

Amended per Rule 26.01. Original filed September 27, 2023.

Court File No. CV-23-00000114-0000

**ONTARIO  
SUPERIOR COURT OF JUSTICE**

BETWEEN



DANIEL HARTMAN

Plaintiff

and

PFIZER CANADA ULC and PFIZER INC and BIONTECH MANUFACTURING GMBH

Defendants

**FRESH AS AMENDED STATEMENT OF CLAIM**

TO THE DEFENDANTS

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.

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.

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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 Sept. 27, 2023 Issued by "electronically issued"  
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

AND TO: United States of America  
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: Pursuant to section 61 of the *Family Law Act*, R.S.O. 1990, c. F.3, as amended, the Plaintiff seeks damages for the loss of care, guidance, and companionship of his son, Sean Hartman, amounting to \$5,000,000. This claim arises from the profound emotional and psychological impact of Sean's untimely death on the Plaintiff, depriving him of the familial relationship and support he would have otherwise enjoyed.
- b. Damages for Psychological Injury: The Plaintiff claims \$5,000,000 in damages for psychological injury, including severe depression and post-traumatic stress disorder, resulting from the Defendants' conduct. This claim is supported by the Plaintiff's ongoing emotional distress and mental health challenges directly attributable to the Defendants' negligence and the resulting death of his son.
- c. Punitive, Exemplary, and/or Aggravated Damages: The Plaintiff claims punitive, exemplary, and/or aggravated damages in the amount of \$40,000,000 due to the Defendants' reckless and egregious conduct. The Defendants prioritized economic gain over safety, failed to conduct necessary safety studies, and misrepresented the vaccine's safety and efficacy, warranting punitive damages to deter similar future conduct.
- d. Special Damages: The Plaintiff claims special damages for lost income, medical expenses, and other pecuniary losses incurred as a result of the Defendants' conduct. The Plaintiff undertakes to provide full particulars of these damages prior to trial, including documentation of lost wages and medical bills.
- e. Pre-judgment interest in accordance with section 128 of the *Courts of Justice Act*, R.S.O. 1990, c. C.43, as amended.

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- f. Post-judgment interest in accordance with section 129 of the *Courts of Justice Act*, R.S.O. 1990, c. C.43, as amended.
- g. The costs of this proceeding on a substantial indemnity basis plus all applicable taxes.
- h. Such further and other relief as to this Honourable Court may seem just.

### **Introduction and Nature of the Claim**

2. The Plaintiff, Daniel Hartman, brings this action against the Defendants, Pfizer Canada ULC, Pfizer Inc., and BioNTech Manufacturing GmbH, alleging negligence, negligent misrepresentation, negligent design, negligent manufacturing, failure to warn, and wrongful death.

3. The Plaintiff contends that the Defendants breached their duty of care in the development, testing, manufacturing, marketing, and sale of the BNT162b2 vaccine, leading to the death of Sean Hartman, the Plaintiff's son, and causing substantial harm to the Plaintiff. The claim is grounded in breaches of statutory duties under the *Food and Drugs Act*, RSC 1985, c. F-27, and *the Food and Drug Regulations*, CRC, c. 870, alongside common law principles of negligence.

### **Definitions**

#### **The following terms are defined to clarify the technical and legal basis of this claim**

4. Absolute Risk Reduction ("ARR") is a statistical measure used to evaluate the effectiveness of an intervention in reducing the risk of an adverse event. ARR measures the absolute difference in event rates between the control group and the vaccinated group. The event rate is the percentage of individuals who develop the disease in each group.

5. Addisonian crisis, also known as an adrenal crisis or acute adrenal insufficiency, is a life-threatening medical emergency caused by a sudden and severe deficiency of the hormone cortisol, which is produced by the adrenal glands.

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6. Adrenal Glands are located above the kidneys and have two main regions:
  - a. Cortex: Produces steroid hormones such as cortisol (stress response and metabolism) and aldosterone (blood pressure regulation).
  - b. Medulla: Produces catecholamines like adrenaline and noradrenaline, critical for the body's "fight or flight" response.
7. Adverse Events Following Immunization ("AEFIs") are defined as any untoward medical occurrence that follows immunization, whether or not it is causally related to the vaccine.
8. Amyloid refers to a type of protein that can form insoluble, fibrous deposits in various organs and tissues, often linked to disease processes.
9. BNT162b2 is the scientific name for the Pfizer-BioNTech COVID-19 vaccine.
10. Contaminants are defined as any unwanted substances whether biological, chemical, or physical that are present in the vaccine.
11. Dense peri-portal chronic inflammation is a means substantial accumulation of chronic inflammatory cells in the portal and periportal regions.
12. Double-stranded RNA ("dsRNA") is a molecule made of two complementary RNA strands forming a double helix, acting as the genetic material for certain viruses called dsRNA viruses. It also triggers the body's innate immune system to defend against viral infections.
13. Endotoxins are toxic substances that are components of the outer membrane of Gram-negative bacteria. They are released when these bacteria die or are destroyed.
14. Fragmented mRNA ("fmRNA") consists of smaller segments derived from the cleavage or degradation of full-length messenger RNA molecules. This can occur naturally within cells as part of mRNA degradation processes, or it may be induced intentionally in laboratory settings, such as during RNA sequencing or analysis. Depending on the context, these fragments may retain

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partial functionality, potentially being translated into proteins or they may be non-functional and affect mRNA vaccines efficacy.

15. Hepatic fat saponification with early calcinosis as a post-mortem finding, is observed in autopsies as areas of necrotic liver tissue where fats have been transformed into soap-like substances (saponification) and early calcium salt deposition (calcinosis) has begun.

16. Immunohistochemical staining of the spike protein is a laboratory technique used to detect and visualize the presence of the spike protein in various organs.

17. Infectivity is the ability of a pathogen, such as a virus, bacterium, or other microorganism, to establish an infection in a host organism. It refers to the pathogen's capacity to enter the host, survive, and multiply within the host's cells or tissues.

18. Lipid Nanoparticles (“LNPs”) are nanoscale particles made of lipids, typically composed of ionizable cationic lipids, phospholipids, cholesterol, and polyethylene glycol (PEG)-lipids. These components work together to encapsulate and protect therapeutic agents, particularly nucleic acids like mRNA, from degradation. LNPs are designed to deliver their cargo into cells by facilitating cellular uptake and enabling endosomal escape, making them a key technology in applications such as mRNA vaccines and gene therapies.

19. Lymphocytic inflammation is defined as inflammation in which lymphocytes are the predominant inflammatory cells in the tissue infiltrate. This type of inflammation occurs when lymphocytes, a subset of white blood cells critical to the immune system, accumulate in a specific tissue, often as part of an immune response.

20. Messenger Ribonucleic Acid (“mRNA”) is a single-stranded RNA molecule that carries genetic instructions from DNA to the ribosomes, where it serves as a template for protein synthesis. In its natural biological role, mRNA is transcribed from DNA to encode the amino acid sequences of proteins. In therapeutic applications, synthetic mRNA is engineered to instruct cells

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to produce specific proteins—such as antigens for vaccines or therapeutic proteins for treating diseases.

21. Myocarditis is a medical condition characterized by inflammation of the heart muscle, specifically the myocardium, which is the muscular layer of the heart responsible for pumping blood. This inflammation can weaken the heart's ability to function effectively, potentially leading to irregular heart rhythms (arrhythmias) or reduced blood-pumping capacity.

22. Myocyte refers to a muscle cell, particularly in the context of cardiac or skeletal muscle. In conditions like myocarditis, inflammatory cells may surround or infiltrate myocytes, indicating inflammation of the heart muscle.

23. Nuclear Hypertrophy refers to the abnormal enlargement of the nucleus within a cell. In conditions like cardiac hypertrophy, where heart muscle cells (cardiac myocytes) increase in size due to increased workload or disease, nuclear hypertrophy is a characteristic feature of the affected cells.

24. Oncogenicity is the ability of an agent, such as a virus, chemical, or genetic mutation, to cause the development of tumors or cancer.

25. Peri-pancreatic fat necrosis refers to the death of adipose tissue surrounding the pancreas. This occurs when pancreatic enzymes leak into the peri-pancreatic region, digesting the fat and initiating a significant inflammatory response. This inflammation amplifies tissue damage and contributes to the formation of saponified fat, which appears as white, chalky deposits during autopsy.

26. Relative Risk Reduction (“RRR”) is statistical measures used to evaluate the effectiveness of an intervention in reducing the risk of an adverse event. RRR measures the relative reduction in risk due to the vaccine, expressed as a percentage of the control group's event rate.

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27. Residual DNA (“rDNA”) refers to trace amounts of deoxyribonucleic acid (DNA) fragments that originate from host cells—such as bacteria or mammalian cells—used in the production of biological products, like vaccines or biopharmaceuticals.

28. RNA Integrity (“RNAI”) refers to the degree to which an RNA (ribonucleic acid) sample remains intact and free from degradation.

29. Serious Adverse Events (“SAEs”) are any unfavorable medical occurrences in a patient or clinical trial participant that result in death, are life-threatening, require hospitalization or prolongation of existing hospitalization or result in persistent or significant disability/incapacity, or are congenital anomalies/birth defects.

30. Spike Protein is a structural feature of the SARS-CoV-2 virus, the virus responsible for COVID-19. These proteins extend from the surface of the virus, giving it a crown-like appearance, and are essential for its ability to infect human cells. The spike protein specifically binds to a receptor on human cells known as ACE2 (angiotensin-converting enzyme 2), enabling the virus to attach and enter the cell.

31. Subdivisible Particles (“SP”) refer to particulate materials or biological entities that can be further divided or broken down into smaller components through mechanical, chemical, or biological processes.

## **The Parties**

### **The Plaintiff**

32. The Plaintiff Daniel Hartman (“Daniel”), resides in the town of Midland in the Province of Ontario.

33. Daniel is the father of Sean Hartman (“Sean”), an end user of BNT162b2, who died on September 27, 2021, at the age of 17.

### **The Defendants**

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34. The Defendant, BioNTech Manufacturing GmbH (“BioNTech”), is a biotechnology company headquartered in Mainz, Germany, at An der Goldgrube 12, 55131. It is engaged in the business of vaccine manufacturing.

35. The Defendant, Pfizer Inc. (“Pfizer Inc.”), is a biopharmaceutical company engaged in the development, sale, and distribution of the Pfizer BioNTech COVID-19 vaccine, also known as Comirnaty, with its head office located at 66 Hudson Boulevard East, New York, NY 10001-2192, USA.

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

(collectively “the Defendants”)

37. The Defendants’ businesses are inextricably interwoven, and each acts the others’ agent for the purposes of the manufacture, marketing, and sale of BNT162b2 in Canada.

38. The Defendants acted pursuant to a common design to develop, test, manufacture, seek regulatory authorization, market, sell, and conduct post-market surveillance of BNT162b2 in Canada. These arrangements and activities included, by way of example:

- a. Pfizer Inc. and BioNTech formed a partnership encompassing design, development, production, testing and profit sharing for BNT162b2.
- b. Pfizer Inc. wholly owns Pfizer Canada ULC and exerts strategic and financial control over Pfizer Canada ULC’s operations, including directing regulatory submissions and distribution.

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- c. Pfizer Canada ULC, acting as an operational conduit for Pfizer Inc. and BioNTech, was responsible for securing regulatory approval for BNT162b2 from Health Canada.
- d. As of August of 2022, the Defendants had earned a combined worldwide revenue of \$98.3 billion from the sale of BNT162b2, demonstrating the scale of their operations and financial interest in the product.

## **Background**

### **Function of BNT162b2**

39. BNT162b2 uses mRNA encapsulated in LNPs to produce the SARS-CoV-2 spike protein. The Defendants designed LNPs to deliver mRNA systemically beyond the injection site, allegedly increasing efficacy.

40. LNPs shield the mRNA from enzymatic degradation, ensuring it reaches cells intact.

41. The mRNA is delivered into cells via LNPs, where it is translated into the spike protein, eliciting an immune response involving antibodies and T-cells.

### **Manufacturing of BNT162b2**

42. Manufacturing BNT162b2 involved two processes: Process 1 was used for small batch production for clinical trials ("Process 1"), and Process 2 was used for mass commercial production ("Process 2"). Each process resulted in different levels of mRNA integrity and contaminants.

43. Process 1 BNT162b2 consisted of: fmRNA between 17.2% to 21.9% of total mRNA; dsRNA of less than 80 to less than 120 pg per microgram of RNA; rDNA between 1 and less than 200 nanograms per milligram of RNA; Endotoxins and SP below detectable limits.

44. As a result, Process 1 BNT162b2 batches had an mRNA integrity of 78.1% to 82.8% and total DNA contamination of approximately 5.96%.

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45. Process 2 BNT162b2 consisted of: fmRNA of up to 45%; dsRNA of up to 240 pg per microgram of RNA; rDNA between 17 and 211 nanograms per milligram of RNA; Detectable Endotoxins and SP.

46. As a result, Process 2 BNT162b2 batches had an mRNA integrity of 55% and total DNA contamination of approximately 10.8%.

47. In or around April 2020, the Defendants completed initial small batch production of BNT162b2 through Process 1.

48. In or around October 2020, the Defendants began large-scale commercial production of BNT162b2 using Process 2.

#### **Clinical Trials**

49. In or around May 4, 2020, the Defendants began the Phase 1 clinical trial consisting of 36 participants using BNT162b2 (Process 1). No participants were under 18 years of age.

50. Pfizer Inc. and BioNTech began Phase 2/3 clinical trials utilizing an Adaptive Trial Design (“ATD”) and a Seamless Phase 2/3 Trial (“SPT”) for BNT162b2 (Process 1).

51. ATD is a flexible approach to clinical trials that permits modifications to the trial protocol based on interim data.

52. SPT is a clinical trial design that integrates phase 2 and phase 3 into a single, continuous protocol.

53. The Defendants utilized ATD and SPT to reduce normal clinical trial timelines for vaccine development from approximately 10 years to less than 1 year. ATD and SPT had never previously been used for development of a vaccine for a novel disease.

54. Phase 2 included 435 participants; Phase 2/3 included 43,548 participants, of whom 21,621 (including 138 aged 16-17) received Process 1 BNT162b2.

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55. In or around July 31, 2020, the Phase 1 clinical trial was concluded.

56. In or around November 1, 2020, the Defendants committed to regulators to study comparative efficacy and safety of BNT162b2 manufactured from Process 1 and 2. Consequently, 252 additional participants were enrolled in the Phase 3 clinical trial to meet the objective.

57. The commitment was not fulfilled as comparative trials were not conducted. The Defendants opted to rely on real-world data to facilitate the comparative trial.

58. On November 14, 2020, the Defendants produced clinical trial safety data for Process 1 BNT162b2, indicating that:

- a. 21,661 study participants had received at least 1 dose;
- b. 4,484 AEFIs were deemed related to BNT162b2 (20.7%);
- c. 240 SAEs were deemed related to BNT162b2 (1.1%); and
- d. 21 SAEs were determined to be life-threatening adverse events (0.1%).

### **The BNT162b2 Representations and Marketing Conduct**

59. On July 1, 2020, the Defendants issued a press release on Process 1 BNT162b2 efficacy, citing early Phase 1 data and claiming that 100% of participants had detectable neutralizing antibodies following two doses.

60. On August 19, 2020, the Defendants issued a press release on Process 1 BNT162b2 announcing a favourable safety and immunogenicity profile.

61. On or around November 9, 2020, the Defendants issued a press release claiming that, based on 94 cases of COVID-19, 8 in the vaccine group and 86 in the placebo group, BNT162b2 was 90% effective with no serious safety concerns noted. They did not specify that the data was from Process 1 and reported efficacy based on RRR, while the ARR was 0.36%.

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62. On November 18, 2020, the Defendants issued a press release on interim Phase 2 and Phase 3 clinical data. The Defendants claimed that based on 170 cases of COVID-19, 8 in the vaccine group and 162 in the placebo group, BNT162b2 was 95% effective. They did not specify that the data was from Process 1 and reported efficacy based on RRR, while the ARR was 0.70%.

63. In December 2020, the Defendants issued a press release on interim Phase 2 and Phase 3 clinical data, confirmed 95% efficacy with favorable safety results noting no serious safety concerns. They did not specify that the data was from Process 1 and reported efficacy based on RRR and did not provide the data upon which efficacy was calculated.

64. On April 1, 2021, the Defendants issued a press release on interim Phase 2 and Phase 3 clinical data. The Defendants stated that based on 927 confirmed symptomatic cases of COVID-19, 77 in the vaccine group and 850 in the placebo group, BNT162b2 was 91.3% effective. The Defendants stated no serious safety concerns were observed. They did not specify that the data was from Process 1 and reported efficacy based on RRR, while the ARR was 3.53%.

65. On May 10, 2021, the Defendants issued a press release stating that Phase 3 clinical trial results, which enrolled 2,260 participants aged 12 to 15 years, showed a vaccine efficacy of 100%. They did not specify that the data was from Process 1 and reported efficacy based on RRR and did not provide the data upon which efficacy was calculated.

66. In addition, at all material times, the Defendants engaged in a widespread advertising and promotion campaign for BNT162b2 including:

- a. Television inclusive of the “Science Will Win” campaign;
- b. Print in medical journals and major Canadian newspapers;
- c. Radio on nationwide stations; and
- d. Digital advertising on online platforms including social media (Facebook, Instagram, X, YouTube, TikTok) and websites.

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67. In addition, the Defendants' funded Canadian immunization advisory groups, which produced materials containing information that supported the Defendants efficacy and safety.

- a. As an example, Pfizer provided funding to the Canadian Immunization Research Network which conducted COVID-19 Vaccine Readiness research and developed materials to advise the Public Health Agency of Canada on the efficacy and safety of BNT162b2.

(collectively, the "Misrepresentations").

### **Regulatory Submissions**

68. On October 9, 2020, Health Canada received the Defendants' submission for approval of BNT162b2, produced and trialed using Process 1 batches, for use in Canada ("Initial Submission").

69. The Initial Submission included an express representation that a comparative analysis between Process 1 and Process 2 BNT162b2 would be added to the ongoing clinical trials. This representation was not fulfilled, and no comparative analysis was released.

70. On December 9, 2020, Health Canada, based on the Defendants' submissions, authorized the BNT162b2 for use in Canada, for individuals 16 years of age and older.

### **Contracts and Delivery**

71. On August 27, 2020, the Defendants executed a supply agreement with the Government of Canada, for up to 76 million doses of BNT162b2.

72. On December 13, 2020, the Defendants delivered the first 30,000 doses of BNT162b2 to Canada. The doses delivered were produced using Process 2.

73. On April 23, 2021, the Defendants executed another supply agreement with the Government of Canada, for up to 125 million doses (2022-2023) and an option for 60 million more in 2024.

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74. The Defendants delivered over 60 million Process 2 doses to Canada, including Sean's dose, without adequate testing.

#### **Sean Hartman-End User of BNT162b2**

75. On August 25, 2021, Sean, who was 17 years of age, attended the Simcoe Muskoka District Health Unit and was administered his first dose of BNT162b2. Sean received a dose from Process 2 (Lot FD7204).

76. At all material times prior to receiving the BNT162b2, Sean was in excellent health.

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

78. On the morning of September 27, 2021, 33 days after receiving BNT162b2, Sean was found deceased in his bedroom by his mother.

79. The post-mortem examination of Sean revealed: Lymphocytic inflammation around myocytes; Nuclear hypertrophy; Amyloid deposits; Hepatic fat saponification with early calcinosis in the liver; Dense peri-portal chronic inflammation of the liver; and Spike protein in the adrenal glands.

#### **Negligence**

##### **Background Facts**

80. At all relevant times, the Defendants owed a duty of care to end users of BNT162b2 to exercise reasonable care in the development, testing, manufacturing, marketing, representation, and sale of BNT162b2.

81. The scope of the Defendants' duty of care to end users of BNT162b2 was further informed by statutory requirements imposed by the *Food and Drugs Act*, RSC 1985, c. F-27 ("FDA"), and the *Food and Drug Regulations*, CRC, c. 870 (the "FDR"), including:

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- a. The prohibition in s. 9(1) of the FDA against labelling, packaging, selling or advertising drugs in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety;
- b. The requirements imposed by s. 21.71 of the FDA to make publicly available information concerning clinical trials or investigational tests of drugs;
- c. The requirement imposed by s. C.01.012 of the FDR to conduct all necessary investigations before making representations regarding the site, rate or extent of release to the body of a medicinal ingredient of a drug, or the availability to the body of a medicinal ingredient of the drug;
- d. The requirements imposed by s. C.01.018(1) of the FDR to prepare annual summary reports of all information relating to adverse drug reactions, and to report whether there has been a significant change in what is known about the risks and benefits of the drug; and
- e. The requirements imposed by s. C.02.020(1) of the FDR to maintain records of product testing and completion thereof.

### **Negligent Misrepresentation**

82. The Defendants made misrepresentations, detailed in paragraphs 59 to 67, with knowledge or reckless disregard for the truth.

83. At all material times, the Defendants knew or ought to have known that:

- a. Advertising, promotion and representation regarding efficacy and safety were based upon limited clinical data and omitted material facts regarding the benefits of BNT162b2, while understating the serious risks particularized in paragraph 92,94;

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- b. For instance, in their November 9, 2020, press release, the Defendants claimed that BNT162b2 was 'more than 90% effective' based on 94 cases of COVID-19, with 8 in the vaccine group and 86 in the placebo group. However, this claim was misleading because it was based on clinical trial data from Process 1 BNT162b2, which had lower levels of contaminants and higher mRNA integrity compared to the commercially distributed Process 2. The Defendants failed to disclose that the vaccine being distributed to the public, including Sean Hartman, was manufactured using Process 2, which had not been directly tested in the clinical trials. This omission created a false impression of the vaccine's safety and efficacy for the version actually received by end users, leading them to believe that the distributed vaccine carried the same low risk profile as the trialed version
- c. Clinical trials were conducted with ATD and SST were not reflective of robust scientific study of efficacy and safety for a vaccine making it virtually impossible to assess long-term or short-term safety risks for widespread use;
- d. Clinical trials were conducted with ATD and SST lead to incomparable and incomplete efficacy and safety data rendering comparisons with vaccines produced through the normal process impossible;
- e. Healthcare professionals and end users in Canada were influenced by marketing conduct and representations of efficacy and safety for BNT162b2; and
- f. Healthcare professionals and end users in Canada were influenced by promotional material produced by the Defendants in the United States.

84. The Defendants funded Canadian immunization advisory groups, which produced materials endorsing the safety and efficacy of BNT162b2. This funding created a conflict of interest, compromising the objectivity of these groups and the public health messaging they disseminated. The Defendants' financial influence led to an overly positive portrayal of the vaccine, which concealed its risks and misled the public, including Sean and his family. As a result,

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Sean and others were deprived of impartial information necessary to make informed decisions about receiving the vaccine.

85. As a result of the Defendants' successful marketing activities and promotional campaign, the use of BNT162b2 became widespread and the Defendants made unprecedented profit.

86. Sean relied on these Misrepresentations, as conveyed through public health messaging and the Defendants' widespread advertising campaign, in deciding to receive BNT162b2.

### **Negligent Design**

87. The Defendants negligently designed BNT162b2 by failing to adhere to industry standards for LNP design in mRNA vaccines.

88. In the field of mRNA vaccine development, LNPs are typically engineered to deliver mRNA to specific target cells, such as immune cells near the injection site, to minimize systemic exposure and reduce the risk of adverse effects. This localized delivery approach is preferred to enhance safety, as it limits the distribution of mRNA and potential contaminants to unintended organs and tissues.

89. The Defendants designed the LNPs in BNT162b2 to allow systemic delivery, which increased the risk of the mRNA and contaminants reaching critical organs, including the heart, liver, and adrenal glands. This design choice deviated from accepted practices in the industry and significantly elevated the risk of severe adverse reactions.

90. The Defendants created a product that was not reasonably safe for use. In particular, at all material times, the Defendants knew or ought to have known that:

- a. design of BNT162b2 created a significant risk harm particularized in paragraphs 92, 94;
- b. It was possible to design the LNPs to remain at the injection site, reducing the risk of systemic adverse effects;

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- c. It was possible to design BNT162b2 to maintain its efficacy while significantly reducing the risk of adverse health consequences;
- d. it was possible to design BNT162b2 as a vaccine which was at least as effective as vaccines with no or a highly reduced risk of adverse health consequences; and
- e. it was possible to conduct clinical trials without ATD and STP.

### **Negligent Manufacturing**

91. The Defendants negligently manufactured BNT162b2 by failing to exercise reasonable care or adhere to drug manufacturing and industry standards.

92. Industry standards for vaccine manufacturing, as outlined by regulatory bodies such as the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA), set strict limits on contaminants to ensure product safety. For example:

- a. Residual DNA (rDNA): The FDA recommends that rDNA in vaccines should not exceed 10 ng per dose. However, Process 2 BNT162b2 contained rDNA levels between 17 and 211 ng per mg of RNA, far exceeding this threshold.
- b. Endotoxins: Acceptable endotoxin levels are typically below 5 Endotoxin Units (EU) per kg of body weight per hour. In contrast, Process 2 BNT162b2 contained detectable levels of endotoxins, posing a risk of systemic inflammation.
- c. Double-stranded RNA (dsRNA): While specific thresholds vary, dsRNA is known to trigger proinflammatory responses, and its presence in vaccines is minimized to avoid immune overactivation. Process 2 BNT162b2 contained up to 240 pg of dsRNA per microgram of RNA, a level that heightened the risk of adverse immune reactions.

93. In November 2020, EMA identified significant discrepancies between Process 1 and Process 2 BNT162b2 batches prior to the vaccine's authorization. Process 1, used in clinical trials,

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maintained 78% mRNA integrity, whereas Process 2, scaled for commercial distribution, averaged only 55% integrity, with increased levels of truncated mRNA species. The EMA warned that these truncated species could result in incomplete spike proteins, potentially triggering unpredictable immune responses or safety issues. Despite these concerns, the Defendants failed to conduct adequate comparability studies, prioritizing rapid rollout over the safety of end users like Sean Hartman.

94. Further particulars of the Defendants' breach of duty care in the manufacturing of BNT162b2 include:

- a. Increased fmRNA, compounded by the LNP design, elevated BNT162b2 safety risks as Spike Protein were systemically delivered causing unexpected immune reactions, such as inflammation, adrenal infection, or autoimmunity, while reducing overall efficacy;
- b. Increased dsRNA elevated BNT162b2 safety risks of proinflammatory responses, cytokine release, lymphocyte recruitment, and chronic immune activation. This was amplified by LNPs delivering dsRNA to immune cells or organs, resulting in potential peri-portal liver and systemic inflammation, myocarditis, pericarditis or autoimmunity;
- c. Increased rDNA elevated BNT162b2 safety risks of disrupted cellular regulation causing abnormal cell growth. This was amplified by LNPs delivering rDNA into cells, resulting in potential persistent Spike Protein production and oncogenesis, resulting in potential Nuclear hypertrophy or cancer;
- d. Introduction of Endotoxins elevated BNT162b2 safety risks of systemic inflammation. This was amplified by LNPs delivering Endotoxin to immune cells, resulting in potential liver fat necrosis and calcification, lymphocytic and myocyte inflammation and septic shock; and

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- e. Introduction of SPs elevated BNT162b2 safety risks of inducing local or systemic inflammation, with toxicological risks. This was amplified by LNPs delivering SP's systemically altering their distribution and inflammatory potential.

95. If the Defendants had exercised the standard of care expected of them, they would not have introduced BNT162b2 into the market in Canada in December of 2020.

96. A reasonable manufacturer, when faced with the information about which the Defendants knew or ought to have known at the time that BNT162b2 was introduced into the marketplace, would not have introduced BNT162b2 into the marketplace. Alternatively, a reasonable drug manufacturer when faced with the results of the BNT162b2 clinical trials and the substantially increased risk of harm through Process 2, would have taken measures to remedy defects prior to release, including manufacturing process enhancements and further safety trials.

#### **Duty and Failure to Warn**

97. At the time of Sean Hartman's vaccination, the product information and public health messaging for BNT162b2 listed only mild and common side effects, such as pain at the injection site, fatigue, and headache. These warnings were based on clinical trial data from Process 1 BNT162b2 and failed to account for the increased risks associated with Process 2, including the potential for systemic inflammation, adrenal insufficiency, myocarditis, and liver damage due to higher contaminant levels.

98. The Defendants did not update the warnings or provide additional disclosures to reflect the differences between the trialed and distributed versions of the vaccine. This omission deprived Sean Hartman and his family of critical information necessary to make an informed decision about receiving the vaccine, directly contributing to the harm he suffered.

99. Moreover, by the time of Sean Hartman's vaccination, scientific evidence had emerged showing a markedly higher risk of myocarditis in young males. Data available to the Defendants documented an incidence of 105.9 myocarditis cases per million doses of BNT162b2 in males aged 16-17, significantly exceeding rates in older populations. Despite this clear signal of risk, the

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Defendants failed to update their warnings or provide targeted guidance to this vulnerable group, leaving Sean Hartman and his family uninformed of the specific danger he faced.

100. Given the novel and expedited nature of BNT162b2's development, which relied on ATD and SPT protocols, the Defendants were under a heightened duty to disclose all known and potential risks, which they failed to do, associated with the vaccine. The compressed timeline and use of unconventional trial methods—unprecedented for a vaccine intended for widespread use—required the Defendants to be transparent about the limitations of the clinical data (based on Process 1) and the untested differences in Process 2. Despite this heightened duty, the Defendants failed to provide adequate warnings or disclosures, thereby breaching their obligation to end users like Sean.

101. A reasonable drug manufacturer, when faced with the information about which the Defendants knew or ought to have known regarding the risks of BNT162b2 would have taken all reasonable steps to warn physicians and end users of those risks including warning of known or foreseeable risks prior to end user taking the vaccine or warn of risks as they became known.

102. Further a reasonable drug manufacture, when faced with the information about which the Defendants knew or ought to have known regarding BNT162b2, would have warned physicians and end users of the lack of clinical data, inability to assess short-term and long-term safety, inclusion of the end user in a comparative data analysis, and the significant risk posed as a result.

103. The full extent of the risks of adverse side effects attendant upon BNT162b2 use was and is in the Defendants' exclusive knowledge and control.

#### **Breach of Duties**

104. The Defendants were responsible for ensuring the safety of BNT162b2 in its development, testing, manufacturing, marketing, and sale, and failed to take reasonable steps to do so, as particularized above.

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105. The Defendants breached duties of care owed to end users in the design, development, manufacturing, marketing, sale, and warnings of BNT162b2 in Canada and as particularized below:

- a. Duty of care in marketing: paragraphs 82-86;
- b. Duty of care in design: paragraphs 87-90;
- c. Duty of care in manufacturing: paragraphs 91-96;
- d. Duty to warn: paragraphs 97-103.

106. The Defendants breached their statutory duties under s. 9(1) of the *Food and Drugs Act*, RSC 1985, c. F-27, which prohibits the labeling, packaging, selling, or advertising of drugs in a manner that is false, misleading, or deceptive. The Defendants' misrepresentations about the safety and efficacy of BNT162b2, as particularized in paragraphs 57-67, violated this provision by creating an erroneous impression of the vaccine's merits and safety. These statutory breaches directly influenced Sean's decision to receive the vaccine, contributing to the harm he suffered.

107. The Defendants committed to regulators that they would conduct comparative studies to assess the efficacy and safety of BNT162b2 produced via Process 1 (used in clinical trials) and Process 2 (used for commercial distribution). Despite this commitment, the Defendants failed to perform these studies, opting instead to rely on real-world data. This failure constitutes a breach of the Defendants' duty of care to regulators, healthcare providers, and end users, including Sean. By not conducting the promised comparative analysis, the Defendants withheld critical information about the differences in safety and efficacy between the trialed and distributed versions of BNT162b2, thereby concealing potential risks inherent in Process 2. This omission directly contributed to the harm suffered by Sean and other end users.

108. The Defendants breached the legal standard for informed consent by failing to adequately disclose the risks associated with BNT162b2, particularly the differences between Process 1 and Process 2. The lack of comparative safety data and the omission of material risk information

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deprived Sean Hartman of the opportunity to make an informed decision about receiving the vaccine.

### **Wrongful Death**

109. The post-mortem examination of Sean Hartman revealed several critical findings that directly correspond to the defects in BNT162b2's design and manufacturing:

110. Lymphocytic inflammation around myocytes and nuclear hypertrophy: These findings are indicative of myocarditis, a condition characterized by inflammation of the heart muscle. Myocarditis is a known risk associated with mRNA vaccines, particularly in young males, and is linked to the systemic delivery of mRNA and contaminants via LNPs.

111. Spike protein in the adrenal glands: The presence of spike protein in the adrenal glands demonstrates that the LNPs delivered the mRNA systemically, leading to adrenal insufficiency. This condition impaired Sean's ability to regulate blood pressure and respond to stress, contributing to his multi-organ failure.

112. Dense peri-portal chronic inflammation and hepatic fat saponification with early calcinosis: These findings point to severe liver damage, likely exacerbated by the high levels of dsRNA, endotoxins, and other contaminants in Process 2 BNT162b2. The liver's role in filtering toxins and regulating metabolism makes it particularly vulnerable to systemic contaminants.

113. These post-mortem findings establish a clear causal link between the defects in BNT162b2 and Sean Hartman's death due to catastrophic multi-organ failure. The Defendants' failure to address these risks in their design, manufacturing, marketing, and warnings were the foreseeable and proximate causes of this tragic outcome.

114. Sean Hartman, who was 17 years old at the time of his vaccination, did not provide informed consent to receive BNT162b2 due to the Defendants' inadequate disclosure of risks, particularly those associated with Process 2's differences from the trialed version. The Defendants failed to ensure that Sean (or his guardians) were sufficiently informed of the

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potential dangers, including the lack of comparative safety data between Process 1 and Process 2. As a result, Sean's decision to receive the vaccine was not voluntary or knowledgeable, depriving him of the opportunity to make an informed choice about his health and safety.

115. The Defendants' conduct in the design, development, testing, manufacturing, distribution, marketing, and sale of BNT162b2, was high-handed, outrageous, reckless, wanton, entirely without care, deliberate, callous, willful, and showed intentional disregard for Sean's safety, indifference to the consequences, and negligent.

116. The Defendants' conduct was not only negligent but also driven by economic considerations, as evidenced by their decision to prioritize rapid production and distribution of BNT162b2 over thorough safety testing and disclosure of risks. The actions by the Defendants demonstrate a willful disregard for public safety, including ignoring or downplaying risks of adverse events from BNT162b2. This reckless and profit-driven behavior warrants punitive damages to deter similar conduct in the future.

117. Daniel pleads that as a result of the untimely death of Sean, he has lost the guidance, care and companionship that he might have otherwise enjoyed if Sean had continued to live, and advances a claim under the *Family Law Act*, R.S.O. 1990, c. F.3, as amended.

118. Additionally, the untimely death of Sean has caused Daniel extraordinary emotional shock and mental anguish, resulting in a severe depression and post-traumatic stress disorder, and he continues to suffer physically and emotionally.

119. Daniel has lost income, expended monies, and required medical care. In addition to his non-pecuniary claims, he is entitled to compensation for the value of his pecuniary losses. Daniel undertakes to provide the full particulars of the special damages claimed by him, including lost income and medical expenses, prior to the trial of this action.

**Particulars are not Exhaustive**

120. The above-mentioned particulars of Defendants' conduct are not meant to be exhaustive.

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121. Daniel expressly reserves the right to provide further particulars of the Defendants' conduct as they become known.

**Conclusion**

122. Daniel claims that this action can be served outside of the Province of Ontario pursuant to Ontario Court Rules 17.02(g)(h).

123. In addition to the foregoing, Daniel relies upon:

- a. *Family Law Act*, R.S.O. 1990, c. F.3;
- b. *Food and Drugs Act*, RSC 1985, c. F-27;
- c. *Food and Drug Regulations*, CRC, c. 870;
- d. *Negligence Act*. R.S.O. 1990, c. N.1;
- e. Section 128 of the *Courts of Justice Act*, R.S.O. 1990, c. C.43, as amended.
- f. section 129 of the *Courts of Justice Act*, R.S.O. 1990, c. C.43, as amended,

124. Daniel therefore claims 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.  
Defendants

Court File No. CV-23-0000114-0000

**ONTARIO  
SUPERIOR COURT OF JUSTICE**

PROCEEDING COMMENCED AT  
SIMCOE

**STATEMENT OF CLAIM**

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