S-188127

NO. .....
VANCOUVER REGISTRY

IN THE SUPREME COURT OF BRITISH COLUMBIA

BETWEEN:

LILIA ZAHARIEVA and MELISSA VERLEG

PLAINTIFFS

AND:

THE CANADIAN AGENCY FOR DRUGS AND TECHNOLOGIES IN HEALTH, THE PAN-CANADIAN PHARMACEUTICAL ALLIANCE, HER MAJESTY THE QUEEN IN RIGHT OF THE PROVINCE OF BRITISH COLUMBIA, THE HONOURABLE ADRIAN DIX, MINISTER OF HEALTH FOR THE PROVINCE OF BRITISH COLUMBIA, STEPHEN BROWN, DEPUTY MINISTER OF HEALTH FOR THE PROVINCE OF BRITISH COLUMBIA, MITCH MONEO, HER MAJESTY THE QUEEN IN RIGHT OF CANADA, THE HONORABLE GINETTE PETITPAS TAYLOR, MINISTER OF HEALTH FOR CANADA, SIMON KENN EDY, DEPUTY MINISTER OF HEALTH FOR CANADA, JANE DOE AND JOHN DOE

DEFENDANTS

Brought under the *Class Proceedings Act,* R.S.B.C. 1996, c. 50

NOTICE OF CIVIL CLAIM

This action has been started by the plaintiffs for the relief set out in Part 2 below.

If you intend to respond to this action, you or your lawyer must

(a) file a response to civil claim in Form 2 in the above-named registry of this court within the time for response to civil claim described below, and

(b) serve a copy of the filed response to civil claim on the plaintiffs.

If you intend to make a counterclaim, you or your lawyer must

(a) file a response to civil claim in Form 2 and a counterclaim in Form 3 in the above-named registry of this court within the time for response to civil claim described below, and

(b) serve a copy of the filed response to civil claim and counterclaim on the plaintiff and on any new parties named in the counterclaim.

JUDGMENT MAY BE PRONOUNCED AGAINST YOU IF YOU FAIL to file the response to civil claim within the time for response to civil claim described below.

Time for response to civil claim

A response to civil claim must be filed and served on the plaintiffs,

(a) if you were served with the notice of civil claim anywhere in Canada, within 21 days after that service,

(b) if you were served with the notice of civil claim anywhere in the United States of America, within 35 days after that service,

(c) if you were served with the notice of civil claim anywhere else, within 49 days after that service, or

(d) if the time for response to civil claim has been set by order of the court, within that time.

Claim of the Plaintiffs

Part 1: STATEMENT OF FACTS

The Parties

1. The first proposed representative Plaintiff, Lilia Zaharieva (hereinafter referred to as "Lilia") is a 31 year old woman living with Cystic Fibrosis "CF". She currently resides in the City of Victoria in the province of British Columbia. Lilia has the specific cystic fibrosis gene mutation referred to as DD508. Her treating physician has prescribed the biologic drug therapy whose trade name is Orkambi. Lilia had been receiving the drug Orkambi through her private insurance coverage as a student at the University of Victoria until

September 2017, at which time she lost that coverage due to changes in the University's drug coverage for students. Ultimately, the manufacturer of the drug Orkambi, Vertex Pharmaceuticals, decided to provide the drug to her on a compassionate use basis reviewable every 90 days. This is only a temporary solution. Her only recourse to this therapy is ultimately by access to the provincial formulary of British Columbia.

2. The second proposed representative Plaintiff, Melissa Verleg (hereinafter referred to as "Melissa"), is a 34 year old mother of two children aged seven and nine. She is married to Bert Verleg. She resides in the City of Vernon in the Province of British Columbia. She also suffers from the specific CF gene mutation known as DD508. She previously had access to Orkambi through her husband's employer benefit program. Her husband's benefit plan was subsequently modified, which resulted in Melissa losing access to the life sustaining drug, Orkambi. Melissa has experienced declining health since she lost access to Orkambi.

3. The First Defendant, The Canadian Agency for Drugs and Technologies in Health "CADTH", is a not-for-profit organization created by provincial and federal governments to provide provincial decision-makers with information pertaining to drugs and medical devices. CADTH has its headquarters in Ottawa, Ontario, and also maintains an office in Toronto. Its membership is comprised of all Deputy Ministers of Health for the federal, provincial and territorial governments in Canada. CADTH Board of Directors are appointed by the member Deputy Minister's and include a majority of Assistant Deputy Minister's responsible for purchasing drugs for the respective government drug plans. The service address for CADTH being 865 Carling Avenue Ottawa, Ontario, K1S 5S8.

4. The Second Defendant, The Pan-Canadian Pharmaceutical Alliance "pCPA", is an arrangement of federal, provincial and territorial health ministries, which report to the Council of the Federation, an organization run by the Premiers of all the Provinces. The pCPA acts as the negotiating body on behalf of the provincial and territorial governments represented on CADTH. pCPA has its headquarters in Toronto, Ontario at the office of the Ministry of Health and Long Term Care for the Province of Ontario. All of its employees are on secondment from the Ministry of Health and Long Term Care. The service address for pCPA being 900 Bay Street Toronto, Ontario, M7A 2E1.

5. The Third Defendant is the British Columbia's Ministry of Health responsible for administering that province's public access to prescription drugs with the address for service as PO BOX 9050, Stn Provincial Government, Victoria, British Columbia, V8W 9E2.

6. The Fourth Defendant, The Honourable Adrian Dix, is the current Minister of Health for the Province of British Columbia with the address for service as P.O. Box 9639, Stn Provincial Government, Victoria BC, V8W 9P1.

7. The Fifth Defendant, Stephen Brown, is the Deputy Minister of Health for the Province of British Columbia with the address of service as PO Box 9639, Stn. Provincial Government, Victoria British Columbia, V8W 9P1.

8. The Sixth Defendant, Mitch Moneo, is the British Columbia CADTH representative. He sits on the Board of Directors of CADTH and is the Assistant Deputy Minister responsible for British Columbia's Pharmaceutical Services Division. The address for service being P.O. Box 9652, Stn Prov. Govt., Victoria, BC V8W 9P4.

9. The Seventh Defendant is the Federal Government of Canada who has representation at CADTH. The address for service is Brooke Claxton Building, Tunney's Pasture, Postal Locator: 0906C, Ottawa, ON K1A 0K9.

10. The Eighth Defendant, The Honourable Ginette Petitpas Taylor, is the Minister of Health for Canada. The address for service being, Brooke Claxton Building, Tunney's Pasture, Postal Locator: 0906C, Ottawa, ON K1A 0K9.

11. The Ninth Defendant, Simon Kennedy, is the Deputy Minister of Health for Canada. In this capacity he sits on the board of CADTH and his department provides the vast majority of funding to CADTH on an annual basis. The address for service being Deputy Minister's Office, Health Canada, Brooke Claxton Building, Tunney's Pasture, Postal Locator: 0906C, Ottawa, Ontario K1A 0K9.

The Class

12. The Plaintiffs bring this action under the *Class Proceedings Act,* 1996 on their own behalf and on behalf of the following class:

> **Class Members:** The subset of Cystic Fibrosis patients who have a DD508 gene mutation and respond positively to the drug therapy known as Orkambi, which normalizes the genetic defect in DD508 cystic fibrosis patients.

Background

Creation of CADTH

13. In or about 1989, CADTH was created by the federal, provincial and territorial governments as a federal not-for-profit corporation. Apart from its constituting documents as required by the *Canada Not-for-profit Corporations Act*, S.C. 2009, c.23, CADTH has no statutory foundation and has no transparency related to any of the decisions taken or the recommendations it makes to provincial health Ministry's specifically related to making determinations regarding whether to fund a new medication in Canada.

14. CADTH is governed by a 13-member Board of Directors, composed of a chair, a regional distribution of federal, provincial and territorial government representatives, specifically, the Assistant Deputy Minister responsible for listing medications on the public formulary, an academic, and two members of the public. Directors are elected by the Deputy Ministers of Health for the represented federal provincial and territorial governments.

15. The Common Drug Expert Committee ("CDEC") provides a recommendation to CADTH members, who are exclusively the Deputy Ministers of Health for the federal, provincial and territorial governments, on whether to negotiate a price for listing a specific drug on the Provincial drug formularies. If the recommendation is negative, then the process ends.

16. If a positive recommendation is given by the CDEC, then negotiations may occur to determine a price with the relevant pharmaceutical company through the pCPA.

17. CADTH conducts assessments of drug review processes for prescription medication known as the Common Drug Review ("CDR"). This review process is overseen by a CADTH committee known as the CDEC. The CDEC review processes and proceedings are not open to the public, nor are proceedings published. Draft reports of the CDEC are only shared with the manufacturer. Neither patients nor their physicians have access to the review processes and proceedings, and can only comment on the CDR's summary of the written submission that is then included in the draft recommendation report to the drug company.

18. If a positive recommendation is received by the CDEC, the pCPA may then negotiate to determine a reduced price on behalf of all CADTH federal, provincial and territorial member governments with the drug manufacturer. The PCPA observes CDEC meetings and has access to information held by CDEC and their internal and third party stakeholders.

19. The recommendations in CDEC reports are opaque, non-transparent, and non-reviewable by any appellate or other body. Despite this, the pCPA relies primarily on a positive CDR report to secure the pCPA a negotiating mandate with the manufacturer of a given drug therapy.

20. There is no meaningful review or appeal from a CDR decision to assess, or allow for, patient-level health impacts.

21. To date, the provincial governments have continually allowed CADTH to direct and establish priorities through the creation of a system of arbitrary guidelines for the pCPA's

negotiating mandate, leading to the purchase of prescription medications by member provincial and territorial jurisdictions.

22. These arbitrary guidelines are not subject to review by any government agency, with the effect that provincial and territorial health policy has been delegated to a process beginning with the CDEC at CADTH and ending, only in a few instances, with the negotiated outcomes delivered by the pCPA.

23. This process does not defer to Health Canada drug approval systems already in place except as a starting point for potential drug selection.

24. As a result of the CADTH-pCPA policymaking process, the Provincial Government Defendants have not purchased a life sustaining drug known as Orkambi, which treats CF patients through their respective public health insurance plans.

Orkambi and Cystic Fibrosis

25. CF is the most common fatal genetic disease affecting Canadian children and young adults. At present, there is no cure for CF. CF causes various negative effects on the body, but mainly affects the digestive system and lungs. The degree of severity of CF differs from person to person, however, the persistence and ongoing infection in the lungs, which results in destruction of lungs and loss of lung function, eventually leads to death of CF patients.

26. The pharmaceutical manufacturer, Vertex Pharmaceuticals Inc. ("Vertex") has introduced a life sustaining treatment for CF called Orkambi that treats CF patients with the DD508 gene mutation by targeting the underlying cause of their particular type of CF.

CF patients have a defective gene, which then expresses a defective protein commonly known as transmembrane conductance regulator ("CFTR Protein"). In CF an abnormal CFTR protein structure, leads to the creation of thick mucus in the lungs and other parts of the body, dramatically shortening life span and causing life threatening deterioration of organs, particularly the lungs.

27. Orkambi does not treat the side effects of CF, but directly corrects the malfunctioning of the CFTR protein for CF patients with the DD508 gene mutation. Orkambi has been approved for use and made available on the public formulary in Germany, the United States, Sweden, Austria, Luxembourg, Denmark, Ireland and Scotland. Currently, other industrialized countries are undergoing price negotiations to ensure that Orkambi is made available to the public.

28. Health Canada has approved Orkambi and recognized it as beneficial for CF patients with the DD508 gene mutation. Following the Health Canada approval in June 2016 the drug was made available and listed on all private insurance open formularies in Canada.

CADTH/CDR Decision to Deny Funding of Orkambi

29. In or around January 2016, Vertex, submitted a request to CADTH that Orkambi be approved by the CDR of CADTH, which is the mandated government authority whose approval is required in order for a drug to be considered for listing on a government drug plan.

30. The first CDR under CADTH was released in mid-2016 and was negative. Specifically, and contrary to Health Canada's recommendation, the CDR stated that the drug was not medically beneficial. This finding is inconsistent with other Health Technology reviews across the industrialized world, all who found that Orkambi was medically beneficial for the treatment of the underlying genetic defect of CF.

31. In or around October 2016, Vertex resubmitted Orkambi to CDR for reconsideration. This request for reconsideration was also denied on the basis that Orkambi is medically ineffective.

32. CADTH, and specifically the CDR as an instrument of government policy, its structure, decision making and review processes in determining access to life sustaining medications are contrary to the principles of fundamental justice. Specifically, CADTH and CDR have, *inter alia*, failed to:

i. be open and transparent with respect to the evidence that is reviewed during the decision making process;

ii. disclose the evidence on which a decision is based prior to rendering the decision;

iii. adequately consider input from patient groups and treating physicians with subject matter expertise in CF;

iv. to consult with CF treating physicians and individuals with relevant subject matter expertise; and

v. disclose to the public, all or sufficient material parts of the evidence on which a decision of the CDR is based.

33. There have been clear recommendations from Health Canada and evidence-based research demonstrating that Orkambi is a medically necessary treatment for patients suffering from DD508, a specific genetic mutation that makes up the vast majority of CF patients.

34. Conversely, as a result of CADTH's arbitrary decision-making process, another CF drug, Kalydeco, which treats nine different CF gene mutations, was recommended by CADTH to have the pCPA negotiate a price with the manufacturer, despite the fact that Health Canada and CADTH acknowledged that Kalydeco treated another seven CF gene mutations equally well. Ultimately, Kalydeco has been listed for only one gene mutation D551 on the formulary of most provinces in 2014, leaving the other CF patients with any one of the nine gene mutations arbitrarily and inexplicably without access to Kalydeco.

Part 2: RELIEF SOUGHT

35. The Plaintiffs on behalf of themselves and the other Class Members claim against the Defendants for:

(a) An order pursuant to the *Class Proceedings Act*, R.S.B.C. 1996, c. 30, certifying this action as a class proceeding and appointing Lilia Zaharieva and Melissa Verleg as representative plaintiffs for the class;

(b) A declaratory order pursuant to the *Supreme Court Act*, R.S.B.C. 1996, c.443, to the effect that the current system of drug approvals and

assessment involving Canadian Agency for Drugs and Technologies in Health ("CADTH") and the pan-Canadian Pharmaceutical Alliance ("pCPA"), as well as the decision not to fund the drug Orkambi for Cystic Fibrosis treatment infringes the *Charter of Rights and Freedoms* of certain Cystic Fibrosis patients with the specific gene mutation known as DD508 of the cystic fibrosis gene;

(c) A declaratory order pursuant to the *Supreme Court Act*, 1996, to the effect that the current system of drug approvals and assessment constitutes an improper delegation of law-making power by the provincial government of British Columbia;

(d) A declaration that the Defendant infringed the Class Members' rights and freedoms guaranteed under section 7 and 15 of the *Canadian Charter of Rights and Freedoms* ("the *Charter*");

(e) A mandatory injunction compelling the government of British Columbia, to negotiate in good faith with the manufacturer Vertex Pharmaceuticals for the purchase of the drug Orkambi to ensure its availability to clinically eligible Cystic Fibrosis patients;

(f) A mandatory injunction compelling the Defendants to institute a more transparent, objective and evidence-based system of drug approvals and procurement;

(g) A mandatory injunction compelling the Defendants to proactively disclose all dealings and information received from or exchanged with non-government entities, including the decision-making roles of other provincial or territorial Ministries of Health, CADTH, and/or the pCPA in carrying out procurement activities related to Cystic Fibrosis medication;

(h) General Damages in the sum of $60,000,000.00;

(i) Punitive and exemplary damages in the sum of $1,000,000.00;

(j) Damages pursuant to section 24(1) of the *Charter*;

(k) Prejudgment interest in accordance with Section 1 of the *Court Order Interest Act*, R.S.B.C. 1996, c.79,as amended;

(l) Party and party costs of this proceeding under Scale C of Appendix B to the Supreme Court Civil Rules, B.C. Reg. 168/2009 pursuant to the *Court Rules Act,* R.S.B.C. 1996 c.80, plus all applicable taxes; and

(m) Such further and other Relief as to this Honourable Court may deem just.

Part 3: LEGAL BASIS

CADTH AND pCPA Attract Charter Obligations

36. The Plaintiffs submit that both CADTH and pCPA exercise governmental functions and are therefore both governmental in nature on the basis that:

(a) The respective formation and mandates of both CADTH and pCPA were created by provincial government actors;

(b) The institution of the CADTH-pCPA policymaking process as well as the working relationship between CADTH and pCPA in reviewing and guiding negotiations in purchasing Orkambi and Kalydeco are decisions of government in relation to provincial healthcare expenditures and individual Canadians as end-users of provincial healthcare systems;

(c) The composition of CADTH's governance structure, as well as the funding directed by the provincial government Defendants to both CADTH and pCPA amount to governmental action;

(d) The provincial governments exercise routine and regular control of CADTH through their deputy ministers who are the members of CADTH and with the assistant deputy ministers of Health who constitute a majority of the Board of Directors of CADTH

(e) Further, the ministries of health have delegated their authority to the pCPA, to negotiate with pharmaceutical companies on their behalf;

(f) CADTH and pCPA engage in activities, namely, decision making with respect to funding of drugs, which are activities that are ascribed to the government;

(g) The activities of CADTH and pCPA are defined by government; and

(h) CADTH and pCPA are the vehicles through which government achieves its objectives.

Section 7 of the Charter

37. Section 7 of the *Charter* provides that:

> Everyone has the right to life, liberty and security of the person and the right not to be deprived thereof except in accordance with the principles of fundamental justice.

38. Pursuant to Section 7, every individual possesses constitutionally protected rights to life and security of the person. The Defendants' lack of transparency and accountability in the decision making process which has led to the refusal to provide Class Members with access to Orkambi, infringes the Class Members rights to life and security of the person.

(a) **Right to Life**

39. The CF treatment drug Orkambi is a medically necessary treatment for CF patients with the gene mutation DD508, without which, patients bearing that CF gene are put at risk of death and progressively serious harm to their organs caused by CF and CF-related symptoms. The denial of access to this life sustaining drug violates the right to life of Class

Members under Section 7 of the *Charter,* which cannot be justified by any principle of fundamental justice legally recognized in Canada. The nature of CF creates a narrow and progressive gradient between the risk to health and the risk to life created by this failure to ensure access to medication.

40. This deprivation is more severe since the *Charter* violation puts the lives of the Class Members at stake. This deprivation exceeds any reasonable limitation on the right to life under Section 7 of the *Charter.*

41. The uncertainty and delay caused by the CADTH-pCPA policymaking process further violates the right to life of Class Members, who continue to suffer from increasingly irrevocable lung damage resulting from CF, CF-related infections, and increasing risk of cardio-pulmonary disease and lung failure, a shorter life span, and mental distress as a result of the increasing threat of death.

(b) **Right to Security of the Person**

42. The continuing refusal of the Defendants to fund the drug Orkambi amounts to a violation of Class Members rights to personal security under Section 7 of the *Charter,* since the inaccessibility of Orkambi leads to a state-imposed deterioration of personal health and well-being of the Class Members.

43. Further, the uncertainty of knowing if, or when, this medication will be funded, results in a state-imposed deterioration of personal health and well-being of the Class Members, for which Health Canada approved drug treatments are available but are being arbitrarily withheld.

44. The inability and/or delay in accessing Orkambi by CF patients of ordinary means violate the principles of fundamental justice.

45. Class Members' Section 7 rights to life and security of the person have been infringed by the Defendants' actions and/or inactions in denying access to Orkambi. Specifically with respect to fundamental life choices about their health, medical treatment and security of the person, which lie at the very core of their independence and sense of dignity.

46. The Defendants have failed to provide the Class Members with reasonable, barrier free access to medically necessary and doctor prescribed medication. Specifically, the Defendants have elected to refuse funding of Orkambi, thereby depriving the Class Members of a life sustaining drug. This engages the Class Members' right to life.

47. The refusal to enter good faith negotiations with Vertex on the basis that the CDR gave a negative recommendation, which was contrary to the approval received by Health Canada, runs contrary to Class Members' Section 7 rights.

48. Health Canada's approval of Orkambi resulted in the drugs availability on all private insurance companies' lists of approved and available medications, subject only to employer benefit plan limitations across Canada.

49. The delegation by Government of both executive and administrative decision-making authority to CADTH is an improper delegation of authority. CADTH has no underlying legislative mandate from any jurisdiction, and the lack of adequate public accountability mechanisms including, but not limited to, the lack of legally structured

oversight by the respective federal, provincial and territorial health ministries is contrary to the principles of fundamental justice. Further, the lack of any system for citizen complaints arising from the denial of access to federally approved drugs, and the absence of all or sufficient access to information on the decision-making procedures and reasons for such decisions amounts to a failure of provincial health ministries to approve and supply such drugs and run contrary to principles of fundamental justice limiting the exercise of state power.

50. The continued deprivation of life sustaining medication from CF patients is arbitrary, unfair. The deprivation of Orkambi is based on considerations that do not respect the individual and collective rights of CF patients' right to life and security of the person. The Defendants' purpose, decision making process, and decisions are not a reasonable limit on access to life sustaining medication for ordinary Canadians in a free and democratic society.

51. In both deciding to engage in, and carrying out, negotiations which affect Canadian citizens, the defendants failed to engage with pharmaceutical companies and each other in an open, transparent and objective manner that demonstrates good faith.

52. The violation of the Plaintiffs' and Class Members' Section 7 *Charter* rights are not justified under Section 1 of the *Charter*. In particular, and without limiting the generality of the foregoing, the denial of Orkambi to the Plaintiffs and Class Members, the creation of the CADTH-pCPA policymaking process as well as its employment as a basis for decisions by Government to deny Orkambi to a specific group of CF patients, do not satisfy, and are not rationally connected to, any substantial or pressing social objective.

53. A decision to categorically deny such a small group of CF patients from life sustaining medication is grossly disproportionate and unreasonable under any public interest calculus.

Section 15 of the Charter

54. Pursuant to Section 15, of the *Charter*, every individual is equal before and under the law and has the right to equal protection and equal benefit of the law without discrimination. The Plaintiffs submit that the refusal to provide access to Orkambi infringes on the Plaintiffs' right to equal treatment.

55. As a result of the Defendants' actions, CF patients requiring Orkambi have been denied medical treatment on a discriminatory basis grounded in their specific gene mutation.

56. The failure to provide Orkambi to the Class Members who require this treatment to survive while deciding to provide Kalydeco to other CF patients of a different gene mutation, draws a formal distinction premised on the specific gene mutations of CF.

57. The Defendants' arbitrary, irrational and unreasonable denial of Orkambi to CF Patients with gene mutation DD805 (Class Members), while simultaneously funding Kalydeco to treat a fractional minority of CF Patients with a different gene mutation, amounts to discrimination, and creates a distinction between the specific gene types of these two Classes of CF patients. The *Canadian Human Rights Act* specifically prohibits discrimination on the basis of genetic characteristics.

58. Both Orkambi and Kalydeco have been approved by Health Canada, which means that they are available for purchase in the Canadian market place. However, Kalydeco has been funded for a specific CF gene mutation, whereas funding for Orkambi has been denied.

59. The violation of the Plaintiffs' and Class Members' Section 15(1) *Charter* rights is not justified under Section 1 of the *Charter*. In particular, and without limiting the generality of the foregoing, the denial of Orkambi to the Class Members, the creation of the CADTH-pCPA evaluation and recommendation process as well as its use to arbitrarily deny Orkambi serve no pressing and substantial state objectives, do not satisfy and are not rationally connected to any substantial or pressing objective. There is no rational connected to any valid state purpose.

Conspiracy to Injure

60. The Provincial Government and the Federal Government colluded and cooperated or otherwise contrived to both permit and confirm the denial of life sustaining medication to all CF patients subject to the CADTH-pCPA policymaking process, resulting in delays and/or denial of both Orkambi and Kalydeco that are causing, or will likely cause injury to the Plaintiffs and, as such, the Defendants are each liable for the tort of civil conspiracy.

61. The Government Defendants' creation of the CADTH-pCPA policymaking process as a replacement for provincial-level health policy processes was a collective, intentional course of action.

62. Permitting and then effectively rubber-stamping public health policy decisions without public accountability for the same, amounts to an improper and unlawful exercise of a statutory power of decision-making under the governing public health statute for British Columbia.

63. The effect of instituting the CADTH-pCPA evaluation and recommendation process amounts to both an act and omission committed in the course of public office by the British Columbia Minister of Health.

64. This course of action essentially delegated the decision making process to a publicly unaccountable econometric cost-benefit analyses process, to the prejudice of the constitutionally protected rights of Class Members to proven life sustaining medical treatment.

65. This type of short-circuiting of responsible public policy implementation developed and instituted through the CADTH-pCPA policymaking process is bereft of any legal authority or accountability with the effect of nullifying the *Charter* rights of patients.

66. The Plaintiffs plead that the Defendants conspired to injure the Plaintiffs, members of the Class, and members of the Canadian public requiring drug treatment at large.

67. All the Defendants, led by the Government Defendants, through unlawful means acted in concert, by agreement or with a common design to threaten the life and security of treatment of CF patients.

68. The Defendants' conduct was unlawful in that, *inter alia*, the Provincial Government Defendant improperly delegated power to the First and Second Defendants,

both of whom are unaccountable subordinate decision makers. The Provincial Government Defendants hold themselves out as representing a public institution accountable to the Canadian public, but have selectively withdrawn their influence through the creation of CADTH and pCPA in order to avoid public oversight and political accountability for life-threatening health policy decisions.

69. By agreeing to provide funds and actively governing CADTH drug assessment processes while arbitrarily delaying or refusing to instruct pCPA in negotiating the procurement of Orkambi and further refusing to incorporate Orkambi patient treatment protocols developed through evidence-based independent research to reduce implementation costs, the Defendants collectively agreed to injure the Plaintiffs and all members of the class.

70. The Defendants knew or ought to have known that their conduct was unlawful and the decision to delay and deny Orkambi to CF patients would cause harm and did cause harm to the Plaintiff and Class Members.

71. As a result of the unlawful denial of life sustaining medication and administrative delays, the Plaintiffs and all Class Members continue to suffer from irrevocable lung damage caused by CF and CF -related infections, an overall shortening of lifespan, and mental distress as a result of the increasing threat of death.

Damages

72. As a result of the Defendants actions, the Plaintiffs and the members of each class have suffered damages including, but not limited to general damages.

73. In the circumstances, the Class Members are entitled to monetary damages pursuant to Section 24(1) of the *Charter* for violation of their constitutional rights and freedoms in order to:

(a) Compensate Class Members for their suffering and loss of dignity;

(b) Vindicate Class Members fundamental rights; and

(c) Deter systemic violations of a similar nature.

74. There are no countervailing considerations rendering damages in this case inappropriate.

75. The Plaintiffs plead and rely upon the following statutes and regulations:

(a) The *Class Proceedings Act*, R.S.B.C. 1996, c. 30;

(b) The *Supreme Court Act*, R.S.B.C. 1996, c.443;

(c) The *Canadian Charter of Rights and Freedoms.* Part I of the Constitution Act, 1982, being Schedule B to the Canada Act 1982 (UK), 1982, c 11;

(d) *Canada Not-for-profit Corporations Act*, S.C. 2009, c.23;

(e) *The Court Order Interest Act*, R.S.B.C. 1996, c.79;

(f) *Regulation 168/2009 of the Court Rules Act,* R.S.B.C. 1996 c.80;

(g) *Crown Liabilities and Proceedings Act*, R.S.C., 1985, c. C-50;

(h) *Canadian Human Rights Act*, R.S.C., 1985, c. H-6; and

(i) *Court Jurisdiction and Proceedings Transfer Act*, R.S.B.C. 2003, c 28.

76. The Plaintiff proposes that this action be tried in the City of Vancouver.

Endorsement for Service Outside British Columbia

77. There is a real and substantial connection between British Columbia and the facts alleged in this proceeding and the Plaintiffs and other Class Members plead and rely upon the *Court Jurisdiction and Proceedings Transfer Act*, R.S.B.C. 2003, c 28 (the "*CJPTA*") in respect of these Defendants. Without limiting the foregoing, a real and substantial connection between British Columbia and the facts alleged in this proceeding exists pursuant to ss. 10 (e) - (i) of the *CJPTA* because this proceeding:

(a) concerns a resident of British Columbia;

(b) concerns contractual obligations that, to a substantial extent, were to be performed in British Columbia and resulted from a solicitation of business in British Columbia;

(c) concerns restitutionary obligations that, to a substantial extent, arose in British Columbia;

(d) concerns a tort committed in British Columbia;

(e) concerns a business carried on in British Columbia; and

(f) is a claim for damages sustained in British Columbia.

Plaintiffs' address for service:	Cambridge LLP c/o DG Barristers Suite 428 - 755 Burrard Street Vancouver, BC V6Z 1X6 **Attention: Chris Macleod & George Douvelos**
Fax number address for service:	604-637-6385
E-mail address for service:	cmacleod@cambridgellp.com george@dgbarristers.com
Place of trial:	Vancouver
The address of the registry is:	Vancouver Law Courts 800 Smithe Street Vancouver, BC, V6Z 2E1

Date: July 24, 2018

Signature of lawyer for Plaintiffs
Christopher MacLeod

Rule 7-1 (1) of the Supreme Court Civil Rules states:

(1) Unless all parties of record consent or the court otherwise orders, each party of record to an action must, within 35 days after the end of the pleading period,

(a) prepare a list of documents in Form 22 that lists

(i) all documents that are or have been in the party's possession or control and that could, if available, be used by any party at trial to prove or disprove a material fact, and

(ii) all other documents to which the party intends to refer at trial, and

(b) serve the list on all parties of record.

Appendix

Part 1: CONCISE SUMMARY OF NATURE OF CLAIM:

This claim is a class action in which the class members will seek to uphold their s. 7 and s. 15 Charter rights, specifically, access to life sustaining treatment for Cystic Fibrosis disease that will meaningfully prolong their lives. In addition, the class members will seek to ensure that transparent evidence-based mechanisms for drug approvals that uphold Charter rights are in place.

Part 2: THIS CLAIM ARISES FROM THE FOLLOWING:

A personal injury arising out of:

[X] another cause

A dispute concerning:

[X] a matter not listed here

Part 3: THIS CLAIM INVOLVES:

[X] a class action

[X] constitutional law

Part 4:

(a) The *Class Proceedings Act*, R.S.B.C. 1996, c. 30;

(b) The *Canadian Charter of Rights and Freedoms.* Part I of the Constitution Act, 1982, being Schedule B to the Canada Act 1982 (UK), 1982, c 11; and

(c) *Crown Liabilities and Proceedings Act*, (R.S.C., 1985, c. C-50.