

**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

**FRESH AS AMENDED 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 , 2005

Issued by \_\_\_\_\_  
Local registrar

Address of court office Ministry of the Attorney General  
7755 Hurontario St.  
Brampton, Ontario  
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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 Plaintiffs, Danielle Elias, and Erich Weibl, claim on behalf of themselves and others similarly situated in Canada:
  - (a) general damages in the amount of \$400,000 for each person prescribed Depo-Provera;
  - (b) special damages for, *inter alia*, medical and other expenses related to testing, treatment and monitoring in an amount to be determined;
  - (c) damages pursuant to the *Family Law Act*, R.S.O. 1990, c F.3 s.61 and similar legislation in other provinces, where applicable, in the amount of \$100,000 for each such plaintiff;
  - (d) punitive, aggravated, and exemplary damages in the amount of \$20,000,000;
  - (e) prejudgement interest in the amount of 10% compounded annually or as otherwise awarded by this Honourable Court;
  - (f) costs on a substantial indemnity basis, including GST; and
  - (g) 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 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.

5. 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.
6. 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.
7. At all material times, the Defendants were carrying on business as, *inter alia*, the manufacturer and distributor of Depo-Provera in Canada.
8. 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 *Negligence Act*, R.S.O. 1990, c. N-1, as amended, and regulations thereunder.

## THE DRUG

9. 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.
10. In the late 1980s and again in the early 1990s Health Canada refused to approve Depo-Provera for contraceptive use in Canada, noting that there were unresolved long term health risks for Canadian women.
11. The United States Food and Drug Administration ("FDA") approved Depo-Provera for use in the U.S.A. in 1992. The FDA's press release regarding this approval stated: "Recent data have also demonstrated that long-term use may contribute to osteoporosis. The manufacturer will conduct additional research to study this potential effect."
12. Depo-Provera was 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. For example, the information sheet for women considering using Depo-Provera stated: "Depo-Provera is one of the most effective ways to prevent pregnancy other than sterilization" and "in actual use, Depo-Provera is more effective [than oral contraceptives at preventing pregnancy] because women sometimes forget to take their "pills"."
13. 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. Between 1999 and 2003 in Canada, its sales more than doubled from \$11.2 million to \$24.1 million per year. Furthermore, in 2004, approximately 625,000 prescriptions for Depo-Provera were filled, worth approximately \$25 million.

## THE RISKS

14. Depo-Provera has been associated with an increased risk of significant bone mineral density ("BMD") loss, including a significantly increased risk of developing osteoporosis at ages below the statistical norm.
15. In a 1991 paper published in the *British Medical Journal*, the lead researcher, Dr. Cundy, concluded that "long term used of DMPA [Depo-Provera] is associated with significant reductions in bone density in the lumbar spine and femoral neck. Use of DMPA should therefore be considered a potential risk factor for osteoporosis." Subsequent studies followed with similar conclusions.
16. As such, the Defendants knew or ought to have known at least as early as 1991 that there was an 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.
17. In addition, the Plaintiffs plead that a number of studies conducted regarding BMD loss that were given "research support" by the defendants in the years just before and the years after the approval in Canada were not published, nor were the results disclosed. For example, Dr. Diane F. Merritt was provided research support to conduct studies for Upjohn as a "principal investigator" between 1995 to 2002. Dr. Merritt's studies have not been published.
18. 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

### Danielle Elias

19. 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.
20. In total, Ms. Elias received Depo-Provera injections for approximately 6 years.
21. 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.
22. 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.
23. 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.
24. Tests conducted after Ms. Elias stopped receiving Depo-Provera injections showed that her bone mineral density is approximately 20 percent below that of an average women of her age: she has osteopenia, the precursor to osteoporosis.
25. 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.

## THE SAFETY UPDATE

26. On November 18, 2004, Pfizer sent to Canadian Health Care Professionals an "Important Safety Update: Potential Effect of DEPO-PROVERA (medroxyprogesterone acetate) on Bone Mineral Density (BMD) changes in adults and adolescents." It stated, 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. It is unknown if use of DEPO-PROVERA during adolescence or early adulthood, a critical period of bone accretion, will reduce peak bone mass and increase the risk of osteoporotic fracture in later life.

27. Also on November 18, 2004, Pfizer sent a similar letter to U.S. Health Care Professionals advising that a Boxed Warning had been added to Depo-Provera's U.S. prescribing information. That letter and boxed warning contained an important piece of information not included in the Canadian letter, namely:

Depo-Provera Contraceptive injection should be used as a long-term birth control method (eg, longer than 2 years) only if other birth control methods are inadequate.

28. This part of the warning was not provided to Canadian Health Care Professionals until June 30, 2005 when Pfizer revised the Depo-Provera product monograph to include a boxed warning about BMD loss.

29. Despite the new warnings, Pfizer continued to make statements about the safety of the drug. An article in *McLeans* on November 24, 2005 stated, in part:

Pfizer Canada Inc., the drug's manufacturer, declined to be interviewed for this article, but issued a statement saying Depo-Provera, which contains synthetic hormone medroxy-progesterone acetate, has "been used safely by millions of women around the world for decades."

## CAUSE OF ACTION

30. 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;
  - (c) adequately warn the Plaintiffs and their physicians that Depo-Provera carries the risk of significant bone mineral density loss;
  - (d) ensure that prescribing physicians were kept fully and completely informed of all risks associated with Depo-Provera;
  - (e) monitor, investigate, evaluate and follow up on adverse reactions to the use of Depo-Provera; and
  - (f) properly inform Health Canada and other regulatory agencies of the risks of BMD loss or related conditions, including osteopenia and osteoporosis, associated with the use of Depo-Provera.
  
31. The Defendants negligently breached their duty of care.
  
32. 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 as it became available from time to time;
- (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 conduct any or any adequate long-term studies of the risks of continued use of Depo-Provera;
- (f) the Defendants failed to provide the Plaintiffs and their 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;
- (g) the Defendants failed to provide the Plaintiffs and their physicians with any or any adequate information and warnings respecting the correct usage of Depo-Provera;
- (h) the Defendants failed to warn the Plaintiffs and their physicians about the need for comprehensive regular medical monitoring to ensure the early discovery of BMD loss;
- (i) the Defendants failed to adequately monitor, evaluate and act upon reports of adverse reactions to Depo-Provera in Canada and elsewhere;
- (j) the Defendants failed to provide any or any adequate updated and current information to the Plaintiffs and their physicians respecting the risks and efficacy of Depo-Provera as it came available from time to time;

- (k) the Defendants failed to provide warnings of the potential hazards of Depo-Provera on package labels;
- (l) 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;
- (m) 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 Plaintiffs and their 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;
- (n) 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;
- (o) 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;
- (p) 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;

- (q) 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;
- (r) the Defendants failed to timely cease the manufacture, marketing 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;
- (s) the Defendants failed to conform with applicable disclosure and reporting requirements pursuant to the *Food and Drugs Act* and its associated regulations;
- (t) the Defendants failed to properly supervise their employees, their subsidiaries and their affiliated corporations;
- (u) the Defendants actively encouraged and/or affirmatively failed to take effective steps to discourage aggressive dispensation of Depo-Provera; and
- (v) the Defendants breached other duties of care to the Plaintiffs and the class of Plaintiffs, details of which breaches are known only to the Defendants.

33. 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**

34. The Plaintiffs' and other class members' injuries and damages were caused by the negligence of the Defendants, their servants and agents.

35. 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.
36. 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.
37. 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.
38. The Plaintiffs claim punitive, aggravated and exemplary damages for the reckless and unlawful conduct of the Defendants.

#### **SERVICE OUTSIDE OF ONTARIO**

39. 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**

40. The Plaintiffs propose that this action be tried in Brampton, Ontario.

December , 2005

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Danielle Elias and Erich Weibl

v.

Pfizer Canada Inc. and Pfizer Inc.

Court File No: CV-05-012802-CP

**ONTARIO  
SUPERIOR COURT OF JUSTICE**

Proceeding commenced at Brampton

**STATEMENT OF CLAIM**

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