examining issues related to prescription drug safety. Drug Safety Canada is a not-for-profit advocacy group promoting regulatory and voluntary change related to the safe use of prescription drugs.

3. Prior to founding DSC in 2002 I worked as a manager at Bell Canada in public affairs in the early 1990's, and then as a specialist in "loyalty" marketing direct to consumers. As a marketing manager I helped establish customer loyalty and relationships similar to those

that I believe drug companies pursue with patients, such as 1-888 numbers, direct mail and advertising.

4. From 1995-1999 I was the Member of Ontario Provincial Parliament for Halton Centre Riding, and I was the Conservative Candidate for Oakville in the 2006 Canadian General Election.

5. On March 19, 2000 we suffered the devastating loss of our fifteen year old daughter Vanessa, who died suddenly at our home after taking a Johnson & Johnson prescription drug - Prepulsid - which she should never have been prescribed. I immediately discovered that Prepulsid was widely prescribed off-label for teens that threw up after meals despite being contraindicated for use by any patient that could be vomiting. Four doctors knew Vanessa had been taking Prepulsid and none of them warned us it could cause deadly heart arrhythmia and was already responsible for 79 such deaths. To prevent further deaths I went public about Prepulsid two days after Vanessa died. Two days after that Johnson & Johnson announced that Prepulsid would be taken off the market.

6. Drug Safety Canada was conceived when people I had never met began calling me within days of Vanessa's death to share their stories about Prepulsid and other dangerous prescription drugs. Since that time I have had innumerable conversations with other victims and their families who often have no other place to turn. Their stories usually concern adverse drug reactions caused by risky drugs for which they had received no safety warning. Many of these incidents relate to the deadly combination of off-label use and over-zealous marketing.

7. In time I discovered that Prepulsid was also widely prescribed for thousands of infants off-label despite being refused approval by Health Canada and the US Food and Drugs Administration (FDA) for paediatric use, and had been promoted widely off-label in the US and Canada in various ways - including direct-to-consumer advertising (DTCA). The FDA had written an official warning letter in June of 1998 to Johnson and Johnson

asking them to suspend all promotional activities, including off-label DTCA brochures which had played a key role in making Prepulsid a blockbuster drug as the body count grew from 1993 to 2000. Attached as Exhibit "A" to this affidavit is a copy of this FDA correspondence.

8. Since losing Vanessa in 2000 I have devoted 20 hours a week in research and advocacy for prescription drug safety on my own, and then as a volunteer under the auspices of Drug Safety Canada. To help address the need for public awareness of the risks of prescriptions drugs and reduce adverse drug reaction injuries and deaths I founded Drug Safety Canada in 2002. I am also writing a book, *Death by Prescription*, which is to be published by Key-Porter Books next year, which deals extensively with issues around DTCA of prescription drugs.

9. As the founder of DSC I have advocated for change in various national forums including The Royal Commission on The Future of Health Care in Canada, The Parliament of Canada - Standing Committee on Health, and two national consultations by Health Canada. I have also acted as an on-camera resource for CBC, CBC Radio, TVO and other media outlets, as well as lecturing on prescription drug safety at the University of Toronto and for various professional conferences and community groups.

10. DSC first became directly involved with DTCA when we appealed in writing to Advertising Standards Canada July 15, 2003 to prevent the continued advertising of Pfizer's drug Lipitor on TV and in the print media – in the campaign known as the "toe tag" ad. Attached as Exhibit "B" to this affidavit is copy of this correspondence.

11. Since its creation, the primary focus for DSC has been on issues relating to effective patient safety warnings, compulsory adverse drug reaction reporting, eliminating conflicts of interest between our doctors and the pharmaceutical industry, reform in 'continuing medical education' of our doctors, DTCA, post-marketing surveillance, risk

management versus the precautionary principle, an arms-length independent drug safety agency for Canada and openness and integrity in clinical trials.

12. DSC offers consumer awareness and education on its website, as well as breaking news on regulatory matters provided there and at drugsafetycanada.blogspot.com. I maintain ongoing and extensive communications with individuals and groups who share DSC concerns about the use, misuse, and promotion of pharmaceutical products, including many individuals who have experiences similar to my own family's or have otherwise suffered the consequences of adverse drug reactions.

13. My concerns with DTCA are as follows:

(a) DTCA is about promoting sales, not about providing balanced information about the benefits and risks of a particular drug. It is often a key part of a broader PR program that includes internet websites that, according to my own survey of several such sites, consistently encourage patients to read all the good news about the drug, and play down the risks - or neglect to mention them at all. Safety information is buried in the pages of 'prescribing information' in terms that few if any patients can understand, and rarely appears on the direct marketing sites for patients. These web sites may also offer 'loyalty club' membership where patients can win points for free rewards, providing personal information that allows marketers to target them directly with more one-sided messages. DTCA is key to making the first contacts to build up club memberships and client databases. Marketers then exploit these 'relationships' to promote drug use, such as sending email reminders to young women to take their pills. Other marketing tools such as 1-800 lines answered by scripted staff work to undermine the most important relationship in medicine - that of a doctor and patient.

(b) DTCA often uses emotion to encourage people to self-diagnose, and then visit their doctor. Ads are often designed to appeal to vulnerable people who may not

be appropriate candidates for a drug because the risks of use outweigh the benefits. For example, in the US, where advertisers must warn consumers about a drug's ill-effects, which they are not required to do under Canadian law, a monotone voice often reads a list of adverse effects while the viewer is visually engaged with entertaining moving images chock full of subliminal messages. For example: Viagra ads that show couples dancing and singing in the streets do not send a message that Viagra can cause serious and sometimes fatal side affects. Xenical ads show a picture of a relatively slim woman in a swim suit. Yet Xenical is not approved safe enough to sell to women with that body-mass index.1

(c) Other DTCA is clearly designed to invoke fear of disease and death in the viewer, and can actually make people sick. For example the "toe tag" ad lists groups of people that may well total over half the population, shows a man's body in a morgue, and asks the question: "What will it be - a test or a final exam?" From a consumer's perspective I can say personally that this ad was sickening and upsetting for my wife and I when we first saw it. The "raging bull" Pfizer campaign says on the screen "Only 25% of those who have a heart attack survive," (paraphrased) as the bull's eye fills with blood. Clearly these ads are not about "information", but emotion. When it comes to annual reports and briefs for politicians, the photos are all of happy families and scientists in lab coats gazing hopefully into test tubes. When it comes to selling their pills, patients get raging bulls.

(d) Also problematic is the vigorous promotion of such new drug products during the Phase IV period.2 This is because some drugs like Vioxx and Prepulsid are not

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1. Canadian Women's Health Network Letter to The Minister of Health. March 30 2005 "Xenical is only approved for the treatment of obesity and is intended for those with a Basal Metabolic Index (BMI) of 30 or over (or 27 and over IF there are co-existing medical conditions)."

[2] Every new drug on the market is in Phase IV of testing. This is because rare and very rare side effects - those that occur in 1/1000 - 1/10,000 - patients can't be identified in clinical trials with less than a few thousand patients. In effect, patients become the unwitting guinea pigs in this phase of the testing process.

identified dangerous until after they are approved and marketed for years. Notwithstanding the inherent risks of phase IV testing, drug companies often invest heavily in DTCA during this period. For example, Merck spent $100 Million promoting Vioxx which rose to $ 2.4 Billion during this Phase IV period, even when they had good evidence it caused heart attacks and strokes. Accordingly, about 35,000 – 55.000 innocent victims died from Vioxx.3

(e) When unacceptable side effects are exposed during this period, the drugs are sometimes withdrawn from the market. Other times they are left on the market with only changes to the small print on official labels that can be 20-50 pages long. In addition, warning letters sent out to doctors regarding dangerous contraindications or other safety notices are not effective in changing prescribing habits.4 Furthermore, DTCA rarely warns patients or doctors about newly discovered risks of prescription drugs.

(f) DTCA is also used to promote the most dangerous use of prescription drugs – termed "off-label". This is perhaps the most worrisome practice in medicine today, because it is responsible for thousands of patient deaths every year.5

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[3] Testimony of Dr, David Graham, Associate Director of Safety at the FDA to the Senate Subcommittee. November 2004 Vioxx was "maybe the single greatest drug-safety catastrophe in the history of this country.'' Dr. Graham put the number in the United States who had suffered heart attacks or stroke as result of taking the arthritis drug Vioxx in the range of 88,000 to 139,000. As many as 40 percent of these people, or about 35,000-55,000, died as a result, Graham said.

[4] CMAJ March 15, 2005 Drug withdrawals from the Canadian market for safety reasons, 1963-2004 Joel Lexchin. Dr. Joel Lexchin reported on the continued rise in the use of Baycol after warnings were sent out to doctors in March 2000 for a dangerous contraindication with Lopid (gemfibrozil), Baycol use went up from the 132nd most prescribed drug to the 82nd most prescribed drug in the two years before it was withdrawn. Bayer had spent almost $ 4 M in 2000 promoting Baycol.

[5]OnLine Journal, Off-label prescribing of prescription drugs: Profits for big pharma and risk to patients By Evelyn Pringle "According to the report, Death by Medicine (2003), by Gary Null, PhD; Carolyn Dean MD, ND; Martin Feldman, MD; Debora Rasio, MD; and Dorothy Smith, PhD, a study on prescription drug use by the elderly conducted by Medco Health Solutions found that 6.3 million senior citizens received more than 160 million prescriptions and a total of 7.9 million medical alerts were triggered by off-label prescribing, with 2.2 million alerts indicating excessive dosages unsuitable for seniors, and about 2.4 million indicating clinically inappropriate drugs for the elderly. Drug companies have promoted the off-label use of psychiatric drugs with children even after their

(g) Other DTCA practices are highly questionable, such as the use of celebrities to promote drugs without disclosing the fact that the celebrity is being paid for such activities. Example: engaging the TV audience in a contrived - and often fearful - story and giving the drug favourable mention during media appearances. 6

(h) Most patients - as high as 70% - do not fill or complete their prescriptions.7 Thus, a prime purpose for DTCA is to get patients to re-start taking their pills.8 But the drug companies do not talk about why patients stop taking them, which is often adverse drug reactions or lack of effectiveness. In either case the patients should be back to see their doctor, not back at their medicine cabinet foraging for useless or risky drugs.

(i) As a former politician, I was lobbied by the representatives for the major pharmaceutical companies, and know how they relate the sales and marketing of their drugs to jobs and a strong economy.9 They routinely stress the connection between investment by the industry, and the policy and law reforms that are the

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own studies have shown the drugs to be dangerous. In 2004, New York Attorney General Eliot Spitzer filed a lawsuit against GlaxoSmithKline for withholding studies that raised doubts about the effectiveness and safety of Paxil in treating children and revealed that more than 2 million prescriptions for Paxil were written off-label to treat children in 2002."

[6] The Truth About the Drug Companies, Angell, Marcia Random House New York. 2004 P. 117 "Lauren Bacall, for instance, in conversation with Matt Lauer on the Today show, spoke about a friend who had become blind from macular degeneration. She urged the audience to get tested for it and mentioned the Novartis drug Visudyne. What she did not reveal is that she was paid by Novartis."

[7] EyeForPharma web site: Patient compliance through education and adherence programs(8/31/2005) "A recent study by the University of Arizona's School of Pharmacy estimates that 70% of all pharmaceutical prescriptions are never consumed, triggering $77 billion in excess healthcare costs each year." http://www.eyeforpharma.com/search.asp?news=47544

[8] Ibid "Consider a frequently mentioned advertising statistic – it costs six times more to gain a new patient than to retain a current one. But the numbers being lost are, in fact, staggering. Clinical researchers estimate that for most drugs patient compliance rates are 50-60%, but with some disease states they drop as low as 10-20%. In the US statin market alone, noncompliance in a single year costs drug companies an estimated $3.9 billion in revenues. For a $1 billion product, a 5% increase in patient compliance can reap $30-40 million in revenue."

[9] As MPP for Halton Centre I was lobbied by senior staff from AstraZeneca, Boeringer Engleheim and SmithKline Beecham (now GlaxoSmithKIine), who did not hesitate to attempt to tie their political contributions to getting their way on regulatory matters.

bailiwick of politicians. DSC believes the decision to put powerful chemicals into your blood stream or that of a little child, or vulnerable senior, should have nothing to do with jobs and the economy. A prescription drug is either needed because it is safe and effective for a patient or it is not needed at all. No one should be taking any drug, or be encouraged to do so, because an international company had promised a politician more jobs in his or her riding, or a local university is getting money to conduct research.

14. DSC has a genuine and substantial interest in the outcome of this case and can represent the perspective of individuals and families who have suffered the consequences of inappropriate marketing of prescription drugs. I believe it can assist the Court in better illuminating the connection between prescription drug safety and marketing.

15. I make this affidavit in support of our application for intervener status in the matter of CANWEST MEDIAWORKS INC. and ATTORNEY GENERAL OF CANADA and for no other improper purpose.

AFFIRMED BEFORE ME AT)
the Town of Oakville, in the Province)
of Ontario, this 3rd day of August)
2006)
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Terence Hart Young
TERENCE HART YOUNG

A Commissioner for taking affidavits

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FOI

Food and Drug Administration
Rockville MD 20857

JUN - 4 1998

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TRANSMITTED VIA FACSIMILE

This is Exhibit....A....referred to in the affidavit of ....TERENCE....YOUNG— sworn before me this ....3RD.... day of ....AUGUST....2006....

.....A COMMISSIONER, ETC.

Cynthia Chianese
Assistant Director, Regulatory Affairs
Janssen Pharmaceutica
P.O. Box 200
Titusville, NJ 08560-0200

Re: **NDA 20-210**
Propulsid (cisapride) Tablets
MACMIS File ID #6704

Dear Ms. Chianese:

This letter is in reference to Janssen Pharmaceutica's (Janssen) submission, dated May 5, 1998, of promotional materials under cover of Form FDA 2253 for Propulsid (cisapride) Tablets. This submission consisted of three promotional brochures identified as JPIPR604, JPIPR605, and JPIPR626. Janssen is promoting Propulsid by disseminating labeling pieces that are false or misleading in violation of the Federal Food, Drug, and Cosmetic Act (Act) and regulations promulgated thereunder. Specific objections follow:

Promotion of Unapproved Uses

In each of the three promotional brochures listed above, Janssen suggests that the use of cisapride is not only effective in the treatment of nocturnal heartburn due to gastroesophageal reflux disease (GERD), but is also effective in treating . This implication is derived from the presentation of data .

However, the approved product labeling states that "[t]here were no consistent effects on daytime heartburn, symptoms of regurgitation, or histopathology of the esophagus." Furthermore, not only is Janssen promoting unapproved uses, Janssen makes efficacy claims that are inconsistent with the cisapride new drug application clinical trial results.

This presentation also suggests that the use of cisapride is effective in regardless of cause. The approved product labeling, however, states that "Propulsid is indicated for the symptomatic treatment of patients with nocturnal heartburn due to gastroesophageal reflux disease." Thus, to suggest that cisapride is effective in instead of restricting its use to only those suffering nocturnal heartburn due to GERD constitutes promotion of an unapproved use.

Lack of Fair Balance

In all three of these promotional brochures, Janssen has confined the presentation of the fair balance information to the back page of each brochure. Janssen fails to include on each page or spread a prominent reference to the presence and location of this distinct location of the presentation of the risk information associated with the use of this product. The approved product labeling contains a boxed warning presenting the contraindications to use of Propulsid with a list of drugs that inhibit the cytochrome P450 3A4 enzyme system of the liver. The use of Propulsid with these drugs may result in drug-drug interactions that cause serious cardiac arrhythmias. Because of the potentially fatal risks associated with the use of this product due to cardiac arrhythmias, without a reference on each spread to the important limitations concerning the appropriate use of this product, these brochures are lacking in fair balance or otherwise misleading.

Representation of Greater Efficacy than Demonstrated in Clinical Trials

In all three of these promotional brochures, Janssen presents the percentage of GERD patients with either poor esophageal peristalsis, incompetent lower esophageal sphincter (LES), and delayed gastric emptying. This presentation is also accompanied by three statements, under the heading "Propulsid benefit" that imply that the use of cisapride "assists esophageal clearance," "increases LES tone," and "promotes gastric emptying." Janssen notes in small type under this graphic presentation that these "Propulsid benefit[s]" were derived from pharmacologic studies rather than clinical studies. The approved product labeling for cisapride notes that "these clinical trials did not show a significant effect on LESP [lower esophageal sphincter pressure]...." Statements that cisapride "assists esophageal clearance," "increases LES tone," and "promotes gastric emptying" imply that the use of Propulsid can effect the underlying disease. Therefore, without disclosing that the use of the drug has no consistent effect on the histopathology of the esophagus is false or misleading.

Requested Actions

Janssen should immediately suspend all promotional activities and materials that convey or contain the allegedly violative claims or information identified in this letter until these allegations are resolved.

In addition, any new or revised information relating to the boxed warning, contraindications, warnings, precautions, and adverse events associated with the use of Propulsid, known to Janssen, should be incorporated in any new or revised promotional materials. Finally, Janssen should propose a plan to assure that existing promotional materials are revised in accord with the revised risk information.

Janssen should submit a written response to DDMAC on or before June 19, 1998, describing the steps that it has taken to ensure that these activities and the use of these materials have been suspended.

Janssen should address any correspondence or additional questions to the undersigned at the Division of Drug Marketing, Advertising, and Communications, HFD-40, Rm 17 B-17, 5600 Fishers Lane, Rockville, Maryland 20857. DDMAC reminds Janssen that only written communications are considered official.

In all future correspondence regarding this matter, please refer to MACMIS ID #6704, in addition to the NDA number.

Sincerely,

Stephen W. Sherman, JD, MBA
Regulatory Review Officer
Division of Drug Marketing,
Advertising, and Communications

"B"

This is Exhibit.....B.....referred to in the affidavit of ...TERENCE YOUNG... sworn before me this ...3RD... day of ...AUGUST... 2006

.....A COMMISSIONER, ETC.

July 15, 2003

Terence H. Young
2030 Merchants Gate
Oakville Ontario
L6M 2Z8

Ms. Janet Feasby
Director of Public Affairs and Communications
Advertising Standards Canada
175 Bloor Street East
South Tower
Toronto, M4W 3R8

Re: Advertising Campaign ostensively a public service message from The Canadian Diabetes Association and The Lipid Nurse Network

WITHOUT PREJUDICE

Dear Janet

I enclose a full page ad taken from MacLean's magazine dated July 21, 03 apparently promoting cholesterol testing. It is part and parcel of a TV ad campaign which has been broadcast repeatedly since last summer on Canadian TV channels. I last saw this ad on CBC a little after 11 pm on June 19th or 26th. Since the summer of 2002 it has been broadcast innumerable times. The magazine ad was also placed in the Globe and Mail- full page numerous times over this past winter. This campaign does not comply with The Code you are designated to enforce and I hereby request you investigate this campaign with the purpose of taking it off the air and out of the media, and impose the appropriate sanction for the breaches it contains.

"The provisions of the code should be adhered to both in letter and spirit."

Disguised Advertising Techniques

This entire campaign is designed to deceive it's commercial intent - to increase sales for Pfizer's Lipitor - the world's largest selling drug, and deceive the viewer regarding a supposed connection between cholesterol and death in order to do so.

I herein describe the content of the TV ad:
1. The narrative, which for some reason goes backwards in time, shows a middle aged man's body being pulled out in a morgue drawer. There is a toe tag, as there is in the magazine /newspaper ad. This is a shocking sight that would make most

people, who have never even been in a morgue, feel uncomfortable or a little sick. Certainly it is shocking.

2. Next is a shot of what one assumes are his wife and children weeping hopelessly. It is clear the man has just died. Obviously it is upsetting to witness their grief.
3. Next is a shot of what one assumes to be the same man running to catch a ball (frisbee?) at a family picnic. He falls to the ground in pain. This instills fear.
4. For some reason all this happens to the tune of Moon River. I can only assume this is because it's a tune recognizable to those who listened to pop music in the sixties and are now vulnerable to heart disease by virtue of their age - in other words the target market for Lipitor.

Sickness, grief and fear...all praying on the viewer's vulnerability and most profound fears: dying or losing a loved one - in a few moments interrupting their a favourite TV show. For what reason?

While the viewer is made vulnerable by the shocking images, an ominous voice-over directs him or her to see their doctor if they belong in a long list of demographic groups. (See the attached magazine ad for the groups mentioned. If memory serves me the list is the same) This "call to action" is clearly the true purpose of the ad. If totaled in number, the groups mentioned would likely cover the majority of our population.

Disguised Advertising Techniques
No advertisement shall be presented in a format or style that conceals its commercial intent.

This ad is designed to help sell Lipitor, but disguised to look like a public service message and never mentions the name of the drug or manufacturer. It is driven and paid for by Pfizer, who put up the Canadian Diabetes Association and Lipid Nurse Network as shills by paying for the ads through "unrestricted educational grants", and exert undue influence by funding these organizations. By naming the Canadian Diabetes Association and Lipid Nurse Network at the end of the ad and showing their logos, viewers are left with the incorrect impression that these two patient groups are the prime drivers behind these ads - that the ads are in the public service. The omission of the financial connections between these groups and Pfizer conceals the commercial intent of the ad, and potential conflict of interest. (The print ad has a vague disclaimer in print so fine few people could read it, but in the TV ad none is audible)

If Pfizer were truly interested in public service messages they could have easily paid for advertising to save the trees, help Ducks Unlimited, improve literacy, or they could have designed ads that encourage viewers to have a more active, healthy life-style. Instead these ads were designed to drive as many people as

possible to their doctor's office in fear, asking for help without knowing what shape that help might take.

Section 11 of The Code "Advertising must not...play upon fears to mislead the consumer."

1.**The ad uses fear to deceive the viewer/reader, implying that anyone with elevated cholesterol will benefit by reducing their risk of death by taking the call to action. This has never been proven.** It certainly instills fear of death or losing a family member as described above. The general impression conveyed is that anyone who fits into the long list of groups mentioned - women over 50, men over 40, and those with two of the following: overweight, physically inactive. smoker, and high blood pressure, should be heading out to their doctor so that they too won't drop dead at a family picnic making their family members cry in agony. This is an extreme message created by the story in the visual and audio narrative. In the full page ad the headline print at the top asks: "Which would you rather have, a cholesterol test or a final exam?" also clearly implying the viewer must make an extreme choice - one or the other. In fact for most people without heart disease- those in the groups - no such choice is necessary because they are not at significant risk. The ad attempts to scare them into thinking they are and must make this decision. This is not only deceptive but because of the fearmongering, highly unfair.

Accuracy and Clarity in The Code (a) "...The focus is on the message as received or perceived, i.e. the general impression conveyed in the advertisement."

2. The ad is also deceptive because it implies that there is a clinically proven connection between one's cholesterol level and death. Cholesterol is a risk factor for heart disease, but so are many other things. And a risk factor is not necessarily a cause. It is deceptive to effectively equate a risk factor with a cause. By depicting a middle aged man (in the print ad the toe tag indicates 42 years old, not overweight) falling dead at a family picnic and combining the voice-over narrative message there is a clear and blunt causal connection drawn between death and his cholesterol level, implying that you can avoid death if you make sure your cholesterol level is not high. This has not been clinically proven and is deceptive.

Accuracy And Clarity (b) Deceptive claims must not be either direct *or implied.*

3. **Even the hidden commercial intent is based on an implied deception. The ad is designed to drive patients into their doctor's offices to ask about the ad, where they are likely to be prescribed Lipitor, Pfizer's 'statin' drug.** Pfizer is well aware that the doctor might prescribe another statin drug, but because the ad

has made an impression on the patient, and because Lipitor is the largest selling statin drug, Lipitor sales will benefit in proportion to the market share it now holds plus the influence the ad has had on patient choice. But there is *no clinical proof that Lipitor confers a health benefit. I attach the main page from Pfizer's Lipitor web site which states clearly that "Lipitor has not been shown to prevent disease or heart attacks." The ad is further deceptive because it implies that such a large benefit - a saved life- is available if one lowers their cholesterol level by taking a drug. **Lipitor has never been proven in a primary prevention trial to reduce overall mortality. In fact, Lipitor is not proven to confer a health benefit. In other words the two main premises implied in the ad 1. That cholesterol causes heart disease and 2) that Lipitor can prevent heart disease, are not proven. Thus the entire message is a fraud.** This is comparable to the self titled doctors that traveled in wagons in the nineteenth century selling their home made 'medicines'. They used deceptive sales tactics, including fear, to convince people that they had a problem their products could help.

* The latest information available comes from the Therapeutics letter which is available on the Therapeutics Initiative website.

Accuracy and Clarity

(b) advertisements must not omit relevant information in a manner that in the result is deceptive.

1. **This section was breached in the TV ad because there is no reason given to the viewer what the proposed solution is to this ominous death threat - taking a drug.** In fact the information that is left out demands the viewers go and speak to their doctor without telling them directly why they should. Instead there is an implication which is unproven. (see above) Creating fear unnecessarily and not explaining the true reason why is also against the code because it is highly unfair to the viewer.

The information is in fact left out for two reasons:

First, it is illegal to advertise prescription drugs in Canada. This is the way Pfizer is getting around the spirit of our law to increase sales of its most profitable product using a front in a form of stealth marketing. A key reason it is illegal to advertise drugs is that most patients are not equipped or trained to judge how effective drugs actually are and what the risks are of taking them. In our courts drug companies have argued that it is up to the "learned intermediaries" (the doctors) to decide what is appropriate for patients. And this ad seems to support that.

However, IMS, who provide highly detailed information to their clients the drug companies, has proven that a large number of doctors in Canada, perhaps the

majority, when asked by a patient for a drug they've seen advertised (usually on US TV) will simply write out a prescription for that drug upon request. This explains the call to action in the ad. All Pfizer has to do is create enough fear in the viewer - using frightening images and credible public interest fronts - to get them to mention the ad to their doctor. The doctors will do the rest.

Second, the proposed solution and true intent of the ad is omitted to maintain the facade that this is a public service message, rather than a way to sell more Lipitor. The financial ties between Pfizer and the CDA and The Lipid Nurse Network are not revealed because that would render the ad ineffective. It is well known that viewers will tolerate more upsetting messages in public service ads such as those created for Mothers Against Drunk Driving than they will in commercial ads. They are also far more likely to follow the call to action and ask their doctor about the ad they saw on TV if they think it was purely in their own interest. They would think "After all, it's the trusted nurses and diabetes advocacy people who are warning me, not a commercial company who stand to make money from it." If viewers knew the true purpose of this ad, many would make a decision on the spot to ignore the message, mute the ad or simply not buy Pfizer products. **The deception of public interest is the key to an increase in sales and future business.**

Additional information that has been omitted to deceive:

All prescription drugs have side effects or cause adverse reactions. About 10,000 people die in Canada and 100,000 in the US every year due to these adverse reactions. That is why US laws demands warnings in the form of voice-overs of a long list of potential adverse reactions in US TV drug ads. Because the true purpose of this campaign is to increase sales for Lipitor, the omission of these warnings creates a danger for patients.
It is well known industry-wide that most doctors do not read the drug company warnings and get most or all of their drug information from commissioned drug company sales representatives who seldom provide warnings. Can sending patients into their doctor's offices to ask about a TV or magazine ad be considered a dangerous thing? Yes, absolutely. That's why the law in the US demands the warnings of adverse reactions be provided in the ads.

Pfizer's own website lists the following adverse reactions shown with Lipitor in pre-market testing: chest pain, insomnia, bronchitis, dizziness, arthritis, infections, sinitus, flu syndrome, abdominal pain and diarrhea. Many other adverse reactions have been reported since, including a former US astronaut and family doctor Duane Graveline MD who was found wondering, confused and didn't recognize his own home after taking Lipitor for six weeks. After a second six weeks on Lipitor he suffered memory loss again. His diagnosis was Transient Global Amnesia, and was related to Lipitor after thousands more patients on Lipitor reported amnesia to the FDA's Medwatch program.

Lipitor, like all drugs has proven nasty side-effects. To not inform the viewers of these real threats while falsely shocking them into believing they are under threat from their own cholesterol is unconscionable.

Pfizer is not only driving patients into their doctor's office in profound fear, they are doing it without telling them their true motivation, without providing them any warning of potential dangerous side effects as safety demands by deceiving them with regards to an unproven threat to their life and the unproven benefit of Lipitor in addressing that threat.

Please let me know how your investigation is going and feel free to call any time for clarification.

Many thanks. Sincerely,

Terence H. Young

Enclosed full page ad for a cholesterol test taken from Macleans magazine.
and page from Pfizer's Lipitor web site.