



Court File No.

**ONTARIO
SUPERIOR COURT OF JUSTICE**

B E T W E E N:

(Court Seal)

DANIEL HARTMAN

Plaintiff

and

PFIZER CANADA ULC and PFIZER INC and BIONTECH MANUFACTURING GMBH

Defendants

STATEMENT OF CLAIM

TO THE DEFENDANT

A LEGAL PROCEEDING HAS BEEN COMMENCED AGAINST YOU by the Plaintiff. 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 Plaintiff's lawyer or, where the Plaintiff does not have a lawyer, serve it on the Plaintiff, 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.

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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.

IF YOU PAY THE PLAINTIFF'S CLAIM, and \$20,000 for costs, within the time for serving and filing your Statement of Defence you may move to have this proceeding dismissed by the Court. If you believe the amount claimed for costs is excessive, you may pay the Plaintiff's claim and \$400 for costs and have the costs assessed by the Court.

TAKE NOTICE: THIS ACTION WILL AUTOMATICALLY BE DISMISSED if it has not been set down for trial or terminated by any means within five years after the action was commenced unless otherwise ordered by the court.

Date _____ Issued by _____
Local Registrar

Address of court office: Suite 301 - 50 Frederick Hobson VC Drive
Simcoe, Ontario N3Y 0E4

TO: Pfizer Canada ULC
17300 Trans-Canada Highway
Kirkland QC H9J 2M5

AND TO: Pfizer Inc
66 Hudson Boulevard East
New York NY 10001-2192
United States of America

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AND TO: BioNTech Manufacturing GMBH
 An der Goldgrube 12
 Mainz 55131
 Germany

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CLAIM

1. The Plaintiff claims:

- (a) Damages for loss of care, guidance and companionship under the Family Law Act, R.S.O. 1990, c. F.3 as amended in the amount of \$350,000.00;
- (b) Damages for nervous shock in the amount of \$200,000.00;
- (c) Damages as a result of the Defendant's negligence in the amount of \$5,000,000.00;
- (d) Damages in product liability in the amount of \$10,000,000.00;
- (e) Punitive or exemplary and/or aggravated damages in the amount of \$20,000,000.00;
- (f) Special damages in an amount to be particularized prior to the trial of this action;
- (g) prejudgment interest in accordance with section 128 of the Courts of Justice Act, R.S.O. 1990, c. C.43, as amended;
- (h) postjudgment interest in accordance with section 129 of the Courts of Justice Act, R.S.O. 1990, c. C.43, as amended;
- (i) the costs of this proceeding, plus all applicable taxes; and
- (j) Such further and other Relief as to this Honourable Court may seem just.

The Parties

2. The Plaintiff Daniel Hartman (“Daniel”) is the father of the deceased, Sean Hartman, who was a minor when deceased, advances this action pursuant to the Family Law Act, s. 61, R.S.O. 1990, c. F.3, s. 61 (1); 1999, c. 6, s. 25 (25); 2005, c. 5, s. 27 (28). Daniel resided in the town of Georgetown in the Province of Ontario.

3. The Defendant, BioNTech Manufacturing GMBH (“BioNTech”) is a Biotechnology company engaged in the business of vaccine manufacturing headquartered in Mainz, Germany with address of An der Goldgrube 12, Mainz, Germany, 55131.

4. The Defendant, Pfizer Canada ULC. (“Pfizer”) is biopharmaceutical company engaged in the development, sale, and distribution of the Pfizer BioNTech COVID-19 vaccine also known as Comirnaty. Pfizer’s head office is located at 17300 Trans-Canada Highway, Kirkland, Quebec H9J 2M5.

5. The Defendant Pfizer Inc is an American multinational pharmaceutical and biotechnology corporation headquartered at The Spiral in Manhattan, New York City. Pfizer Inc. is located at 66 Hudson Boulevard East, New York, NY 10001-2192 USA.

6. For the purposes of this document, the Defendant Pfizer Canada ULC and Pfizer Inc will collectively be referred to as (“Pfizer”).

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Background

7. The Department of Health Canada (“Health Canada”) is the regulatory agency overseen by the Minister of Health, who is responsible for discharging the operational role of regulatory approval, monitoring, and compliance of Covid-19 vaccinations for use in Canada.

8. Health Canada’s review of vaccine and drug authorization is governed by the Food and Drug Regulations C.R.C., C.870.

9. On September 16, 2020, the Minister of Health, pursuant to subsection 30.1(1) of the Food and Drugs Act, issued the Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19. (“the Order”).

10. The Order, inter alia, allowed for a ‘fast track’ process for approvals from Health Canada for COVID-19 vaccines. Under the fast-track process manufactures were able to apply for authorization of sale and distribution of Covid-19 vaccines without the completion of all research studies and Health Canada committed to review new evidence of a vaccine as it become available on a rolling basis.

11. On September 17, 2020, Health Canada published a guidance document supporting the Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19 stating, inter alia:

- (a) “Authorizations under this Interim Order will be granted only if Health Canada determines that the benefits and risks of the product are supported by evidence

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that the drug is safe, effective and of high quality. This takes into consideration the uncertainties related to the drug in the context of an urgent public health need related to COVID-19”.

- (b) “Health Canada will assess and monitor the safety and effectiveness of all products authorized under the Interim Order. Health Canada will take immediate action, including the suspension or cancellation of authorizations or establishment licenses, if required, to protect the health and safety of Canadians”.

12. The Defendants, Pfizer and BioNTech entered into an agreement with Canada for the purchase of a minimum of 20 million doses up to a maximum of 76 million doses of the Pfizer-BioNTech’s Covid-19 vaccination (“the Purchase Agreement”). The particulars of the Purchase Agreement are in the exclusive control of the Defendants.

13. On October 9, 2020, Health Canada received Pfizer-BioNTech’s submission for approval of their COVID-19 vaccine for use in Canada, utilizing the process outlined in the Order.

14. On November 18, 2020, Pfizer-BioNTech released and published updated results of their Phase 3 clinical trials, for the Pfizer and BioNTech Covid-19 vaccination stating that the vaccine is 95 per cent effective at preventing COVID-19. (“Study 1”).

15. The results of the Study 1 showed that 8 out of 18,198 individuals who received the Covid-19 vaccination developed/contracted Covid-19 (“Vaccinated group”).

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16. The results of Study 1 showed that 162 out of 18,325 patients who did not receive the Covid-19 vaccination developed/contracted Covid-19 (“Placebo group”).

17. The difference between the Vaccinated and Placebo group was 0.88%.

18. Study 1 showed that of 18,198 individuals in the Vaccination group, 5770 individuals (26.7%) had an adverse reaction.

19. Study 1 showed that of the 18,325 individuals in the Placebo group, 2638 individuals (12.2%) had an adverse reaction.

20. On December 9, 2020, Health Canada authorized the Pfizer vaccine for use in Canada under the Order for individuals 16 years of age and older.

21. On or around December 9, 2020, Health Canada published the Regulatory Decision Summary for the Pfizer-BioNTech’s Covid-19 vaccination (“Decision Summary”)

22. The Decision Summary cited Study 1 and stated “: Compared to placebo, vaccine efficacy was evaluated to be 95% (with 95% confidence interval (CI) of 90.3% to 97.6%) in subjects without prior evidence of SARS-CoV-2 infection 7 days after the second administration of the vaccine”.

23. The Pfizer-BioNTech’s Covid-19 vaccination was built on mRNA technology which had never before been used in the delivery of vaccinations on Canadian citizens and in particular coronaviruses which includes SARS-CoV-2.

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24. On December 9, 2020, the Defendants Pfizer and BioNTech issued a press release stating “Today’s decision from Health Canada is a historic moment in our collective fight against the COVID-19 pandemic and is a major step towards returning to normalcy in Canada. I’d like to acknowledge the tremendous efforts of Pfizer and BioNTech colleagues around the world who have contributed to the development of this vaccine,” says Cole Pinnow, President, Pfizer Canada. “We commend Health Canada for its careful and thorough assessment of our COVID-19 vaccine and timely action to help protect Canadians.”

25. On or around December 14, 2020, Canada began to administer the Pfizer-BioNTech’s Covid-19 vaccine on the Canadian population.

26. On April 1, 2021, Pfizer-BioNTech released and published updated results of their Phase 3 clinical trials, stating: “Pfizer and BioNTech Confirm High Efficacy and No Serious Safety Concerns Through Up to Six Months Following Second Dose in Updated Topline Analysis of Landmark COVID-19 Vaccine Study.” (“Study 2”).

27. The results of Study 2 showed 77 out of 20,998 patients who received the Covid-19 vaccination developed/contracted Covid-19 with no evidence of previous SARs-CoV-2 infection and 81 out of 22,166 patients who received the Covid-19 vaccination developed/contracted Covid-19 with or without evidence of previous infection.

28. The results of Study 2 showed 850 out of 21,096 with or without evidence of previous SARs-CoV-2 who did not receive the Covid-19 vaccination developed/contracted Covid-19

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(“Placebo group”) and 873 out of 22,320 with or without evidence of previous infection who did not receive the Covid-19 vaccination developed/contracted Covid-19.

29. The difference between the Vaccinated and the Placebo group with no previous SARs CoV-2 infection was 3.6%

30. The difference between the Vaccinated and the Placebo group with or without evidence of previous SARS CoV-2 infection was 3.5%.

31. Study 2 showed that of 21,923 individuals in the Vaccination group 5241 individuals (23.9%) had a “related adverse event” and 127 (0.6%) suffered “any serious adverse event”.

32. Study 2 showed that of 21,921 of the Placebo group, 1311 (6.0%) had a “related adverse event” and 116 (0.5%) suffered “any serious adverse event”.

33. The difference in adverse events reflects an increase of +300% in related adverse events and + 10% in serious adverse events between the vaccinated group and the placebo group from Study 1.

34. Study 2 shows deaths resulting from the vaccination prior to unblinding the study was at 15 deaths and the Placebo group with 14 deaths.

35. Study 2 shows that after unblinding the study and members of the Placebo group joined the vaccination group, an additional 5 deaths were recorded totaling 20 deaths in the vaccination group opposed to 14 deaths in the Placebo group.

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36. Between December 9, 2020, and August 25, 2021, the Defendants, issued no statements, press releases, or public representations that a possible side effect of receiving the Pfizer-BioNTech COVID-19 vaccination was death.

37. Between December 9, 2020, and August 25, 2021, the Defendants did not issue any clarification, statements, or representations that the clinical studies conducted by Pfizer and BioNTech demonstrated that the Pfizer-BioNTech COVID- 19 vaccination was minimally effective.

38. On August 25, 2021, Sean Hartman, who was 17 years of age, attended the Simcoe Muskoka District Health Unit and was administered his first COVID-19 vaccine consisting of the Pfizer-BioNTech COVID-19 mRNA vaccine Lot FD7204. Sean received the vaccine in his left deltoid.

39. At all material times prior to receiving the Pfizer-BioNTech COVID- 19 vaccination, Sean Hartman was in excellent health.

40. On August 29, 2021, Sean Hartman attended the Emergency department at the Stevenson Memorial Hospital presenting with right shoulder pain, a rash to his face and vomiting. Sean was discharged with NSAIDs for pain and discomfort.

41. On the morning of September 27, 2021, 33 days after receiving the Pfizer-BioNTech COVID- 19 vaccination, Sean Hartman was found deceased in his bedroom by his mother.

42. The Plaintiff pleads that Sean Hartman died as a result of the Pfizer-BioNTech COVID- 19 vaccination.

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Duty of Care

43. The Defendants, Pfizer and BioNTech, owed a duty of care to Sean Hartman to accurately inform him of all risks associated with the Pfizer-BioNTech COVID- 19 vaccination.

44. The Defendants, Pfizer and BioNTech, owed a duty of care to Sean Hartman when making representations regarding the testing, safety and efficacy of the Pfizer-BioNTech COVID- 19 vaccination.

45. The Defendants, Pfizer and BioNTech, owed a duty of care to Sean Hartman in the manufacturing, testing, sale, distribution, reporting, and administration of the Pfizer-BioNTech COVID- 19 vaccination.

46. The Defendants, Pfizer and BioNTech owed a duty to warn Sean Harman of the risks associated with the safety and efficacy of the Pfizer-BioNTech COVID- 19 vaccination.

Breach of Standard of Care

47. The Plaintiff pleads that the Defendant Pfizer and BioNTech breached the standard of care for the manufacturing, testing, sale, distribution, reporting, and administration of the Pfizer-BioNTech COVID- 19 vaccination.

48. The Defendant Pfizer and BioNTech deviated from best practices when developing a vaccination contrary to known guidelines and industry standards in Canada.

49. The Defendant further breached the standard of care when they knowingly and recklessly disregarded and misrepresented the results of the safety trials by inter alia,:

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- (a) Knowingly providing an incorrect characterization of the efficacy data;
- (b) Intentionally discounting safety results of adverse events on vaccinated individuals in the study;
- (c) Not highlighting all safety results and adverse events revealed in the studies conducted; and,
- (d) Not immediately halting the Study and subsequent vaccine administration on Canadians due to the known safety concerns revealed in the Study.

Negligent Misrepresentation

50. The Plaintiff pleads that the Defendants made representations regarding the safety of the Pfizer-BioNTech COVID- 19 vaccination that the Defendants knew or ought to have known were inaccurate. Alternatively, the Plaintiff submits that the Representations were made recklessly when the Defendants had insufficient information, while representing themselves as having sufficient information.

51. The Plaintiff pleads that the representations made by the Defendants were unreasonable in the face of the risks that were known or ought to have been known. Alternatively, the representations made by the Defendants were unreasonable in the face of the lack of direct information known to such a degree that the representations were negligent.

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52. The Plaintiff pleads that the Defendants negligently misrepresented the safety of the vaccine and did not disclose the risks associated with the vaccine which include but are not limited to myocarditis and pericarditis. The particulars include, inter alia:

- (a) Failed to disclose that individuals under 40 had an increased risk of myocarditis after receiving the mRNA COVID-19 vaccine;
- (b) Failed to disclose that rates of myocarditis were higher in adolescent males;
- (c) Inadequate testing was performed to ensure the safety and efficacy of the vaccine;
- (d) The Defendants failed to complete post market surveillance and inform the Government of Canada and the public of the results;
- (e) The Defendants failed to accurately, candidly, promptly and truthfully disclose the issues with the COVID-19 vaccine;
- (f) The Defendants failed to identify, implement, and verify that the procedures in place to address post market surveillance risks were in place to address issues, complaints, and timely notification of concerns;

53. The Plaintiff pleads that Sean Hartman reasonably and foreseeably relied on the representations made by the Defendants that the Pfizer-BioNTech COVID- 19 vaccination was safe and effective.

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54. The Plaintiff pleads that as a direct and proximate result of the negligent misrepresentations of the Defendants described above, Sean Hartman took the Pfizer-BioNTech COVID- 19 vaccination and died as a result.

Product Liability

55. The Plaintiff pleads that the Pfizer-BioNTech COVID- 19 MRNA vaccination was not properly conceived, designed, formulated, tested, researched, studied, packaged, distributed, sold, and placed in the stream of commerce.

56. The Plaintiff pleads that the Pfizer-BioNTech COVID- 19 MRNA vaccination was not a reasonably safe product because of, but not limited to, the following grounds:

- (a) the foreseeable risks exceeded the benefits associated with the product;
- (b) the product was more dangerous than ordinary consumers, including the Sean Hartman, would expect;
- (c) the product did not have adequate, effective warnings and instructions in light of the dangers associated with its use;
- (d) the product was inadequately tested; and
- (e) the product was not fit for the purpose for which it was intended.

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57. The Plaintiff pleads that the Defendants negligently failed to ensure that Pfizer-BioNTech COVID- 19 vaccination was not dangerous to recipients, and that it was fit for the intended purpose and of merchantable quality.

58. The Defendants impliedly warranted that Pfizer-BioNTech COVID- 19 vaccination to be of merchantable quality and safe and fit for its intended and foreseeable uses.

59. The Plaintiff pleads that the Defendants breached their implied warranty because the Pfizer-BioNTech COVID- 19 vaccination was not, and is not, of merchantable quality or safe or fit for intended use.

60. As a direct and proximate result of the breach of implied warranty, the Sean Hartman suffered death. As result, the Plaintiff claims damages flowing from such breach.

Negligence and Wrongful Death

61. The Plaintiff pleads that the Defendants, Pfizer and BioNTech were negligent in their development, testing, manufacturing, licensing, assembly, distribution, marketing and sale of the mRNA COVID-19 and breached the standard of care owed to Sean Hartman. which included:

- (a) Knowing there were significant risks associated with taking the COVID-19 vaccine which include but are not limited to myocarditis and pericarditis;
- (b) Knowing that the COVID-19 vaccine was not safe and, in many instances, dangerous and fatal and failed to warn the public, health care providers and the

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regulatory authorities ultimately misleading the public that their product was safe and effective when it wasn't;

- (c) Continuing to promote and sell the COVID-19 vaccine with known risks to their vaccine product;
- (d) Failing to continue to analyze incoming data, research and science on both their product specifically, and mRNA technology generally; and
- (e) Failing to properly, adequately, and fairly warn Sean Hartman of the magnitude of the risk of developing serious injuries or death.

62. The Plaintiff pleads that the Defendants, Pfizer and BioNTech knew or ought to have known that the Pfizer-BioNTech COVID- 19 vaccination was not providing the protection, safety and efficacy that was being marketed and failed to perform the function and purpose for which it was intended.

63. The Plaintiff pleads that the Defendants, Pfizer and BioNTech concealed the fact the Pfizer-BioNTech COVID- 19 vaccination had severe possible risks and outcomes when administered including but not limited to myocarditis, pericarditis and death, to the public, health care providers, and regulatory authorities including Health Canada.

64. The Plaintiff pleads that as a foreseeable and proximate result of the Defendants, Pfizer and BioNTech's, negligence, Sean Hartman's death occurred.

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65. The Plaintiff pleads that the wrongful death of his son Sean Hartman, was caused by the negligence of the Defendants.

Conclusion

66. The Plaintiffs claim that this action can be served outside of the Province of Ontario pursuant to *Ontario Court Rules* 17.02(g)(h).

67. In addition to the foregoing the Plaintiffs rely upon:

- (a) Section 61(1) *Family Law Act*, R.S.O. 1990, c. F.3
- (b) *Negligence Act*. R.S.O. 1990, c. N.1
- (c) Section 128 of the *Courts of Justice Act*, R.S.O. 1990, c. C.43, as amended.
- (d) section 129 of the *Courts of Justice Act*, R.S.O. 1990, c. C.43, as amended,

68. The Plaintiffs therefore claim the relief set out in paragraph 1.

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(Date of issue)

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RCP-E 14A (June 9, 2014)

DANIEL HARTMAN
Plaintiff

-and- PFIZER CANADA ULC et al.
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SUPERIOR COURT OF JUSTICE**

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STATEMENT OF CLAIM

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