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**ONTARIO
SUPERIOR COURT OF JUSTICE**

BETWEEN:

Danielle Elias and Erich Weibl

Plaintiffs

- and -

Pfizer Canada Inc. and Pfizer Inc.

Defendants

Proceeding under the *Class Proceedings Act*, 1992

STATEMENT OF CLAIM

TO THE DEFENDANTS

A LEGAL PROCEEDING HAS BEEN COMMENCED AGAINST YOU by the plaintiffs. The claim made against you is set out in the following pages.

IF YOU WISH TO DEFEND THIS PROCEEDING, you or an Ontario lawyer acting for you must prepare a statement of defence in Form 18A prescribed by the Rules of Civil Procedure, serve it on the plaintiffs' lawyer or, where the plaintiffs do not have a lawyer, serve it on the plaintiffs, and file it, with proof of service, in this court office, WITHIN TWENTY DAYS after this statement of claim is served on you, if you are served in Ontario.

If you are served in another province or territory of Canada or in the United States of America, the period for serving and filing your statement of defence is forty days. If you are served outside Canada and the United States of America, the period is sixty days.

Instead of serving and filing a statement of defence, you may serve and file a notice of intent to defend in Form 18B prescribed by the Rules of Civil Procedure. This will entitle you to ten more days within which to serve and file your statement of defence.

IF YOU FAIL TO DEFEND THIS PROCEEDING, JUDGMENT MAY BE GIVEN AGAINST YOU IN YOUR ABSENCE AND WITHOUT FURTHER NOTICE TO YOU. IF YOU WISH TO DEFEND THIS PROCEEDING BUT ARE UNABLE TO PAY LEGAL FEES, LEGAL AID MAY BE AVAILABLE TO YOU BY CONTACTING A LOCAL LEGAL AID OFFICE.

Date December 13, 2005

Issued by



Local registrar

Address of court office Ministry of the Attorney General
7755 Hurontario St.
Brampton, Ontario
L6W 4T6

TO: Pfizer Canada Inc.
17300 Trans-Canada Highway
Kirkland, QC H9J 2M5

AND TO: Pfizer Inc.
235 East 42nd Street
New York, NY 10017
USA

CLAIM

1. The Plaintiff, Danielle Elias, claims on behalf of herself and others similarly situated in Canada:
 - (a) general damages in the amount of \$200,000 each;
 - (b) special damages for, *inter alia*, medical and other expenses related to testing, treatment and monitoring in an amount to be determined;
 - (c) punitive, aggravated, and exemplary damages in the amount of \$5,000,000;
 - (d) prejudgement interest in the amount of 10% compounded annually or as otherwise awarded by this Honourable Court;
 - (e) costs on a substantial indemnity basis, including GST; and
 - (f) such further and other relief as this Honourable Court may deem just.
2. The Plaintiffs, Danielle Elias and Erich Weibl, are individuals residing in Mississauga, Ontario.
3. Erich Weibl is the spouse of Danielle Elias and is pursuing his claim in that capacity.
4. The Plaintiff, Erich Weibl, on his own behalf, and on behalf of similarly situated persons in Canada, claims damages in the amount of \$100,000 for each pursuant to the *Family Law Act*, R.S.O. 1990, c F.3 s.61.
5. The Defendant, Pfizer Canada Inc., is a corporation with its headquarters in Kirkland, Quebec. Pfizer Canada Inc. is currently involved in and/or responsible for the research, development, manufacturing, sales, distribution and marketing of Depo-Provera. At all material times, Pfizer Canada Inc. was an affiliate of Pfizer Inc.

6. The Defendant, Pfizer Inc., is a U.S. company with its headquarters in New York, New York. Pfizer Inc. is currently involved in and/or responsible for the research, development, manufacturing, sales, distribution and/or marketing of Depo-Provera in Canada. Initially, Depo-Provera was developed, marketed and sold by Pharmacia and Upjohn Company, a subsidiary of Pharmacia Corp. ("Pharmacia"). In April 2003, Pfizer Inc. acquired Pharmacia. As a result of this acquisition, Pfizer Inc. is now responsible for all liabilities which result from any acts or omissions of Pharmacia which occurred prior to that acquisition. At all material times, Depo-Provera was manufactured, marketed, sold and/or distributed in Canada directly or indirectly through an agent, affiliate or subsidiary of Pharmacia or Pfizer Inc. References herein to the actions or omissions of the "Defendants" include Pfizer Inc., Pfizer Canada Inc. and the companies for whose actions they are responsible.
7. The business of each of Pfizer Canada Inc. and Pfizer Inc. (collectively "Pfizer") is inextricably interwoven with that of the other and each is the agent of the other for the purposes of the manufacture, marketing, sale and/or distribution of Depo-Provera in Canada.
8. At all material times, the Defendants were carrying on business as, *inter alia*, the manufacturer and distributor of Depo-Provera in Canada.
9. In bringing this action on behalf of a class of people in Canada who were prescribed Depo-Provera, to be further defined in the motion for certification, the Plaintiffs plead and rely upon the provisions of the *Class Proceedings Act*, 1992, S.O. 1992, c.6 and the *Food and Drugs Act*, R.S.C. 1985, c. F.27 and regulations thereunder.

THE DRUG

10. Depo-Provera (medroxyprogesterone acetate injectable suspension, USP) is a contraceptive. It is typically prescribed to prevent pregnancy, however, it is also used to treat endometriosis and as a palliative treatment of certain cancers.
11. Depo-Provera was first approved for marketing and sale in Canada as a contraceptive in or about April 1997. The Defendants immediately and heavily promoted Depo-Provera as a better option than other forms of contraceptives.
12. Since its introduction into the Canadian market, sales of Depo-Provera in Canada have been strong. For example, it is one of the top 5 most commonly prescribed drugs for Canadian women aged 17 to 23. Furthermore, between 1999 and 2003 in Canada, its sales more than doubled from \$11.2 million to \$24.1 million per year.

THE RISKS

13. Depo-Provera has been associated with an increased risk of significant bone mineral density loss, including a significantly increased risk of developing osteoporosis at ages below the statistical norm.
14. The Defendants knew or ought to have known at least as early as 1991 that there was a significant increased risk of significant bone mineral density loss, including early development of osteoporosis, from receiving injections of Depo-Provera. The Defendants failed to adequately apprise the Plaintiffs or physicians of those risks.
15. Neither the patient information pamphlet nor the prescribing information provided to physicians and pharmacists in Canada, warned of the serious risk to all women of significantly reduced bone mineral density associated with receiving Depo-Provera injections.

THE EVENTS

16. The Plaintiff, Danielle Elias, was prescribed Depo-Provera by her physician and she received her first injection in early 1998. Ms. Elias stopped receiving Depo-Provera injections in or about August 1998 to try to conceive a child. Her child was born in September 1999 and soon afterwards she began taking Depo-Provera again, and continued taking it until December 2004.
17. In total, Ms. Elias received Depo-Provera injections for approximately 6 years.
18. Ms. Elias received Depo-Provera injections in accordance with the package label and consumer information pamphlet, and in the manner it was intended to be used.
19. In the time period before and during Ms. Elias receiving injections of Depo-Provera she received no warnings about the increased risk of significant bone mineral density loss.
20. Ms. Elias first learned that Depo-Provera might affect her bone mineral density on or about December 30, 2004 when she attended at her doctor's office for her regular injection of Depo-Provera. Her doctor handed her a copy of Pfizer's November 18, 2004 letter advising, in part:

As a result of new clinical studies, one with adults and one with adolescents, we now have clinical data regarding the use of Depo-Provera and its associated effect on bone mineral density (BMD). The data suggest that women who use DEPO-PROVERA Contraceptive Injection may lose significant BMD. Bone loss is greater with increasing duration and may not be completely reversible.
21. Tests conducted after Ms. Elias stopped receiving Depo-Provera injections showed that her bone mineral density is below that of an average women of her age.
22. Had Ms. Elias been aware of the potential for significant bone mineral density loss that she might experience from taking Depo-Provera, she would not have taken the drug.

CAUSE OF ACTION

23. The Defendants at all material times owed a duty of care to the Plaintiffs to:
- (a) ensure that Depo-Provera was fit for its intended or reasonably foreseeable use;
 - (b) conduct appropriate testing to determine whether and to what extent injection of Depo-Provera posed serious health risks, including the risk of significant bone mineral density loss; and
 - (c) adequately warn the Plaintiff and her physicians that Depo-Provera carries the risk of significant bone mineral density loss.
24. The Defendants negligently breached their duty of care.
25. The Plaintiffs state that their damages were caused by the negligence of the Defendants. Such negligence includes but is not limited to the following:
- (a) the Defendants failed to ensure that Depo-Provera was not dangerous to recipients during the course of its use and that the drug was fit for its intended purpose and of merchantable quality;
 - (b) the Defendants failed to adequately test Depo-Provera in a manner that would fully disclose the magnitude of the risks associated with its use, including but not limited to the risk of significant bone mineral density loss;
 - (c) the Defendants failed to give Health Canada complete and accurate information;
 - (d) the Defendants failed to conduct any or any adequate follow-up studies on the efficacy and safety of Depo-Provera;

- (e) the Defendants failed to provide the Plaintiff and her physicians with any adequate warning of the risks associated with injections of Depo-Provera, including but not limited to the risk of significant bone mineral density loss;
- (f) the Defendants failed to provide the Plaintiff and her physicians with any or any adequate information and warnings respecting the correct usage of Depo-Provera;
- (g) the Defendants failed to provide any or any adequate updated and current information to the Plaintiff and her physicians respecting the risks and efficacy of Depo-Provera as it came available from time to time;
- (h) the Defendants failed to provide warnings of the potential hazards of Depo-Provera on package labels;
- (i) The Defendants failed to provide adequate warnings of the risks associated with Depo-Provera, including the risk of significant bone mineral density loss in all persons receiving Depo-Provera, on the customer information pamphlets in Canada;
- (j) the Defendants, after noticing problems with Depo-Provera as early as the 1990s, failed to issue adequate warnings, timely recall the drugs, publicize the problem and otherwise act properly and in a timely manner to alert the public, including warning the Plaintiff and her physicians of the drugs' inherent dangers, including but not limited to the danger of significant bone mineral density loss in all persons receiving Depo-Provera;

- (k) the Defendants failed to establish any adequate procedures to educate their sales representatives and prescribing physicians respecting the correct usage of Depo-Provera and the risks associated with the drug;
 - (l) the Defendants represented that Depo-Provera was safe and fit for its intended purpose and of merchantable quality when they knew or ought to have known that these representations were false;
 - (m) the Defendants misrepresented the state of research, opinion and medical literature pertaining to the purported benefits of Depo-Provera and its associated risks, including the risk of significant bone mineral density loss in all persons receiving Depo-Provera;
 - (n) the misrepresentations made by the Defendants were unreasonable in the face of the risks that were known or ought to have been known to the Defendants;
 - (o) the Defendants failed to timely cease the manufacture and/or distribution of Depo-Provera when they knew or ought to have known that this drug caused or could cause significant bone mineral density loss;
 - (p) the Defendants actively encouraged and/or affirmatively failed to take effective steps to discourage aggressive dispensation of Depo-Provera;
 - (q) the Defendants breached other duties of care to the Plaintiff and the class of Plaintiffs, details of which breaches are known only to the Defendants.
26. The risks associated with Depo-Provera injections, including the risk of significant bone mineral density loss in all persons receiving Depo-Provera, were in the exclusive knowledge and control of the Defendants. The extent of the risks was not known and could not have been known to the Plaintiffs. The Plaintiffs' injuries would not have

occurred but for the negligence of the Defendants in failing to ensure that Depo-Provera was safe for use or, in the alternative, for providing an adequate warning of the risks associated with Depo-Provera to the Plaintiffs and to the Plaintiffs' physicians.

DAMAGES

27. The Plaintiffs' and other class members' injuries and damages were caused by the negligence of the Defendants, their servants and agents.
28. As a result of the Defendants' negligence, the plaintiffs have suffered and continue to suffer serious personal injuries and pain and suffering, including but not limited to significant bone mineral density loss.
29. As a result of the conduct of the Defendants, the Plaintiffs and other class members suffered and continue to suffer expenses and special damages, of a nature and amount to be particularized prior to trial.
30. Some of the expenses related to the medical treatment that the Plaintiffs and class members have undergone, and will continue to undergo, have been borne by the various provincial health insurers including the Ontario Health Insurance Plan ("OHIP"). As a result of the negligence of the Defendants, the various provincial health insurers have suffered and will continue to suffer damages.
31. The Plaintiffs claim punitive, aggravated and exemplary damages for the reckless and unlawful conduct of the Defendants.

SERVICE OUTSIDE OF ONTARIO

32. The Plaintiffs plead and rely on section 17 (g), (h), (o) and (p) of the Rules of Civil Procedure, allowing for service *ex juris* of the foreign defendants. Specifically, this originating process may be served without court order outside Ontario in that the claim is:

- (a) in respect of a tort committed in Ontario (rule 17.02(g));
- (b) in respect of damages sustained in Ontario arising from a tort or breach of contract wherever committed (rule 17.02(h));
- (c) against a person outside Ontario who is a necessary and proper party to this proceeding properly brought against another person served in Ontario (rule 17.02(o)); and
- (d) against a person carrying on business in Ontario (rule 17.02(p)).

PLACE OF TRIAL

33. The plaintiffs propose that this action be tried in Brampton, Ontario.

December 13, 2005

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London, ON N6A 3V8

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Solicitors for the Plaintiffs

CV-05-012802-CF

Danielle Elias v. Pfizer Canada Inc. and Pfizer Inc.

Court File No:

**ONTARIO
SUPERIOR COURT OF JUSTICE**

Proceeding commenced at Brampton

STATEMENT OF CLAIM

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