Parker v. Pfizer Canada Inc., 2012 ONSC 3681 (CanLII)

CITATION: Parker v. Pfizer Canada Inc. 2012 ONSC 3681
COURT FILE NO.: 08-CV-368950CP
DATE: 20120621

ONTARIO
SUPERIOR COURT OF JUSTICE

B E T W E E N:

Kenneth R. Parker

Plaintiff

- and -

Pfizer Canada Inc. and Pfizer Inc.

Defendants

Proceeding under the *Class Proceedings Act, 1992*

COUNSEL:

- Bryan C. McPhadden, Douglas Lennox, Idan Erez, and Eric Lafreniere, for the Plaintiff
- William McNamara, Teresa Walsh, and Randy Sutton, for the Defendants

HEARING DATES: May 29 and 30, 2012

PERELL, J.

REASONS FOR DECISION

A. INTRODUCTION

[1] This is a certification motion in a proposed products liability class action under the *Class Proceedings Act, 1992*, S.O. 1992, c. 6.

[2] In Canada, the Defendant Pfizer Canada Inc. ("Pfizer") sells the prescription drug varenicline under the brand name CHAMPIX®, as a treatment for tobacco (nicotine) addiction. Kenneth R. Parker, the proposed Representative Plaintiff, alleges that as a consequence of ingesting CHAMPIX®, he and other members of the proposed class, experienced neuropsychiatric adverse events ("NAEs"), including suicidal and homicidal ideation.

[3] Mr. Parker sues Pfizer Canada and its parent American corporation, Pfizer Inc. for various types of products liability negligence, but the claim that he seeks to certify for the purposes of a class proceeding is a "breach of a duty to warn" claim. Mr. Parker seeks general damages in the amount of $100 million plus aggravated and punitive damages totaling $50 million, and he also pleads waiver of tort.

[4] Mr. Parker's proposed class action is prosecuted by a consortium of law firms from Ontario and other provinces. Similar actions against the Pfizer Defendants have been commenced in Alberta, British Columbia, and Québec, but those actions have been stayed. Some of the proposed representative plaintiffs from the stayed actions provided evidence for this proposed class action, and these witnesses; namely, Simon Dunn, Patricia Clow, and Patrick Dion stand ready to be additional representative plaintiffs in the Ontario action.

[5] The Pfizer Defendants resist certification, and they submit that the duty to warn claim should not be certified for several reasons, as follows:

- The Defendants submit that there is no basis in fact for a duty to warn claim against Pfizer Inc., which does not manufacture CHAMPIX® in Canada.
- In a submission directed mainly at the certification criteria of an identifiable class, common issues, and preferable procedure, the Defendants submit that there is no basis in fact for a duty to warn claim.
- The Defendants submit that Mr. Parker has failed to meet the very low burden of showing some basis in fact for his claim. They submit that all Mr. Parker has is the evidence of an expert witness, Dr. Martin Tremblay, but the Defendants submit that Dr. Tremblay's evidence is either inadmissible because he wants for the qualifications to proffer expert evidence or, his evidence is insufficient to show a basis in fact for a duty to warn claim. The rhetorical version of this submission is that surely there needs to be more than Dr. Tremblay's unqualified and uninformed opinion to justify putting the Defendants to the enormous expense of defending a duty to warn claim.
- The Defendants submit that, in any event, the class definition is overbroad and should be narrowed.
- The Defendants submit that, in any event, the common issues want for commonality and utility and should not be certified.
- The Defendants submit that a class action is not the preferable procedure, and they submit that the Litigation Plan is deficient largely because of the numerousness of individual issues and the unmanageability of the common issues trial.

[6] For the reasons that follow, I agree with some but not all of the Defendants' arguments. I do not agree with their ultimate argument that the action should not be certified as a class action.

[7] Although Pfizer Inc. must remain in the action for the claims against it that are not part of the certification motion and that may be advanced by Mr. Parker in his individual action or by Class members in individual actions, I agree that there is no basis in fact for a duty to

warn claim against Pfizer Inc., and, therefore, the action should be stayed against Pfizer Inc. until after the common issues trial.

[8] I agree that the Class definition is too broad and the common issues too imprecise, but these technical problems can be fixed based on the current fully argued record, and I shall, therefore, amend the Class definition and the common issues, as described below. What emerges is a focussed and manageable class action.

[9] Notwithstanding the arguments of the Defendants, which may be the foundation for a formidable defence, I disagree that there is no basis in fact for a duty to warn claim against Pfizer Canada.

[10] In my opinion, with fixes to the Class definition and to the common issues, all the certification criteria are satisfied. For the reasons that follow, I certify a duty to warn claim against Pfizer Canada with an amended Class definition and amended common issues.

B. ORGANIZATION OF THIS DECISION

[11] I shall organize this decision under the following headings:

- Introduction
- Organization of this Decision
- The Claim being Advanced for Certification
- Evidentiary Background
- Factual Background
  - The History of the Marketing of CHAMPIX®
  - The Use of CHAMPIX® by Messrs. Parker, Dunn and Dion and Ms. Clow
- Gatekeeping, Some Basis in Fact, and the Evidence of Dr. Tremblay
- Certification
  - Introduction
  - Cause of Action Criterion
  - Identifiable Class
  - Common Issues
  - Preferable Procedure
  - Representative Plaintiff and Litigation Plan
- Conclusion

C. THE CLAIM BEING ADVANCED FOR CERTIFICATION

[12] It is very important to emphasize at the outset that Mr. Parker is seeking certification of a class action that is narrower than his pleaded products liability claim against the Pfizer Defendants. Although his Amended Statement of Claim alleges other heads of negligence, he seeks certification only of his duty to warn claim.

[13] In his statement of claim, he pleads numerous allegations of negligence for which he does not propose as the basis for certification. For example, he pleads that the Defendants negligently failed to study varenicline's effects, both before and after the drug was marketed, and that they failed to adequately study varenicline to determine the risk of serious injury or death associated with its use. Further, he alleges intentional misrepresentation and suppression of information by the Defendants in the pursuit of profits from the sale of CHAMPIX®. Although these allegations have not been abandoned, Mr. Parker did not base his certification motion on them.

[14] It is quite appropriate for a plaintiff to frame his or her certification motion to

make it more amenable to certification, and Mr. Parker focuses his certification motion on the Defendants' alleged failure to warn. For the purposes of the certification motion, the core allegations of the failure to warn claim are found in paragraphs 7 to 11, 30, 46 to 51, and 72 (e) to (i) and (t) of the Amended Statement of Claim, which state:

> 7. The Plaintiff was not aware of the risk of serious injury and death associated with and caused by using varenicline.
>
> 8. The Plaintiff's healthcare providers were not aware of the risk of serious injury and death associated with and/or caused by varenicline.
>
> 9. The Plaintiff's health care providers would not have prescribed varenicline had they known that varenicline could cause serious injury and death including suicide, attempted suicide, seizures, panic attacks, chest pains, new onset of seizures, aneurysm, and shortness of breath.
>
> 10. The Plaintiff would not have purchased and used varenicline had the Defendants properly disclosed the risks of serious injury and/or death associated with and/or caused by the drug.
>
> 11. At the time the Plaintiff ingested varenicline, none of the drug label, the package insert, or the package containing the product, provided adequate warnings that using varenicline carried a risk of experiencing serious injury and/or death including such injury as experienced by the Plaintiff.
>
> 30. The Defendants knew or ought to have known that varenicline increases the risk of causing serious injuries and death including suicide and attempted suicide.
>
> 46. The information contained on the label and package insert for varenicline contains no warning and/or inadequate warning of risk for serious injury and/or death.
>
> 47. The Defendants knew or should have known that varenicline posed a risk for causing serious injury and/or death.
>
> 48. The varenicline label and package insert in use when the Plaintiff's physician and Class members' physicians prescribed the drug did not provide the Plaintiff's and Class members' physicians with an adequate warning about the increased risk of serious injury and death from varenicline.
>
> 49. The varenicline label and package insert in use when the Plaintiff and class members purchased and ingested the drug did not provide the Plaintiff and Class members with an adequate warning about the increased risk of serious injury and death from varenicline.
>
> 50. The information contained in the product label and package insert is insufficient for many reasons, including but not limited to the following:
>
> (a) the label fails to explicitly warn of increased risk for serious injury and/or death; and,
>
> (b) the label fails to reference the severity of such serious injuries; and/or
>
> (c) the label fails to provide adequate information advising consumers of appropriate
>
> action if certain adverse events are experienced.
>
> 51. The Defendants should have strengthened the label warning and notified consumers of any potential problems at the first reports of adverse reactions - particularly life-threatening reactions, and the risk of serious injury and death.
>
> 72. The Defendants breached their duty of care owed to the Plaintiff and Class members. The particulars of the Defendants' negligence are as follows: …
>
> (e) They failed to provide the Plaintiff and Class members and their physicians with any or adequate warnings of the inherent risks associated with varenicline;
>
> (f) They failed to provide any or adequate updated and current information to the Plaintiff and Class members and their physicians respecting the risks and effects of varenicline as such information became available;
>
> (g) They failed to provide prompt warning of potential risks and adverse side effects associated with varenicline on the product monograph and in the product labelling;

> (h) They failed to warn the Plaintiff and Class members and their physicians about the need for comprehensive regular medical monitoring to ensure early discovery of potentially adverse events;
>
> (i) After receiving actual or constructive notice of problems associated with varenicline, they failed to issue adequate warning, withdraw or recall the drug, publicize the problems and otherwise act properly and in a timely manner to alert the public, the Plaintiff and Class members and their physicians of the drug's inherent dangers; …
>
> (t) They failed to provide any or adequate warning to the health profession and to the Plaintiff and Class members; …

[15] The analysis that follows focuses on the duty to warn claim that Mr. Parker seeks to certify for a class proceeding. As will be seen, the duty to warn claim focuses and particularizes the "risk of serious of injury and death" that is referred to in the Statement of Claim.

D. EVIDENTIARY BACKGROUND

[16] Mr. Parker filed affidavits from:

- Kenneth Parker, the proposed Representative Plaintiff
- Simon Dunn, Patricia Clow, Patrick Dion, proposed additional Representative Plaintiffs
- Dr. Martin Tremblay, psychiatrist and professor of medicine at the University of Montréal
- Peter Tuovi, a lawyer of McPhadden Samac Tuovi, lawyers of record for Mr. Parker.

[17] The Defendants filed affidavits from:

- Anne Tomalin, an expert in the regulation of pharmaceutical products in Canada
- Mehmet Sofuoglu, a psychiatrist and an associate professor at Yale University School of Medicine with a Ph.D. in pharmacology. He specializes in the evaluation and treatment of nicotine addiction and other addictive disorders.
- Paul G. Sackman, a family physician from Calgary Alberta, specializing in community medicine
- Robin Cardillo, who provided regulatory and marketing materials for CHAMPIX® and the medical records of Mr. Parker, Mr. Dunn, Mr. Dion and Ms. Clow.

E. FACTUAL BACKGROUND

1. The History of the Marketing of CHAMPIX®

[18] Cigarette smoking is the leading preventable cause of death. In Canada, it causes an estimated 37,000 premature deaths annually, and worldwide, it is estimated that there are 5.5 million deaths annually attributable to smoking. Smoking-related diseases include lung cancer, strokes, and coronary heart disease.

[19] Nicotine is the primary psychoactive substance in tobacco, and it is highly addictive.

[20] Quitting smoking (withdrawal from nicotine addiction) is itself a mental health problem. Nicotine withdrawal symptoms include negative mood symptoms, such as irritability, frustration or anger, anxiety, dysphoric or depressed mood, restlessness, difficulty concentrating, insomnia, decreased heart rate, and increased appetite. The act of quitting smoking is in and of itself, highly stressful and is associated with negative mood symptoms, including anger, anxiety and sadness. Further, persons already suffering from psychiatric issues and other substance addictions are commonly also smokers, and stopping smoking may exacerbate their underlying psychiatric disorder.

[21] The Defendants are pharmaceutical companies. Pfizer Inc. is a State of Delaware corporation with its head office in the City of New York. Pfizer Canada is a Canadian corporation with its head office in the City of Kirkland, Québec.

[22] The Defendants developed the drug varenicline as a means for cigarette smokers to quit smoking. It is a treatment for nicotine addiction. Pfizer Canada manufacturers and, since April 2007, markets the drug in Canada under the brand name CHAMPIX®.

[23] Varenicline has been approved for use in Canada, the United States, Europe, and Australia. CHAMPIX® continues to be sold in Canada and is quite effective for its intended purpose of a smoking cessation treatment.

[24] There is an elaborate and extensive regulatory approval process for the introduction of new drugs into the Canadian market. The manufacturer must provide Health Canada with detailed reports of the testing undertaken to establish the safety and effectiveness of the new drug for its intended purpose, including all clinical (*i.e.*, human) and non-clinical (*i.e.*, animal and laboratory) data available for the drug. The scrutiny continues after the approval of the drug for public use.

[25] The pre-marketing studies for CHAMPIX® included multiple double-blind placebo-controlled clinical trials in which several thousand chronic smokers received varenicline. The most common adverse events reported in patients attempting to quit smoking with CHAMPIX® were nausea, abnormal dreams, constipation, flatulence and vomiting.

[26] The drug bupropion (marketed as Zyban or Wellbutrin) is another drug treatment for smoking cessation. It is an anti-depressant medication that, since 1998, has also been approved for use as a smoking cessation treatment. Zyban was introduced to the market before CHAMPIX®. Notably, Zyban is sold along with a product monograph with “black box” warnings about possible adverse affects from the drug’s use.

[27] CHAMPIX® is also sold with a product monograph. The wording of the monograph is approved by Health Canada as part of a very rigorous and elaborate approval process. Product monographs for drugs follow a standard format and consist of three parts. Part I is addressed to health professionals and describes the drug’s indications and contraindications. Part I also provides warnings of possible adverse reactions from the drug. Part II contains detailed scientific information and includes a technical description of the drug’s pharmacology and toxicology, as well as a presentation of the outcomes of clinical trials. Part III is addressed to consumers, and it describes what the drug is, what it does, when it should not be used, and what its side effects are. Part III provides other warnings and precautions directly to the users of the drug.

[28] Four CHAMPIX® monographs are relevant to this proposed class action. The nucleus of this case is a failure to warn associated with three of the four monographs.

[29] The fundamental allegation of Mr. Parker is that the monographs dated January 2007, December 2007, and May 2008 failed to warn of the risk of neuropsychiatric adverse

events. He alleges that the Defendants did not give an adequate warning until the fourth monograph dated May 28, 2010. The May 28, 2010 monograph contained a "black boxed" warning, which, based on the evidence of Dr. Martin Tremblay, Mr. Parker accepts as a warning adequate to satisfy Pfizer's duty to warn.

[30] Based largely on Dr. Tremblay's evidence, which relies, in part, on the comparability of Zyban and CHAMPIX®, Mr. Parker submits that an adequate warning could and should have been provided to consumers from the outset and that the first three monographs are inadequate and the Defendants failed in their duty to warn. Mr. Parker submits that the earlier monographs could and should have been similar to the black boxed May 2010 monograph. For present purposes, the pertinent excerpts from the May 28, 2010 monograph are set out below:

CHAMPIX®

(varenicline tartrate tablets)

PART 1: HEALTH PROFESSIONAL INFORMATION

INDICATIONS AND CLINICAL USE

Adults

CHAMPIX® (varenicline tartrate tablets) is indicated for smoking-cessation treatment in adults, in conjunction with smoking-cessation counseling

See Serious WARNINGS AND PRECAUTIONS, Psychiatric Symptoms …

WARNINGS AND PRECAUTIONS

Serious WARNINGS and PRECAUTIONS

Psychiatric Symptoms:

There have been post-marketing reports of serious neuropsychiatric symptoms in patients being treated with CHAMPIX® (varenicline tartrate), including depressed mood, agitation, aggression, hostility, changes in behavior, suicide related events, including ideation, behavior, attempted suicide and suicide, as well as worsening of pre-existing psychiatric disorder. These events have occurred in patients with and without pre-existing psychiatric disorders (see also WARNINGS AND PRECAUTIONS, Psychiatric Symptoms).

Some reported cases may have been complicated by the symptoms of nicotine withdrawal in patients who stopped smoking. Depressed mood may be a symptom of nicotine withdrawal. Depression, rarely including suicidal ideation, has been reported in smokers undergoing a smoking cessation attempt without medication. However, some of these symptoms have occurred in patients taking CHAMPIX® who continued to smoke. All patients being treated with CHAMPIX® should be observed for neuropsychiatric symptoms.

Important Recommendations Regarding Psychiatric Symptoms:

- The benefits and risks of all options for quitting smoking should be discussed with the patient before initiating treatment.

- All patients attempting to quit smoking with CHAMPIX®, as well as their families and caregivers, should be alerted about the need to monitor for depressed mood, agitation, aggression, hostility, suicidal ideation or behavior, or changes in behavior or thinking that are not typical for the patient.

- Patients should be instructed to stop taking CHAMPIX® immediately and contact their doctor if they experience, or if others observe, these symptoms. In many post-marketing cases, resolution of symptoms after discontinuation of CHAMPIX® was reported, although in some cases the symptoms persisted; therefore, ongoing monitoring and supportive care should be provided until symptoms resolve.

- Regarding alcohol intake: Patients should be advised that alcohol intake may increase the risk of experiencing psychiatric adverse events during treatment with CHAMPIX®.

- Regarding patients with psychiatric history: Patients with concomitant psychiatric conditions, even if well controlled, or with a history of psychiatric symptoms, should be diligently monitored by a healthcare professional for new or worsened psychiatric events.

Psychiatric Symptoms (see also ADVERSE REACTIONS, Post-Marketing Experience). There have been post-marketing reports of serious neuropsychiatric symptoms in patients being treated with CHAMPIX®, including anxiety, psychosis, mood swings, depressed mood, agitation, aggression, hostility, changes in behavior or thinking, suicidal ideation, suicidal behavior and suicide, as well as worsening of pre-existing psychiatric disorder (previously diagnosed or not) (see Serious WARNINGS and PRECAUTIONS).

There are a number of confounding factors which may have contributed, including effects of nicotine withdrawal due to partial or complete smoking discontinuation; concomitant, or history of psychiatric conditions; and the concomitant use of other CNS drugs and/or alcohol. However, there are cases for which these confounding factors did not appear to be present, including cases where symptoms occurred within the first week of initiating CHAMPIX®, prior to initiating smoking cessation. There have been other cases where symptoms developed following cessation of CHAMPIX® therapy.

It is not known whether these events are occurring at a rate and severity which is different from the background rate for smoking cessation in the general population, or in the psychiatric population (treated or untreated), or different from the rates for other drugs in the class of smoking cessation (see ADVERSE REACTIONS, Neuropsychiatric Adverse Events).

Pre-existing Psychiatric Disorder or Symptoms
Patients with serious psychiatric disorders such as schizophrenia, bipolar disorder, and major depressive disorder did not participate in the pre-marketing studies of CHAMPIX® and the safety and efficacy of CHAMPIX® in such patients have not been studied (see also Special Populations, Use of CHAMPIX® in Patients with Concomitant Conditions, Psychiatric Patients).

Patients with concomitant psychiatric conditions, even if well controlled, or with a history of psychiatric

symptoms, should be diligently monitored by a health care professional for new or worsened psychiatric events. ….

Information for Patients

Consumer Information is included in the package of CHAMPIX® dispensed to the patient.

Prior to prescribing CHAMPIX®, physicians should:

• Discuss with the patient the expected benefits and risks of CHAMPIX®, as well as those of all smoking-cessation options.

• Inform the patients that quitting smoking, with or without CHAMPIX®, may be associated with nicotine withdrawal symptoms (including depression or agitation) or exacerbation of pre-existing psychiatric disorder. …

• Inform the patient that there have been post-marketing reports of serious neuropsychiatric symptoms in patients being treated with CHAMPIX®, including anxiety, psychosis, mood swings, aggression, depressed mood, agitation, hallucinations, hostility, changes in behavior or thinking, suicidal ideation, suicidal behavior and suicide, as well as worsening of pre-existing psychiatric disorder.

• Inform the patient that these events have occurred in people with previous psychiatric disorder, as well as those with no previous history.

• Encourage the patient to reveal any history of psychiatric disorder prior to initiating treatment.

• Patients with a history of serious psychiatric disorder should be informed that this patient population did not participate in the pre-marketing studies of CHAMPIX®, and therefore the safety and efficacy of CHAMPIX® in such patients have not been studied.

• Patients with concomitant psychiatric conditions, even if well controlled, or with a history of psychiatric symptoms, should be informed that if they are prescribed CHAMPIX®, they will be diligently monitored by their physician for new or worsened psychiatric events.

Patients receiving CHAMPIX® should be given the following instructions by the physician:

• Patients should be instructed to read the patient information leaflet supplied with every CHAMPIX® prescription before starting their CHAMPIX® pills. This leaflet is approved by Health Canada and is Part III of the CHAMPIX® Product Monograph. …

• Patients should be encouraged to inform friends and family members/caregivers of their quit attempt which includes treatment with CHAMPIX® and ask for their support and help in monitoring for any changes in behaviour or thinking that are not typical for the patient.

• Patients should be informed that if they develop agitation, hostility, depressed mood or changes in behavior or thinking that are not typical for them, or develop suicidal ideation or suicidal behavior, CHAMPIX® should be discontinued immediately, and symptoms reported to their healthcare provider.

• Patients should be advised that drinking alcohol may increase the risk of experiencing psychiatric adverse events during treatment with CHAMPIX®.

• Patients should be informed that they may experience vivid, unusual or strange dreams during treatment with CHAMPIX®. …

Less Common Clinical Trial Adverse Drug Reactions

In the paragraphs that follow, the frequency of less commonly reported adverse events from clinical trials is presented. The variability associated with adverse event reporting and the terminology used to describe adverse events limit the value of the quantitative frequency estimates provided. It is important to emphasize that although the events reported occurred during treatment with CHAMPIX®, they were not necessarily caused by it. …

Psychiatric Disorders: *Frequent:* Anxiety, Depression, Emotional disorder, Irritability, Restlessness.

Infrequent: Aggression, Agitation, Disorientation, Dissociation, Mood swings, Panic reaction, Bradyphrenia, Thinking abnormal. *Rare:* Euphoric mood, Hallucination, Psychotic disorder, Suicidal ideation, Suicide.

Post-Marketing Experience

The following adverse events have been reported during post-approval use of CHAMPIX®. Because these events are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Psychiatric Symptoms

There have been reports of depressed mood, agitation, aggression, hostility, anxiety, changes in behavior or thinking, mania, psychosis, hallucinations, paranoia, delusions, homicidal ideation, mood swings, suicidal ideation and completed suicide in patients attempting to quit smoking while taking CHAMPIX® (see WARNINGS AND PRECAUTIONS, Psychiatric Symptoms). Of the cases with information provided, the majority reported possible contributing factors, including primarily prior psychiatric history and/or concurrent psychiatric medications. Smoking status at the time of event onset was not reported in most cases.

Smoking cessation with or without treatment is associated with nicotine withdrawal symptoms and the exacerbation of underlying psychiatric illness. The role of CHAMPIX® in these reports is not known (see also WARNINGS AND PRECAUTIONS, Psychiatric Symptoms).

PART III: CONSUMER INFORMATION “CHAMPIX®"' (varenicline tartrate tablets)

Read this information each time you refill your prescription in case new information has been added.

This leaflet is part III of a three-part "Product Monograph" published when CHAMPIX® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about CHAMPIX®. Contact your doctor or pharmacist if you have any questions about the drug.

What is the most important information I should know about CHAMPIX®?

Some people have had changes in behavior, hostility, agitation, aggression, depressed mood, and suicidal thoughts or actions while taking CHAMPIX® to help them quit smoking. Some people had these symptoms when they began taking CHAMPIX®, and others developed them after several weeks of treatment or after stopping CHAMPIX®.

If you, your family, or caregiver notice agitation, hostility, depression or changes in behavior or thinking that are not typical for you, or you develop any of the following symptoms, stop taking CHAMPIX® and call your healthcare provider right away:

- thoughts about suicide or dying, or attempts to commit suicide
- new or worse depression, anxiety or panic attacks
- feeling very agitated or restless
- acting aggressive, being angry, or violent
- acting on dangerous impulses
- an extreme increase in activity and talking (mania)
- abnormal thoughts or sensations
- seeing or hearing things that are not there (hallucinations)
- feeling people are against you (paranoia)
- feeling confused
- other unusual changes in behavior

When you try to quit smoking, with or without CHAMPIX®, you may have symptoms that may be due to nicotine withdrawal, including urge to smoke, depressed mood, trouble sleeping, irritability, frustration, anger, feeling anxious, difficulty concentrating, restlessness, decreased heart rate, and increased appetite or weight gain. Some people have even experienced suicidal thoughts when trying to quit smoking without medication. Sometimes quitting smoking can lead to worsening of mental health problems that you already have, such as depression.

Before taking CHAMPIX®, tell your doctor if you have ever had depression or other mental health problems. You should also tell your doctor about any symptoms you had during other times you tried to quit smoking, with or without CHAMPIX®. See "SIDE EFFECTS AND WHAT TO DO ABOUT THEM" …

Serious Warnings and Precautions

• Some people have had changes in behavior, hostility, agitation, aggression, depressed mood, and suicidal thoughts or actions while taking CHAMPIX® to help them quit smoking. Some people developed them within days or weeks of starting CHAMPIX®, or after stopping taking the drug.

• These psychiatric symptoms have occurred in people with previous mental health issues, as well as in those with no previous history.

• For more information on this, go to the section at the front of this leaflet "What is the most important information I should know about CHAMPIX®".

• Be sure to have a discussion with your doctor about the risks and benefits of all options, including CHAMPIX®, before deciding whether to start CHAMPIX®.

• If you experience emotional, behavioral or psychiatric changes that are unusual for you while on CHAMPIX®, stop taking the drug right away, and talk to your doctor.

• Drinking alcohol may increase the risk of experiencing psychiatric events during your treatment with CHAMPIX®.

• You are encouraged to inform friends and family members of your quit attempt which includes treatment with CHAMPIX® and ask for their support and help in monitoring for potential psychiatric symptoms.

Psychiatric Symptoms

Quitting smoking can be associated with changes m mood and behavior, with or without taking medication to help quit. Some patients taking CHAMPIX® may experience unusual feelings of agitation, depressed mood, hostility, aggression, changes in behavior or have impulsive or disturbing thoughts such as thoughts of self-harm or harm to others.

Stop taking CHAMPIX® right away and tell your doctor if you experience these symptoms in a way that is not typical for you, or if you have thoughts of self-harm or harm to others. In a few cases, these symptoms have occurred after stopping CHAMPIX® (see SIDE EFFECTS AND WHAT TO DO ABOUT THEM).

It is not known if these symptoms occur more often in people treated with CHAMPIX® compared to those attempting to quit without any medication or with other smoking cessation medications.

INTERACTIONS WITH THIS MEDICATION

Drinking alcohol during treatment with CHAMPIX® may increase the risk of psychiatric symptoms. …

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Whether you are taking medication to stop smoking or not, the following are symptoms you may feel: depressed, short-tempered, frustrated or angry, nervous, impatient; have difficulty concentrating. Your appetite may increase, and you may gain some weight.

Like all medicines, CHAMPIX® can cause side effects, although not everybody gets them. The common side effects are mostly mild to moderate and these usually occur in the first weeks of treatment. Some of the most

common side effects you should be aware of include:

- Nausea, vomiting
- Trouble sleeping,
- Headache
- Abnormal dreams (vivid, unusual, or increased dreaming; rarely may include nightmares)
- Sleepiness, tiredness, dizziness
- Constipation, diarrhea, gas

Tell your doctor immediately if you experience unusual feelings of agitation, aggression, depressed mood, hostility, hallucinations, changes in behavior or suicidal thoughts. Stop taking CHAMPIX® if you experience these symptoms in a way that is not typical for you, or if you have thoughts of self-harm or harm to others. These symptoms have been reported in patients trying to stop smoking with or without CHAMPIX®. It is not known if these symptoms are related to CHAMPIX® (see WARNINGS AND PRECAUTIONS).

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom/effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency medical attention
		Only if severe	In all cases	
Rare See Warnings & Precautions	Psychiatric Symptoms		X	X (if severe, or if involves potential harm to self or others

[31] The January 2007, December 2007, and May 2008 monographs do not contain black boxed warnings, but they do contain information about the use of CHAMPIX®. For example, the January 2007 monograph notes that smoking cessation, with or without pharmacotherapy, has been associated with various symptoms such as depressed mood and anxiety and with the exacerbation of underlying psychiatric illness. The January 2007 monograph reports, among other things, that psychiatric disorders, including anxiety, depression, emotional disorder, aggression, agitation, mood swings, panic reaction, abnormal thinking, euphoric mood, hallucination, psychotic disorder, suicidal ideation and suicide had been observed in some patients attempting to quit smoking with CHAMPIX®.

[32] The Defendants submit that given what it knew or ought to have known, the January 2007 monograph provided an adequate warning about the use of CHAMPIX®.

[33] The Defendants make similar arguments about the December 2007 and May 2008 monographs that progressively provide new and more detailed information garnered about the use of CHAMPIX®. All of the monographs were subject to the rigorous scrutiny of the Health Canada regulators.

2. The Use of CHAMPIX® by Messrs. Parker, Dunn, and Dion and Ms. Clow

[34] Between April 2007 and June 2010, Health Canada received more than 1,200 adverse event reports associated with varenicline. Some of these adverse events were nneuropsychiatric adverse events and there were 33 reported deaths.

[35] In 2007, as part of his treatment for diabetes, Mr. Parker, who resides in Burlington, Ontario, was told by his family doctor to quit smoking and to stop drinking alcohol.

Mr. Parker was prescribed CHAMPIX® in August 2007, and he used CHAMPIX® from August to November or December of 2007. On January 3, 2008, he had an emotional breakdown at his place of work and on February 4, 2008, his wife interrupted his preparations to commit suicide at his home. At the time of these incidents, Mr. Parker was having personal difficulties at work and marital problems, and he was taking an anti-depressant and insomnia medication and he had not stopped drinking alcohol.

[36] Simon Dunn, who resides in Calgary, Alberta began using CHAMPIX® in mid-December 2007. He had unsuccessfully attempted to quit smoking before and had used Zyban, among other therapies. Within a few days after using CHAMPIX®, he experience bizarre dreams of violent content. He reported this experience to his doctor who, nevertheless, continued to prescribe CHAMPIX®. On January 21, 2008, under the influence of alcohol, Mr. Dunn experienced an uncontrollable rage. He assaulted members of his family and was arrested. While in police custody, he attempted suicide and was hospitalized and taken off CHAMPIX®. During the psychiatric assessment, Mr. Dunn described a childhood marked by domestic abuse and sexual abuse by his mother.

[37] Patricia Clow of Sooke, British Columbia is the estate representative of her daughter, Heidi Clow, deceased. Patricia and Heidi both had the rank of steward in the Canadian Navy. Heidi used CHAMPIX® from June 2009 until October 2009 when she died. Heidi committed suicide on October 4, 2009 at 22 years of age. Heidi seemed to be very happy with her career in the navy and what circumstances might have driven her to take her life are not known. Patricia Clow, Heidi's mother blames CHAMPIX® as the cause of an otherwise mysterious suicide.

[38] Patrick Dion of Chambly, Québec is a long-time smoker who suffered chronic anxiety. He had been prescribed anti-anxiety medication at various times. He began using CHAMPIX® in April, 2010, and while taking CHAMPIX® experienced paranoia, depression, and suicidal ideation. He stopped using the drug in May 2010, and 2 days after stopping, he experienced neuropsychiatric adverse events and was hospitalized in the psychiatric ward at the Haut-Richelieu Hospital. At the time of these events, he was experiencing marital difficulties and he was also experiencing sleep disruption following the birth of his second child.

F. GATEKEEPING, SOME BASIS IN FACT, AND THE EVIDENCE OF DR. TREMBLAY

[39] For certification, the plaintiff in a proposed class proceeding must show "some basis in fact" for each of the certification requirements, other than the requirement that the pleading discloses a cause of action: *Hollick v. Toronto (City)*, 2001 SCC 68 (CanLII), [2001] 3 S.C.R. 158 at para. 25; *Taub v. Manufacturers Life Insurance Co.* 1998 CanLII 14853 (ON SC), (1998), 40 O.R. (3d) 379 (Gen. Div.), aff'd reflex, (1999), 42 O.R. (3d) 576 (Div. Ct.).

[40] The Defendants argue that in determining whether to certify an action as a class action, the court plays a gatekeeper function and that if the plaintiff fails to show some basis in fact for his or her claim, certification should be denied. For the case at bar, the Defendants argue that there is no basis in fact for certification criteria pursuant to subsections 5(1)(b) to (e) of the *Class Proceedings Act*. More particularly, the Pfizer Defendants argue that there is no basis in fact for the proposed common issues, and, thus, like a collapsing house built of stacked cards, the other certification criteria are not satisfied.

[41] The Defendants' submission that there is no basis in fact for the proposed common issues is based on their argument that Mr. Parker's case for certification absolutely

depends on Dr. Tremblay's evidence, but Dr. Tremblay is all of: not qualified, not reliable, not credible, and not correct.

[42] With due respect to this valiant attempt to avoid the certification of an action that when narrowed to a duty to warn case is suitable for certification, the Defendants' argument fails and, at best, the argument indicates that they may have a strong defence on the merits of the common issues trial.

[43] Dr. Tremblay is a Montréal psychiatrist and adjunct professor of psychiatry at the Université de Montréal. He has a Masters degree in neurological sciences (MSc.). In his clinical practice, he has treated over 20,000 patients with psychiatric problems. The majority of his patients are smokers, and he regularly helps patients withdraw from nicotine. He does not prescribe CHAMPIX® for his patients, but says that he has observed in his patients adverse events likely from varenicline use.

[44] Dr. Tremblay was asked to provide an opinion on the side effects, if any, associated with the ingestion of varenicline and on the adequacy of the information provided by the manufacturer of the product to treating physicians.

[45] Dr. Tremblay expressed the opinion that in 2004, bupropion (Zyban) was associated with severe neuropsychiatric events and since 2006, similar adverse events were reported with the use of varenicline (CHAMPIX®). He expressed the opinion that from the outset of the use of CHAMPIX® in the Canadian market in April 2007, its product monograph should have included the same warnings as found in the product monograph of Zyban. It was his opinion that there were sufficient indications of adverse neuropsychiatric events from CHAMPIX® to immediately give the warning that was later found in the May 2010 CHAMPIX® monograph.

[46] The Defendants submit that Dr. Tremblay's expertise and experience does not qualify him to provide these opinions, because he is not a pharmacologist and he has no education in the sciences that would explain the dynamics of either varenicline or bupropion in the brain, nor does he have any expertise regarding the treatment of nicotine addiction or pharmaceutical treatments for such addiction. Further, they submit that Dr. Tremblay is not qualified to say anything about the adequacy of the warning in the CHAMPIX® monographs, because he has no education, training or expertise regarding the regulation of prescription drugs in Canada or with respect to the design, development, testing, manufacturing, marketing, sale or post-marketing reporting of prescription drugs.

[47] I would agree that Dr. Tremblay is not qualified to give an opinion about whether CHAMPIX® actually causes neuropsychiatric adverse events, for which opinion, expertise in pharmacology or perhaps another branch of the health sciences would be necessary, but I do, however, think that as a practicing clinical psychiatrist, he is, for the purposes of a certification motion, qualified to express an opinion about whether and when a drug monograph for CHAMPIX® would be adequate to provide a treating doctor with the information that he or she needed about possible adverse side effects from the drug. He is also qualified to report and provide evidence of patients who have experienced neuropsychiatric adverse events during or after using CHAMPIX®.

[48] Monographs are written for doctors like Dr. Tremblay, and although he does not prescribe varenicline for his patients, his patients included smokers who were using CHAMPIX® to cease smoking. Dr. Tremblay is a "learned intermediary" (see discussion below) and a representative of the type of health care professional to whom Pfizer normally would communicate about the use of CHAMPIX® and about associated risks from that use.

[49] It will ultimately be a matter for the Court to determine whether, as a legal matter, the CHAMPIX® monographs provided an adequate warning to doctors, but, as a member of intended audience for the publication and as a professional familiar with the use of product monographs, in my opinion, he is qualified to express an opinion for a certification motion about the adequacy of the monographs to satisfy a duty to warn and his evidence is admissible to show that the common issues and associated certification criteria have some basis in fact.

[50] I appreciate that evidence tendered on motion for certification must meet the usual standards for admissibility and that one determines whether evidence is admissible before deciding the utility, if any, of the evidence. See *Martin v. Astrazeneca Pharmaceuticals PLC,* 2012 0NSC 2744 (S.C.J.); and *Williams v. Canon Canada Inc.,* 2011 ONSC 6571 (CanLII), 2011 ONSC 6571 (S.C.J.). However, the some basis in fact standard used for establishing utility on a motion for summary judgment is very low. The certification criteria are not meant to be a test of the merits of the plaintiff's case and while the court plays a gatekeeper role, it is a gatekeeper within the parameters established by the *Class Proceedings Act*. See *Waldman v. Thomson Reuters Corporation*, 2012 ONSC 1138 (CanLII), 2012 ONSC 1138 at paras. 112-133.

[51] It takes little evidence to open the certification gate, but a great deal of evidence and persuasion to close it. The requirement that there be some basis in fact to support the common issues does not require the plaintiffs to indicate the evidence to be advanced at the certification stage, nor does it determine the admissibility of evidence: *2038724 Ontario Ltd v. Quizno's Canada Restaurant Corp.*, [2009] O.J. No. 1874 (Div. Ct.), affd. 2010 ONCA 466 (CanLII), 2010 ONCA 466, leave to appeal to S.C.C. refd. [2010] S.C.C.A. No. 348. In *Quizno's*, the Divisional Court stated at para. 74:

> 74. The requirement that there be an evidentiary foundation - or some basis in fact - to support the certification criteria does not include a preliminary merits test and should not involve an assessment of the merits. It is not an onerous requirement. The plaintiffs are not required to indicate the evidence upon which they will prove these issues. The certification stage focuses on the form of the action. The question at the certification stage is not whether the claim is likely to succeed, but whether the suit is appropriately prosecuted as a class action: *Hollick* at paras. 16, 25.

[52] At the certification stage, it is not necessary to engage in the debate about the relative strengths and weaknesses of the expert evidence: *2038724 Ontario Ltd v. Quizno's Canada Restaurant Corp.*, *supra*, ONCA at para. 45. In any event, even if I were to conclude that Dr. Tremblay's evidence provided no basis in fact for the duty to warn claim and its common issues, it would be an error not to consider whether there was some other basis in fact to ground the common issues. See *2038724 Ontario Ltd v. Quizno's Canada Restaurant Corp.*, *supra*.

[53] In my opinion, in the case at bar, the evidence of Messrs. Parker, Dunn, and Dion and Mrs. Clow along with some of the documentary evidence filed by Mr. Tuovi also establishes some basis in fact for the common issues about a duty to warn by Pfizer Canada. The contemporaneous or near contemporaneous neuropsychiatric events experienced by those using the drug provides some basis in fact to the claim that there was a failure to warn by the manufacturer of the drug.

[54] I, however, do not see some basis in fact for a duty to warn claim against Pfizer Inc., which does not manufacture varenicline in Canada. Standing alone, the position of a shareholder, even a controlling shareholder, in a manufacturer is insufficient to impose a manufacturer's duty: *Harrington v. Dow Corning Corp.*, [1996] B.C.J. No. 734 (Sup.Ct.), aff'd. 2000 BCCA 605 (CanLII), 2000 BCCA 605, leave to appeal to S.C.C. ref'd. [2001] S.C.C.A. No. 21; *Martin v. Astrazeneca Pharmaceuticals PLC*, 2012 ONSC 2744 (CanLII), 2012 ONSC 2744 at paras. 121-122; *Hughes v. Sunbeam Corp. (Canada)*, [2000] O.J. No. 4595 (S.C.J.) at paras. 58-59, varied 2002 CanLII 45051 (ON CA), (2002), 61 O.R. (3d) 433 (C.A.), leave to appeal to S.C.C. refused, [2002] S.C.C.A. No. 446. Pfizer Inc. has no direct relationship to Mr. Parker or the

other putative Class members who used varenicline manufactured and marketed by Pfizer Canada. There is no dispute that CHAMPIX® was sold in Canada by Pfizer Canada pursuant to Health Canada's approval, and that all of the information available to Class members or their physicians relating to CHAMPIX® was from Pfizer Canada. Any duty to warn or breach thereof would be the responsibility of Pfizer Canada.

[55] Therefore, I conclude that this action should not be certified as against Pfizer Inc. Mr. Parker's action against Pfizer Inc. should be stayed until after the common issues trial.

G. CERTIFICATION

1. Introduction

[56] Pursuant to s. 5(1) of the *Class Proceedings Act, 1992*, the court shall certify a proceeding as a class proceeding if: (a) the pleadings disclose a cause of action; (b) there is an identifiable class; (c) the claims of the class members raise common issues of fact or law; (d) a class proceeding would be the preferable procedure; and (e) there is a representative plaintiff who would adequately represent the interests of the class without conflict of interest and who has produced a workable litigation plan.

[57] For an action to be certified as a class proceeding, there must be a cause of action shared by an identifiable class from which common issues arise that can be resolved in a fair, efficient, and manageable way that will advance the proceeding and achieve access to justice, judicial economy, and the modification of behaviour of wrongdoers: *Sauer v. Canada (Attorney General)*, [2008] O.J. No. 3419 (S.C.J.) at para. 14, leave to appeal to Div. Ct. refused, [2009] O.J. No. 402 (Div. Ct.).

[58] On a certification motion, the question is not whether the plaintiff's claims are likely to succeed on the merits, but whether the claims can appropriately be prosecuted as a class proceeding: *Hollick v. Toronto (City)*, 2001 SCC 68 (CanLII), [2001] 3 S.C.R. 158 at para. 16.

[59] The test for certification is to be applied in a purposive and generous manner, to give effect to the important goals of class actions -- providing access to justice for litigants; promoting the efficient use of judicial resources; and sanctioning wrongdoers to encourage behaviour modification: *Western Canadian Shopping Centres Inc. v. Dutton*, 2001 SCC 46 (CanLII), [2001] 2 S.C.R. 534 at paras. 26 to 29; *Hollick v. Toronto (City)*, 2001 SCC 68 (CanLII), [2001] 3 S.C.R. 158 at paras. 15 and 16.

[60] The purpose of a certification motion is to determine how the litigation is to proceed and not to address the merits of the plaintiff's claim; there is to be no preliminary review of the merits of the claim: *Hollick v. Toronto (City)*, 2001 SCC 68 (CanLII), [2001] 3 S.C.R. 158 at paras. 28 to 29.

2. Cause of Action Criterion

[61] In his Statement of Claim, Mr. Parker alleges that the Defendants were negligent in the design, development, testing, manufacturing, marketing, sale, and post-marketing of CHAMPIX®. He also pleads that the Defendants were negligent in failing to warn the users of CHAMPIX® of potential risks associated with using the drug. As already noted above, Mr. Parker does not seek to certify all of his causes of action. Mr. Parker focuses on his duty to warn claim and alleges that the Defendants failed to provide an adequate, timely warning regarding the risk of NAEs associated with CHAMPIX® use.

[62] A manufacturer of a product has a duty to warn consumers of dangers inherent in

the use of the product of which the manufacturer has knowledge or ought to have knowledge: *Hollis v. Dow Corning Corp.*, 1995 CanLII 55 (SCC), [1995] 4 S.C.R. 634 at para. 20; *Lambert v. Lastoplex Chemicals Co.*, 1971 CanLII 27 (SCC), [1972] S.C.R. 569 at p. 574; *Bow Valley Husky (Bermuda) Ltd. v. Saint John Shipbuilding Ltd.*, 1997 CanLII 307 (SCC), [1997] 3 S.C.R. 1210.

[63] A manufacturer may discharge its duty to warn consumers by providing an adequate warning to a "learned intermediary." In the case of prescription drugs, the duty of manufacturers to warn consumers is discharged if the manufacturer provides prescribing physicians, rather than the consumers, with an adequate warning of the potential dangers associated with the use of the drug: *Buchan v. Ortho Pharmaceutical (Canada) Ltd.* 1986 CanLII 114 (ON CA), (1986), 54 O.R. (2d) 92 (C.A.) at paras. 23, 59. The legal theory here is that where a consumer places primary reliance on the judgment of a learned intermediary and not the manufacturer of the product, then the manufacturer will satisfy its duty to warn the consumer by adequately warning the learned intermediary of the risks inherent in the use of the product: *Hollis v. Dow Corning Corp.*, *supra*, at paras. 28 to 29; *Buchan v. Ortho Pharmaceutical (Canada) Ltd.*, *supra*, at para. 59.

[64] The Pfizer Defendants delivered a statement of defence and did not challenge that Mr. Parker has pleaded a cause of action.

[65] In my opinion, Mr. Parker has adequately pleaded a duty to warn claim in negligence where the product is distributed through a learned intermediary.

[66] Mr. Parker's action satisfies the first criterion for certification as a class action.

3. Identifiable Class

[67] In defining class membership, there must be a rational relationship between the class, the causes of action, and the common issues, and the class must not be unnecessarily broad or over-inclusive: *Pearson v. Inco Ltd*. 2006 CanLII 913 (ON CA), (2006), 78 O.R. (3d) 641 (C.A.) at para. 57, rev'g [2004] O.J. No. 317 (Div. Ct.), which had aff'd [2002] O.J. No. 2764 (S.C.J.).

[68] The definition of an identifiable class serves three purposes: (1) it identifies the persons who have a potential claim against the defendant; (2) it defines the parameters of the lawsuit so as to identify those persons bound by the result of the action; and (3) it describes who is entitled to notice: *Bywater v. Toronto Transit Commission*, [1998] O.J. No. 4913 (Gen. Div.).

[69] Mr. Parker proposes the following definition for the classes:

> All persons in Canada, including their estates, who were prescribed and ingested and/or purchased CHAMPIX® during the Class Period (the "Class");
>
> All persons who by reason of his or her relationship to a member of the Class are entitled to make claims under any of the Dependants Statutes in Canada as a result of the death or personal injury of such member of the Class (the "Family Class"); and
>
> All provincial or territorial health insurers who are entitled to assert a claim pursuant to the *Hospitals Act*, R.S.A. 2000, c. H-12, s. 62 and related provincial and territorial legislation ("Health Insurer Class")";
>
> "Class Period" means from April 2, 2007 until May 31, 2010;
>
> "Dependants Statutes" means the *Family Law Act* (Ontario), *Family Compensation Act* (B.C.), *Fatal Accidents Act* (Alberta), *Tort-Feasors Act* (Alberta), *Fatal Accidents Act* (Saskatchewan) *Fatal Accidents Act* (Manitoba), *Code civil* (Quebec), *Loi sur la protection du consommateur* (Quebec), *Fatal Accidents Act* (New Brunswick), *Fatal Accidents Act* (P.E.I.), *Fatal Injuries Act* (Nova Scotia), *Fatal Accidents Act* (Newfoundland), *Fatal Accidents Act* (Nunavut), *Fatal Accidents Act* (Northwest

Territories), and *Fatal Accidents Act* (Yukon);

[70] The Defendants argue that the proposed Classes are over-inclusive because they include individuals (and their family members and insurers) who simply "were prescribed and ingested and/or purchased CHAMPIX®", but did not suffer the alleged harm. Thus, it is submitted that the Class definition is not rationally connected to the focus of the claim, which is a failure to warn about the risk of neuropsychiatric adverse events.

[71] The Defendants also argue that the proposed Class definition is vague and uncertain because neuropsychiatric adverse events are entirely subjective and do not provide an objective way to identify the Class and this uncertainty, in turn, leads both to the impossibility of stating common issues and to an unmanageable action and the failure to satisfy the preferable procedure criterion. The Defendants submit that this uncertainty in defining the class distinguishes this proposed class action from other pharmaceutical products liability class actions.

[72] I agree with the Defendants that there are problems of over breadth and vagueness in the proposed Class definition. However, unlike the Defendants, I do not believe that these problems are incurable. The solution is to introduce some precision in defining the Class. In my opinion that precision may be found in the May 28, 2010 product monograph. Since Mr. Parker uses the May 28, 2010 monograph as an adequate measure of a warning, Pfizer's language, which was scrutinized by Health Canada, can be used as a means of defining who should be included as members of the Class and who will receive notice of the class action and be bound by its outcome. It hardly lies in Pfizer's mouth to assert that its own language is too vague and imprecise to give notice to the same audience that is constituted by the Class members.

[73] All but the first paragraph of the proposed definition is satisfactory. I, therefore, amend the first paragraph of the Class definition, as set out below:

> All persons in Canada: (a) who ingested CHAMPIX® during the Class Period and (b) who while taking or after taking CHAMPIX® to help them quit smoking experienced any of the following neuropsychiatric adverse events or psychiatric symptoms:
>
> - thoughts about suicide or dying, or attempts to commit suicide
> - new or worse depression, anxiety or panic attacks
> - feeling very agitated or restless
> - acting aggressive, being angry, or violent
> - acting on dangerous impulses
> - an extreme increase in activity and talking (mania)
> - abnormal thoughts or sensations
> - seeing or hearing things that are not there (hallucinations)
> - feeling people are against you (paranoia)
> - feeling confused
> - other unusual changes in behavior.

[74] In my opinion with the above amendment, the class definition satisfies the second criterion for certification.

4. Common Issues

[75] For an issue to be a common issue, it must be a substantial ingredient of each Class member's claim and its resolution must be necessary to the resolution of each Class member's claim: *Hollick v. Toronto (City),* 2001 SCC 68 (CanLII), [2001] 3 S.C.R. 158 at para. 18.

[76] The fundamental aspect of a common issue is that the resolution of the common issue will avoid duplication of fact-finding or legal analysis: *Western Canadian Shopping Centres Inc. v. Dutton*, 2001 SCC 46 (CanLII), [2001] 2 S.C.R. 534 at para. 39.

[77] An issue is not a common issue if its resolution is dependent upon individual

findings of fact that would have to be made for each Class Member: *Fehringer v. Sun Media Corp*., [2003] O.J. No. 3918 (Div. Ct.) at paras. 3, 6. Common issues cannot be dependent upon findings which will have to be made at individual trials, nor can they be based on assumptions that circumvent the necessity for individual inquiries: *Nadolny v. Peel (Region)*, [2009] O.J. No. 4006 (S.C.J.) at paras. 50-52; *Collette v. Great Pacific Management Co.*, [2003] B.C.J. No. 529 (B.C.S.C.) at para. 51, var'd on other grounds 2004 BCCA 110 (CanLII), (2004) 42 B.L.R. (3d) 161 (B.C.C.A.); *McKenna v. Gammon Gold Inc.*, [2010] O.J. No. 1057 (S.C.J.) at para. 126, leave to appeal granted [2010] O.J. No. 3183 (Div. Ct.), var'd 2011 ONSC 3882 (Div. Ct.).

[78] An issue can satisfy the common issues requirement even if it makes up a very limited aspect of the liability question and even though many individual issues remain to be decided after its resolution. In determining the commonality of a question, the focus is on the commonality of the question, and it is an error to focus on those aspects of the claim that would require individual determination. The comparative extent of individual issues is not a consideration in the commonality inquiry although it is a factor in the preferability assessment. See *Cloud v. Canada (Attorney General)* 2004 CanLII 45444 (ON CA), (2004), 73 O.R. (3d) 401 (C.A.) at paras. 51 to 65, leave to appeal to S.C.C. ref'd, [2005] S.C.C.A. No. 50.

[79] The common issue criterion presents a low bar: *Carom v. Bre-X Minerals Ltd.* 2000 CanLII 16886 (ON CA), (2000), 51 O.R. (3d) 236 (C.A.) at para. 42; *Cloud v. Canada (Attorney General)* (2004), O.R. (3d) 401 (C.A.) at para. 52; *203874 Ontario Ltd. v. Quiznos Canada Restaurant Corp*., [2009] O.J. No. 1874 (Div. Ct.), aff'd [2010] O.J. No. 2683 (C.A.), leave to appeal to S.C.C. ref'd [2010] S.C.C.A. No. 348. An issue can be a common issue even if it makes up a very limited aspect of the liability question and even though many individual issues remain to be decided after its resolution: *Cloud v. Canada (Attorney General) supra,* at para. 53.

[80] Mr. Parker proposes eleven questions for the common issues trial. Subject to one general comment, I will address the questions *seriatim*. The general comment is that as already noted above there is no basis in fact for a duty to warn claim against Pfizer Inc. and the common issues should be adjusted accordingly.

[81] Proposed **question 1** is: "Can ingesting CHAMPIX® cause an increased risk of neuropsychiatric adverse events, including suicidal behaviour?"

[82] Question 1 should be and is amended to state:

> 1. Does using CHAMPIX® increase the risk of the patient experiencing any of the following neuropsychiatric adverse events or psychiatric symptoms?
>
> - thoughts about suicide or dying, or attempts to commit suicide
> - new or worse depression, anxiety or panic attacks
> - feeling very agitated or restless
> - acting aggressive, being angry, or violent
> - acting on dangerous impulses
> - an extreme increase in activity and talking (mania)
> - abnormal thoughts or sensations
> - seeing or hearing things that are not there (hallucinations)
> - feeling people are against you (paranoia)
> - feeling confused
> - other unusual changes in behavior.

[83] As explained by the British Columbia Court of Appeal in *Harrington v. Dow Corning Corp.*, *supra*, at paras. 42 to 45, typically the first two steps in a products liability action are: (1) determining whether the product is defective or whether although non-defective, the product has a propensity to injure; and (2) determining what the manufacturer knew about the dangerousness of its product. The first step, known as the general causation step, determines

whether the product is capable of causing harm. The second step is part of determining whether the manufacturer had a duty of care not to sell the product or to sell it only with an appropriate warning.

[84] Amended question 1 is a general causation question. As noted earlier in this judgment, in my opinion, there is some basis in fact for the general causation common issue. It is also a very productive common issue that does not depend upon the individual experiences or individual claims of class members.

[85] Visualize, if the common issues trial determines that CHAMPIX® does not increase the risk of suicide or attempts to commit suicide, this determination would bind Mr. Parker, Mr. Dunn, and Ms. Clow and their claims would fail as would the claims of any Class member with a claim based on suicide or attempted suicide. Conversely, if the common issues trial established that using CHAMPIX® does increase thoughts about suicide or dying, or attempts to commit suicide, then individual Class members who experienced these symptoms will have advanced their claims of a failure to warn.

[86] In *Boulanger v. Johnson & Johnson Corp*., [2007] O.J. No. 179 (S.C.J.), leave to appeal ref'd [2007] O.J. No. 1991 (S.C.J.), the plaintiffs sought to have certified as a common issue whether the drug Prepulsid can cause or materially contribute to cardiac arrhythmia, including ventricular tachycardia, cardiac arrest, prolonged QT, *torsades de pointes*, ventricular fibrillation, sudden death and other heart disease. The defendants submitted that the question of whether Prepulsid caused this list of adverse cardiac events was not a common issue because each type of adverse cardiac event would have to be looked at individually. Justice E. M. Macdonald certified the question and she stated at para. 33, in a passage that I would adopt as applicable to the case at bar with adjustments by substituting CHAMPIX® for Prepulsid and neuropsychiatric adverse events for cardiotoxity:

> 33. At this stage of the proceedings, the representative plaintiff is not required to put forward evidence that each and every member of the proposed class suffered an adverse cardiac event. It is sufficient that the representative plaintiff has presented some evidence of cardiotoxity associated with Prepulsid ingestion. This makes the proposed common issue rationally connected to the proposed class, since Prepulsid ingestion is a prerequisite for class membership. The resolution of this common issue will therefore move the litigation forward for all class members.

[87] The general causation question in the case at bar is distinguishable from the question in *Merck Frosst Canada Ltd. v. Wuttunee*, [2009] S.J. No. 179 at paras 144 to 145 (Sask. C.A.), leave to appeal to S.C.C. refused, [2008] S.C.C.A. No. 512, where the question of whether the drug Vioxx increased the risk of high blood pressure would be irrelevant to those whose claim was based on other adverse conditions or injuries.

[88] Warnings are by their nature addressed generally to the audience of users of the prescription drug. In the case at bar, the diversity of neuropsychiatric adverse affects or injuries does not eradicate the common complaint that the Class member would have avoided experiencing his or her injury if adequately warned about the list of NAEs or psychiatric symptoms that were black boxed in the May 2010 monograph. A general causation question is appropriate for the case at bar.

[89] Proposed **question 2** is:

> 2. Is CHAMPIX® ineffective and/or defective and/or unfit for the purpose for which it was intended as designed, developed, fabricated, manufactured, sold, imported, distributed or otherwise placed into the stream of commerce in Canada by one or both of the defendants?

[90] I do not certify question 2 because it is not connected to the failure to warn claim that Mr. Parker proposes for certification. Question 2 is an example of the other negligence claims

that are included in the Amended Statement of Claim.

[91] Proposed **question 3** is:

> 3. Did any of the defendants owe a duty of care to the Class members? If so, what was the standard of care? Did any of the defendants breach the standard of care? If so, who, when and why?

[92] Proposed question 3, which will become question 2, should be and is amended to state:

> 2. Did Pfizer Canada breach a duty to warn the users of CHAMPIX® whose prescription came with the product monographs dated: (a) January 2007; (b) December 2007, or (c) May 2008?

[93] It is not disputed that as a drug manufacturer in Canada that Pfizer Canada had a duty to warn the Canadian users of CHAMPIX®, so no useful purpose is served by asking whether the Defendants had a duty to warn. What is useful and common is the question of whether Pfizer Canada breached or satisfied its duty to warn during the currency of each of the three product monographs. This question is the common issue at the heart of this lawsuit. This question focuses on the duty of care step described by the British Columbia Court of Appeal in *Harrington v. Dow Corning Corp.*, *supra*.

[94] It may turn out that the Court at the common issue trial may provide a nuanced answered to the duty of care question. It is, for instance, conceivable that the first and second monograph might be found inadequate, but the third compliant with a duty to warn. That the Court may provide a nuanced answer does not detract from the commonality of the question. The nuanced answer rather provides judicial economy by setting parameters for which class members may move forward to have their individual issues determined.

[95] Proposed **question 4** is as follows:

> 4. Did any of the defendants have a duty to warn the Class members of the risks of harm from CHAMPIX®? If so, did any of them fail to warn in a timely manner? If so, who, when and how?

[96] I do not certify question 4 because with new question 2, this question is now redundant.

[97] Proposed **question 5** is as follows:

> 5. Is each defendant responsible in law for the acts or omissions of the other defendant in respect of the sale and marketing of CHAMPIX® in Canada?

[98] I do not certify question 5 for the same reason that I did not certify question 2.

[99] Proposed **question 6** is:

> 6. Are Class members entitled to special damages for medical costs incurred in the treatment of health complications related to having ingested CHAMPIX®?

[100] I do not certify proposed question 6 because the entitlement of Class members to special damages cannot be determined until it is determined that they are entitled to damages, which entitlement depends upon success at the individual issues trials. Proposed question 6 is premature and is not common.

[101] Proposed **question 7** is:

> 7. Are the defendants liable for damages resulting from the purchase and consumption of CHAMPIX®?

[102] I do not certify proposed question 7 because the entitlement of Class members to

damages cannot be determined until after individual issues trials. For example, it is conceivable that the Court might conclude that Pfizer Canada breached a duty to warn owed to Class members who used CHAMPIX® during the first monograph, but these Class members would still have to show that they were harmed by the duty to warn and that the type of harm they suffered was compensable in damages. Proposed question 7 is premature and is not a common question.

[103] Proposed **question 8** is:

> 8. Are the defendants liable for the subrogated health care costs of Class members incurred in the treatment of conditions related to taking CHAMPIX®?

[104] I do not certify proposed question 8 for reasons similar to why I do not certify proposed questions 6 and 7.

[105] Proposed **question 9** and proposed **question 10** are:

> 9. By virtue of waiver of tort, are the defendants liable on a restitutionary basis:
>
> (a) to account to any of the Class, including the provincial insurers with subrogated or direct claims, for any part of the proceeds of the sale of CHAMPIX®? Or in the alternative,
>
> (b) such that a constructive trust is to be imposed on the proceeds of the sale of CHAMPIX® for the benefit of the Class, including provincial health insurers with subrogated or direct claims.
>
> 10. If liability is found under the waiver of tort above, in what amount and for whose benefit is such an account to be made, or in what amount, and for whom are such proceeds held?

[106] Proposed questions 9 and 10, which will become question 3, should be amended to state:

> 3. If Pfizer Canada breached a duty to warn, would this wrongdoing entitle a Class member pursuant to the doctrine of waiver of tort to a remedy measured by Pfizer Canada's gain from its wrongdoing.

[107] The rationale for this new question is as follows. The proposed question 10 is unacceptable, because it cannot be answered at the common issues trials. Question 10 asks the Court to decide which members of the Class are to recover proceeds and to what extent. However, for the Court to judiciously and fairly answer this question, it would need information about the individual circumstances of the Class members, which obviously is not a common issue for the Class. Moreover, the individual circumstances of Class members are complex and go beyond the questions of whether an individual Class member can prove causation and quantify his or her damages. Some Class members will have to prove that their injury is a compensable injury, because in the absence of a physical injury, to recover damages for psychological injury, a class member must show that he or she suffers from a recognizable psychiatric illness: *Healey v. Lakeridge Health Corp.*, 2011 ONCA 55 (CanLII), 2011 ONCA 55. Further, I do not see how the Court could fairly quantify a restitutionary award without information about the extent of the damages that are being waived in order to pursue a restitutionary award. In my opinion, the most that can be achieved in advancing a claim based on waiver of tort is the new question 3.

[108] Although I am certifying this waiver of tort question, I have decided to make this certification without prejudice to Pfizer Canada bringing a motion to decertify the waiver of tort question.

[109] It has become conventional to certify waiver of tort as a common issue. See *Peter v. Medtronic*, [2007] O.J. No. 4828 (S.C.J.), leave to appeal ref'd [2008] O.J. No. 1916 (Div. Ct.); *LeFrancois v. Guidant Corp.*, [2008] O.J. No. 1397 (S.C.J.) and [2008] O.J. No. 3459 (S.C.J.), leave to appeal ref'd [2009] O.J. No. 36 (Div. Ct.) and *Lambert v. Guidant Corp.*, [2009] O.J. No. 1910 (S.C.J.), leave to appeal ref'd [2009] O.J. No. 4464 (S.C.J.); *Heward v. Eli Lilly & Co.*, [2007] O.J. No. 404 (S.C.J.), aff'd [2008] O.J. No. 2610 (Div. Ct.); *Robinson v. Medtronic, Inc.*,

[2009] O.J. No. 4366 (S.C.J.).

[110] However, in my opinion, it is time to revisit the convention, which is based, in part, on the ongoing uncertainty about the waiver of tort doctrine that began eight years ago with *Serhan v. Johnson & Johnson* 2004 CanLII 1533 (ON SC), (2004), 72 O.R. (3d) 296 (S.C.J.), leave to appeal granted [2004] O.J. No. 4580 (S.C.J.), aff'd reflex, (2006), 85 O.R. (3d) 665 (Div. Ct.), leave to appeal to C.A. ref'd Oct. 16, 2006, leave to appeal to S.C.C. ref'd [2006] S.C.C.A. No. 494.

[111] Starting with *Serhan,* the theory goes that since it is not plain and obvious that waiver of tort is not available, it is appropriate to certify waiver of tort as a common issue. However, in my opinion, it is not necessary to wait for a trial judgment. The answers to questions about the scope of waiver of tort are purely matters of legal policy that do not require an evidentiary record and, indeed, the questions would be better answered by posing hypothetical questions not confined to a particular evidentiary record. Hypothetical questions that would be relevant are whether, when and to what extent a restitutionary award should circumvent established principles of tort, contract, and property law that limit the extent of a wrongdoer's liability.

[112] In the case at bar, because certifying waiver of tort has become fashionable, neither party argued the point, so I will say nothing more about how waiver of tort policy questions should be answered and I simply say that in the immediate case or in other cases, the certification of waiver of tort questions should be revisited.

[113] Proposed **question 11** is:

> 11. Following a determination of any compensation owed by one or both of the Defendants to Class members, should one or both of the Defendants pay punitive damages? Should punitive damages be assessed in aggregate? If so, in what amount and how should punitive damages be distributed?

[114] Proposed question 11, which will become question 4, should be and is amended to state:

> 4. If Pfizer Canada breached a duty to warn would its conduct justify an award of punitive damages?

[115] For the reasons I expressed in *Robinson v. Medtronic Inc.*, [2009] O.J. No. 4366 (S.C.J.), aff'd [2010] O.J. No. 3056 (Div. Ct.), a claim for punitive damages will not be suitable for a common issue when the Court cannot make a rational assessment about the appropriateness of punitive damages until after individual assessments of the compensatory losses of Class members has been completed. However, where the ultimate determination of the entitlement and quantification of punitive damages must be deferred until the conclusion of the individual trials, the question of whether the defendants' conduct was sufficiently reprehensible or high-handed to warrant punishment is capable of being determined as a common issue at the common issues trial: *Chalmers (Litigation guardian of) v. AMO Canada Co.*, 2010 BCCA 560 (CanLII), 2010 BCCA 560.

[116] I therefore conclude that in Mr. Parker's proposed class action, there are four questions that satisfy the common issues criterion for certification. The waiver of tort issue may be revisited but the outcome of any motion about waiver of tort would not affect the other questions or the other certification criteria.

5. Preferable Procedure

[117] Preferability captures the ideas of: (a) whether a class proceeding would be an appropriate method of advancing the claims of the Class members; and (b) whether a class proceeding would be better than other methods such as joinder, test cases, consolidation, and any

other means of resolving the dispute: *Markson v. MBNA Canada Bank* 2007 ONCA 334 (CanLII), (2007), 85 O.R. (3d) 321 (C.A.) at para. 69, leave to appeal to S.C.C. ref'd, [2007] S.C.C.A. No. 346; *Hollick v. Toronto (City)*, 2001 SCC 68 (CanLII), [2001] 3 S.C.R. 158.

[118] For a class proceeding to be the preferable procedure for the resolution of the claims of a given Class, it must represent a fair, efficient, and manageable procedure that is preferable to any alternative method of resolving the claims: *Cloud v. Canada (Attorney General)* 2004 CanLII 45444 (ON CA), (2004), 73 O.R. (3d) 401 (C.A.) at paras. 73-75, leave to appeal to S.C.C. ref'd, [2005] S.C.C.A. No. 50.

[119] Whether a class proceeding is the preferable procedure is judged by reference to the purposes of access to justice, behaviour modification, and judicial economy and by taking into account the importance of the common issues to the claims as a whole, including the individual issues: *Markson v. MBNA Canada Bank* 2007 ONCA 334 (CanLII), (2007), 85 O.R. (3d) 321 (C.A.) at para. 69, leave to appeal to S.C.C. ref'd, [2007] S.C.C.A. No. 346; *Hollick v. Toronto (City)*, 2001 SCC 68 (CanLII), [2001] 3 S.C.R. 158.

[120] In considering the preferable procedure criterion, the court should consider: (a) the nature of the proposed common issue(s); (b) the individual issues which would remain after determination of the common issue(s); (c) the factors listed in the Act; (d) the complexity and manageability of the proposed action as a whole; (e) alternative procedures for dealing with the claims asserted; (f) the extent to which certification furthers the objectives underlying the Act; and (g) the rights of the plaintiff(s) and defendant(s): *Chadha v. Bayer Inc.* reflex, (2001), 54 O.R. (3d) 520 (Div. Ct.) at para. 16, aff'd 2003 CanLII 35843 (ON CA), (2003), 63 O.R. (3d) 22 (C.A.), leave to appeal to S.C.C. ref'd, [2003] S.C.C.A. No. 106.

[121] Numerous cases have held that a class proceeding will not satisfy the requirement that it be the preferable procedure to resolve the common issues if the common issues are overwhelmed or subsumed by the individual issues such that the resolution of the common issues will, in substance, mark just the beginning of the process leading to a final disposition of the claims of Class members: *Western Canadian Shopping Centres Inc. v. Dutton*, 2001 SCC 46 (CanLII), [2001] 2 S.C.R. 534 at para. 39; *Abdool v. Anaheim Management Ltd.* 1995 CanLII 5597 (ON SCDC), (1995), 21 O.R. (3d) 453 (Div. Ct.) at paras. 134, 135; *Williams v. Mutual Life Assurance Co.*, [2000] O.J. No. 3821 (S.C.J.); *Zicherman v. Equitable Life Insurance Co. of Canada*, [2003] O.J. Nos. 1160 and 1161 (C.A.), aff'g [2001] O.J. No. 4952 (Div. Ct.), which aff'd 2000 CanLII 22704 (ON SC), (2000), 51 O.R. (3d) 54 (S.C.J.) and *Zicherman v. The Equitable Life Assurance Company of Canada*, [2000] O.J. No. 5144 (S.C.J.); *Gariepy v. Shell Oil Co.*, [2002] O.J. No. 2766 (S.C.J.), aff'd [2004] O.J. No. 5309 (Div. Ct.).

[122] The Defendants in the case at bar, make the "inevitably argument," which is that inevitably, this action will break down into individual proceedings, creating a monster of complexity that would made a common issues trial unproductive.

[123] However, that the common issues trial may leave significant individual issues to be resolved, does not necessarily mean that a class proceeding is not the preferable procedure, because it will often be the case that the common issues trial will not be determinative of the defendant's liability and the *Class Proceedings Act, 1992*, provides powerful procedural mechanisms and powerful compensation distribution mechanisms that permit the court to take a variety of approaches to resolving the claims of class members: *Cassano v. Toronto-Dominion Bank,* 2007 ONCA 781 (CanLII), 2007 ONCA 781 at para. 60.

[124] I am satisfied that notwithstanding there will be individual issues trials to determine causation and whether the individual's damages are compensable, a class action is the preferable procedure for the Class members' claims. I see no other practicable alternative and a class proceeding will achieve: (a) some judicial economy; (b) behaviour modification (if Pfizer

Canada is found to be negligent); and (c) otherwise unavailable access to justice for those harmed.

[125] In deciding that Mr. Parker's action satisfies the preferable procedure criterion, I simply note, but do not rely on, the fact that product liability actions have been certified by Canadian courts. See: *Wilson v. Servier Canada Inc.* 2000 CanLII 22407 (ON SC), (2000), 50 O.R. (3d) 219 (S.C.J.), leave to appeal ref'd reflex, (2000), 52 O.R. (3d) 20 (S.C.J.), leave to appeal to S.C.C. ref'd [2001] SCCA No 88. (S.C.C.); *Boulanger v. Johnson & Johnson Corp*., [2007] O.J. No. 179 (S.C.J.), leave to appeal ref'd [2007] O.J. No. 1991 (S.C.J.); *Bouchanskaia v. Bayer Inc.* 2003 BCSC 1306 (CanLII), 2003 BCSC 1306; and *Goodridge v. Pfizer Canada Inc*., 2010 ONSC 1095 (CanLII), 2010 ONSC 1095. I note, however, that product liability actions have also failed to be certified. See: *Martin v. Astrazeneca Pharmaceuticals PLC*, 2012 ONSC 2744 (CanLII), 2012 ONSC 2744 (S.C.J.); *Williams v. Canon Canada Inc.*, 2011 ONSC 6571 (CanLII), 2011 ONSC 6571; *Wuttunee v. Merck Frosst Canada Ltd.*, 2009 SKCA, leave to appeal to S.C.C. ref'd [2008] S.C.C.A. No. 512.

[126] Each action should be considered on its own merits, and I conclude that Mr. Parker's action satisfies the preferable procedure criterion.

6. Representative Plaintiff and Litigation Plan

[127] The representative plaintiff must be a member of the Class asserting claims against the defendant, which is to say that the representative plaintiff must have a claim that is a genuine representation of the claims of the members of the Class to be represented or that the representative plaintiff must be capable of asserting a claim on behalf of all of the Class members as against the defendant: *Drady v. Canada (Minister of Health)*, [2007] O.J. No. 2812 (S.C.J.) at paras. 36-45; *Attis v. Canada (Minister of Health)*, [2003] O.J. No. 344 (S.C.J.) at para. 40, aff'd [2003] O.J. No. 4708 (C.A.).

[128] Provided that the representative plaintiff has his or her own cause of action, the representative plaintiff can assert a cause of action against a defendant on behalf of other Class members that he or she does not assert personally, provided that the causes of action all share a common issue of law or of fact: *Boulanger v. Johnson & Johnson Corp.*, [2002] O.J. No. 1075 (S.C.J.) at para. 22, leave to appeal granted, [2002] O.J. No. 2135 (S.C.J.), varied 2003 CanLII 45096 (ON SCDC), (2003), 64 O.R. (3d) 208 (Div. Ct.) at paras. 41 and 48, varied [2003] O.J. No. 2218 (C.A.); *Matoni v. C.B.S. Interactive Multimedia Inc*., [2008] O.J. No. 197 (S.C.J.), at paras. 71-77; *Voutour v. Pfizer Canada Inc*., [2008] O.J. No. 3070 (S.C.J.); *LeFrancois v. Guidant Corp*., [2008] O.J. No. 1397 (S.C.J.) at para. 55.

[129] Whether the representative plaintiff can provide adequate representation depends on such factors as: his or her motivation to prosecute the claim; his or her ability to bear the costs of the litigation; and the competence of his or her counsel to prosecute the claim: *Western Canadian Shopping Centres Inc. v. Dutton*, 2001 SCC 46 (CanLII), [2001] 2 S.C.R. 534 at para. 41.

[130] The proposed Class Counsel have excellent qualifications and there was no serious challenge to the appropriateness of Mr. Parker as a representative plaintiff, and I see no purpose at this juncture in adding additional representative plaintiffs or any reason to establish subclasses.

[131] The Litigation Plan, however, was seriously challenged by the Defendants; particularly about its deficient treatment of the relationship between common issues and individual issues. The current plan does not respond to the reality that the common issues trial will necessarily have to be followed by individual issue trials. Numerous other deficiencies were pointed out in the current proposed Litigation Plan, but for present purposes, I need not detail those deficiencies because they should and can be addressed by the preparation of a new Litigation

Plan.

[132] The proposed Litigation Plan is sufficient to satisfy the last criterion for certification, but it will have to be substantially amended and rewritten to take into account the outcome of the certification motion, which has reduced the proposed common issues from eleven to four.

[133] A litigation plan is always a work in progress, and if the other four criteria are satisfied, then any deficiencies in the plan can be corrected by amending the plan, which usually can be accomplished at a case conference.

[134] In the case at bar, I unconditionally certify the class action but I direct that a new litigation plan be prepared and served on the defendant. The defendant may propose revisions and, if necessary, I will settle the plan at a case conference.

[135] I therefore conclude that the fifth criterion for certification has been satisfied.

H. CONCLUSION

[136] For the above reasons, I conclude that Mr. Parker's motion should be granted.

[137] If the parties cannot agree about the matter of costs, they may make submissions in writing beginning with Mr. Parker's submissions within 20 days of the release of these Reasons for Decision, followed by the Defendants' submissions within a further 20 days.

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Perell, J.

Released: June 21, 2012

CITATION: Parker v. Pfizer Canada Inc. 2012 ONSC 3681
COURT FILE NO.: 08-CV-368950CP
DATE: 20120621

ONTARIO
SUPERIOR COURT OF JUSTICE

BETWEEN:

Kenneth R. Parker

Plaintiff

- and -

Pfizer Canada Inc. and Pfizer Inc.

Defendants

REASONS FOR DECISION

Perell, J.

Released: June 21, 2012

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